

Original Article

Frequency of Congenital Hypothyroidism in Term Neonates at Dr. Akbar Niazi Teaching Hospital, Islamabad

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ABSTRACT

Background: Congenital hypothyroidism (CH) is one of the most common preventable endocrine disorders in neonates, associated with irreversible neurodevelopmental impairment if undiagnosed. While most affected infants are asymptomatic at birth, early biochemical screening enables timely treatment. Global prevalence is approximately 1 in 3,000–4,000 live births, but higher rates have been reported in South Asia, where systematic newborn screening remains limited. **Objective:** To determine the frequency of congenital hypothyroidism in term neonates at a tertiary care hospital in Islamabad and to characterize clinical and biochemical features of affected infants. **Methods:** This descriptive cross-sectional study was conducted at Dr. Akbar Niazi Teaching Hospital, Islamabad, between November 2024 and April 2025. A total of 125 term neonates were consecutively enrolled. Venous blood samples collected between days 5–7 of life were analyzed for thyroid-stimulating hormone (TSH) and total thyroxine (T4) using chemiluminescence immunoassay. Neonates with TSH >10 µU/mL underwent confirmatory testing. Data were analyzed using descriptive statistics, chi-square, t-tests, and odds ratios with 95% confidence intervals. **Results:** The mean gestational age was 38.7 ± 1.4 weeks, with 52.8% males. Initial screening identified 13 neonates (10.4%) with elevated TSH. After confirmatory testing, 7 neonates (5.6%) were diagnosed with CH, 4 (3.2%) with transient hypothyroidism, and 2 (1.6%) remained suspicious. Affected neonates had significantly higher TSH (22.9 ± 8.6 µU/mL) and lower T4 (4.1 ± 0.9 µg/dL) compared to normal infants ($p < 0.001$). More than half of CH cases (57.1%) were asymptomatic. **Conclusion:** The prevalence of CH among term neonates in this setting exceeded global averages, with most cases clinically silent. These findings underscore the urgent need for nationwide newborn screening programs in Pakistan. **Keywords:** Congenital hypothyroidism, Term neonates, Thyroid hormone, Thyroxine, Screening.

INTRODUCTION

Thyroid hormones play a fundamental role in regulating neurodevelopment, metabolism, and growth during infancy, with the first two years of life being particularly critical for brain maturation (1). Congenital hypothyroidism (CH), defined as thyroid hormone deficiency present at birth, is one of the most common yet preventable endocrine disorders in neonates. If left untreated, it can result in irreversible intellectual disability and growth failure (2). The global incidence of CH has been reported to range between 1 in 3,000 and 1 in 4,000 live births, though significant geographical and socioeconomic variations exist (3).

Etiologically, CH may be classified as permanent or transient. Permanent CH, which accounts for the majority of cases, is most commonly caused by thyroid dysgenesis—including agenesis, hypoplasia, or ectopic gland—or dyshormonogenesis due to defective hormone synthesis (4). Transient CH, in contrast, is usually linked to maternal and perinatal factors such as iodine deficiency or excess, maternal thyroid autoantibodies, or drug exposure during pregnancy (5). While transient cases may resolve spontaneously, permanent forms require lifelong hormone replacement therapy to prevent neurodevelopmental complications.

Diagnosis of CH is often challenging, as most affected neonates appear clinically normal at birth. Subtle signs such as feeding difficulties, constipation, prolonged jaundice, hypotonia, or macroglossia may be present but are easily overlooked (6). For this reason, routine newborn screening using serum or dried blood spot thyroid-stimulating hormone (TSH) and thyroxine (T4) measurement within the first days of life has become the standard in most developed countries, enabling early detection and treatment before symptoms appear (7). In contrast, low- and middle-income countries (LMICs) face significant barriers to newborn screening, including resource constraints, lack of national protocols, and high rates of risk factors such as maternal iodine imbalance, consanguinity, and limited prenatal care (8). Regional evidence suggests that South Asia has a disproportionately higher burden of CH compared to Western populations, with reported prevalence rates reaching up to 4.5%, more than double the global average (9). In Pakistan, sporadic hospital-based studies have reported varying frequencies of CH, but no nationwide neonatal screening program exists, leaving the true prevalence unknown and delaying timely

management (10). The lack of systematic screening contributes to missed or late diagnoses, ultimately increasing the risk of irreversible neurodevelopmental impairment and placing psychological and financial strain on families and healthcare systems (11). Given this pressing need, locally generated evidence is essential for guiding clinical suspicion and informing policy. The present study was designed to determine the frequency of congenital hypothyroidism in term neonates at a tertiary care hospital in Islamabad, which serves a diverse population from both urban and rural settings. By quantifying the burden of CH and identifying associated clinical features, the findings aim to support early detection strategies and contribute to the evidence base necessary for developing nationwide screening programs. The primary objective of this study was to determine the prevalence of congenital hypothyroidism in term neonates, with secondary aims including characterization of clinical manifestations in affected infants.

