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Original Research Article

Optical Coherence Tomography (OCT) Based Assessment of Subclinical Ocular Changes in Pediatric Thalassemia Patients

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Abstract

Background: β-thalassemia major is a chronic hereditary hemoglobin disorder requiring lifelong blood transfusions, which lead to iron overload and subsequent oxidative tissue damage. Ocular involvement is a recognized but often subclinical complication in pediatric patients. Early detection of these changes is essential to prevent irreversible visual impairment.

Aim: To assess subclinical ocular changes using Optical Coherence Tomography (OCT) in pediatric patients with β-thalassemia major and to compare findings with healthy controls, while evaluating the impact of deferoxamine therapy and disease duration.

Materials and Methods: This hospital-based cross-sectional observational study included 100 participants (50 β-thalassemia major patients and 50 age- and sex-matched healthy controls) aged 5–18 years. All participants underwent comprehensive ophthalmic examination and spectral-domain OCT. Parameters analyzed included central and average macular thickness, retinal nerve fiber layer (RNFL) thickness (global and quadrant-wise), and subfoveal choroidal thickness. Statistical analysis was performed using SPSS version 27.0, with $p < 0.05$ considered statistically significant.

Results: Thalassemia patients demonstrated significantly reduced central macular thickness (238.4 ± 18.6 µm vs 252.1 ± 16.9 µm), average macular thickness (271.6 ± 14.2 µm vs 283.9 ± 13.5 µm), and RNFL thickness (94.2 ± 8.7 µm vs 101.5 ± 7.9 µm) compared to controls ($p < 0.001$). Quadrant-wise RNFL and subfoveal choroidal thickness were also significantly decreased ($p < 0.05$). Deferoxamine users showed significantly lower average macular and RNFL thickness compared to non-users ($p < 0.05$). A significant negative correlation was observed between disease duration and OCT parameters, indicating progressive retinal and choroidal thinning with longer disease duration.

Conclusion: Pediatric β-thalassemia major patients exhibit significant subclinical retinal, optic nerve, and choroidal alterations detectable by OCT. Disease duration and deferoxamine therapy appear to influence these changes. OCT is an effective non-invasive tool for early detection, and regular screening is recommended for timely intervention and prevention of visual morbidity.

Keywords: β-thalassemia major; Optical Coherence Tomography; Retinal Nerve Fiber Layer; Macular Thickness; Choroidal Thickness; Deferoxamine.

Introduction

β-thalassemia major is a hereditary hemoglobin disorder characterized by defective β-globin chain synthesis, resulting in chronic hemolytic anemia and ineffective erythropoiesis. Regular blood transfusions, which are essential for survival, lead to progressive iron overload and subsequent oxidative tissue damage (Uzun F, 2017) [1]. Iron accumulation generates reactive oxygen species, causing lipid peroxidation and cellular injury, particularly in metabolically active tissues such as the retina and optic nerve[1]. Consequently, patients with β-thalassemia major are at increased risk of developing multisystem complications, including significant ocular involvement. Ocular manifestations in thalassemia are multifactorial and may result from chronic hypoxia, iron toxicity, and adverse effects of iron chelation therapy. These manifestations include retinal pigment epithelium degeneration, venous tortuosity, optic neuropathy, and macular changes (Mahmoud H, 2022) [2]. Importantly, many of these changes remain subclinical in pediatric patients and are not

detectable through routine ophthalmological examination. Early identification of these subtle alterations is therefore crucial to prevent irreversible visual impairment.

