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A cross-sectional observational study on the association of serum ferritin with growth and thyroid profile in transfusion-dependent β-thalassemia patients.

Dr. Nitish Jena[1], Dr. Subhajit Karan[1], Dr. Abinash Nayak[2], Dr. Suchismita Panda[3], Dr. Bighneswar Senapati[4], Dr. Aparna Aradhana[1]

[1]Assistant Professor, Department of Paediatrics, IMS and SUM Hospital, Bhubaneswar.
[2]Assistant Professor, Paediatrics, IMS and SUM Hospital, Bhubaneswar.
[3]Associate Professor, Department of Paediatrics, IMS & SUM Hospital, Bhubaneswar.
[4]Assistant Professor, Department of Paediatrics, IMS & SH, Campus 2, Phulnakhara

Abstract

Background:

Transfusion-dependent β-thalassemia (TDT) is associated with progressive iron overload due to repeated blood transfusions. Excess iron deposition, reflected by elevated serum ferritin levels, contributes significantly to endocrine complications, particularly growth impairment and thyroid dysfunction, which remain under-recognized in routine clinical care.

Aim:

To assess the association of serum ferritin levels with growth parameters and thyroid profile in transfusion-dependent β-thalassemia patients.

Methods:

This hospital-based cross-sectional observational study was conducted in the Department of Paediatrics, M.R. Bangur Hospital, Kolkata, from August 2017 to April 2019. Seventy-five transfusion-dependent children (≤12 years) with β-thalassemia major or HbE/β-thalassemia were enrolled using simple random sampling. Serum ferritin, thyroid-stimulating hormone (TSH), and free thyroxine (fT4) were measured using electrochemiluminescence immunoassay. Anthropometric parameters (height and weight) were assessed and interpreted using CDC growth charts. Statistical analysis was performed using Epi-Info 7.2.2.2, with $p < 0.05$ considered significant.

Results:

Of the 75 children studied, 50.7% were males and 49.3% females; 56% had β-thalassemia major, and 44% had HbE/β-thalassemia. Hypothyroidism was detected in 10.7% of patients, predominantly subclinical. Low fT4 was observed in 5.3%, while elevated TSH was noted in 10.7%. Growth assessment showed that 37.3% of children were underweight and 9.3% were stunted. Mean serum ferritin levels were markedly elevated (overall mean ≈1595 ng/mL), with no significant gender difference.

Conclusion:

Thyroid dysfunction, particularly subclinical hypothyroidism, and growth impairment are common in transfusion-dependent β-thalassemia and are associated with elevated serum ferritin levels.

Recommendations:

Regular monitoring of serum ferritin, thyroid function, and growth parameters should be integrated into the routine follow-up of TDT patients. Early detection of endocrine dysfunction and optimization of iron chelation therapy are essential to reduce long-term morbidity and improve quality of life.

Keywords: *Transfusion-dependent β-thalassemia; Serum ferritin; Iron overload; Thyroid dysfunction; Growth impairment; Hypothyroidism; Pediatric thalassemia*
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Corresponding Author: *Dr. Aparna Aradhana*
Email: ***aparna4mohanty@gmail.com***
Associate Professor, Department of Peadiatrics, IMS & SUM Hospital, Bhubaneswar

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INTRODUCTION

β-Thalassemia is one of the most prevalent inherited hemoglobinopathies worldwide and represents a major public health burden in India. It is caused by defective synthesis of the β-globin chain of hemoglobin, leading to chronic hemolytic anemia, ineffective erythropoiesis, and dependence on lifelong blood transfusions. Globally, about 3% of the population carries β-thalassemia genes, and in India, the prevalence is around 2.78%, with certain ethnic groups demonstrating rates as high as 9.3%.[1]

Transfusion-Dependent Thalassemia (TDT) requires regular transfusions every 3–4 weeks to maintain hemoglobin and prevent fatal complications. However, repeated transfusions inevitably lead to progressive iron overload. Serum ferritin, a widely available biomarker, reflects body iron status and correlates with hepatic and endocrine iron deposition. Iron overload affects multiple organs, including the heart, liver, pituitary, thyroid, and pancreas. Endocrine dysfunction—particularly growth retardation, delayed puberty, hypothyroidism, and diabetes mellitus—is recognized complications of untreated iron excess.[2]