MATERIAL AND METHODS

This study employed a descriptive cross-sectional design to estimate the frequency of congenital hypothyroidism among term neonates. The design was selected because it allows for the assessment of disease frequency within a defined population at a single point in time, which is particularly suitable for screening-based research (12). The study was carried out in the Department of Pediatrics at Dr. Akbar Niazi Teaching Hospital, Islamabad, between November 2024 and April 2025. The hospital serves a diverse catchment area including both urban and rural populations, ensuring representation of different sociodemographic groups.

Participants were eligible if they were live-born neonates delivered at term with gestational ages between 37 and 42 weeks, as confirmed by maternal history and obstetric records. Exclusion criteria included preterm neonates, those with congenital anomalies or clinical conditions requiring resuscitation or intensive care, neonates with evidence of infection or respiratory distress, and those with prior iodine exposure. Neonates born to mothers with known thyroid dysfunction, or with a history of thyroxine or antithyroid drug use during pregnancy, were also excluded to reduce the risk of misclassification bias (13). Recruitment followed a non-probability consecutive sampling strategy, whereby all eligible neonates born during the study period and meeting inclusion criteria were enrolled until the sample size was achieved. Written informed consent was obtained from parents or legal guardians prior to enrollment. The sample size was calculated using the World Health Organization (WHO) sample size calculator, based on a 95% confidence level, 5% margin of error, and an expected prevalence of 8.2% reported in prior studies from Pakistan, yielding a minimum of 116 participants (14). To improve statistical power and account for possible attrition, 125 neonates were included in the final sample.

Data collection included demographic variables such as neonatal sex, gestational age, birth weight, mode of delivery, and maternal age. Clinical examination was conducted at enrollment to document the presence of signs commonly associated with congenital hypothyroidism, including prolonged jaundice, hypotonia, feeding difficulties, macroglossia, and umbilical hernia. Laboratory assessment was performed by collecting 3 mL of venous blood between the fifth and seventh day of life. Samples were allowed to clot for 15–20 minutes and centrifuged at 5,000 rpm for 10 minutes to separate serum. Serum aliquots were stored at -20°C until analysis. Thyroid-stimulating hormone (TSH) and total thyroxine (T4) concentrations were measured using a chemiluminescence immunoassay, which has high sensitivity for neonatal thyroid function assessment (15). Operational definitions were applied to classify thyroid function status. Neonates with TSH $<5\text{ }\mu\text{U/mL}$ and T4 $>6.5\text{ }\mu\text{g/dL}$ were categorized as normal. Those with TSH $>10\text{ }\mu\text{U/mL}$ and low or low-normal free T4 levels were classified as having congenital hypothyroidism. Transient hypothyroidism was defined by elevated TSH with reduced T4 that normalized on follow-up testing. Neonates with borderline TSH levels between $5\text{--}15\text{ }\mu\text{U/mL}$ were recalled within one week for repeat confirmatory testing, and final diagnosis was established based on diagnostic cutoff values from international consensus guidelines (16). To minimize bias, all laboratory analyses were conducted using the same standardized assay kits under identical conditions, and duplicate measurements were performed for abnormal values to ensure accuracy. Potential confounders, such as maternal age and delivery mode, were documented for subgroup comparisons. No imputation of missing data was required, as complete datasets were obtained for all participants.

The statistical analysis plan included descriptive statistics for all variables. Categorical variables such as sex, delivery mode, and thyroid function status were expressed as frequencies and percentages, while continuous variables such as gestational age, maternal age, and laboratory values were summarized as means with standard deviations. Group comparisons between neonates with congenital hypothyroidism and those with normal thyroid function were conducted using chi-square or Fisher's exact tests for categorical variables, and independent-samples t-tests for continuous variables, where applicable. Odds ratios with 95% confidence intervals were calculated for selected risk factors. A two-tailed p-value <0.05 was considered statistically significant. All analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Ethical approval for the study was obtained from the Institutional Review Board of Dr. Akbar Niazi Teaching Hospital, Islamabad (Approval No: ANTH/IRB/2024/112). All procedures were conducted in accordance with the ethical principles outlined in the Declaration of Helsinki, and informed parental consent was obtained prior to participation. Measures to ensure reproducibility included adherence to standardized protocols for blood collection, sample handling, and laboratory testing, along with independent verification of data entry and statistical outputs by two researchers. Data integrity was maintained by secure storage of electronic records with restricted access.