Recent studies have demonstrated significant alterations in OCT parameters among patients with β-thalassemia major. Uzun F et al. (2017) reported a statistically significant reduction in RNFL thickness in children with thalassemia compared to healthy controls, suggesting early optic nerve involvement.[1] Global and quadrant RNFL thicknesses were significantly reduced in thalassemia patients, with some parameters correlating with disease duration and iron chelation therapy (Firdous M, 2024) [3]. In pediatric patients, these changes are often subclinical and may not be detected through routine ophthalmological examination. Studies have shown that ocular abnormalities are associated with disease severity, duration, and serum ferritin levels, indicating a progressive nature of ocular involvement (Lubis B, 2024) [4]. Uzun F et al. (2017) reported significantly reduced RNFL thickness in children with thalassemia compared to healthy controls, suggesting early optic nerve involvement.[1] Özer O et al. (2024) evaluated retinal vascular changes using OCT angiography and found significant alterations in retinal perfusion parameters in patients with hemoglobinopathies, including β-thalassemia, suggesting early microcirculatory impairment [5].

Aim & Objectives

Aim: To assess subclinical ocular changes using Optical Coherence Tomography (OCT) in pediatric patients with β-thalassemia major and to compare these findings with age- and sex-matched healthy controls, along with evaluating the effect of deferoxamine therapy and disease duration on OCT parameters.

Objectives

1. To evaluate and compare macular thickness, retinal nerve fiber layer (RNFL) thickness, and choroidal thickness between pediatric β-thalassemia major patients and healthy controls using OCT.
2. To analyze the association between OCT parameters and clinical variables such as hemoglobin levels, serum ferritin, and duration of transfusion therapy in thalassemia patients.
3. To compare OCT parameters between deferoxamine users and non-users among thalassemia patients.
4. To determine the correlation between disease duration and OCT parameters in pediatric β-thalassemia major patients.
5. To identify early subclinical ocular changes in thalassemia patients for timely intervention and prevention of visual complications.

Materials & Methods

Study Design and Setting: This hospital-based cross-sectional observational study was conducted in the Department of Ophthalmology, in collaboration with the Departments of Radiology and Paediatrics (Hematology–Oncology Unit), at Narayan Medical College & Hospital (NMCH), Jamuhar, Rohtas, Bihar, India.

Study Population: The study included paediatric patients diagnosed with β-thalassemia major and healthy age- and sex-matched controls.

- **Study group:** 50 paediatric patients with thalassemia major
- **Control group:** 50 healthy participants without systemic disease
- **Age range:** 5–18 years

Only one eye per participant (eye with better OCT signal quality) was included for analysis.

Study Period: The study was carried out over a period of one year ant ten months, from January 2023, to October, 2024.

Sample Size

A total of 100 participants were included:

- 50 thalassemia major patients
- 50 healthy controls

Inclusion Criteria

Thalassemia Group

- Confirmed diagnosis of β-thalassemia major
- Age between 5 and 18 years
- On regular blood transfusion and iron chelation therapy
- Cooperative for ophthalmic examination and OCT imaging
- Availability of recent hemoglobin and serum ferritin values
- Written informed consent from parents/guardians and assent from children where applicable

Control Group (Healthy age- and sex-matched controls were recruited from)

- Age between 5 and 18 years
- No history of hematological disorders (thalassemia, sickle cell disease, etc.)
- No systemic illness affecting ocular health (e.g., diabetes, hypertension)
- Normal age-appropriate visual acuity
- Siblings of patients, Children attending pediatric or ophthalmology outpatient departments, and Local school-going children.
- Willingness to participate with parental consent and child assent

Exclusion Criteria (Both Groups)

- Other hemoglobinopathies
- Refractive error > ±4 diopters (spherical equivalent)
- Axial length <21 mm or >25 mm
- Congenital ocular abnormalities (e.g., congenital cataract)
- History of ocular trauma or intraocular surgery
- Amblyopia
- Any ocular or systemic disease affecting the retina or optic nerve
- Poor-quality OCT images
- Unwillingness to participate

Ethical Approval: The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from parents or legal guardians of all participants, and the study adhered to the principles of the Declaration of Helsinki.

