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# Assessment of Quality of Life among Beta-Thalassemia Major Patients Attending the Hematology Outpatient Clinics at Cairo University Hospital

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## Abstract

**AIM:** This paper aimed at assessing the quality of life (QoL) among beta ( $\beta$ )-thalassemia major patients using the short-form-36questionnaire (SF-36) and determining the factors associated with it.

**METHODS:** A cross-sectional study was conducted among  $\beta$ -thalassemia major patients who were attending the hematology outpatient clinic at Cairo University Hospital using the consecutive sampling technique. Data were collected between October 2016 and March 2017. The QoL was assessed for patients aged  $\geq 17$  years. During the study period, a total number of 112 patients were included for participation.

**RESULTS:** The mean age of the studied group was  $18.32 \pm 1.33$  years. Most of the included patients (93.63%) had 1 monthly blood transfusion. The mean total score of SF-36 was  $44.90 \pm 7.54$ . Among the QoL domains of the studied patients, the "general health perception" domain was the most affected one with a mean score of (add the value of the score here), while the "vitality" domain was the least affected one. No statistically significant difference was reported between males and females regarding different QoL domains except for the "vitality" domain which mean score was significantly higher in males compared to females ( $p = 0.05$ ). The age at onset of the disease and at first blood transfusion was the most documented factors to be positively correlated with the QoL among the studied patients.

**CONCLUSION:** This study revealed that the QoL in thalassemia major patients is compromised. QoL assessment should be performed for all thalassemia patients to determine and implement the necessary interventions that focus on the affected domains.

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**Keywords:** Thalassemia major; Quality of life; Blood transfusions; Tertiary care hospital

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## Introduction

Beta ( $\beta$ )-thalassemia is considered as a major public health problem in the Mediterranean region and Southeast Asia [1], especially in the Middle East and North Africa where a high percentage of thalassemia major patients and carriers has been reported. This is attributed to consanguineous marriage in these areas [2]. In Egypt, about 4.5% of the population are  $\beta$ -thalassemia carriers [3].

Thalassemia major patients undergo a rigorous remedy regimen that starts in infancy including frequent blood transfusions and iron chelating therapy [4]. At present, patients with this disease have longer life expectancies because of the advancements in its treatment [5]. However, these longer life expectancies are associated with some challenges including frequent blood transfusions, daily use of iron chelators, cardiac and hepatic problems as well as splenectomy; all these challenges affect the patient's quality of life (QoL) by affecting his mental, physical, social, and educational functions [6].

Despite the recent evidence demonstrating the importance of improved QoL in treating chronic diseases such as thalassemia and controlling their symptoms [7], the QoL of patients with thalassemia major have been assessed in very few studies in Egypt [8]. The authorities providing services to patients with this disease should be acquainted with its physical and psychological consequences to create a better living environment for them [6]. Therefore, the current study aimed at assessing the health-related QoL (HRQoL) among  $\beta$ -thalassemia major patients in the hematology clinic of the Children Hospital, Cairo University during a period of 6 months using the short-form-36 questionnaire (SF-36) and determining the factors associated with it.

## Methods

### Study setting and design

The current study is an analytical cross-sectional study involving  $\beta$ -thalassemia major patients

aged >17 years who were attending the hematology outpatient clinics at the Children University Hospital, Cairo University. The patients involved in the study were chosen from the waiting area and interviewed in one of the clinics.

### **Sample size and sampling technique**

A consecutive sample of adolescents and adults with  $\beta$ -thalassemia major who attended the hematology outpatient clinics for treatment and blood transfusion at the participating hospital during the study period and was eligible to be surveyed was recruited to participate in the study. They have been registered there since diagnosis and follow-up for life. The number of patients involved in this study is 112. The subjects selected were patients with confirmed  $\beta$ -thalassemia major, aged >17 years, and willing to participate in the study. Patients with impaired cognitive function or severe clinical condition that limit their ability to participate in the study were excluded from the study. Participants recruitment started in January 2019 and continued for 6 months.

### **Data collection tools**

#### *SF-36 during the interview with thalassemia major patients*

The Arabic version of SF-36 tool was used to assess HRQoL outcomes. SF-36 is a generic questionnaire that measures two major subjective health concepts: Physical and mental health. The form covers 36 items yielding a profile of eight concepts: Physical functioning, role limitations due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitations due to emotional problems, and mental health. The reliability and validity of SF-36 are documented in all available language versions [9], [10], [11], [12].

In this study, the responses of participants to each SF-36 item were scored and summed according to a standardized scoring protocol and expressed as a score on a 0–100 scale for each of the eight health concepts. Higher scores point out to better self-perceived health or a higher level of function [13].

