

Research Article

Clinical Complications of Thalassemia with Emphasis on Iron Overload and Outcomes of Iron Chelation Therapy

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ABSTRACT

Introduction: β -thalassemia is an inherited disorder causing ineffective erythropoiesis and chronic anemia, with transfusion-dependent patients requiring lifelong transfusions that predispose to progressive iron overload. Excess iron commonly affects the liver, heart, endocrine system, skeleton, and skin. Serum ferritin is widely used to monitor iron burden, while oral chelation is essential for reducing iron accumulation. This study evaluated iron overload, related complications, chelation response, and associations of ferritin, adherence, and chelator dose among children with TDT.

Materials and Methods: This hospital-based observational study included 30 children with transfusion-dependent β -thalassemia receiving regular transfusions and oral chelation therapy over two years. Demographic, clinical, transfusion, chelation, adherence, biochemical, echocardiographic, and hepatic imaging data were recorded. Iron burden and treatment response were assessed using baseline and post-treatment serum ferritin levels. Associations with complications, adherence, and chelator dose were analysed using Fisher's exact test, with $p < 0.05$ considered significant.

Results: The study included 30 children with TDT; 56.7% were female, 80.0% were diagnosed within the first year, 76.7% required transfusions every 3 weeks, and 70.0% had undergone splenectomy. Hemolytic facies (46.7%) and hyperpigmentation (36.7%) were the commonest complications. Baseline ferritin exceeded 2500 ng/mL in 63.3%, while after chelation 73.3% had ferritin ≤ 2500 ng/mL. Cardiomegaly with pulmonary hypertension was significantly associated with ferritin > 3000 ng/mL (33.3% vs 0%; $p = 0.014$). Adherence was significantly higher with final chelator doses ≤ 30 mg/kg (94.1% vs 61.5%; $p = 0.027$).

Conclusion: Iron overload was common and associated with clinically important complications, particularly cardiac involvement. Oral chelation therapy reduced serum ferritin levels, while adherence was significantly associated with lower chelator requirements. These findings emphasize regular monitoring of iron burden, complications, treatment response, and adherence in children with transfusion-dependent β -thalassemia.

Keywords: Beta-Thalassemia, Iron Overload, Iron Chelating Agents, Ferritins, Blood Transfusion, Treatment Adherence and Compliance.

INTRODUCTION

β -thalassemia is an inherited hemoglobin disorder characterized by reduced or absent β -globin synthesis, resulting in ineffective erythropoiesis and chronic anemia.¹ Children with transfusion-dependent β -thalassemia (TDT) require lifelong red-cell transfusions to maintain adequate hemoglobin levels and support normal growth and development.² However, repeated transfusions progressively increase body iron stores because the body lacks an effective physiological mechanism for iron excretion.³ Despite improved survival with

modern transfusion and chelation therapy, iron overload remains an important cause of long-term morbidity and mortality in TDT.^{2,3}

Excess iron predominantly accumulates in the liver, heart, and endocrine organs, contributing to hepatic and cardiac dysfunction, growth impairment, diabetes mellitus, hypothyroidism, hypoparathyroidism, hypogonadism, and other endocrine complications.^{2,3} Regular surveillance for iron-related organ dysfunction is therefore essential.² Serum ferritin is widely used for routine monitoring because it is accessible and suitable for serial assessment, although it is an

indirect marker influenced by inflammation, infection, hepatitis, and tissue injury.³ Iron chelation is fundamental to TDT management, with deferasirox and deferiprone available as oral agents and deferoxamine as a parenteral chelator.^{2,3} Chelation response is influenced by baseline iron burden, dose, treatment duration, transfusional iron intake, and adherence; inadequate adherence is associated with greater iron overload and higher ferritin levels.^{3,4}

Accordingly, assessment of iron burden, associated complications, and chelation response remains clinically important. Serum ferritin should be interpreted alongside clinical and organ-specific assessments because its relationship with tissue iron is not always linear.^{2,3} The present study therefore evaluated iron overload, clinical complications, and response to oral chelation among children with TDT, focusing on changes in serum ferritin and its association with complications, treatment adherence, and chelator dose.