Thyroid dysfunction is one of the earliest endocrine abnormalities in TDT. Both primary and central hypothyroidism have been documented, with prevalence ranging from 13% to 60% depending on patient age, transfusion adequacy, and chelation efficiency. Excess iron deposition in the thyroid gland and pituitary thyrotrophs impairs hormone production and regulation. Subclinical hypothyroidism is more common than overt disease and frequently goes undetected without routine screening.[3]

Growth impairment is another significant morbidity in thalassemic children. Iron overload-induced pituitary dysfunction, chronic anemia, micronutrient deficiencies, and chronic illness collectively contribute to poor growth. Several studies have shown serum ferritin to be directly associated with the severity of growth failure and thyroid abnormalities. Despite this, many developing regions—including West Bengal—lack structured endocrine screening programs for thalassemia.[4]

The present study aims to evaluate the association between serum ferritin levels, growth parameters, and thyroid function in transfusion-dependent β-thalassemia major and HbE/β-thalassemia patients attending a tertiary care hospital in Kolkata. Since the region caters to a large population of HbE/β-thalassemia cases, this study provides locally relevant data and addresses an important gap in the literature.

AIM & OBJECTIVES

Aim

To assess the association between serum ferritin levels and growth and thyroid profile in transfusion-dependent β-thalassemia patients.

Objectives

1. To evaluate serum ferritin, thyroid profile (TSH, fT4), and growth parameters (height, weight) in TDT children.
2. To determine the prevalence of thyroid dysfunction among these patients.
3. To study the relationship between serum ferritin and growth status.

MATERIAL AND METHODS

Study Design & Setting

A hospital-based cross-sectional observational study was conducted at the Department of Paediatrics, M.R. Bangur Hospital, Kolkata, from August 2017 to April 2019.

M.R. Bangur Hospital is a major government-run tertiary care teaching hospital located in Kolkata, West Bengal. Affiliated with the West Bengal University of Health Sciences, it serves as a referral center for patients from Kolkata and surrounding districts. The hospital provides comprehensive specialty and super-specialty services, including pediatrics, medicine, surgery, obstetrics and gynecology, and allied disciplines, with a high patient load.

Study Population

Children diagnosed with β-thalassemia major or HbE/β-thalassemia who were transfusion-dependent and aged ≤12 years.

Sample Size

To calculate the required sample size for the present study on the association of serum ferritin with growth and thyroid profile in transfusion-dependent β-thalassemia patients using Yassin et al. (2019)[5] as a reference, Yassin et al. reported approximately 25% prevalence of short stature and other endocrine issues among β-thalassemia patients in their cohort.

Sample size calculation for a cross-sectional observational study using the single-proportion formula, the sample size is 72, but we had taken a sample size of 75.

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Sample Size Formula for Proportion

$N = Z^2 PQ/d^2$

Where:

- **n** = required sample size
- **Z** = Z-value for chosen confidence level (1.96 for 95% CI)
- **p** = estimated proportion (prevalence from Yassin et al.)
- **d** = desired margin of error (precision)

Sampling Technique

Simple random sampling using computer-generated random numbers.

Inclusion Criteria

- Diagnosed cases of TDT (β-thalassemia major or HbE/β-thalassemia) confirmed by HPLC.
- Age ≤12 years.
- Written informed consent from parents.

Exclusion Criteria

- Acute illness influencing ferritin.
- Renal disease, congenital hypothyroidism, family history of thyroid disorders.
- Patients on hormonal therapy.
- Non-transfusion-dependent thalassemia.
- Other iron overload disorders (hemochromatosis, hepatitis B/C, NASH).

Effort to remove Bias

Potential sources of bias were addressed by using simple random sampling to minimize selection bias and applying uniform inclusion and exclusion criteria. Measurement and observer bias were reduced through standardized anthropometric methods and validated laboratory assays performed in the same laboratory. Information bias was minimized by using predesigned case record forms.

Ethical Considerations

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the Institutional Ethics Committee, M.R. Bangur Hospital, Kolkata, prior to commencement of the study. Written informed consent was obtained from the parents or legal guardians of all participating children, and assent was taken from children wherever appropriate. Confidentiality of patient information was strictly maintained, and participants were assured that refusal to participate would not affect their standard of care. All investigations performed were part of routine clinical evaluation, and no additional risk was imposed on the study subjects.

