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A COMPARISON OF NEONATAL THYROID PARAMETERS OF CORD BLOOD AND NEWBORN VENOUS BLOOD AMONGST NEW-BORNS OF AVMC

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ABSTRACT

Background: Hypothyroidism may be congenital or may be acquired which might or may not have a delayed onset. Incomplete thyroid development and decreased thyroid hormone biosynthesis is a result of congenital hypothyroidism. Screening is usually missed in areas where testing is not done and is the reason for new cases of hypothyroid cases. India has a higher incidence of neonatal hypothyroidism. **Aim:** To evaluate whether cord blood can be used as a primary thyroid screening tool. **Method:** The study was taken up in the department of pediatrics of a tertiary teaching hospital. A total of 200 babies were taken for the study during the whole study period. The cord blood at the time of delivery and 48-hour serum blood was collected and sent to the lab for thyroid profile estimation. **Results:** The study consisted of 106 males and 94 female infants. Among the 200 subjects, 167 were term babies and 33 were preterm. The mode of delivery was 77.5% had lower segment cesarean section and the remaining 22.5% were normal deliveries. The mean birth weight was 2.810 kgs. The mean TSH 6.99±4.81, the mean T3 level was 80.43±39.06 and the meanT4 level among the subjects was 10.90±4.59. The systemic venous blood was collected after 48 hours for thyroid profiling. The mean TSH was 4.65±4.03, the mean T3 level was 114.205±38.27 and the mean T4 level among the subjects was 13.89±5.60. On comparison of cord blood, TSH and systemic venous blood TSH association were noted which was statistically significant. Association was between cord blood T3 and 48-hour venous blood was present and statistically significant. Cord blood for T4 and venous blood for T4 association was seen and statistically significance present. **Conclusion:** from the present study, it can be suggested cord blood can be used as a marker for thyroid screening tool.

KEYWORDS: Cord blood, Systemic Venous blood, TSH, T3, and T4.

INTRODUCTION

Most infants are screened for thyroid profile of newborn in the 1st few weeks of birth, in areas with no screening program, severely affected infants usually manifest features within the 1st week of life, but in infants with milder hypothyroidism, clinical manifestations may be masked for months.[1]

Newborn screening (NBS) for congenital hypothyroidism (CH), has led to the virtual disappearance of the intellectual disability (defined as an intelligence quotient (IQ) of roughly 70 or less, along with functional impairment) that was observed in up to 28% of affected individuals in the pre-NBS era.[2]

The incidence of Neonatal hypothyroidism in different parts of the world ranges from 1 in 4000[4] to 1 in 2000[5] to as high as 1 in 600[6] in developing countries like India have a higher incidence of Neonatal hypothyroidism.[5,6]

There are a good number of quality data available with widely variable results across geography about the incidence or prevalence of Neonatal hypothyroidism in India. There are many major studies done in India so far, on the incidence of congenital hypothyroidism in study[7] reported 1:2640 (1998) and second study[8] (ICMR) showed 1:1130 new-borns (2007-2012). The increasing trend might be because of extensive screening campaigns led by the Government of India detecting more undiagnosed cases previously hidden.

Over the last several years, reports from newborn screening programs around the world have described an increase in the incidence of congenital hypothyroidism, and a factor which contributes to this change may be increased screening of patients at higher risk of congenital hypothyroidism, including premature infants and particular ethnic populations such as Hispanics and Asians. The methodological changes in newborn screening appear to be another major factor in the rising

incidence of congenital hypothyroidism, specifically the widespread lowering of thyroid-stimulating hormone (TSH) screening cut-offs that leads to the detection of milder cases.[3]

Congenital hypothyroidism (CH), one of the preventable reasons for Mental retardation (MR) and also the most common congenital endocrine disorder of childhood.[9] The neurodevelopmental outcome is usually better if treatment is started in the early weeks of Life.[10] The maternal thyroid hormones crossing through the placenta give protection to the fetal brain masking the clinical signs.[11] In addition to this even, the most severe forms of CH have some functioning residual thyroid tissue further making clinical diagnosis difficult.[12]

In the majority of screening programs in India, samples were collected within 5-6 days of age, but healthy babies are getting discharged early in our country, it is very difficult to follow up with all early discharged babies so a cord blood sample is a good option.[14] Thus, cord blood thyroid parameters are a failsafe practical thyroid screening method and are getting popular slowly in countries.[12,13] around the world. In the first week of life, mixed cord blood samples of TSH values showed comparable results with filter paper samples.[15] The use of cord blood TSH is becoming popular in screening programs for its simplicity and accessibility. The Indian Academy of Pediatrics (IAP) has announced comprehensive guidelines for the use of cord blood samples for thyroid.[15]

AIM

To evaluate whether cord blood can be used as a primary thyroid screening tool.

