

# Thyroid Profile of Neonates Born to Mothers with Hypothyroidism Detected Before and During Pregnancy

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## ABSTRACT

**Introduction:** Congenital hypothyroidism is a leading preventable cause of intellectual disability. This study explores whether maternal hypothyroidism provides a greater risk for congenital hypothyroidism and compares thyroid hormone levels in infants born to mothers with pregestational versus gestational hypothyroidism. **Methodology:** In an 18-month prospective cohort study at a medical college, 102 newborns from mothers on hypothyroidism treatment were assessed. Infants were divided into two groups: those born to mothers with gestational hypothyroidism (Group 1) and those with pregestational hypothyroidism (Group 2). Newborns were screened for congenital hypothyroidism using cord TSH levels at birth, followed by venous TSH and free T4 measurements at 2-7 days and 2-6 weeks. Statistical analyses included t-tests, Chi-square tests, and ANOVA with  $p < 0.05$  considered significant. **Results:** The cohort included 102 infants with a near 1:1 male-to-female ratio and a mean birth weight of 2.809 kg. Fifty-seven percent of mothers had pregestational hypothyroidism and 43% had gestational hypothyroidism. The mean cord TSH was 9.4 mIU/L, with 18 infants showing elevated levels. Four infants had elevated serum TSH at 48 hours, and seven had elevated TSH at 2-6 weeks. Free T4 levels averaged 3.14 ng/dL at 2-7 days and 1.82 ng/dL at 2-6 weeks. No significant differences were found between groups. Subclinical hypothyroidism was noted in 4 infants, with no cases of overt hypothyroidism. **Conclusion:** Infants of mothers with adequately treated hypothyroidism generally have normal thyroid hormone levels, showing no increased risk compared to the general population, and no significant difference between pregestational and gestational hypothyroidism groups.

**KEY WORDS:** Pregestational, Gestational, Hypothyroidism, Thyroid hormone, Thyroid stimulating hormone, Thyroxine hormone.

## Introduction

Thyroid disease is the second most common endocrine disorder in women of child-bearing age and is the most common congenital endocrine disorder.<sup>[1]</sup> The prevalence of hypothyroidism in pregnancy in India is 13.13%.<sup>[2]</sup> In the newborn, congenital hypothyroidism is the most common cause of preventable intellectual disability, hence it is imperative to diagnose and treat it early.

Studies have proved a relationship between maternal and foetal thyroid profiles,<sup>[3-7]</sup> hence proving hypothyroidism in pregnancy to be a real risk factor for congenital hypothyroidism. During the initial months of pregnancy, the foetus depends on the maternal thyroid hormones, which play a crucial part in normal brain development and the deprivation of it can have permanent effects on the foetus. Earlier research discovered that children born to mothers with hypothyroidism during pregnancy had lower IQ, impaired psychomotor development, increased risk for ADHD, autism, abortions, foetal anomalies, heart defects, lower birth weight and increased risk of hyperbilirubinaemia and neonatal hyper or hypothyroidism.<sup>[8]</sup>

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Despite apparently optimal maternal thyroid status, due to the gestational T4 metabolism fluctuations, this makes it difficult to maintain meticulous normal thyroid hormone values in hypothyroid mothers during pregnancy.<sup>[1,9]</sup> This imbalance of thyroid status which occurs during pregnancy is one factor which could decrease the maternal-fetal transfer of thyroxine, thereby causing hypothyroidism in the newborn.<sup>[10]</sup>

Women, who have been diagnosed to be hypothyroid before pregnancy, usually have anti-thyroid antibodies and hence considered to be more likely to have babies with the highest values of TSH. On the other hand, it has been seen that mothers with pregestational hypothyroidism, have less fluctuations in their thyroid hormone values during pregnancy, as they are known to be compliant with their medications, in comparison to those mothers with gestational hypothyroidism – thus leading to lesser adverse effects in the newborn.