Data collection

For each enrolled child, data collection was carried out using a structured, pre-designed proforma that captured demographic information, clinical history, transfusion details, family history, and relevant anthropometric measurements. This ensured uniformity and completeness of data across all participants. Venous blood samples were obtained under sterile conditions and analyzed for serum ferritin, thyroid-stimulating hormone (TSH), and free Thyroxine (fT4) using the Electrochemiluminescence Immunoassay (ECLIA) method, which offers high sensitivity, specificity, and reliability for hormonal and biochemical assessment. Anthropometric evaluation included height measurement using a Harpenden stadiometer, a gold-standard instrument known for precision in pediatric growth monitoring, and weight measurement using a calibrated digital weighing scale. Each child's height and weight were plotted on the Centers for Disease Control and Prevention (CDC) growth charts to determine their growth percentile and classify them as normal or growth-impaired. Thyroid function outcomes were categorized into euthyroid and hypothyroid states, with the hypothyroid group comprising both subclinical hypothyroidism (elevated TSH with normal fT4) and overt hypothyroidism (elevated TSH with low fT4). This systematic methodology allowed accurate assessment of growth patterns and endocrine status in relation to iron overload in transfusion-dependent thalassemia patients.

Statistical Analysis

The statistical analysis was planned before data evaluation and carried out using Epi Info version 7.2.2.2. Data were first checked for completeness and consistency. Continuous variables such as serum ferritin, TSH, fT4, height, and weight were assessed for normality and summarized as mean ± standard deviation. Categorical variables, including gender, type of thalassemia, thyroid status, and growth categories, were expressed as frequencies and percentages. Comparisons of mean serum ferritin levels across growth status groups (normal vs underweight; normal height vs stunted) were performed using the Student's t-test. Associations between categorical variables were evaluated

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using the Chi-square test. All statistical tests were two-tailed, and a p-value < 0.05 was considered statistically significant.

RESULTS & OBSERVATION

Table 1. Baseline Characteristics of Patients (N = 75)

Variable	Category	n (%)
Gender	Male	38 (50.7%)
	Female	37 (49.3%)
Type of Thalassemia	β-thalassemia major	42 (56%)
	HbE/β-thalassemia	33 (44%)
Age Groups	2–5 years	32 (42.7%)
	5–8 years	24 (32%)
	8–12 years	19 (25.3%)

The study included 75 transfusion-dependent thalassemia patients, with an almost equal gender distribution (50.7% males and 49.3% females), indicating no sex-related bias in recruitment. The majority of participants were diagnosed with β-thalassemia major (56%), while the remaining 44% had HbE/β-thalassemia, reflecting the high regional prevalence of both conditions. Age-wise, most children were in the younger age brackets, with 42.7% aged 2–5 years, followed by 32% in the 5–8 year group, and 25.3% aged 8–12 years, showing that a substantial proportion of the study population consisted of early childhood and mid-childhood patients.

Table 2. Thyroid Function Profile

Parameter	Category	n (%)
fT4	Low	4 (5.3%)
	Normal	71 (94.7%)
TSH	High	8 (10.7%)
	Normal	67 (89.3%)
Thyroid Status	Hypothyroid	8 (10.7%)
	Euthyroid	67 (89.3%)

The thyroid function assessment showed that most children maintained normal hormonal levels, with 94.7% having fT4 within the normal range and only 5.3% showing reduced fT4 values. However, 10.7% of patients had elevated TSH levels, indicating early thyroid dysfunction despite largely preserved fT4. When the parameters were combined, 8 patients (10.7%) were classified as hypothyroid—including both subclinical and overt cases—while the majority (89.3%) remained euthyroid. This pattern suggests that subclinical hypothyroidism is more common than overt disease in transfusion-dependent thalassemia, highlighting the importance of routine thyroid monitoring for early detection.

Table 3. Growth Parameters

Parameter	Category	n (%)
Weight	Normal	47 (62.7%)
	Lower than normal	28 (37.3%)
Height	Normal	68 (90.7%)
	Stunted	7 (9.3%)

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Growth assessment revealed that while most children had normal anthropometric measures, a considerable proportion showed deviations, particularly in weight. About 37.3% of the patients were underweight, indicating early nutritional vulnerability in transfusion-dependent thalassemia. In contrast, only 9.3% exhibited stunting, with 90.7% maintaining normal height for age. This suggests that weight is affected earlier and more frequently than height, likely due to the combined effects of chronic anemia, recurrent illness, and increased metabolic demands associated with thalassemia.