Clinical and Systemic Assessment: Detailed clinical history was obtained for thalassemia patients, including age at diagnosis, disease duration, frequency of transfusions, and type and duration of iron chelation therapy (deferoxamine, deferiprone, or deferasirox). Recent hemoglobin and serum ferritin levels were recorded from medical records. Demographic variables including age, sex, and body mass index (BMI) were documented for all participants.

Ophthalmic Examination: All participants underwent a comprehensive ophthalmologic evaluation comprising:

- Best-corrected visual acuity
- Intraocular pressure measurement
- Slit-lamp examination of the anterior segment
- Dilated fundus examination

Investigations

Refractive and Biometric Measurements

- Auto-refraction: KR-800 autorefractometer (Topcon, Tokyo, Japan)
- Axial length: Nidek AL-Scan (Nidek, Aichi, Japan)

Optical Coherence Tomography (OCT): Spectral-domain OCT was performed using Cirrus HD-OCT 4000 (Carl Zeiss Meditec, Dublin, CA, USA). Scanning protocols included macular cube, optic disc cube, and HD 5-line raster scans.

The following parameters were analyzed:

- Central macular thickness (CMT)
- Macular volume
- Ganglion cell complex (GCC) thickness
- Retinal nerve fiber layer (RNFL) thickness (global and quadrant-wise)
- Optic nerve head parameters
- Choroidal thickness (subfoveal and at 1 mm nasal and temporal to the fovea and optic disc)

Choroidal thickness was measured manually as the distance between the outer border of the retinal pigment epithelium and the inner scleral surface by an experienced ophthalmologist.

Role of Radiologist in This Study: Radiologists play a supportive role in ensuring high-quality OCT imaging and accurate interpretation of retinal and choroidal structures. They contribute to standardizing imaging protocols, improving measurement reliability, and correlating ocular findings with systemic iron overload (e.g., MRI).

Additionally, they assist in multidisciplinary evaluation and research by enabling precise image analysis and identification of early imaging biomarkers.

Primary outcome: Comparison of OCT-derived retinal, RNFL, GCC, and choroidal parameters between thalassemia patients and controls

Secondary outcomes: Correlation of OCT parameters with serum ferritin levels, age, disease duration, and chelation therapy type and duration

Statistical Analysis: Data were entered into Microsoft Excel 365 and analyzed using SPSS software (version 26.0).

- Normality of data was assessed using Kolmogorov–Smirnov and Shapiro–Wilk tests
- Independent t-test was used for normally distributed quantitative variables
- Mann–Whitney U-test was used for non-normally distributed variables
- Chi-square test or Fisher's exact test was used for qualitative variables
- Pearson's correlation analysis was performed to assess relationships between ocular parameters and systemic factors
- A p-value < 0.05 was considered statistically significant

Results

Table 1: Demographic and Clinical Characteristics of Study and Control Groups

Variable	Category	Thalassemia Group (n = 50)	Control Group (n = 50)	p-value
Age (years)		11.6 ± 3.4	11.9 ± 3.1	0.64
Age group (years)	5–10	20 (40.0%)	18 (36.0%)	0.91
	11–14	18 (36.0%)	20 (40.0%)	
	15–18	12 (24.0%)	12 (24.0%)	
Gender	Male	27 (54.0%)	26 (52.0%)	0.84
	Female	23 (46.0%)	24 (48.0%)	
Height (cm)		134.2 ± 12.8	136.5 ± 13.1	0.37
Weight (kg)		29.6 ± 8.4	31.2 ± 7.9	0.33

Table 1 and figure 1, presents the demographic and clinical characteristics of the study population comprising pediatric patients with β-thalassemia major and age- and sex-matched healthy controls. The mean age of participants in the thalassemia group was 11.6 ± 3.4 years, which was comparable to 11.9 ± 3.1 years in the control group, with no statistically significant difference (p = 0.64). When stratified into age groups, the distribution was similar between the two groups, with the majority of participants falling within the 5–10 years and 11–14 years categories. Specifically, 40.0% of thalassemia patients and 36.0% of controls were in the 5–10 years group, while 36.0% and 40.0%, respectively, were in the 11–14 years group. The 15–18 years category included 24.0% participants in both groups. This comparable distribution was statistically non-significant (p = 0.91), indicating appropriate age matching.