OBJECTIVES

1. To evaluate cord blood thyroid parameters.
2. To evaluate systemic venous blood thyroid parameters.
3. Compare association between Cord blood thyroid parameters with systemic venous blood thyroid parameters.

Study Design: Prospective observational study.

Study Population: Newborn babies born to mothers delivered in Aarupadai Veedu Medical College and Hospital, Puducherry.

Study Area: This study was conducted in the Department of Paediatrics, AARUPADAI VEEDU MEDICAL COLLEGE AND HOSPITALKIRUMAMPAKKAM, PUDUCHERRY.

Study Period: June 2019 to October 2020.

Inclusion Criteria

1. All newborn

Exclusion Criteria

1. At the risk of sepsis
2. Instrumental delivery (vacuum and forceps)
3. Birth asphyxia

Sample Size

Considering the prevalence of congenital hypothyroidism as 15.15% in a study by Sudha Rathna et al[38] the sample size was calculated for our study using the formula

$N = 4pq/L^{2.}$

- p= 15.15%
- q= 84.85 (100-p)
- L=30%

The sample size works out to 249 subjects with the above formula and considering the dropout rate between 10% to 20% the total number of subjects worked out to 200.

Sampling technique

Simple stratified sampling method.

Study Variables

Cord blood and venous blood at 48 hours for TSH, T3, and T4.

Study Tools

Pre-designed pre-tested questionnaire.

Data Collection Methodology

- The approval from the ethics committee was obtained for this study.
- Informed consent regarding participation in the study is obtained in the regional language.
- The pre-designed pre-tested questionnaire was explained to the mother or caregiver.
- Babies were clinically assessed for age, sex, gestational age, birth weight, previous history of jaundice in the family, day of onset of jaundice, a pattern of feeding, fever, and other neurological symptoms.
- A complete clinical examination of the baby was also carried out.
- 2ml of blood was drawn in a sterile manner from the umbilical cord & venepuncture on subsequent analysis at >48 hours of life from neonates.
- All these samples were sent with sterile disposable syringes & needles.
- The test tubes contained Plain RED tubes & they were taken to the lab and processed.

Data Analysis

- The collected data were coded, entered into a Microsoft Excel worksheet, and exported to SPSS. Data were analyzed using SPSS version 21. Data are presented as a percentage in categories and then presented as tables and graphs. Pearson test for correlation was used for a test of significance.

RESULTS

Table 1: Distribution of subjects according to sex (n=200).

Sex	Frequency	Percent
Male	106	53
Female	94	47
Total	200	100%
Sex ratio: 1.12:1		

In the present study, a total of 200 subjects were considered which had 106 male babies and 94 were females. The sex ratio was 1.12:1.

Table 2: Distribution of subjects according to gestational age (n=200).

Gestational age	Frequency	Percent
<37 weeks	33	16.5
38-41 weeks	167	83.5
Total	200	100%

Table 2 shows the gestational age among the subjects was 83.5% babies were term (38-41 weeks) and 16.5% were preterm (<37 weeks).

Table 3: Distribution of subjects according to parity (n=200).

Parity	Frequency	Percent
Primi	63	31.5
Multiparous	137	68.5
Total	200	100%

The subjects were distributed according to parity were 68.5% were multiparous and the remaining 31.5% were primi's.

Table 4: Distribution of subjects according to a mode of delivery (n=200).

Mode of delivery	Frequency	Percent
Normal vaginal delivery	45	22.5
LSCS	155	77.5
Total	200	100%

The table shows the distribution of subjects according to the mode of delivery were 77.5% were lower segment cesarean section and 22.5% were normal deliveries.

Table 5: Distribution of subjects according to maternal thyroid (n=200).

Hypothyroidism	Frequency	Percentage
YES	30	15%
No	170	85%
Total	200	100%

The infant's mother's thyroid status was noted was 85% of the mothers did not have hypothyroidism and 15% of them had hypothyroidism.