MATERIALS AND METHODS

This hospital-based observational study was conducted over a period of two years in the Department of Pediatrics, Karwar Institute of Medical Sciences, after obtaining approval from the Institutional Ethics Committee. The study included 30 children diagnosed with transfusion-dependent β -thalassemia who were attending the outpatient/hematology clinic, receiving regular blood transfusions, and undergoing oral iron chelation therapy. Written informed consent was obtained from the parents or guardians before enrolment, and confidentiality of participant information was maintained throughout the study.

Children with transfusion-dependent β -thalassemia receiving chelation therapy were eligible for inclusion. Children who had received multiple transfusions and chelation for other hematological disorders, including sickle cell anemia, hereditary spherocytosis, dyserythropoietic anemia, and autoimmune hemolytic anemia, were excluded. Patients lost to follow-up, defined as failure to attend the monthly hematology clinic for at least three months, were also excluded. The study used convenience sampling based on the available population of eligible children attending the institution during the study period.

Data were collected using a structured study proforma and included age, sex, birth weight, age at diagnosis, presenting clinical features, family history, transfusion frequency,

splenectomy status, age at initiation and duration of chelation therapy, chelator dose, treatment adherence, and parental educational status. Children were evaluated for clinical and organ-related complications, including hemolytic facies, hyperpigmentation, cardiac abnormalities, hepatic abnormalities, thyroid dysfunction, altered blood glucose, skeletal abnormalities, renal dysfunction, and abnormalities of vision and hearing. Available biochemical investigations, viral-marker screening, echocardiographic findings, and hepatic imaging findings were recorded.

Iron burden was assessed using serum ferritin levels. Baseline ferritin values recorded before the assessed period of chelation and subsequent ferritin values following treatment were documented, along with starting and final chelator doses. The response to oral chelation was assessed by the change in serum ferritin levels. Treatment adherence was recorded according to the regularity of chelator intake. Associations between baseline ferritin levels and selected complications, including cardiomegaly, hemolytic facies, hepatic echotexture, and skeletal abnormalities, were evaluated. The relationships of treatment adherence with post-treatment ferritin levels and final chelator dose were also assessed.

Data were entered into Microsoft Excel and analysed using SPSS software; the version was not specified in the source document. Categorical variables were summarized as frequencies and percentages, while quantitative variables, where available, were described using appropriate measures of central tendency and dispersion. Associations between categorized baseline serum ferritin levels and selected clinical complications, and between treatment adherence and chelator-related variables, were assessed using Fisher's exact test because of the small sample size and sparse cell frequencies. A two-sided p-value <0.05 was considered statistically significant.

RESULTS

The largest proportion of children belonged to the 6–9-year age group (33.3%), with a slight female predominance (56.7%). Most had normal birth weight (83.3%). A family history of similar illness was present in 16.7%, while 10.0% reported sibling death due to the same disease (Table 1). Most children were diagnosed within the first year of life, with 46.7% diagnosed at 6–12 months and 33.3% before 6 months. Pallor was present in 100.0% at diagnosis, while 73.3% had jaundice. Other

presenting symptoms were reported in 83.3% of children. (Figure 1)

Table 1: Baseline Demographic and Family Characteristics of Children with Transfusion-Dependent B-Thalassemia (N=30)

Characteristic	Category	n (%)
Age group	1 to 5 years	6 (20.0%)
	6 to 9 years	10 (33.3%)
	10 to 14 years	7 (23.3%)
	15 to 19 years	7 (23.3%)
Gender	Male	13 (43.3%)
	Female	17 (56.7%)
Birth weight	Normal birth weight (≥ 2.5 kg)	25 (83.3%)
	Low birth weight (< 2.5 kg)	5 (16.7%)
Family history of similar illness	Present	5 (16.7%)
	Absent	25 (83.3%)
Sibling death due to same disease	Present	3 (10.0%)
	Absent	27 (90.0%)