Gender distribution was also similar between the groups, with males constituting 54.0% of the thalassemia group and 52.0% of the control group, while females accounted for 46.0% and 48.0%, respectively. The difference was not statistically significant (p = 0.84), suggesting adequate matching in terms of sex.

Regarding anthropometric parameters, the mean height of patients in the thalassemia group was 134.2 ± 12.8 cm compared to 136.5 ± 13.1 cm in the control group, while the mean weight was 29.6 ± 8.4 kg and 31.2 ± 7.9 kg, respectively. These differences were not statistically significant (p = 0.37 for height and p = 0.33 for weight).

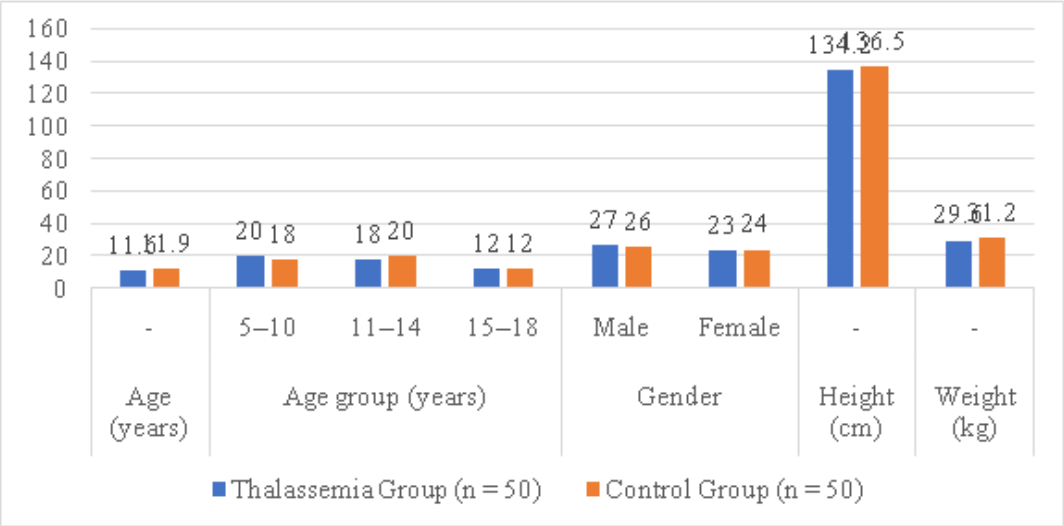

Figure 1: Demographic and Clinical Characteristics of Study and Control Groups

Table 2: Clinical Parameters (Thalassemia Group Only)

Variable	Mean ± SD / n (%)
Hemoglobin (g/dL)	7.8 ± 1.1
Serum ferritin (ng/mL)	1825 ± 640
Duration of transfusion therapy (years)	8.2 ± 3.1
Regular transfusion (every 3–4 weeks)	42 (84.0%)
Irregular transfusion	8 (16.0%)

Table 2 summarizes the clinical profile of pediatric patients with β-thalassemia major included in the study. The mean hemoglobin level among the patients was 7.8 ± 1.1 g/dL, indicating a state of