Table 6: Distribution of subjects according to birth weight (n=200)

Birth weight	Frequency	Percent
Normal birth weight (2.5 kgs-3.5kgs)	165	82.5
Low birth weight (<2.5kgs)	34	17
Very low birth weight (<1500 gms)	1	0.5
Total	200	100
Mean birth weight: 2.810±0.587		

The birth weight of all the subjects was 82.5% were normal, 17% were low birth weight babies and 0.5% were very low birth weight. The mean weight among the subjects was 2.810±0.587.

Table 7(a): Distribution of subjects according to means cord blood thyroid profile levels (n=200).

Cord blood thyroid profile	Mean
TSH	6.99 ± 4.81 mIU/L
T3	80.43 ± 39.06 ng/dl
T4	10.90 ± 4.59 mcg/dl

Table 7(a) shows the means of cord blood thyroid profile were the mean TSH was 6.99 mIU/L, mean T3 was 80.43 ng/dl and 10.90 mcg/dl was the T4 mean.

Table 7(b): Distribution of subjects according to Systemic venous blood thyroid profile levels at 48 hours

Systemic venous blood thyroid profile	Mean
TSH	4.65 ± 4.03 mIU/L
T3	114.09 ± 38.27 ng/dl
T4	13.89 ± 5.60 mcg/dl

Table 7(b) shows the means of capillary venous blood thyroid profile were the mean TSH was 4.65 mIU/L, mean T3 was 114.09 ng/dl and 13.89 mcg/dl was the T4 mean.

Table 8: Association between cord blood TSH and Systemic venous blood TSH.

TSH levels	Mean	SD	95% CI		p-value
			Lower	Upper	
Cord TSH	6.9919	4.819	1.5864	3.0941	**P<0.001***
Venous blood TSH	4.6516	4.097			

Table 8 shows the association between cord blood TSH and Systemic venous TSH. The findings of this study suggest a statistical significance (p<0.001) were TSH screening at birth is useful and the systemic venous blood report strengthening the suggestion for screening and diagnosing hypothyroidism.

Table 9: Association between cord blood T3 and systemic venous T3 levels.

T3 levels	Mean	SD	95% CI		p-value
			Lower	Upper	
Cord T3	80.43	39.381	40.4623	25.4189	**P<0.001***
Venous T3	114.09	40.4693			

The association on the comparison between cord blood T3 and systemic venous blood T3. A high significance (p<0.001) was noted between the former two.

From the present study cord, T3 for screening is needed followed by systemic venous testing to ascertain thyroid disorders.

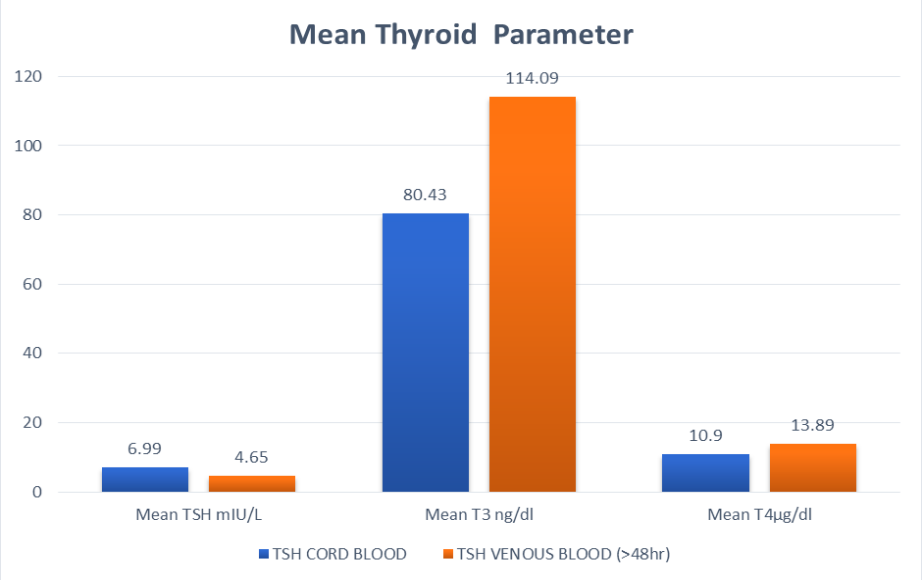
Table 10: Association between cord blood T4 and Systemic venous blood T4 level.

T4 levels	Mean	SD	95% CI		p-value
			Lower	Upper	
Cord T4	10.90	4.596	3.91840	2.06270	**P<0.001***
Venous T4	13.89	5.600			

The association of T4 levels on comparison of cord blood and systemic venous blood. A highly significant value (p<0.001) was observed between the two.