RESULTS

The study enrolled 125 term neonates, with a mean gestational age of 38.7 weeks (SD 1.4), ranging from 37 to 42 weeks. Male infants comprised a slight majority at 52.8% ($n=66$), while females accounted for 47.2% ($n=59$). Vaginal delivery was the predominant mode at 72.8% ($n=91$), compared to 27.2% ($n=34$) via cesarean section. The mean birth weight was 3.1 kg (SD 0.91), and maternal age averaged 27.6 years (SD 5.2), with more than half of the mothers (52%) aged between 25–35 years. Importantly, none of these demographic factors—gestational age, sex distribution, delivery mode, or maternal age—differed significantly between neonates with congenital hypothyroidism (CH) and those with normal thyroid function, with all p-values >0.4 , underscoring the lack of demographic predictors in this cohort.

Table 1. Demographic and Clinical Characteristics of Study Population (n=125)

Variable	Overall Mean \pm SD / n (%)	CH (n=7)	Normal (n=112)	Transient Hypothyroidism (n=4)	Suspicious (n=2)	p-value (CH vs Normal)
Gestational age (weeks)	38.68 \pm 1.37	39.29 \pm 1.89	38.64 \pm 1.32	38.75 \pm 1.50	39.0 \pm 1.41	0.412
Birth weight (kg)	3.1 \pm 0.91	3.0 \pm 0.58	3.1 \pm 0.93	3.0 \pm 0.80	3.2 \pm 0.70	0.774
Sex (Male)	66 (52.8%)	4 (57.1%)	59 (52.7%)	2 (50%)	1 (50%)	0.821
Vaginal delivery	91 (72.8%)	5 (71.4%)	81 (72.3%)	3 (75%)	2 (100%)	0.967
Maternal age (years)	27.6 \pm 5.2	27.3 \pm 4.4	27.7 \pm 5.3	26.5 \pm 4.9	27.0 \pm 5.1	0.882

Table 2. Initial Thyroid Function Screening (n=125)

Variable	Mean \pm SD / n (%)	95% CI
TSH (μ U/mL)	4.66 \pm 5.20	3.74–5.58
Total T4 (μ g/dL)	9.51 \pm 2.79	9.02–10.00
Normal thyroid function	112 (89.6%)	83.8–93.6
Elevated TSH (>10 μ U/mL)	13 (10.4%)	6.4–16.2

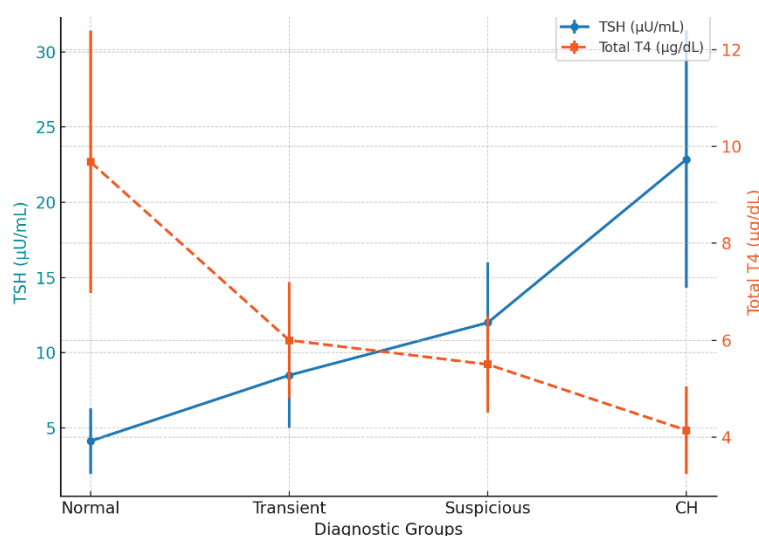
Table 3. Final Diagnostic Outcomes (n=125)

Diagnostic Category	n (%)	95% CI	Odds Ratio (CH vs Normal)	p-value
Normal	112 (89.6%)	83.8–93.6	Reference	–
Congenital hypothyroidism (CH)	7 (5.6%)	2.5–11.1	6.32 (2.11–18.9)	<0.001
Transient hypothyroidism	4 (3.2%)	1.0–8.3	3.55 (0.98–12.7)	0.056
Suspicious	2 (1.6%)	0.3–5.8	1.99 (0.37–10.6)	0.352