chronic anemia despite ongoing transfusion therapy. This reflects the underlying ineffective erythropoiesis and the need for regular blood transfusions to maintain adequate hemoglobin levels. The mean serum ferritin level was markedly elevated at 1825 ± 640 ng/mL, suggestive of significant iron overload, which is a well-known consequence of repeated blood transfusions. Elevated ferritin levels indicate increased body iron stores and are associated with a higher risk of systemic complications, including potential ocular toxicity. The average duration of transfusion therapy was 8.2 ± 3.1 years, highlighting the chronic nature of the disease and prolonged exposure to transfusion-related effects. This prolonged duration may contribute to cumulative iron deposition and its associated complications over time. With respect to transfusion patterns, the majority of patients, 42 (84.0%), were receiving regular transfusions at intervals of every 3–4 weeks, which is the standard management protocol for maintaining hemoglobin levels. However, a smaller proportion of patients, 8 (16.0%), were receiving transfusions irregularly, which may predispose them to fluctuations in hemoglobin levels and increased disease-related complications.

Table 3: Comparison of Optical Coherence Tomography (OCT) Parameters between Thalassemia Major and Control Groups

OCT Parameter	Thalassemia Group (n = 50)	Control Group (n = 50)	't' Value	p-value
Central Macular Thickness (µm)	238.4 ± 18.6	252.1 ± 16.9	3.85	<0.001*
Average Macular Thickness (µm)	271.6 ± 14.2	283.9 ± 13.5	4.41	<0.001*
Retinal Nerve Fiber Layer (RNFL) Average (µm)	94.2 ± 8.7	101.5 ± 7.9	4.41	<0.001*
RNFL Superior Quadrant (µm)	116.3 ± 10.5	123.8 ± 9.6	3.73	<0.001*
RNFL Inferior Quadrant (µm)	119.7 ± 11.2	127.9 ± 10.4	3.78	<0.001*
RNFL Nasal Quadrant (µm)	72.8 ± 7.9	78.6 ± 7.1	3.88	<0.001*
RNFL Temporal Quadrant (µm)	68.5 ± 6.4	72.3 ± 6.1	3.06	0.003*
Choroidal Thickness (Subfoveal, µm)	262.7 ± 22.8	278.9 ± 21.4	3.67	<0.001*

RNFL: Retina nerve fibre layer thickness; Note: *p < 0.05 considered statistically significant.

Table 3 presents the mean central macular thickness was significantly lower in the thalassemia group (238.4 ± 18.6 µm) compared to the control group (252.1 ± 16.9 µm), with a highly significant difference (p < 0.001). Similarly, the average macular thickness was reduced in thalassemia patients (271.6 ± 14.2 µm) as compared to controls (283.9 ± 13.5 µm), which was also statistically significant (p < 0.001). These findings indicate macular thinning in patients with β-thalassemia major.

The retinal nerve fibre layer (RNFL) thickness showed a significant reduction across all measured parameters in the thalassemia group. The mean RNFL thickness was 94.2 ± 8.7 µm in thalassemia patients, significantly lower than 101.5 ± 7.9 µm observed in controls (p < 0.001). On quadrant-wise analysis, the superior, inferior, nasal, and temporal RNFL thicknesses were all significantly reduced in the thalassemia group. Specifically, superior RNFL thickness was 116.3 ± 10.5 µm in thalassemia patients compared to 123.8 ± 9.6 µm in controls (p < 0.001), while inferior RNFL thickness was 119.7 ± 11.2 µm versus 127.9 ± 10.4 µm (p < 0.001). Nasal and temporal quadrants also showed significant thinning, with values of 72.8 ± 7.9 µm and 68.5 ± 6.4 µm in the thalassemia group compared to 78.6 ± 7.1 µm and 72.3 ± 6.1 µm in controls, respectively (p < 0.001 and p = 0.003).

In addition, subfoveal choroidal thickness was significantly reduced in the thalassemia group (262.7 ± 22.8 µm) compared to the control group (278.9 ± 21.4 µm), with a statistically significant difference (p < 0.001).

