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Development and Validation of Bio-psychosocial Problems Scale for Patients with Thalassemia

Toseef Imtiaz, Amina Muazzam
Lahore College for Women University, Lahore, Pakistan

Ambreen Anjum
The Islamia University of Bahawalpur, Pakistan

Abstract

Thalassemia major is a severe blood disease related to complete destruction of blood cells of patients. The survival rate of patients with thalassemia major is very low and patient's death toll is high in early age especially in childhood or teenage if not treated properly. Patients suffer from many problems related to physiological, psychological, social and financial issues. International and Local research available on Thalassemia covers these problems in distinct studies however, no any specific scale was developed for patients of thalassemia major to address all problems. So, this research aimed to construct a scale to measure bio-psychosocial problems comprehensively. For this purpose data was collected from 349 patients of three thalassemia centers of Lahore, Pakistan. In phase I, statements about (physical health, psychological problems and social problem issues) thalassemia patients particularly thalassemia major were gathered. Out of these 24 bio-psychosocial problems, 20 problems were screened. Factors of scale were explored in phase II. 3 factors (social, biological and psychological) for bio-psychosocial were identified. To confirm factor structure of bio-psychosocial problems scale, confirmatory factor analysis was applied in phase III and results depicted good fit model. In phase IV, psychometric validation proved the indigenous scale as a reliable tool for assessment of problems for the concerned population.
Keywords: *Bio-psychosocial problems, quality of life, symptoms, thalassemia*

Introduction

Thalassemia major is a complicated blood disease found in different geographical regions including England, America Canada, Germany, Eastern Europe and Asia (Vickinsky & Mackenzie, 2015). It is transmitted from parents to off spring. Thalassemia major mostly develops due to defect of genes from both parents of the child. Those patients who inherit defective genes from both parents are called homozygous. Beta thalassemia is one of the types of thalassemia also named as Mediterranean anemia or coleen anemia. Patients who receive defective genes from single parent are the patients of heterozygous beta thalassemia or thalassemia minor (Galanello & Origa, 2010). The geographical distribution shows that 0-5% has thalassemia trait and 40% of the population are genetic carriers (Vickinsky & Mackenzie, 2015). In eastern Mediterranean, 60% population may be genetic carrier and 0.2 % has thalassemia trait. In Europe 1-2% has a thalassemic trait and 12% of the population may be genetic carrier. One to 30% of the Southeast Asia population has thalassemia trait and up to 40% is genetic carrier. Fifty percent of the population in Sub-Saharan Africa, while 60% in Western pacific may be genetic carrier only. Estimation of beta thalassemia in children is 5000 to 9000 (5-7%) per annum. It means 8-9 million carriers are present in the total population. Most of the patients live in rural areas and medical facilities for diagnosis of this disease are limited to be provided by charity organizations only (Ansari. et al, 2011).

Correspondence concerning this article should be addressed to Dr Amina Muazzam Tenured Associate Professor in Applied Psychology Department Lahore College for Women University, Lahore, Pakistan
Email amina_muazzam@hotmail.com

The biological symptoms associated with thalassemia major are jaundice, fatigue and increase in heart rate. The size of heart also enlarged, physical development of patients slows down and they cannot do work of daily routine. The infant with this disease becomes weak, fragile, and irritable and cries in routine. Severe anemia also affects the defense mechanism system of the body and the bone marrow expands. The red blood cells develop in bone marrow so it expands 30 times more against to compensate the low level of blood cells. The changes occur in bones such as the abnormal size of head, the expansion of upper jaw, changes in the shape of joints, ribs and backbone and the bones become thin, weak and breaks up due to expansion in them (Smith, 2015). The intestine starts to absorb more level of iron against anemia which is very harmful for the patient of thalassemia because the breakup of blood cells is not due to decrease in iron in body. The body becomes overloaded with iron due to its absorption and causes new dangers. It is necessary to take tests of thalassemia careers before the birth of their child. Psychological problems that a patient face due to physical or biological problems include the similar symptoms common in stress, anxiety, depression and somatization. Other symptoms include hopelessness, depression, aggression, irritability, fear of death, lack of confidence, loneliness, deprivation, more than normal care, inferiority complexes (Galanello & Origa, 2010). Research work has been conducted on psychosocial problems of patients of thalassemia major but not on the combine bio-psychosocial problems due to thalassemia major. Many researchers used several clinical scales to measure psychosocial problems such as Developmental Psychopathological Checklist (Kumaravel, Jaganathen, Balaji, Karthik & Pugalendhiraja, 2016), Strengths and difficulties questionnaires (SDQ) by Goodman (2001) , State and Trait Anxiety bySpielberger, Gorsuch, Lushene, Vagg& Jacobs (1983), Children Depressive Inventory (CDI) (Kovacs, 1983), Symptoms Checklist-90 (SCL-