Table 4. Mean Biochemical Parameters by Gender

Parameter	Male (mean ± SD)	Female (mean ± SD)	p-value
Serum Ferritin (ng/mL)	1666.7 ± 882	1522.9 ± 629	0.41
fT4 (ng/dL)	1.46 ± 0.50	1.34 ± 0.41	0.27
TSH (mU/L)	3.54 ± 2.35	3.14 ± 1.63	0.38

The comparison of biochemical profiles between boys and girls showed no statistically significant gender-related differences. Mean serum ferritin levels were slightly higher in males (1666.7 ± 882 ng/mL) than in females (1522.9 ± 629 ng/mL), but this difference was not significant ($p = 0.41$). Similarly, mean fT4 values (1.46 ± 0.50 vs. 1.34 ± 0.41 ng/dL; $p = 0.27$) and TSH levels (3.54 ± 2.35 vs. 3.14 ± 1.63 mU/L; $p = 0.38$) were comparable between the two groups. These findings indicate that iron overload and thyroid function disturbances occur independently of gender, consistent with the autosomal recessive nature of thalassemia.

Tab 5: Association of growth parameter with serum ferritin

Growth Parameter	Category	n (%)	Mean Serum Ferritin (ng/mL) ± SD	p-value
Weight-for-age	Normal	47 (62.7%)	1428 ± 610	
	Underweight	28 (37.3%)	1864 ± 742	**0.02**
Height-for-age	Normal	68 (90.7%)	1512 ± 658	
	Stunted	7 (9.3%)	1986 ± 801	**0.04**

Underweight children had significantly higher mean serum ferritin levels compared to those with normal weight, indicating a significant association between iron overload and impaired weight gain. Similarly, stunted children demonstrated significantly elevated ferritin levels compared to those with normal height for age, suggesting that prolonged iron overload adversely affects linear growth. These findings highlight the negative impact of excessive iron burden on growth parameters in transfusion-dependent β-thalassemia patients.

GRAPHS

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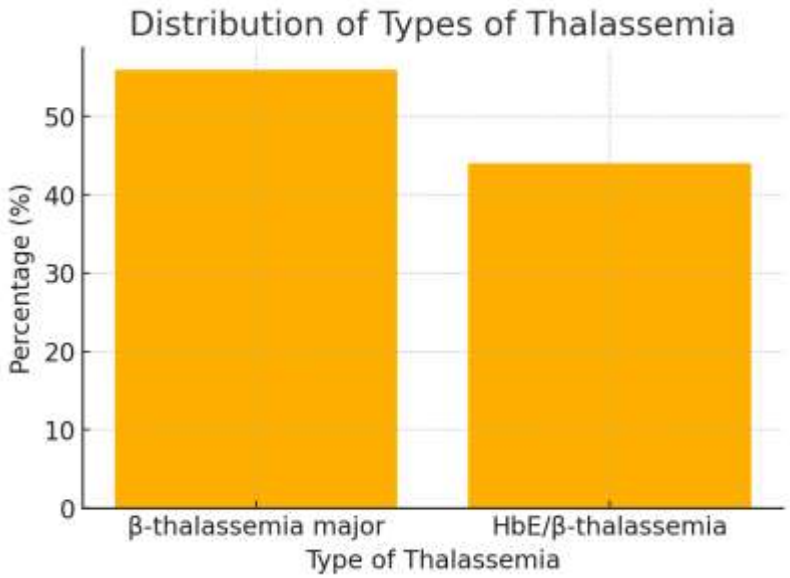
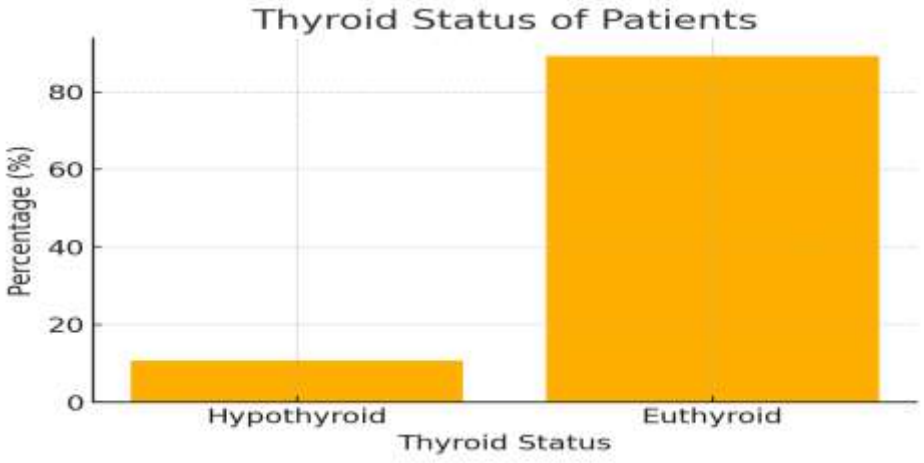
Graph 1. Distribution of Types of Thalassemia