Concluding from the table, T4 is important and necessary for screening for thyroid.

Bar chart showing the comparison of mean TSH, T3, T4 of cord blood and capillary venous blood



- Shows the comparison of mean cord blood and systemic venous blood TSH levels. The cord blood (blue bar) mean was 6.99 mIU/L and systemic venous blood (red bar) TSH mean was 4.65 mIU/L.
- Shows the comparison of mean cord blood and venous blood T3 levels. The cord blood (blue bar) T3 mean was 80.43ng/dl and capillary venous blood (red bar) T3 mean was 114.09ng/dl.
- Shows the comparison of mean cord blood and venous blood T4 levels. The cord blood (blue bar) T4 mean was 10.90 mcg/dl and capillary venous blood (red bar) T3 mean was 13.89mcg/dl.

DISCUSSION

A. In the present study a total of 200 subjects were considered 53% were male babies and 47% were females. The sex ratio was 1.12:1. Around 54.5% of babies were term and 45.5% were preterm.

The present study sample selection is different as compared to a study conducted by Sunil R et al in which females were higher as compared to males. The male to female ratio was found to be 1:1.07 and all the babies had a gestational age of ≥ 37 weeks.[16]

The present study sample selection is almost similar to a study conducted by Armanian AM et al in which 50.2% were males and 49.8% were females. The mean

gestational age of babies in this study was found to be 37.75 ± 2.28 weeks.[17]

The present study sample selection is similar to another study by Subhash P et al in which 57.1% were males and 42.9% were females and 81.1% were term babies and 18.9% were preterms.[18]

B. In this study 68.5% were multiparous and the remaining 31.5% were primi. The mode of delivery was lower segment cesarean section in 77.5% of the study population and 22.5% were normal deliveries.

The present study sample selection is almost similar to a study Armaninan AM et al in which 61.14% were Caesarean section deliveries and 38.86% were normal vaginal deliveries.[17]

The present study was similar to a study conducted by Sheetal GL et al in which 32.58% were primi's and 67.41% were multiparous. Around 35.13% were normal vaginal deliveries and 62.14% were cesarean sections.[19]

The present study was comparable to another study by Suresh S et al in which 44.6% of mothers were primigravida, and multigravida constituted 55.4% of the study group. The findings with relation to mode of delivery were different as compared to our study. In their study, 59% and 4% neonates were delivered through Normal Vaginal Delivery (NVD) and Assisted Vaginal Delivery respectively while 37% neonates were delivered through Caesarean Section.[20]

C. In the present study 74% of babies had normal birth weight, 16.5% were low birth weight babies, 5.5% were 3.5kgs and 4% were very low birth weight. The mean weight among the subjects was 2.810±0.587 kg.

The present study was almost comparable to a study by Poyekar S et al in which 23.1% were low birth weight and 76.9% were normal birth weight.[18]

The present study was almost similar to a study by Sheetal G et al in which 68.84% had normal birth weight and 27.27% were low birth weight and 3.57% had very low birth weight.[18]

The present study findings were different from a study conducted by Suresh S et al in which 0.8% neonates weighed <2.5 kg and 98.9% neonates had normal birth weight and 0.3% had weight >3.5 kg.[20]

D. In this study majority of 87% of the subjects had TSH levels within the normal range (2.43 - 24.3 mIU/L), 11.5% had decreased levels (<2.43mIU/L) and 1.5% of subjects had elevated levels (>24.3 mIU/L). The mean cord blood TSH level was 6.99±0.347 mIU/L.

The present study findings were similar to a study by Sunil et al in which 70% of babies had normal TSH levels. Around 0.46% had decreased levels and 29.03% had increased levels of TSH. The mean value of TSH was 12.88 mIU/dL.[16]

The present study findings were different as compared to a study by Sheetal G et al in which the mean value of CBTSH was 7.82 µIU/mL (range 0.112–81.4, SD = 5.48). Around 4.39% neonates had elevated TSH >16.10 µIU/mL. TSH levels were <1.0 among 1.02% of neonates.[19]

The present study findings were consistent with a study conducted by Suresh S et al in which Repeat TSH and T4 Levels in Neonates with CBTSH Level of >20mIU/L at birth were found to decline on the 7th and 21st day of illness.[20]

The present study findings were similar to a study conducted by Kayode A et al in which the mean serum T3 and T4 cord values 48 hours after birth were found to be in the normal range i.e., 101.38 and 1.06 nmol.[23]

In this study, the association between cord blood TSH and 48 hours TSH was done and it was found that there is a statistically high significance ($p<0.001$) of screening for TSH levels at birth and 48 hours for diagnosing hypothyroidism.