90) (Jain, Bagul & Porwal, 2013), Child Behavior Checklist (Aydinok, Erermis, Bukusoglu, Yilmaz & Solak, 2005) Semi-structured Interview, The Patient Health Questionnaire by Spitzer et.al (1994), The Hospital Anxiety and Depression Scale (Zigmond&Snaith,1983). The Middex Hospital Questionnaire (Crown & Crisp, 1966), Mc Gill Quality of Life Questionnaire (Cohen, Mount, Strobel & Bui, 1995), Pediatric Quality of Life Inventory(Vami, Seid & Rode, 1999) and Quality of Life SF-36 Questionnaire (Babaei, Askarizadeh & Tohidi, 2017). There was no any specific scale developed to measure combine bio-psychosocial problems of such patients in both Western and Asian countries. The goal was to construct an indigenous tool to assess biological, psychosocial and other problems of patients of thalassemia major.

Method

Phase 1: Item Generation

Problems related to thalassemia major were listed. List of problem were gathered through review of literature, interview of physicians and interview of patients.

Step1: Literature Review: For theoretical understanding of bio-psychosocial problems, previous scales were studied in detail which were used to assess problems of thalassemia patients were studied. To study the literature digital library of Lahore College for Women University were approached (Sabah et al., 2019; Sarwar, 2019). Sixty articles were (key words for using was bio-psychosocial problems among patients with thalassemia major) studied using databases like Springer Link, Jstor, Chicago Journals, Taylor and Francis, and Science Direct and Wiley Inter Sciences.

Step2: Expert Interviews: Three physicians (Hematologist) from different thalassemia centers of Lahore, Pakistan were selected using purposive sampling. (Hassan, Muazzam& Anjum,2019). Detailed interviews were conducted with physicians using open-ended questions to gather information about the symptoms of thalassemia major and the different problems that thalassemia patients face in their lives. These questions were asked by each expert one by one. All answers were written on a notebook. Physicians reported that thalassemia patients face physical problems (body aches, stomach problem), Psychological problems (depression, anxiety, low quality of life, stresses, aggression, irritability, and some shows lack of confidence), and social problems (isolation, less communication and social support, fear of infectious disease to others).

Step3: Interviews with Patients: Focus group interviews were also conducted with 10 thalassemia patients (male=5, female=5) aged between 12 to 40 years. The age 12 and above was selected because half of the population with thalassemia died before reaching the age of 12 (Silvestroni & Aassemie, 1998). Moreover, less than 12 years of age children cannot report and explain their problems well. These patients were selected by different thalassemia centers of Lahore, Pakistan using homogeneous purposive sampling. They were encouraged to share their all sort of problems they face in their daily routine due to the disease. They reported that with several psychological and physical problems, people avoid to have contact with them due to fear of having contiguous disease. All items were audio recorded and transcribed latter.

Step 4: Content Validity: To find out the items content validity index (I-CVI) and scale content validity (S-CVI) of bio-psychosocial problems scale for thalassemia patients , 6 practicing physicians (with at least 6years' experience in the treatment of thalassemia patients who were getting chelation therapy and rapid blood transfusion) were chosen. Experts were requested to carefully read each item on the list and rate items according to relevance of subject on 1 to 4 (not relevant to highly relevant). Furthermore, items content validity was calculated as prescribed by Lynn (1986).Twenty four items were selected by calculating quantitative content value index.