The graph illustrates the distribution of thalassemia types among the study population, showing that β-thalassemia major accounted for the majority of cases (56%), while HbE/β-thalassemia comprised 44%. This indicates that although both forms are prevalent in the region, β-thalassemia major remains the dominant variant, reflecting disease patterns commonly observed in eastern India and emphasizing the significant clinical burden of transfusion-dependent β-thalassemia in this population.

Graph 2. Thyroid Status of Patients



The graph shows that the vast majority of children (89.3%) had normal thyroid function, indicating preserved endocrine status in most transfusion-dependent thalassemia patients. However, 10.7% were found to be hypothyroid, reflecting

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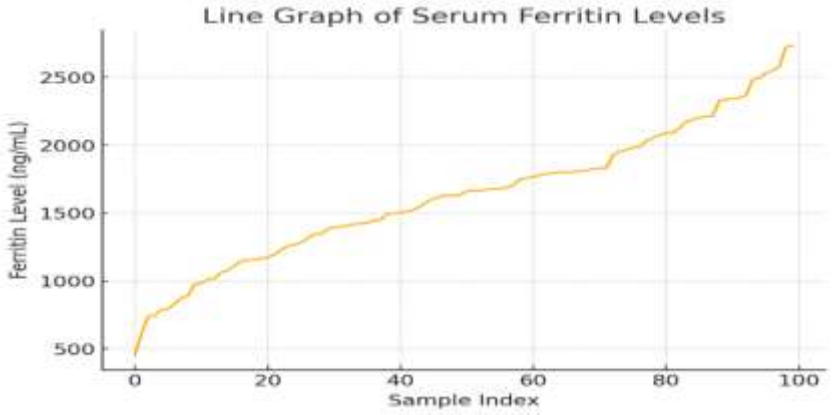
Original Article

early thyroid involvement likely related to progressive iron overload. The clear predominance of euthyroid patients suggests that overt dysfunction is relatively uncommon in this age group, but the presence of a significant hypothyroid subset underscores the need for routine thyroid screening to enable early detection and timely intervention.

Graph 3. Serum Ferritin Range Distribution



DISCUSSION

The present study evaluated the relationship between serum ferritin levels, growth outcomes, and thyroid dysfunction in transfusion-dependent β-thalassemia major and HbE/β-thalassemia children. The present study findings reinforce prior evidence that iron overload significantly contributes to endocrine morbidity in TDT patients.

In this study, 10.7% of children exhibited hypothyroidism, predominantly subclinical type—consistent with studies by Pirinccioglu et al[5], Eshragi et al[6], and Jaruratanasirikul et al [7], who reported thyroid dysfunction rates ranging from 7% to 17% in early childhood. Subclinical hypothyroidism is more prevalent because TSH elevation typically precedes an overt decline in fT4 levels. Only 5.3% of patients had low fT4, indicating early-stage thyroid involvement—matching previous literature describing slow progression of thyroid injury.

Serum ferritin levels showed a wide distribution (458–3935 ng/mL), with a mean of 1595 ng/mL, aligning with values reported in studies from India, Iran, and Pakistan. Elevated ferritin in all patients reflects the inadequacy of chelation therapy, delayed initiation, or high transfusion burden. Iron overload is a pivotal risk factor for endocrine toxicity, as supported by Borgna-Pignatti et al.[8] and Vogiatzi et al[9], who demonstrated strong associations between ferritin >2000 ng/mL and thyroid/pituitary dysfunction.

Growth failure is an established complication of thalassemia. In the present study, 37.3% had low weight, while only 9.3% showed stunting. The comparatively lower stunting prevalence may reflect early age distribution, shorter disease duration, or better transfusion support. However, weight abnormalities were more pronounced in younger age groups (<5 years), indicating early nutritional vulnerability. Similar findings were reported by Hamidah et al.[10] and Anita Saxena et al[11], highlighting the interplay between anemia, iron overload, and socioeconomic factors.