#### *Patients' files*

A separate sheet was generated to collect the required data from each patient's medical record: Age, gender, age at onset of the disease, age at the first blood transfusion, the frequency of blood transfusion, history of splenectomy, and complications (e.g., diabetes mellitus, and cardiomyopathy). Laboratory data (within the 3 months before the study) were collected from the patients' files including serum ferritin (SF), alanine transaminase (ALT), aspartate transaminase (AST),

pre-transfusion hemoglobin (Hb), and iron chelation treatment including age at the start of chelation, type of chelation, and compliance of the patient to it.

### **Ethical considerations**

The Medical Committee in the Pediatric Department of Faculty of Medicine, Cairo University revised and approved the study protocol. Informed consent was obtained from each participant after the proper orientation of the study's impact and objectives as well as data confidentiality. For the participants under 18 years old, assent and parental consent were obtained. Interviewing patients individually were considered to keep their privacy. All procedures for data collection were treated with confidentiality according to Helsinki Declarations of biomedical ethics [14].

### **Data management and statistical analysis**

The data were coded, entered, and analyzed using the statistical package SPSS version 21. For categorical data, frequency and percentage were used for reporting and Chi-square was used for comparison. For continuous data, mean and standard deviation were used for reporting the quantitative normally distributed data, while median and interquartile range were used for reporting non-normally distributed quantitative data. Mann–Whitney test was used to compare the differences between two independent groups. Spearman's rho non-parametric correlation was used to test the association between quantitative variables.  $p \leq 0.05$  was considered as statistically significant.

## **Results**

A total number of 112  $\beta$ -thalassemia major patients were enrolled in the present study during its period. As revealed in Table 1, more than half of the patients (56.2%) were males. Most patients (94.6%) were receiving once-per-month blood transfusion. All of the enrolled patients were receiving iron chelation therapy; about half of them (49.1%) were on deferoxamine. Moreover, most of the studied patients (98.2%) reported that they underwent splenectomy.

As demonstrated in Table 2, the mean age at onset of the disease was 6.71 months and the mean baseline Hb before blood transfusion was 7.07 mg/ml, while the median SF level was 660.00 (541.25–784.50) ng/dl.

As shown in Table 3, the mean total QoL score of the studied patients was  $44.90 \pm 7.54$ . According to severity, the "general health perception" domain was the most severely affected domain in the patients'

**Table 1: Demographic and clinical characteristics of the enrolled  $\beta$ -thalassemia major patients**

Characteristics	(n=112)
Age in years (Mean $\pm$ SD)	18.32 $\pm$ 1.33
Sex (n %)	
Male	63 (56.2)
Frequency of blood transfusion (n %)	
Every 1 month	106 (94.6)
Every 3 weeks	6 (5.4)
Iron chelator (n %)	
DFP (deferiprone)	55 (49.1)
DFO (deferrioxamine)	49 (43.8)
DFX (deferasirox)	8 (7.1)
Compliance to iron chelator (n %)	
Yes	74 (66.1)
No	38 (33.9)
Complications of the disease (more than one answer) (n %)	n=41
Hepatomegaly	26 (63.4)
Cardiomyopathy	9 (22.0)
Diabetes Mellitus	6 (14.6)
Splenectomy (n %)	
Yes	110 (98.2)
No	2 (1.8)

QoL, while the “vitality” was the least affected one. As revealed from Figure 1, no statistically significant difference was reported between males and females

**Table 2: Medical history and laboratory investigations of the enrolled  $\beta$ -thalassemia major patients**

Item	Mean $\pm$ SD (n = 112)
Age at onset of the disease (month)	6.71 $\pm$ 1.54
Age of 1 <sup>st</sup> blood transfusion (month)	7.06 $\pm$ 1.61
Age of splenectomy (years)	7.61 $\pm$ 1.12
Age of start chelation (years)	2.86 $\pm$ 0.59
SF level (ng/dl) <sup>a</sup>	1654.63 $\pm$ 943.33
Hb before blood transfusion (mg/dl)	7.07 $\pm$ 0.20
AST (U/L) <sup>a</sup>	47.10 $\pm$ 16.51
ALT (U/L) <sup>a</sup>	62.82 $\pm$ 18.72

SF: Serum ferritin; AST: Aspartate transaminase; ALT: Alanine transaminase; Hb: Hemoglobin; <sup>a</sup>The reference range for ferritin level is 7.0–140.0 ng/ml, AST (10–40 U/L), ALT (7–56 U/L).