Table 1

Experts' rating and Item' CVIs for the Bio-Psychosocial scale (N=6)

Items	1	2	3	4	5	6	No. in agree	Item CVI
1	4	4	2	4	4	4	5	**.83**
2	4	4	3	4	3	4	6	**1**
3	4	3	4	4	4	4	6	**1**
4	2	3	3	2	2	4	3	**.**5
5	4	2	4	4	4	4	5	**.83**
6	4	4	4	2	4	4	5	**.83**
7	4	3	4	4	4	4	6	**1**
8	4	4	2	4	4	4	5	**.83**
9	4	4	4	4	4	4	6	**1**
10	4	3	4	4	4	4	6	**1**
11	4	3	4	4	3	4	6	**1**

12	2	4	4	3	4	4	5	**.83**
13	4	3	4	4	3	4	6	**1**
14	4	3	3	4	4	4	6	**1**
15	4	2	4	4	3	4	5	**.83**
16	4	4	4	4	4	4	6	**1**
17	4	4	4	4	4	4	6	**1**
18	3	2	3	4	2	3	4	**.**67
19	4	4	4	4	4	4	6	**1**
20	4	4	3	3	4	4	6	**1**
21	2	2	3	4	2	3	3	**.**5
22	4	4	4	4	4	4	6	1
23	3	4	4	4	4	4	6	**1**
24	2	2	3	4	2	3	3	.5

Note. .CVI = .83 or above are bold
Total number of items = 23.98/24 = .98. Following Lynn's (1986) criteria above .90 is marvelous.

Step5: Pilot Study: A Pilot testing was used was to assess appropriateness of the 20 items newly developed scale consisting of 20 items with CVI values of .83 or higher. For this purpose, a sample of 51patients (female: n=30, male: n = 21) with thalassemia major were selected. The mean age of these patients was 16.30 years (*SD*=5.66). Items were scored on 4 point rating (never to much more). Participants rated these items according to the degree that each applied to them. Criteria for item retention was endorsement received <20% and > 80 %. Through this process no items was found ambiguous, all 20 items were retained.

Phase II: Construct validity through factor analysis

Following Cronbach and Meehl (1955) scale construct validity was checked. Sample: Thalassemia patients (n=349, male = 158, female = 191) age ranged 12 years and above were collected using purposive sampling.

The thalassemia patients were taken from thalassemia centers. Both male and female patients were included.

Procedure: The thalassemia patients were taken from three thalassemia centers of Lahore after their written consent. They were briefed about the purpose of the study. 20 items finalized after pilot study were presented to thalassemia patients. They were asked to rate these items at 5 point ratings. After the collection of information they were thanked.

Results: Varimax Rotation method was used for factors extraction (Kim & Mueller, 1978). Items were selected according to their Eigen value (greater than 1). To test adequacy of sample Kaiser Myer Olkin (KMO) test was used. Bartlett Test was also employed and results showed adequate distribution of the data with 5191.40 ($p < .000$).

Table 3

Eigen Values, Variance and factors' Cumulative Percentage of factors

Factors	Eigen Values	Variance %	Cumulative %
1	9.70	48.52	48.52
2	2.29	11.46	59.99
3	1.58	7.91	67.90

% = Percentage

Table 5 is showing the factor loadings of 20 items extracted by using varimax Rotation method.

Table 4

Factor Loadings of 20 items of Bio-Psychosocial scale for thalassemia patients (BPSSTP) for three factors (N=349)

Sr. no	Item no.	Statements	Social	Biological	Psychological
1	1	Different types of pains in body		.699	
2	2	Feeling fatigue in body		.775	
3	8	Nausea due to medication and blood transfusion		.813	
4	10	Feeling weakness due to loss of blood or iron deficiency		.775	
5	11	Difficult to walk and work properly due to fatigue n disease		.782	
6	12	Problems due to diet plans and use of less iron food		.685	
7	13	Problems due to iron overload and blood transfusion		.733	
8	4	Feeling tension			.651
9	5	Frequent crying or weeping			.744
10	6	Feeling sensitivity			.729
11	7	Continuous disturbing thoughts due to illness			.708
12	9	Feeling restlessness			.658
13	11	Low body image than others			.684
14	12	Awareness about the process of blood transfusion			.708
15	2	By arrangement by yourself for transfusion	.783		
16	9	Feeling inferior in participating different social functions.	.803		
17	8	People in your surroundings are worried about your illness	.842		
18	10	Parents are completely aware of your illness	.821		
19	12	Parents are worried due to expenses on your treatment	.852		
20	17	Frequent visit towards hospital due to illness	.798		

All 20 items were retained by using Verimax Rotation method. Seven items were extracted as factor 1 which was related to “social and other problems of thalassemia patients”. Seven items were extracted as factor 2 related to “biological problems of thalassemia patients”. Six items were extracted as factor 3 related to “psychological problems of thalassemia patient”.