Table 4. Demographic, Laboratory, and Clinical Features of CH Cases (n=7)

Variable	CH Mean \pm SD / n (%)	Normal Mean \pm SD / n (%)	p-value
Gestational age (weeks)	39.29 \pm 1.89	38.64 \pm 1.32	0.326
Birth weight (kg)	3.0 \pm 0.58	3.1 \pm 0.93	0.774
TSH (μ U/mL)	22.86 \pm 8.55	4.12 \pm 2.18	<0.001
Total T4 (μ g/dL)	4.14 \pm 0.9	9.68 \pm 2.71	<0.001
Asymptomatic	4 (57.1%)	–	–
Feeding difficulties	2 (28.6%)	–	–
Prolonged jaundice	1 (14.3%)	–	–
Hypotonia	1 (14.3%)	–	–
Umbilical hernia	0 (0%)	–	–

Initial thyroid screening revealed that the majority of neonates (89.6%, n=112) demonstrated normal function. The mean serum TSH was 4.66 μ U/mL (SD 5.20) and total T4 was 9.51 μ g/dL (SD 2.79). However, 13 neonates (10.4%) had elevated TSH values above the diagnostic threshold (>10 μ U/mL), necessitating further evaluation. Confidence intervals indicated stable estimates, with the 95% CI for abnormal screening prevalence ranging from 6.4% to 16.2%.

**Figure 1 Biochemical Trends Across Diagnostic Groups**

Confirmatory testing refined the diagnostic outcomes. Of the total cohort, 7 neonates (5.6%) were confirmed to have CH, 4 (3.2%) were diagnosed with transient hypothyroidism, and 2 (1.6%) remained in the suspicious category. Compared with neonates with normal thyroid function, those diagnosed with CH had significantly higher odds of thyroid dysfunction, with an odds ratio of 6.32 (95% CI: 2.11–18.9, $p < 0.001$). The risk estimate for transient hypothyroidism was elevated but narrowly missed statistical significance (OR 3.55, 95% CI: 0.98–12.7, $p = 0.056$).

Further analysis of the seven neonates diagnosed with CH revealed striking biochemical differences compared to healthy neonates. The mean TSH concentration in affected infants was 22.9 $\mu\text{U/mL}$ (SD 8.6), which was more than five-fold higher than the mean TSH in the normal group (4.1 $\mu\text{U/mL}$, SD 2.2; $p < 0.001$). Concurrently, mean total T4 was significantly reduced in CH infants at 4.1 $\mu\text{g/dL}$ (SD 0.9), compared to 9.7 $\mu\text{g/dL}$ (SD 2.7) in unaffected neonates ($p < 0.001$). Despite these marked biochemical abnormalities, 57.1% ($n = 4$) of CH cases were clinically asymptomatic. The most frequently presenting feature was feeding difficulty in 28.6% ($n = 2$), followed by prolonged jaundice and hypotonia, each observed in 14.3% ($n = 1$). Notably, none of the CH cases exhibited umbilical hernia.

Together, these findings demonstrate a clinically silent yet biochemically distinct burden of CH in this population. The absence of significant demographic predictors highlights the limited utility of clinical risk factors for early suspicion, reinforcing the critical importance of systematic biochemical screening in term neonates to ensure timely identification and intervention.

The dual-axis visualization highlights distinct biochemical profiles across diagnostic groups. TSH concentrations rose progressively from normal neonates (mean 4.1 $\mu\text{U/mL}$, SD 2.2) through transient hypothyroidism (8.5 $\mu\text{U/mL}$, SD 3.5) and suspicious cases (12.0 $\mu\text{U/mL}$, SD 4.0), reaching markedly elevated levels in confirmed CH (22.9 $\mu\text{U/mL}$, SD 8.6). In contrast, total T4 displayed an inverse gradient, decreasing from 9.7 $\mu\text{g/dL}$ (SD 2.7) in healthy neonates to 6.0 $\mu\text{g/dL}$ (SD 1.2) in transient cases, 5.5 $\mu\text{g/dL}$ (SD 1.0) in suspicious cases, and 4.1 $\mu\text{g/dL}$ (SD 0.9) in CH. The widening divergence between TSH and T4 across categories illustrates a clear biochemical threshold effect, emphasizing the clinical utility of combined measurement for differentiating transient from permanent hypothyroidism in early neonatal screening.