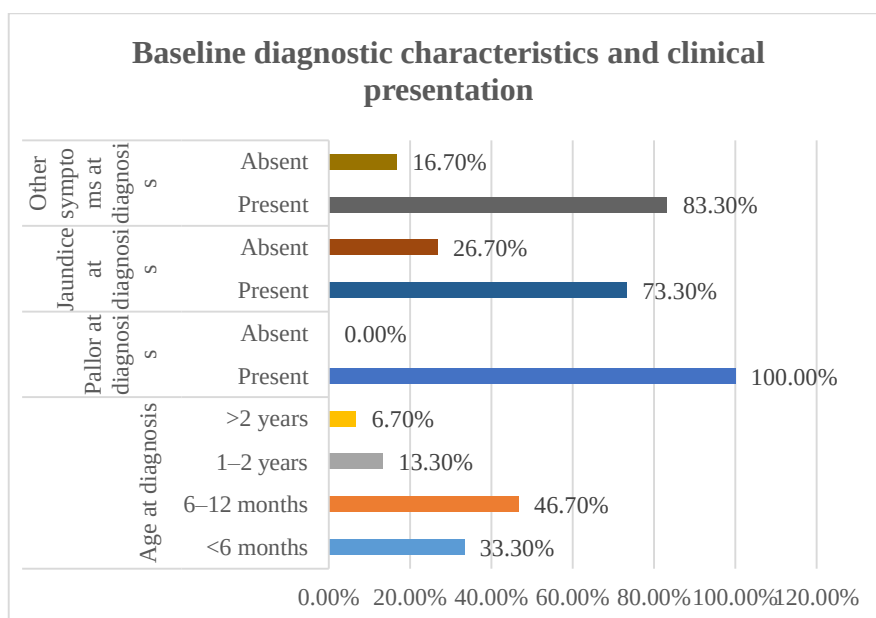


Figure 1: Baseline Diagnostic Characteristics and Clinical Presentation of Children with Transfusion-Dependent B-Thalassemia (N=30)

Most children received blood transfusions every 3 weeks (76.7%), while 70.0% had undergone splenectomy. Chelation therapy was initiated between 1 and 5 years of age in 76.7% of children. The duration of chelation was < 5 years in 50.0%, 5–10 years in 40.0%, and > 10 years in 10.0% (Table 2). Hemolytic facies was the most common complication, affecting 46.7% of children, followed by hyperpigmentation in 36.7%. Elevated hepatic

enzymes were present in 20.0%, while cardiomegaly with pulmonary hypertension and abnormal echocardiography were each observed in 16.7%. Thyroid abnormalities, skeletal abnormalities, and altered hepatic echotexture each occurred in 10.0%. No abnormalities in vision, hearing, renal function, or viral-marker screening were reported (Table 3).

Table 2: Baseline Transfusion, Splenectomy, And Chelation Characteristics Of Children With Transfusion-Dependent B-Thalassemia (N=30)

Characteristic	Category	n (%)
Blood transfusion interval	Every 3 weeks	23 (76.7%)

	Every 4 weeks	5 (16.7%)
	Every 5 weeks	2 (6.7%)
Splenectomy	Yes	21 (70.0%)
	No	9 (30.0%)
Age at initiation of chelation	1 to 5 years	23 (76.7%)
	6 to 10 years	5 (16.7%)
	11 to 15 years	2 (6.7%)
Duration of chelation	<5 years	15 (50.0%)
	5–10 years	12 (40.0%)
	>10 years	3 (10.0%)

Table 3: Clinical and Organ-Related Complications Among Children with Transfusion-Dependent B-Thalassemia (N=30)

Clinical/organ-related finding	n (%)
Hemolytic facies	14 (46.7%)
Hyperpigmentation	11 (36.7%)
Cardiomegaly with pulmonary hypertension	5 (16.7%)
Abnormal echocardiography (ejection fraction <50%)	5 (16.7%)
Abnormal vision or hearing	0 (0.0%)
Positive viral markers	0 (0.0%)
Abnormal random blood glucose	1 (3.3%)
Abnormal thyroid status*	3 (10.0%)
Skeletal abnormality†	3 (10.0%)
Renal abnormality	0 (0.0%)
Abnormal hepatic echotexture‡	3 (10.0%)
Elevated hepatic enzymes§	6 (20.0%)

* Reported as subnormal TSH with normal T4.

† Reported as fractures associated with osteopenic changes.