Seven items that loaded on biological problems of thalassemia included pain in body, fatigue, nausea due to blood transfusion and medication, problems due to iron deficiency, it’s difficulty in walking and work properly due to fatigue and disease, problems due to diet plans and use of low iron food, problems due to iron overload and blood transfusion. Seven items were extracted as psychological problems including worry, crying, sensitivity related to illness, thoughts about disease, anxiety, increase in disease due to worriedness, poor body image. Six items related to social and other problems including awareness about the procedure of blood transfusion, blood arrangement by themselves for transfusion, inferiority complex in participating different social functions, financial problems for treatment of patients to their parents, frequentvisit to hospitals for treatment of thalassemia.

Phase-III: Confirmatory Factor Analysis (CFA)

EFA revealed three factor solutions of the 20 items of bio-psychosocial problems scale for thalassemia patients. These 3 factors were verified by using confirmatory factor analysis.

Procedure: Sample of 349 patients of thalassemia major was taken using purposive sampling technique for CFA (Bentler, 1990). These patients were also going through the procedure of blood transfusion, chelation therapy and treatment for thalassemia major in different thalassemia centers. Consent was taken from authority of these centers as well as patients and their informers in case. Age range of these patients was between 12 to 30 years. In the present study various indices were used to explain the good model fit for example

To test model criteria that was used e.g. Comparative fit Index (Bentler & Bentler, 1980).

,Tucker-Lewis Index (TLI), and root mean square (Bollen, 1990).