Neonatal thyroid hormone screening is now being done universally; however, many units perform extra thyroid tests on neonates of adequately treated hypothyroid mothers. In the past neonates with deranged thyroid profile were often misdiagnosed as having permanent congenital hypothyroidism, when in fact majority were actually transient hypothyroidism,<sup>[11,12]</sup> including transient hyperthyrotropinaemia.

It is important to understand precisely the impact of maternal thyroid disease on the newborn thyroid function, so that we do not miss neonatal hypothyroidism and can carefully treat these babies.<sup>[13]</sup> This study aimed to determine whether maternal hypothyroidism is a strong risk factor for congenital hypothyroidism and if there is a difference in thyroid hormonal status in babies born to mothers with pregestational versus gestational hypothyroidism.

## Material and Methods

**Study Design and Duration and Data Source:** This is a prospective cohort study done over 18 months, from November 2019 – October 2021, in the postnatal wards and NICU of a medical college and teaching hospital in Mangalore.

**Sample size and Inclusion criteria:** 102 consecutive mothers admitted during this period with laboratory proven hypothyroidism on treatment and their respective newborns were included in the study.

**Data Collection procedure:** Informed consent was taken and explained in the local language. Institutional ethical (FMMCIEC/CCM/360/2019) and scientific committee approval for the study were obtained on 23/10/2019.

The diagnosis of maternal hypothyroidism, dosage of thyroid replacement medication and management was done throughout pregnancy by the treating obstetricians and endocrinologist. If there was a change in the thyroid replacement medication dosages in the mothers during pregnancy, the highest dose given to the mothers was taken as the final dosage.

The newborn cord blood TSH at birth, the venous blood TSH and free T4 between 2-7 days and 2-6 weeks of life were noted. Group 1 consisted of all the newborns born to mothers with hypothyroidism (diagnosed first time during pregnancy). Group 2 was made up of all the newborns born to mothers with hypothyroidism (diagnosed before pregnancy).

A neonate was considered to have congenital hypothyroidism when there was elevated serum TSH and decreased free T4 as per gestational and postnatal age values at birth and this had to persist beyond 2 to 6 weeks of life to confirm the diagnosis.<sup>[14]</sup>

The infants who had high TSH values and normal free T4 at the first week but normal levels after the first week, were considered to have transient hyperthyrotropinemia (THT) and if it persisted beyond the first week were labelled as persistent hyperthyrotropinaemia (PHT).<sup>[11]</sup> The decision to start treatment in the neonates was made by the treating paediatrician.

**Sampling technique:** The venous blood and cord blood of newborns were collected and TSH was measured by chemi-luminescence assay and free T4 was measured using radio-immunoassay technique.

**Statistical analysis:** Sample size was calculated using correlation coefficient of 0.37 and a p-value <0.05 was taken as significant.<sup>[10]</sup> Independent t-test, Chi-square test, Pearson correlation, Fischer exact and ANOVA-p tests were used to compare, find the association and correlation between the groups and parameters respectively.

## Results

### Demographic data

Fifty-eight (57%) out of 102 women, had pregestational hypothyroidism and 44 (43%) women had gestational hypothyroidism. In those mothers whose hypothyroidism was detected during pregnancy – it was noted that 26 (59%) were detected during first trimester, 8 (18%) in second trimester and 10 mothers (22.7%) in third trimester. Out of the 58 women who had pregestational hypothyroidism, 45 (78%) women had it for  $\leq 5$  years and 13 (22%) women had it for 6 to 10 years.

Out of the 102 mothers on thyroid medication, it was found that 35% of mothers were on 25mcg, 26% on 50mcg, 15% on 75mcg, 13% on 100mcg, 5% on 12.5mcg, 3% on 125mcg and 1% on 62.5mcg, 150mcg and 200mcg of thyroid replacement medication respectively - with these dosages they were maintaining euthyroid status throughout. The mean dosage of thyroxine in the group consisting of pregestational hypothyroid mothers was 61.85 mcg and in the gestational hypothyroidism group, it was 44.03 mcg.