‡ Reported as mild fibrotic changes.

§ Reported as elevated SGPT.

Before treatment, 63.3% of children had serum ferritin levels above 2500 ng/mL, including 23.3% with levels >5000 ng/mL. After

treatment, 73.3% had ferritin levels ≤2500 ng/mL, indicating a shift toward lower ferritin categories. At initiation, 66.7% received chelator doses of 20–30 mg/kg, while final dosing was more widely distributed, with 43.3% receiving doses above 30 mg/kg (Table 4).

Table 4: Distribution of Serum Ferritin Levels and Chelator Doses Before and After Oral Chelation Therapy Among Children with Transfusion-Dependent B-Thalassemia (N=30)

Parameter	Category	n (%)
Serum ferritin before treatment	1000 to 2500 ng/mL	11 (36.7%)
	>2500 to 3000 ng/mL	4 (13.3%)
	>3000 to 5000 ng/mL	8 (26.7%)
	>5000 ng/mL	7 (23.3%)
Serum ferritin after treatment	<1000 ng/mL	3 (10.0%)
	1000 to 2500 ng/mL	19 (63.3%)
	>2500 to 3000 ng/mL	5 (16.7%)
	>3000 to 5000 ng/mL	3 (10.0%)
Starting chelator dose	<20 mg/kg	10 (33.3%)
	20 to 30 mg/kg	20 (66.7%)
Final chelator dose	<20 mg/kg	4 (13.3%)
	20 to 30 mg/kg	13 (43.3%)
	>30 to 40 mg/kg	12 (40.0%)
	>40 mg/kg	1 (3.3%)

Cardiomegaly with pulmonary hypertension was observed exclusively among children with

baseline serum ferritin >3000 ng/mL and showed a statistically significant association

with higher ferritin levels (33.3% vs 0.0%; $p=0.014$). Hemolytic facies and abnormal hepatic echotexture were more frequent in the higher-ferritin group, but these associations were not statistically significant. Skeletal abnormalities were uncommon and showed no significant association with ferritin category (Table 5). Adherence was observed in 81.5% of

children with post-treatment serum ferritin ≤ 3000 ng/mL and 66.7% of those with levels >3000 ng/mL; this association was not statistically significant ($p=0.542$). In contrast, adherence was significantly higher among children receiving a final chelator dose ≤ 30 mg/kg compared with those receiving >30 mg/kg (94.1% vs 61.5%; $p=0.027$) (Table 6).

Table 5: Association Between Baseline Serum Ferritin Levels and Selected Clinical and Organ-Related Complications Among Children with Transfusion-Dependent B-Thalassemia (N=30)

Complication		Ferritin		p-value [#]
		≤ 3000 ng/mL	>3000 ng/mL	
		n (%)	n (%)	
Cardiomegaly with pulmonary hypertension	Yes	0 (0.0%)	5 (33.3%)	0.014*
	No	15 (100.0%)	10 (66.7%)	
Hemolytic facies	Yes	5 (33.3%)	9 (60.0%)	0.143
	No	10 (66.7%)	6 (40.0%)	
Abnormal hepatic echotexture	Yes	0 (0.0%)	3 (20.0%)	0.067
	No	15 (100.0%)	12 (80.0%)	
Skeletal abnormality	Yes	2 (13.3%)	1 (6.7%)	0.542
	No	13 (86.7%)	14 (93.3%)	

Fisher's exact test; * Statistically significant at $p<0.05$.

Table 6: Association of Adherence to Oral Chelation Therapy with Post-Treatment Serum Ferritin Levels and Final Chelator Dose Among Children with Transfusion-Dependent B-Thalassemia (N=30)

Variable	Category	Non-adherent	Adherent	Total	p-value [#]
		n (%)	n (%)	N (%)	
Post-treatment serum ferritin	≤ 3000 ng/mL	5 (18.5%)	22 (81.5%)	27 (100.0%)	0.542
	>3000 ng/mL	1 (33.3%)	2 (66.7%)	3 (100.0%)	
Final chelator dose	≤ 30 mg/kg	1 (5.9%)	16 (94.1%)	17 (100.0%)	0.027*
	>30 mg/kg	5 (38.5%)	8 (61.5%)	13 (100.0%)	

Fisher's exact test; * Statistically significant at $p<0.05$.