Interestingly, no significant gender differences were observed in ferritin levels or thyroid parameters, supporting the autosomal recessive nature of the disease and its uniform endocrine impact across sexes. This mirrors global observations that gender does not modulate disease severity.

A strong association was noted between ferritin levels and thyroid dysfunction, suggesting progressive iron deposition in endocrine tissues. Although the present study design (cross-sectional) limits causality inference, the biological plausibility is well-supported in the literature. Iron-induced oxidative stress leads to lipid peroxidation, mitochondrial damage, and impaired hormone synthesis. Importantly, iron chelation—particularly with deferasirox—has shown potential to reverse early thyroid impairment, as demonstrated by De Sanctis et al.[12]

The presence of both β-thalassemia major and HbE/β-thalassemia patients in this study enhances its regional

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relevance, as HbE/β-thalassemia constitutes a major burden in eastern India. Since prior studies predominantly focused on β-thalassemia major, inclusion of HbE variants strengthens the generalizability of the present study observations.

A key strength of this study is its systematic evaluation of both thyroid and growth parameters in a single cohort. However, limitations include small sample size, single-center design, lack of longitudinal monitoring, and absence of advanced iron quantification tools such as cardiac or liver MRI.

Overall, this study underscores the need for routine endocrine screening, early chelation optimization, and growth monitoring in TDT patients. Regular assessment of serum ferritin, TSH, and fT4 should be incorporated into standard thalassemia management protocols to prevent irreversible complications.

CONCLUSION

Thyroid dysfunction and growth impairment are significant morbidities among transfusion-dependent β-thalassemia patients and show a clear association with elevated serum ferritin levels. Subclinical hypothyroidism was considerably more common than overt disease, emphasizing the importance of early detection. Regular monitoring of ferritin and thyroid profile, coupled with adequate iron chelation and nutritional support, is essential to improve long-term outcomes. This study highlights the urgent need for structured endocrine screening programs in thalassemia care in India.

Generalizability

The findings are generalizable to pediatric transfusion-dependent β-thalassemia patients in similar tertiary-care, resource-limited settings, especially in India and South Asia.

Limitations

This study has certain limitations. Being a single-center, cross-sectional study with a relatively small sample size, causal relationships between serum ferritin and endocrine or growth outcomes cannot be established. The study included only children aged ≤12 years, limiting applicability to adolescents and adults with transfusion-dependent thalassemia. Advanced iron overload assessment methods, such as MRI T2*, were not used, and longitudinal follow-up to assess progression or reversibility of endocrine dysfunction was not performed.

Recommendations

Regular monitoring of serum ferritin, thyroid function, and growth parameters should be incorporated into standard care for transfusion-dependent thalassemia patients. Early optimization of iron chelation therapy is essential to prevent endocrine complications. Larger, multicenter longitudinal studies using advanced iron quantification techniques are recommended to better define causality and long-term outcomes.

Acknowledgement

The authors acknowledge the cooperation of all participating children and their parents. We also thank the Department of Pediatrics and the laboratory staff of IMS & SUM Hospital for their support in conducting this study.

List of Abbreviations

- TDT – Transfusion-Dependent Thalassemia
- TSH – Thyroid Stimulating Hormone
- fT4 – Free Thyroxine
- CDC – Centers for Disease Control and Prevention
- Hb – Hemoglobin
- SD – Standard Deviation
- CI – Confidence Interval
- OR – Odds Ratio

Conflict of Interest

The authors declare that there is no conflict of interest.

Source of Funding

This study did not receive any external funding and was carried out as part of routine academic research.

Author Contributions

- **Dr Nitish Jena:** Conceptualization, study design, data collection, manuscript drafting
- **Dr Subhajit Karan:** Data analysis, interpretation, literature review
- **Dr Abinash Nayak:** Clinical assessment, data acquisition
- **Dr Suchismita Panda:** Supervision, critical revision of manuscript
- **Dr Bighneswar Senapati:** Statistical analysis and methodology support
- **Dr Aparna Aradhana:** Overall supervision, final approval of manuscript

All authors read and approved the final manuscript.

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Original Article

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author Biography

All authors are faculty members in the Department of Pediatrics at IMS & SUM Hospital, Bhubaneswar, with clinical and academic expertise in pediatric hematology and endocrinology. Their research interests include transfusion-dependent disorders, endocrine complications of chronic diseases, and pediatric growth and development.

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