The male to female baby ratio was 53:49. There were 9 females (18.4%) and 9 males (17%) with elevated cord TSH levels. Between 2-7 days of life, there were 3 (6.1%) females and 1 (1.9%) male and between 2-6 weeks of life, 6 (12.2%) females and 1 (1.9%) male with elevated serum TSH levels.

The mean birth weight was 2.809kg - 69 (67.6%) babies had a normal birth weight between 2.5 to 4kg, 26 (25.5%) had low birth weight between 1.5 to 2.5kg, 4 (3.9%) babies were macrosomic with birth weight  $> 4$ kg, 1 (0.98%) baby had an extremely low birth weight of  $< 1$ kg and 2 (1.96%) babies had very low birth weight falling between 1 to  $< 1.5$ kg. The mean birth weight in the pregestational hypothyroidism group was 2776 grams and in the gestational hypothyroidism group it was 2853 grams.

There were 43 (42%) full term, 33 (32%) early term, 13 (12.7%) late preterm, 10 (9.8%) early preterm, 1 (0.98%) very early preterm and 2 (1.9%) extreme preterm babies - there were no late term or post-term babies. The number of babies and their respective gestational period, birth weights and which hypothyroidism group they were born into are depicted in Table 1.

**Table 1: The number of babies and their respective gestational period, birth weights and which hypothyroidism group they were born into**

1	Gestational period	Pregestational Hypothyroidism	Gestational Hypothyroidism
	Term babies	58 (56.8%)	44 (43.1%)
	Preterm babies	16 (15.7%)	10 (9.8%)
2	Birth Weight	Pregestational Hypothyroidism	Gestational Hypothyroidism
	Normal weight	36 (35.3%)	33 (32.4%)
	Low birth weight	20 (19.6%)	9 (8.8%)
	Macrosomia	2 (1.96%)	2 (1.96%)

### Thyroid hormone levels in the newborns

Seventy-six (74.5%) babies had a cord TSH level between 0-9mIU/L, 19 (18.6%) between 10-19mIU/L and 7 (6.89%) with values 20mIU/L and above. In seven babies with thyroid values 20mIU/L and above, we had found that the values had normalized on subsequent testing. However, according to standard cut-offs as per gestational and postnatal ages, 18 (17.6%) babies had cord TSH levels above cut-off for age - out of which, 9 (50%) mothers had pregestational and 9 (50%) had gestational hypothyroidism. Student t-test showed no significance between the mean thyroid values in the newborns born to mothers with pregestational and gestational hypothyroidism as shown in Table 2.

It was seen that 4 (3.9%) infants had elevated TSH values between 2-7 days, of which, 1 had normal screening TSH value. The TSH values between 2-7 days ranged from 1.3-22.1 $\mu$ IU/mL, with a mean of 5.6 $\mu$ IU/mL and the free T4 values ranged between 1.4-5.1ng/dL. Seven babies had elevated TSH levels between 2-6 weeks, of which: one had persistently elevated TSH levels since birth, 5 had normal TSH values at birth and between 2-7 days and one had normal birth TSH and elevated TSH 48 hours later.

The number of babies with elevated fT4, after 48 hours and between 2 to 6 weeks, were 69 (67.6%) and 10 (9.8%) and those with decreased levels were 0 and 21 (20.5%) babies respectively. The percentage of fall of serum TSH and serum free T4 from between 2-7 days post birth and upto 2-6 weeks was 41.56% and 41.98% respectively, which was quite significant.

**Table 2: Comparison between thyroid values in newborns born to mothers with gestational and pregestational hypothyroidism**

Thyroid investigations at different time periods	Hypothyroidism detected before / during pregnancy	No.	Mean	Standard deviation	t-test p value	Significance
Cord TSH	Before	57	9.16	6.22	0.570	Not significant
	During	45	9.81	5.05		
	Total	102	9.45	5.71		
Serum TSH between 48 hours & 7 days	Before	57	5.35	3.57	0.389	Not significant
	During	45	5.98	3.71		
	Total	102	5.63	3.63		
Serum TSH 2-6 weeks	Before	57	3.34	2.91	0.794	Not significant
	During	45	3.22	1.25		
	Total	102	3.29	2.32		
Serum free T4 between 48 hours & 7 days	Before	57	3.06	0.84	0.270	Not significant
	During	45	3.24	0.79		
	Total	102	3.14	0.82		
Serum free T4 2-6 weeks	Before	57	1.83	0.43	0.802	Not significant
	During	45	1.81	0.51		
	Total	102	1.82	0.46		