Table 4: Comparison of OCT Parameters According to Deferoxamine Usage in Thalassemia Major Patients

OCT Parameter	Deferoxamine Users (n = 30)	Non-Users (n = 20)	't' Value	p-value
Central Macular Thickness (µm)	234.6 ± 17.9	244.2 ± 18.1	1.89	0.065
Average Macular Thickness (µm)	268.3 ± 13.7	276.5 ± 14.1	2.01	0.049*
RNFL Average Thickness (µm)	92.1 ± 8.2	97.5 ± 8.9	2.18	0.034*
RNFL Superior Quadrant (µm)	113.9 ± 9.8	119.8 ± 10.7	2.06	0.045*
RNFL Inferior Quadrant (µm)	117.2 ± 10.6	122.9 ± 11.3	1.90	0.063
RNFL Nasal Quadrant (µm)	71.1 ± 7.4	75.6 ± 8.1	2.02	0.048*
RNFL Temporal Quadrant (µm)	67.2 ± 6.1	70.3 ± 6.6	1.73	0.089
Subfoveal Choroidal Thickness (µm)	258.4 ± 21.9	269.8 ± 22.5	1.97	0.054

Note: *p < 0.05 considered statistically significant.

Table 4 present the mean central macular thickness was lower in deferoxamine users (234.6 ± 17.9 µm) compared to non-users (244.2 ± 18.1 µm); however, this difference was not statistically significant (p = 0.065). In contrast, the average macular thickness showed a statistically significant reduction in deferoxamine users (268.3 ± 13.7 µm) compared to non-users (276.5 ± 14.1 µm) (p = 0.049), indicating possible macular involvement associated with therapy or disease severity. Regarding the retinal nerve fiber layer (RNFL), the average RNFL thickness was significantly lower in deferoxamine users (92.1 ± 8.2 µm) compared to non-users (97.5 ± 8.9 µm) (p = 0.034). On quadrant-wise analysis, superior RNFL thickness was also significantly reduced in the deferoxamine group (113.9 ± 9.8 µm vs 119.8 ± 10.7 µm; p = 0.045). Similarly, nasal RNFL thickness was significantly lower in users (71.1 ± 7.4 µm) compared to non-users (75.6 ± 8.1 µm) (p = 0.048). However, some parameters did not show statistically significant differences. Inferior RNFL thickness was lower in deferoxamine users (117.2 ± 10.6 µm) compared to non-users (122.9 ± 11.3 µm), but the difference was not significant (p = 0.063). Temporal RNFL thickness also showed a reduction in users (67.2 ± 6.1 µm vs 70.3 ± 6.6 µm), which did not reach statistical significance (p = 0.089). Subfoveal choroidal thickness was also reduced in deferoxamine users (258.4 ± 21.9 µm) compared to non-users (269.8 ± 22.5 µm), but this difference was not statistically significant (p = 0.054), although it approached significance.

Table 5: Correlation between OCT Parameters and Disease Duration in Thalassemia Major Patients

OCT Parameter	Mean ± SD	Pearson Correlation (r)	p-value
Central Macular Thickness (µm)	238.4 ± 18.6	-0.42	0.002*
Average Macular Thickness (µm)	271.6 ± 14.2	-0.45	0.001*
RNFL Average Thickness (µm)	94.2 ± 8.7	-0.48	<0.001*
RNFL Superior Quadrant (µm)	116.3 ± 10.5	-0.44	0.001*
RNFL Inferior Quadrant (µm)	119.7 ± 11.2	-0.41	0.003*
RNFL Nasal Quadrant (µm)	72.8 ± 7.9	-0.39	0.005*
RNFL Temporal Quadrant (µm)	68.5 ± 6.4	-0.36	0.009*
Subfoveal Choroidal Thickness (µm)	262.7 ± 22.8	-0.43	0.002*

Table 5 demonstrates the Central macular thickness showed a moderate negative correlation with disease duration (r = -0.42), which was statistically significant (p = 0.002). Similarly, average macular thickness also demonstrated a significant negative correlation (r = -0.45, p = 0.001), suggesting that prolonged disease duration is associated with gradual macular thinning.