DISCUSSION

Transfusion-dependent β -thalassemia causes progressive iron overload from repeated transfusions, leading to cardiac, hepatic, endocrine, skeletal, and other complications. Evaluating iron burden, treatment response, and adherence is therefore essential to identify high-risk children and optimize chelation therapy. This two-year hospital-based observational study included 30 children with

TDT receiving regular transfusions and oral chelation at Karwar Institute of Medical Sciences. Convenience sampling was used, with appropriate exclusions and parental consent. Data on demographics, clinical features, transfusion and splenectomy history, chelation duration, dose, adherence, and parental education were recorded. Multisystem complications, biochemical tests, viral markers, echocardiography, hepatic imaging, and

baseline and post-treatment serum ferritin were assessed.

The present study showed a slight female predominance, with 17 (56.7%) females and 13 (43.3%) males. Although Pinto VM et al.⁵ (2020) described individual female patients with thalassemia, aged 19 and 40 years, direct comparative pediatric cohorts demonstrating a female majority were not identified. In contrast, most published studies reported male predominance. Vachhani UN et al.⁶ (2020) observed 76.0% males and 24.0% females (38 vs. 12), while Abubakar SM et al.⁷ (2024) reported 68.18% males (15 males vs. 7 females). Similarly, İncefidan İ et al.⁸ (2026) documented 55.0% males (17 males vs. 14 females), and Shah AWA et al.⁹ (2026) reported 52.0% males among treated cases. Thus, the female predominance observed in the present cohort differs from the predominantly male distribution reported previously and may reflect regional variation in the patient population or differences in institutional referral patterns.

A notably high proportion of children in the present study had undergone splenectomy, accounting for 21 (70.0%) patients, while only 9 (30.0%) remained unsplenectomised. The use of splenectomy to reduce transfusion requirements, particularly in resource-constrained settings, has also been described by Pinto VM et al.⁵ (2020), who reported a patient undergoing splenectomy at 5 years of age after initiation of regular transfusions. However, the rate observed in the present study was substantially higher than that reported by İncefidan İ et al.⁸ (2026), in which only 9 of 31 patients (29.0%) had undergone splenectomy. Pinto VM et al.⁵ (2020) further emphasized that contemporary transfusion protocols maintaining pre-transfusion hemoglobin above 9.0–9.5 g/dL suppress ineffective erythropoiesis and splenomegaly, thereby reducing the need for splenectomy. The 70.0% splenectomy rate in the present cohort therefore suggests greater reliance on surgical management, potentially reflecting differences in regional clinical practices and blood availability. Although splenectomy may decrease transfusion requirements, its long-term risks, particularly post-splenectomy sepsis and thrombosis, remain important considerations in pediatric patients.

Cardiac involvement was clinically important in the present study, with cardiomegaly associated with pulmonary hypertension in 5 children (16.7%) and abnormal echocardiography with LVEF <50% in 5