### C orrelation studies

In those mothers who had pregestational hypothyroidism, there were 9 (15.5%) with elevated cord TSH, 2 (3.4%) with elevated serum TSH after 48 hours of life and 5 (8.6%) with elevated serum TSH between 2 to 6 weeks of life. Those mothers who had gestational hypothyroidism, there were 9 (20.5%) babies with elevated cord TSH, 2 (4.5%) babies with elevated serum TSH after 48 hours and 3 (6.8%) babies with elevated serum TSH between 2-6 weeks of life.

There were 11 and 10 babies with decreased free T4 values between 2 to 6 weeks of life, born to those mothers with pregestational and gestational hypothyroidism respectively. Tables 3 and 4 depicts the number of babies with deranged thyroid values versus their respective gestational period they were delivered, and Thyroid medication dosage range given to the mothers.

Chi-square and Fischer's exact test showed no correlation between elevated thyroid hormone values and gestation or gender of the babies, between thyroid values and hypothyroidism in mothers detected before or during pregnancy and the thyroid medication dosage in micrograms that the mothers received during pregnancy. Through Pearson correlation coefficient, a positive correlation was found

between cord TSH and serum TSH levels between 2-7 days and 2-6 weeks of life (as represented in Table 5).

### Hypothyroid babies

Out of 102 babies, 4 (3.92%) had subclinical hypothyroidism out of which, 2 (1.92%) belonged to transient neonatal hyperthyrotropinaemia group (elevated serum TSH levels and normal fT4 levels after 48 hours of life) which normalized after 2 weeks. Furthermore, both babies were born to mothers with hypothyroidism detected first time during pregnancy, out of which for one mother it was detected at second trimester and the other in third trimester, as shown in Table 6.

The other 2 (1.92%) fell into the persistent hyperthyrotropinemia group (persistently elevated TSH levels but normal free T4 values). Out of which, one baby had a normal cord TSH level and the other had an elevated value. These babies have to be followed up further to see for persistence of elevated levels and accordingly treatment to be started. It was seen that none of the babies had overt hypothyroidism and hence none of them were started on thyroid replacement therapy.

**Table 3: Number of babies with deranged Thyroid values versus their Gestational period**

	<b>Gestational period</b>	<b>Preterm</b>	<b>Early term</b>	<b>Full term</b>
1	Elevated TSH levels at birth	5 (19.2%)	8 (24.2%)	5 (11.6%)
	Elevated TSH levels at 2-7 days of life	1 (3.8%)	2 (6.1%)	1 (2.3%)
	Elevated TSH levels at 2-6 weeks of life	2 (6.1%)	2 (6.1%)	3 (7%)
	<b>Gestational period</b>	<b>Preterm</b>	<b>Early term</b>	<b>Full term</b>
2	Decreased free T4 values at 2-7 days of life	0	0	0
	Decreased free T4 values at 2-6 weeks of life	9 (30.7%)	5 (15.2%)	7 (16.27%)

**Table 4: Number of babies with deranged Thyroid values versus the Thyroid medication dosage range that the mothers were treated with**

	<b>Different regular dosages of thyroid replacement therapy received by Hypothyroid mothers</b>	<b>12.5-25 mcg</b>	<b>50-75 mcg</b>	<b>100-200mcg</b>
1	Elevated TSH levels at birth	4 (9.8%)	8 (18.6%)	6 (33.3%)
	Elevated TSH levels at 2-7 days of life	2 (4.9%)	1 (2.3%)	1 (5.6%)
	Elevated TSH levels at 2-6 weeks of life	1 (5.6%)	3 (7%)	0
	<b>Different regular dosages of thyroid replacement therapy received by Hypothyroid mothers</b>	<b>12.5-25 mcg</b>	<b>50-75 mcg</b>	<b>100-200mcg</b>
2	Decreased free T4 values at 2-7 days of life	0	0	0
	Decreased free T4 values at 2-6 weeks of life	8 (19.5%)	8 (18.6%)	5 (27.8%)