The retinal nerve fiber layer (RNFL) parameters exhibited even stronger negative correlations. The average RNFL thickness showed a moderate negative correlation (r = -0.48) with high statistical significance (p < 0.001), indicating that longer disease duration is associated with greater thinning of the optic nerve fibers. On quadrant-wise analysis, superior RNFL thickness had a correlation coefficient of -0.44 (p = 0.001), while inferior RNFL thickness showed a correlation of -0.41 (p = 0.003), both statistically significant. Nasal and temporal RNFL quadrants also demonstrated significant negative correlations, with r values of -0.39 (p = 0.005) and -0.36 (p = 0.009), respectively. In addition, sub foveal choroidal thickness was found to be negatively correlated with disease duration (r = -0.43, p = 0.002), indicating progressive choroidal thinning over time.

Discussion

In present study, the mean age of participants in the thalassemia group (11.6 ± 3.4 years) was comparable to that of the control group (11.9 ± 3.1 years), with no significant difference (p = 0.64). Similar findings were reported by Pua TS et al. (2024), who observed a mean age of 11.60 ± 3.28 years in pediatric OCT studies, demonstrating that age distribution in such populations is typically comparable when proper matching is performed [6]. Additionally, Karaca EE et al. (2017) reported mean ages of 13.7 ± 2.1 years in thalassemia patients and 14.3 ± 2.2 years in controls, with no statistically significant difference (p > 0.05), supporting the adequacy of age matching in similar studies [7].

The age group distribution in the present study also showed no significant difference (p = 0.91), indicating balanced representation across pediatric age categories. This is consistent with findings by Abdel-Baset AA et al. (2023), who reported no significant variation in age stratification between thalassemia and control groups, ensuring comparability in OCT-based analyses [8]. Gender distribution was also comparable between the two groups, with males constituting 54.0% in the thalassemia group and 52.0% in controls (p = 0.84). Similar gender distributions have been reported in previous studies. Lubis B et al. (2024) observed no statistically significant gender difference between thalassemia patients and controls, suggesting that gender does not significantly influence OCT parameters in pediatric populations [4].

Anthropometric parameters, including height and weight, were slightly lower in the thalassemia group compared to controls; however, these differences were not statistically significant ($p > 0.05$). This finding aligns with Yilmaz I et al. (2022), who reported marginally lower growth parameters in thalassemia patients but without statistical significance, indicating that growth retardation may not always be pronounced in well-managed pediatric cases [9]. Similarly, Nye J (2023) highlighted that factors such as age, gender, and axial length may influence retinal thickness, but baseline anthropometric differences are often minimal when groups are properly matched [10].

In present study, no statistically significant differences in age, gender, height, or weight ($p > 0.05$). This indicates appropriate matching and minimizes confounding variables. Similar demographic comparability has been reported by El-Ghoneimy AA et al. (2020), who found no significant differences between thalassemia patients and controls in baseline characteristics ($p > 0.05$), ensuring that observed OCT changes were disease-related rather than demographic variations [11].

In present study, chronic anemia (mean hemoglobin 7.8 ± 1.1 g/dL), elevated serum ferritin levels (1825 ± 640 ng/mL), and prolonged transfusion duration (8.2 ± 3.1 years), indicating significant disease burden and iron overload.

These findings are consistent with Hamed AM et al. (2018), who reported mean hemoglobin levels of 8.1 ± 1.3 g/dL and ferritin levels exceeding 1500 ng/mL in pediatric thalassemia patients, correlating with systemic complications including ocular involvement [12].

Present study revealed significant thinning of macular, RNFL, and choroidal structures in the thalassemia group ($p < 0.001$). Central macular thickness (238.4 ± 18.6 µm vs 252.1 ± 16.9 µm) and average macular thickness (271.6 ± 14.2 µm vs 283.9 ± 13.5 µm) were significantly reduced, indicating early macular involvement. These findings are in agreement with Abdelazeem KM et al. (2021), who reported significantly reduced macular thickness in thalassemia patients ($p < 0.01$), suggesting subclinical retinal damage [13].