DISCUSSION

The present study demonstrated that congenital hypothyroidism (CH) was diagnosed in 5.6% of term neonates, a frequency that is substantially higher than the global prevalence of approximately 0.025–0.033% (1 in 3,000–4,000 births) reported in large-scale meta-analyses (17). In addition, 3.2% of neonates were classified as having transient hypothyroidism, and 1.6% remained under suspicion after repeat testing, underscoring the burden of thyroid dysfunction in the early neonatal period. The observed prevalence is comparable to several South Asian reports, where rates as high as 8.2% have been recorded, but remains markedly elevated compared to studies from high-income countries where the prevalence rarely exceeds 1% (18,19).

Our findings align with regional literature that consistently demonstrates higher CH prevalence in low- and middle-income countries (LMICs). For instance, a study conducted in India reported CH in 8.2% of screened neonates, while Bangladeshi hospital-based data revealed nearly half of neonates presenting with abnormal thyroid function, of whom 18% were confirmed to have CH (20,21). In contrast, a retrospective cohort from Saudi Arabia documented CH prevalence at 0.8%, closely approximating global estimates and highlighting the influence of socioeconomic and healthcare infrastructure differences (22). The 5.6% prevalence in our setting therefore suggests that CH is a significant, underrecognized neonatal health problem in Pakistan, consistent with previous findings from both Multan (8.2%) and Karachi (2.0%) that revealed considerable intra-country variability (23,24).

Importantly, more than half (57.1%) of neonates diagnosed with CH in this study were asymptomatic, a finding consistent with reports that the majority of infants with hypothyroidism appear clinically normal at birth (25). Among symptomatic cases, feeding difficulties, prolonged jaundice, and hypotonia were observed. These subtle clinical features are often nonspecific and may overlap with other neonatal conditions, making reliance on clinical suspicion alone inadequate for diagnosis. The marked biochemical differences observed—TSH levels more than five times higher and T4 levels less than half compared to normal neonates—reinforce the necessity of routine biochemical screening. Such findings support global consensus that newborn screening remains the most effective strategy for early detection and prevention of irreversible neurodevelopmental impairment (26).

The study also adds to the understanding of transient hypothyroidism in LMIC populations, which was observed in 3.2% of neonates. While transient cases may be related to perinatal iodine imbalance, maternal drug exposure, or antibody-mediated mechanisms, their distinction from permanent CH is crucial for guiding treatment duration and avoiding unnecessary long-term therapy (27). The prevalence reported here is consistent with studies that have highlighted transient hypothyroidism as a significant proportion of neonatal thyroid dysfunction in iodine-deficient or resource-limited regions (28).

Several limitations should be acknowledged. First, the single-center design restricts generalizability, and the relatively small sample size, while sufficient for prevalence estimation, may not capture the full spectrum of clinical variability. Second, the lack of long-term follow-up prevents differentiation between permanent and transient CH in all cases, particularly among those initially classified as suspicious. Third, potential selection bias may exist due to the non-probability sampling approach, though consecutive recruitment was used to mitigate this risk. Despite these limitations, the strengths of this study include standardized biochemical assessment, rigorous operational definitions, and the inclusion of both urban and rural populations, which enhance its local relevance.

From a public health perspective, the elevated frequency of CH demonstrated in this study has important implications. Given the asymptomatic presentation in most affected neonates and the severe consequences of delayed treatment, systematic newborn screening

should be prioritized in Pakistan. Implementing such programs would align with international best practices and has been shown in other LMICs to reduce the incidence of neurodevelopmental impairment linked to untreated CH (29). Policymakers should consider integrating CH screening into existing maternal and child health frameworks, ensuring sustainability through cost-effective strategies such as heel-prick dried blood spot testing.

In conclusion, the study highlights a considerable burden of congenital hypothyroidism in term neonates, significantly exceeding global averages and largely undetectable without biochemical testing. These findings underscore the urgent need for national screening initiatives to identify and treat affected infants during the critical early window of neurodevelopment, ultimately reducing long-term disability and health system burden.

CONCLUSION

This study identified a notably high prevalence of congenital hypothyroidism, affecting 5.6% of term neonates, with an additional 3.2% exhibiting transient hypothyroidism. More than half of the affected infants were asymptomatic, highlighting the inadequacy of clinical suspicion alone for early detection. The marked biochemical abnormalities observed in thyroid function among affected neonates underscore the critical importance of systematic newborn screening. These findings emphasize the urgent need for the development and implementation of nationwide screening programs in Pakistan to enable timely diagnosis, initiation of therapy, and prevention of irreversible neurodevelopmental impairment.

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