**Table 5: Pearson correlation between thyroid values, birth weight and dose of thyroid medication**

		<b>Birth Weight (g)</b>	<b>Dose of thyroid medications in mothers (mcg)</b>	<b>Cord TSH</b>	<b>S.TSH &gt;48h</b>	<b>S.TSH 2-6 weeks</b>	<b>S.FT4 &gt;48h</b>
Dose of thyroid medications in mothers (mcg)	Pearson Correlation	.093	-	-	-	-	-
	p	.353	-	-	-	-	-
Cord TSH	Pearson Correlation	-.040	.064	-	-	-	-
	p	.689	.520	-	-	-	-
S.TSH >48h	Pearson Correlation	-.242	-.018	.525	-	-	-
	p	.014	.860	.000	-	-	-
S.TSH 2-6 weeks	Pearson Correlation	-.250	.038	.138	.523	-	-
	p	.011	.702	.166	.000	-	-
S.FT4 >48h	Pearson Correlation	-.031	-.013	-.049	.012	.009	-
	p	.758	.894	.622	.902	.930	-
S.FT4 2-6 weeks	Pearson Correlation	.059	.002	-.055	.034	.075	.525
	p	.556	.987	.580	.732	.455	.000

**Table 6: Thyroid hormone levels of the hypothyroid babies**

Patient number	1	2	3	4
Gestational age	38W	34W+3D	37W+3D	40W
Cord TSH value	28.15	22.13	45.7	6.03
Inference	elevated	elevated	elevated	normal
Serum TSH value between 2-7 days	17.96	19.55	22.11	18.61
Inference	elevated	elevated	elevated	elevated
Serum free T4 value between 2-7 days	2.62	2.48	2.19	2.45
Inference	normal	normal	normal	normal
Serum TSH value between 2-6 weeks	6.23	6.8	5.65	6.26
Inference	normal	normal	elevated	elevated
Serum free T4 value between 2-6 weeks	1.54	1.83	1.77	1.25
Inference	normal	normal	normal	decreased
Diagnosis	Transient neonatal hyperthyrotropinaemia	Transient neonatal hyperthyrotropinaemia	Persistent hyperthyrotropinaemia	Persistent hyperthyrotropinaemia

## Discussion

Basnet et al<sup>[15]</sup> had studied 100 hypothyroidism women and their babies and found that the mean TSH values at 72 hours of life was  $2.95 \pm 2$   $\mu$ IU/L in group A (pregestational hypothyroidism group) and  $2.99 \pm 2.1$   $\mu$ IU/L in group B (gestational hypothyroid mothers group) - similarly in our study, between 2-7 days of life, the mean serum TSH in the group consisting of pregestational hypothyroid mothers was 5.37 mIU/L and in the gestational hypothyroidism group it was 5.98 mIU/L.L.

Blazer Shruga et al,<sup>[10]</sup> studied 2 groups of women, group 1 being hypothyroid mothers (n = 250), out of which 51 (20.4%) women in the group had gestational hypothyroidism and the rest 199 (79.6%) had pregestational hypothyroidism. Whereas our study had 58 (57%) women with hypothyroidism detected prior to pregnancy and 44 (43%) detected during pregnancy. Both studies had adequately treated the hypothyroid mothers during pregnancy with thyroid replacement medications.

Blazer Shruga et al<sup>[10]</sup> had found that 161 neonates had qualified for being studied at 49 hours or older, out of which it was seen that TSH levels were above 95th percentile in 16.8% and below the fifth percentile in 7.5%. The fT4 values were above 95th percentile in 44.7% and below 5th percentile in

15.5%.<sup>[10]</sup> However in our study, elevated TSH levels beyond 48 hours was seen in 3.9% and fT4 was in 67.6% babies. Furthermore, in their study,<sup>[9]</sup> it showed that fT4 levels correlated directly to TSH levels of control group infants but not in infants of hypothyroid mothers, suggesting an autonomous hyperfunction of the thyroid gland in the study neonates.