Similarly, RNFL thickness was significantly decreased across all quadrants in the present study. The average RNFL thickness (94.2 ± 8.7 µm vs 101.5 ± 7.9 µm) showed a highly significant difference ($p < 0.001$). Comparable findings were reported by El-Shazly AA et al. (2020), who observed significant RNFL thinning in thalassemia patients, particularly in superior and inferior quadrants ($p < 0.001$), indicating optic nerve involvement due to chronic hypoxia and iron toxicity [14].

Choroidal thickness was also significantly reduced in the study group (262.7 ± 22.8 µm vs 278.9 ± 21.4 µm; $p < 0.001$), suggesting microvascular compromise. This is supported by Yousef YA et al. (2019), who demonstrated reduced choroidal thickness in transfusion-dependent thalassemia patients, attributing it to chronic anemia and vascular dysregulation [15].

The effect of deferoxamine therapy showed that patients receiving deferoxamine had lower OCT parameters compared to non-users, with statistically significant reductions in average macular thickness and RNFL parameters ($p < 0.05$). However, central macular thickness and choroidal thickness did not show statistically significant differences. These findings are consistent with Khalifa YM et al. (2022), who reported that deferoxamine therapy may contribute to retinal toxicity, leading to structural changes detectable on OCT, although the extent varies depending on dosage and duration [16].

The correlation analysis demonstrated a significant negative correlation between disease duration and OCT parameters, indicating progressive thinning with longer disease duration. The strongest correlation was observed with RNFL thickness ($r = -0.48$, $p < 0.001$), followed by macular and choroidal thickness. Similar findings were reported by Taneja R et al. (2023), who found that longer disease duration was significantly associated with reduced RNFL and macular thickness ($p < 0.01$), highlighting the cumulative effect of chronic hypoxia and iron overload [17].

Limitations of the Study

- **Small sample size:** The study included only 50 patients and 50 controls, which may limit the generalizability of the findings.
- **Cross-sectional design:** The study design does not allow assessment of causal relationships or progression of ocular changes over time.
- **Single-centre study:** Findings may not be representative of the broader population due to limited geographic and demographic diversity.
- **Use of one eye per participant:** Although done to ensure better OCT signal quality, it may not fully represent bilateral ocular involvement.
- **Lack of detailed chelation therapy analysis:** Variations in dosage, duration, and type of iron chelation therapy were not extensively evaluated.
- **Absence of axial length and refractive error assessment:** These factors may influence OCT parameters and were not accounted for in the analysis.
- **Limited evaluation of other ocular parameters:** Functional assessments such as

visual field analysis or electrophysiological studies were not included.

Conclusion

The present study demonstrates that pediatric patients with β-thalassemia major exhibit significant subclinical ocular changes as detected by Optical Coherence Tomography. There was a statistically significant reduction in central and average macular thickness, RNFL thickness across all quadrants, and subfoveal choroidal thickness in thalassemia patients compared to healthy controls ($p < 0.05$), indicating early retinal, optic nerve, and choroidal involvement.

Additionally, deferoxamine therapy was associated with a significant reduction in certain OCT parameters, particularly average macular thickness and RNFL thickness, suggesting a possible contribution of iron chelation therapy to ocular structural changes.

A significant negative correlation was observed between disease duration and OCT parameters, indicating progressive thinning of retinal and choroidal structures with increasing duration of illness. This highlights the cumulative effect of chronic anemia, iron overload, and long-term transfusion therapy on ocular health.

Overall, OCT serves as a valuable, non-invasive tool for the early detection of subclinical ocular changes in pediatric β-thalassemia major patients. Regular ophthalmic screening using OCT is recommended for early diagnosis and timely management to prevent irreversible visual impairment.

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