In the present study, the association between cord blood T3 and 48 hours T3 was done and it was found that there is a statistically high significance ($p<0.001$) of screening for T3 levels at birth and 48 hours for diagnosing congenital hypothyroidism.

In this study, the association between cord blood T4 and 48 hours T4 was done and it was found that there is a statistically high significance ($p<0.001$) of screening for T4 levels at birth and 48 hours for diagnosing congenital hypothyroidism.

The present study findings were similar to a study by Sunil et al in which TSH levels were assessed at birth and 72 hours and it helped in diagnosing congenital hypothyroidism at an early stage and also further helped in the initiation of treatment.[16]

Similar findings were noted in a study by Poyekar S et al in which screening of cord blood at birth for TSH levels helped in early identification of congenital hypothyroidism.[18]

The present study findings were similar to a study conducted by Sheetal G et al in which follow up of TSH, T3, and T4 levels proved to be an important tool in identifying congenital hypothyroidism.[19]

The present study findings were also similar to a study conducted by Suresh S et al in which repeat TSH and T4 Levels in Neonates with CBTSH Level of >20mIU/L -82 neonates with CBTSH level of >20mIU/L were followed

up on the 7thday and 21stday of life. On the 7th day, 12 neonates had raised TSH and low T4. On the 21st day out of these 12 neonates, only two neonates had significantly raised TSH and low values of T4. Treatment was started for these two neonates.[20]

The present study findings were different to a study conducted by Kayode AA et al in which the mean cord TSH levels (13.59 mU l (-1)) compared with 72 h serum TSH levels (10.25 mU l (-1)) was also insignificant p = 0.3.[23]

The present study findings were similar to a study conducted by Amit Gupta et al in which Changes in TSH levels in response to T3 and T4 blood levels at birth and 48 hours formed the basis of screening for congenital hypothyroidism.[21]

The present study findings were consistent with a study conducted by Ravi Bhatia et al in which estimating repeat TSH levels in neonates who had higher levels of TSH at birth helped in early diagnosis of congenital hypothyroidism.[22]

Present study	**Previous studies**
Sex ratio: 1.12:1	Sunil R: 1:1.07
	Armanian: 1.02:1
Gestational age mean: 38.6±2.02	Armanian: 37.75±2.28
NVD: 22.5% LSCS: 77.5%	Armanian: 38.86% 61.14%
Primi: 31.5% Multiparous: 68.5%	Sheetal S: 32.58 : 67.41
	Suresh: 44.6% : 55.4%
Normal birth weight mean: 82.5% LBW: 17% VLBW: 0.5%	Poyekar: 76.9% : 23.1%
	Sheetal G: 68.84% : 27.7% : 3.57%
Mean cord TSH: 6.99±4.81mIU/L	Sunil et al: 12.88 mIU/L Armanian: 7.6±6.2 mIU/L Poyekar: 8.9 mIU/L Sheetal G: 7.82 mIU/L Amit: 8.75 mIU/L Ravi Bhatia: 6.811 mIU/L
Cord T3 mean: 80.43±39.06 ng/dl	Kayode: 75.48 ng/dl
Cord T4 mean: 10.90±4.59 mcg/dl	Desai: 83.3% had normal levels
Mean TSH @48 hours: 4.65±4.03 mIU/L	Suresh: >20 mIU/L
Mean T3@ 48 hours: 114.09±38.27 ng/dl	Kayode: 106 mg/dl
Mean T4 @ 48 hours: 13.89±5.60 mcg/dl	Kayode: 75.48 mcg/dl
Cord TSH* TSH @48 hours: p<0.001	Sunil, Sheetal G, Poyekar, Suresh, Kayode, Amit and Ravi Bhatia: p≤0.05.
Cord T3* T3 @48 hours: p<0.001	
Cord T4* T4 @48 hours: p<0.001	

CONCLUSION

We can safely use a cord blood Thyroid parameter for screening for congenital hypothyroidism instead of 48 hr sample.

There was a significant association (p<0.001) was noted between cord blood and venous blood among all three parameters (TSH, T3, and T4).

Large population‑based studies required to established Cord blood thyroid parameters as an initial screening test in the diagnosis of thyroid disorders.

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