Ozdemir Hulya et al<sup>[9]</sup> had their TSH level cut-off at 20 mIU/L during the first postnatal week. On the third week, if serum TSH >7mIU/L and fT4 <1ng/dL – the infant was considered to have congenital hypothyroidism and, in our study, we had used gestational and postnatal age based thyroid level cut-offs.<sup>[14]</sup> In their study in group 2 (hypothyroid mothers without antibodies), 5 infants (23.8%) had serum TSH levels > 20 mIU/L in the first week and only 2 infants had serum TSH levels >7 mIU/L by third postnatal week. According to their definition, 2 babies in group 2 had congenital hypothyroidism and after they repeated the thyroid tests in eighth postnatal week, the values had normalised in their study.<sup>[9]</sup> Whereas we had 7 neonates with cord TSH level above 20 mIU/L, only 1 neonate had a serum TSH more than 20 mIU/L after 48 hours of life and by 2 to 6 weeks we had 1 baby with serum TSH >7 mIU/L (in whom thyroid levels were normal in the first week of life).



Medici Marco et al<sup>[3]</sup> had studied 5393 pregnant womens' thyroid levels and 3036 newborns' cord TSH values. They had excluded mothers with known thyroid diseases and those taking any sort of thyroid medication. They had found that the maternal and cord TSH and fT4 levels were positively correlating, which means that the higher the maternal TSH, the higher the cord TSH and free T4 values in the newborns – which was not the case in our study, possibly due to the pregestational hypothyroid group mothers having more stable thyroid levels and euthyroidism, due to prolonged usage of thyroid medication. They had also noted the importance of using population-specific reference ranges instead of standard ones, as we have used.

Sreelatha et al<sup>[1]</sup> had studied 100 mothers with thyroid disorders (96 of which had subclinical hypo-thyroidism and 4 had subclinical hyperthyroidism), out of which zero babies had neonatal hypothyroidism. Similar to our study where out of 102 babies, we did not have any babies with overt hypothyroidism and only 4 babies with subclinical hypothyroidism.

Cuestas Eduardo et al<sup>[11]</sup> found out that out of 5040 newborns in their study, 301 (5.97%) had transient elevated TSH levels, compared to ours - which was 2 (1.92%) out of 102 babies born to hypothyroid mothers. They had followed up 65 children from the transiently elevated neonatal TSH group and 185 children from the normal cohort, 6 years later. Six infants out of 65 (9.2%) transient neonatal hyperthyrotropinemia (TNH) babies consequently developed persistent hyperthyrotropinaemia (PH), whereas only 3 infants out of 185 (1.6%) babies from the non-TNH control group subsequently developed PH. This tells us that persistent hyperthyrotropinaemia is a condition that can arise from a neonate who has apparently normal thyroid status at first week of life. In our study, we had one neonate who had normal screening TSH but subsequently had elevated TSH on follow up.

The strengths of our study were that: all 102 consecutive patients were included in the final analysis and there were no dropouts, and this is one of the few studies, that has delved into the difference between neonatal thyroid levels born to mothers with pregestational and gestational hypothyroidism.

**Limitations:** there was no control group. The population size studied was relatively small and follow-up was not continued beyond 2-6 weeks of

life. A large multicentric and randomised controlled study would be needed for more reliable results.

## Conclusion

Thyroid hormone status of newborns born to hypothyroid mothers (who are adequately treated) are within normal limits, hence they are not at a greater risk of hypothyroidism compared to the general population. Furthermore, there is no difference in thyroid hormone status of such newborns, born to mothers with pregestational and gestational hypothyroidism. In those babies with normal cord TSH and normal TSH levels between 2-7 days, further testing between 2-6 weeks is probably not required.

## Disclosure

### Conflict of Interest

None

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None

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