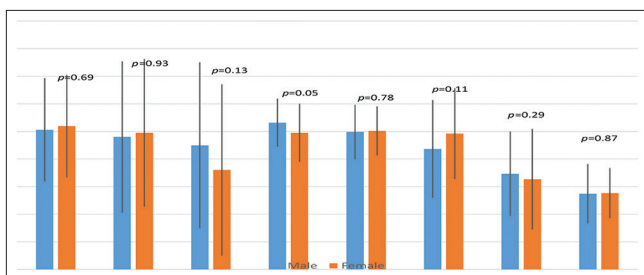
regarding different QoL domains except for the “vitality” domain where the mean score was significantly higher in males than in females ( $p = 0.05$ ).

**Table 3: HRQoL of the enrolled patients with  $\beta$ -thalassemia major according to SF-36 scoring form**

Subscales	Mean $\pm$ SD (n = 112)
Physical functioning	51.16 $\pm$ 18.56
Physical role limitation	48.66 $\pm$ 27.02
Bodily pain	33.82 $\pm$ 16.57
General health perception	27.54 $\pm$ 10.00
Vitality	51.56 $\pm$ 9.68
Mental health	49.96 $\pm$ 9.42
Social functioning	46.09 $\pm$ 17.29
Emotional role limitation	41.07 $\pm$ 30.67
Total SF-36	44.90 $\pm$ 7.54

HRQoL: Health-related quality of life; SF-36: Short-form-36 questionnaire.

Table 5 illustrates a statistically significant weak positive correlation between the age at onset of the disease, “physical functioning” domain ( $p = 0.02$ ), and the “bodily pain” domain ( $p = 0.019$ ) with the total SF-36

**Figure 1: Comparison between mean scores for SF-36 domains in male and female patients**

score ( $p = 0.001$ ) in addition to another significant weak positive correlation between the age at splenectomy

**Table 4: Correlation between quality subscales SF-36 and different demographic, clinical, and laboratory investigations of the studied thalassemia patients**

Characteristics	Physical functioning	Physical role limitation	Emotional role limitation	Vitality
Age				
r**	-0.028	0.047	-0.129	-0.096
p-value	0.767	0.623	0.176	0.312
Age of onset				
r**	0.209	0.075	0.158	0.123
p-value	0.027	0.429	0.096	0.196
Age of 1 <sup>st</sup> transfusion				
r**	0.173	0.121	0.111	0.020
p-value	0.068	0.203	0.246	0.832
Age of splenectomy				
r**	-0.142	0.130	0.276	-0.007
p-value	0.139	0.175	0.004	0.943
AST				
r**	0.096	-0.014	-0.029	0.109
p-value	0.316	0.887	0.759	0.251

r\*\* Spearman's rho correlation coefficient; AST: Aspartate transaminase; SF-36: Short-form-36 questionnaire.

and the “emotional role limitation” domain ( $p = 0.004$ ). The statistical analysis also revealed a statistically significant weak negative correlation between AST level and the “mental health” domain ( $p = 0.042$ ). A weak positive correlation between the age at first blood transfusion and total score of QoL was also revealed. Moreover, it was found that the “physical role limitation,” “social function,” and “vitality” domains do not correlate with ALT or SF level of the studied thalassemia patients (Table 5).

**Table 5: Correlation between quality subscales SF 36 and different demographic, clinical, and laboratory investigations of the studied thalassemia patients**

Characteristics	Mental health	Pain	General health	Total SF 36
Age, AST, ALT				
r**	0.024	-0.103	-0.214	-0.170
p-value	0.803	0.280	0.024	0.073
Age of onset				
r**	-0.109	0.222	0.158	0.297
p-value	0.253	0.019	0.097	0.001
Age of 1 <sup>st</sup> transfusion				
r**	-0.056	0.118	0.107	0.263
p-value	0.558	0.216	0.260	0.005
Age of splenectomy				
r**	0.020	-0.034	0.003	0.026
p-value	0.838	0.727	0.976	0.787
AST				
r**	-0.193	-0.100	-0.133	0.000
p-value	0.042	0.293	0.162	0.998

r\*\* Spearman's rho correlation coefficient; AST: Aspartate transaminase; SF-36: Short-form-36 questionnaire; ALT: Alanine transaminase.