(16.7%). These findings are consistent with the recognized cardiac consequences of iron overload. Pinto VM et al.⁵ (2020) and Saliba AN et al.¹⁰ (2015) emphasized that myocardial iron deposition may lead to cardiomyopathy, arrhythmias, and pulmonary hypertension and has historically represented a major cause of mortality in TDT. Pinto VM et al.⁵ (2020) additionally described severe myocardial iron overload with a cardiac MRI T2* value of 8.3 ms. Conversely, Abubakar SM et al.⁷ (2024) demonstrated favorable cardiac outcomes following Deferasirox therapy, with mean cardiac MRI T2* improving significantly from 19.55 ± 5.42 ms to 28.23 ± 12.38 ms ($p=0.0016$) over 12 months, while mean LVEF remained within the normal range and increased from 54.36% to 56.19% ($p=0.005$). Compared with cohorts such as those of İncefidan İ et al.⁸ (2026) and Abubakar SM et al.⁷ (2024), where clinical heart failure was uncommon and ventricular function was generally preserved, the 16.7% prevalence of cardiac abnormalities in the present study indicates a clinically relevant burden of myocardial involvement, particularly among children with persistently elevated iron stores. An important finding of the present study was the significant relationship between baseline serum ferritin and cardiac complications. Cardiomegaly with pulmonary hypertension occurred exclusively among children with baseline ferritin >3000 ng/mL, affecting 33.3%, compared with 0.0% among those with ferritin ≤3000 ng/mL ($p=0.014$). This relationship is supported by previous evidence linking marked hyperferritinemia with organ dysfunction. Shah AWA et al.⁹ (2026) identified serum ferritin as a significant independent predictor of thyroid and systemic organ dysfunction ($p<0.001$), while Pinto VM et al.⁵ (2020) and Saliba AN et al.¹⁰ (2015) described increasing risks of cardiac siderosis, cardiomyopathy, and hepatic fibrosis when serum ferritin remains chronically elevated at approximately 2500–3000 ng/mL or above. However, İncefidan İ et al.⁸ (2026) found no statistically significant correlation between serum ferritin and cardiac T2 MRI ($p>0.05$)*, emphasizing that ferritin does not necessarily reflect organ-specific myocardial iron deposition. Thus, the significant association identified in the present study ($p=0.014$) supports serum ferritin as a useful and readily accessible marker for identifying children at increased risk of cardiac complications, particularly where MRI T2 is unavailable. Nevertheless, ferritin should

complement rather than replace organ-specific assessment whenever advanced imaging is accessible.

The present study also demonstrated a statistically significant association between treatment adherence and final chelator dose ($p=0.027$). Adherence was substantially higher among children receiving a final dose ≤ 30 mg/kg, with 16 of 17 (94.1%) being adherent, compared with 8 of 13 (61.5%) receiving >30 mg/kg. Saliba AN et al.¹⁰ (2015) and Pinto VM et al.⁵ (2020) discussed gastrointestinal symptoms, nausea, skin rash, and mild creatinine elevation among adverse effects associated with Deferasirox therapy, which may adversely influence long-term treatment acceptance and adherence. In contrast, İncefidan İ et al.⁸ (2026) reported an overall compliance rate of 93.5% (29/31) among patients receiving Deferasirox at 21–28 mg/kg/day, without a significant dose-related decline in compliance. Vachhani UN et al.⁶ (2020) similarly reported that 95.0% of patients remained compliant while receiving Deferasirox at 30 mg/kg/day. The decline in adherence from 94.1% at ≤ 30 mg/kg to 61.5% at >30 mg/kg in the present study therefore represents a clinically important finding. However, because the observational analysis establishes an association rather than causation, it cannot confirm that higher doses themselves caused poorer adherence. Children requiring dose escalation may also have had greater iron burden, treatment difficulties, or other factors influencing adherence. Nevertheless, the findings underscore the importance of balancing adequate chelation intensity with tolerability and adherence when managing children requiring higher chelator doses.

Strengths and Limitations

The study's strengths included evaluation of multiple dimensions of transfusion-dependent β -thalassemia, integrating iron burden, clinical and organ-related complications, chelation response, treatment adherence, and chelator dose within the same cohort. Assessment of ferritin before and after chelation enabled evaluation of treatment response, while analysis of ferritin–complication relationships provided clinically relevant findings. However, the small sample size of 30 children, single-centre setting, and convenience sampling limited statistical power and generalizability. The observational design precluded causal inference, while reliance on serum ferritin alone

without MRI-based hepatic or cardiac iron quantification limited precise assessment of tissue iron overload and its organ-specific consequences.

CONCLUSION

The study demonstrated a substantial burden of iron overload and related complications among children with transfusion-dependent β -thalassemia, with hemolytic facies, hyperpigmentation, hepatic abnormalities, and cardiac involvement being prominent. Oral chelation therapy was associated with a clear shift toward lower serum ferritin levels. Higher baseline ferritin was significantly associated with cardiomegaly with pulmonary hypertension, supporting the adverse impact of iron overload. Although adherence was not significantly related to post-treatment ferritin, it was significantly associated with lower final chelator doses. Overall, the findings support regular monitoring of iron burden, complications, adherence, and chelation requirements.

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