## Discussion

The current study revealed a low mean total QoL score (44.90  $\pm$  7.54) among the enrolled  $\beta$ -thalassemia major patients. This may be attributed to the challenge of having a normal daily life with the procedures of treating a chronic disease like thalassemia including frequent hospital visits for transfusions and iron chelation therapy complications such as hepatitis, cardiomyopathy, and diabetes. It may be also attributed to patients' non-compliance to iron chelators as reported by one-third of the study participants. It is recognized that the presence of comorbidities among thalassemia children is a strong predictor of poor physical health

and low total QoL score [15]. The total QoL in this study is lower than the scores reported in other studies conducted among thalassemia major patients [16], [17]; this could be attributed two reasons. The first reason is that we do not have definite definition or measurements for QoL; it is a social concept affected by the cultural and contextual factors [18]. The second one is that the study was performed in a university hospital offering free services; therefore, its attendees are from the low socio-economic sector of the population and the financial status of patients reflects their QoL [19].

In the current study, the highest mean score was for the “vitality” domain followed by “physical functioning.” This could be explained by the regular blood transfusion among the surveyed patients which can improve the physical health status. This mean score is less than those revealed from other studies Baraz *et al.*, 2016 [1]; Jameel *et al.*, 2016 [7] which may be attributed to the difference between studies regarding the age at onset of the disease, compliance to treatment, and frequency of blood transfusion.

The lowest mean score among QoL domains was for “general health perception.” The possible explanation for this finding is that all the study participants were transfusion dependent and experienced symptoms of anemia such as fatigue and weakness before blood transfusion because blood transfusion is given only at low Hb levels due to scarcity of blood supply in Egypt. Hence, this might affect the general health perception negatively.

The results also demonstrated a low mean score in the “mental health” domain. Khani and Ansari study revealed the same results Khani *et al.* [1]; Ansari *et al.* [19]; this may be attributed to the emotional exhaustion the patients experience because of the disease treatment procedures as the blood transfusion and chelation therapy require frequent invasive measures and hospital visits El Dakhakhny *et al.* [20].

There was no statistically significant difference between males and females regarding different QoL domains except for the “vitality” domain in which its mean score was significantly higher in males than females. On the contrary, Baraz *et al.* [1], Emadi Dehaghi *et al.* [17], and Hassan *et al.* [18] found no significant differences between males and females regarding all QoL domains.

In consistent with a study conducted by Caocci *et al.* [21], among the Middle Eastern children with  $\beta$ -thalassemia a significant positive correlation between the age at onset of the disease, “physical functioning” domain, and total QoL score was revealed. This could be explained by the fact that younger patients could have fewer experiences in dealing with their illness and may have trouble understanding the disease they suffer from, while older children could have more knowledge about thalassemia and would be able to understand the support from their parents, caregivers, or peers to

allow them to cope better with the disease Mikelli and Tsiantis [22]. In contrast to the current study findings, Adib-Hajbaghery *et al.* [16] reported that there was no significant correlation between the age at onset of the disease and QoL scores. This contradiction might be explained by the different scales used to assess the QoL such as sample size, age group, geographical regions, race, culture, and health-care quality.

A significant weak positive correlation between the age at splenectomy and “emotional role limitation” domain was revealed. This might be due to the size and shape of the scaras well as the patients’ sense of embarrassment because of their skin appearance.

Even though the current proof demonstrates the severe mortality and morbidity that might be caused by long-term iron overload [2], SF level did not show any association with the QoL among thalassemia patients in the current study. The possible explanation for this finding is that the SF level is not an accurate measure of iron burden. Recent methods for detecting iron overload as magnetic resonance imaging are not accessible to all patients in our community. Moreover, baseline Hb levels did not show any association with the QoL in thalassemia patients appropriate anemia control for the almost acceptable QoL where more than half of thalassemia patients had Hb level greater than 7 g/dL might be the explanation for this finding. Transfusion practice in Egypt mainly depends on the availability of blood units where transfusion is usually given at Hb level of 7 g/dl or less.

The age at first transfusion before 4 years was found to be significantly associated with HRQoL with low total summary scores [23]. In the current study, a significant positive correlation was revealed between the age of onset of blood transfusion and QoL. This agrees with a previous study conducted by Saha *et al.*, [24].

Restricting the sample of patients to only attendants of a hematology outpatient clinic in one hospital may have limited these findings for convenience. Additional studies are needed to develop a full picture of QoL among thalassemia patients. There is a wide room for further progress in determining the QoL among thalassemia patients.

## Conclusion

The low mean total QoL score noted portrays the burden of thalassemia disease in its patients despite the effective management of their treatment. The age at onset of the disease and age at first blood transfusion are the most documented factors to be associated with the QoL among the enrolled thalassemia patients. The current study findings show that we need more holistic methodologies for treating thalassemia patients



which take into consideration the emotional and social aspects of patients, the physical one. The study results also reflect our need for an educational program which train thalassemia patients to deal with the physical, emotional, and social burdens of the disease.

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