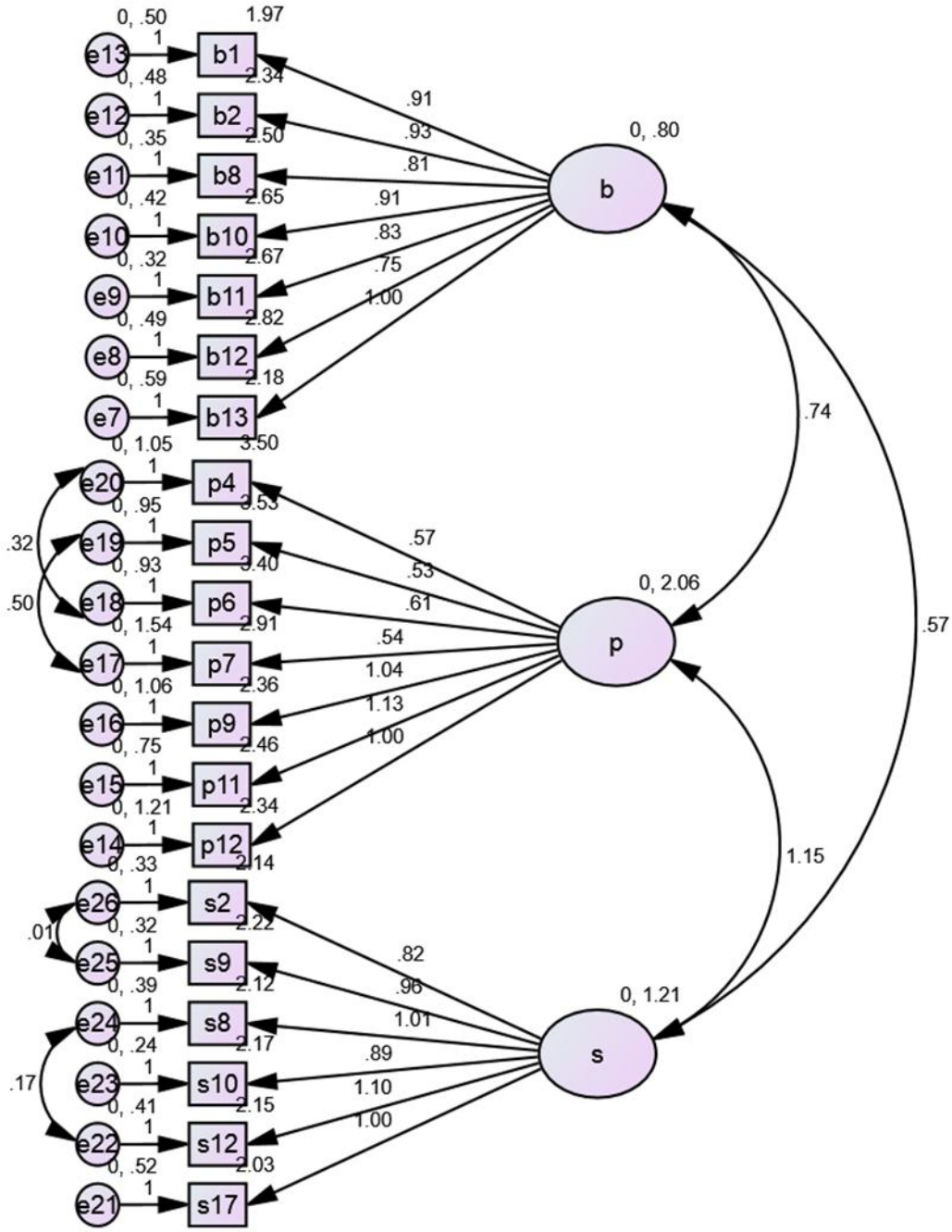

Figure 1. Final Model of BPSSTP

Figure 1 shows findings of factor loading of BTSSTP. This model of BPSSTP consists of 20 items. There are 7 items in biological symptoms factor. Second factor contains 7 items labeled as psychological factor. There are 6 items in social problems factor. Factor loading are according to Hair, Black, Babin and Anderson (2010) criteria. The range of factor loadings is .54 and above.

Table 5

Indices for model fit BPSSTP (N = 349)

Model	*Df*	*χ2/df*	*TLI*	*CFI*	*GFI*	*RMSEA*
3factor solution	163	2.47	.94	.95	.95	.06

df= degree of freedom, *GFI*= Goodnessof fit index, *TLI*= Tucker-Lewis index, *CFI*= comparative fix index, *RMSEA*= root mean square error of approximation,

Bio-psychosocial problems scale for thalassemia patients conformed with three subscales.

Phase IV: Establishing Psychometric Properties of BPSSTP

The psychometric properties of BPSSTP were established by determining alpha reliability, convergent validity and discriminative validity.

Reliability of BPSSTP

Cronbach's alpha (N=349) confirmed internal consistency of scale .93. Alpha reliability showed that this scale was highly consistent and reliable. The alpha coefficient of the subscales related to biological, psychological and social problems items were showing highly internal consistency and reliability, .90, .88 & .82.

Table 6

Reliability of BPSSTP with mean and SD (N=349)

Scales	*K*	*α*	*M*	*SD*
BPSSTP	20	.93	50.45	17.67
Biological	7	.90	17.13	5.78
Psychological	7	.88	20.49	8.39
Social	6	.94	12.82	6.56

K= number of scale items, *A*= Alpha reliability, *M*=Mean, *SD*=Standard deviation

The alpha coefficient values shows that BPSSTP is a highly reliable scale for assessing biological, psychological and social problems of patients of thalassemia major. Scale reliability was also confirmed.

Convergent Validity

To analyze convergent validity of scale relationship between Symptom Checklist (Derogatis, 1977) and Bio-psychosocial problems scale was analyzed. Symptom checklist was used as similar construct since it is constructed to measure **s**ymptoms of psychopathology. One hundred patients (female= 50, male= 50) of thalassemia major. Participants were gathered using purposive sample strategy. Consent from authority figures of 3 thalassemia centers of Lahore, Pakistan was taken to collect the data. Verbal consent from patient was also taken after telling them the purpose of this study. Developed bio-psychosocial problems scale for thalassemia patients BPSSTP and Symptom Checklist were administered individually. Correlation method was used to analyze the relationship between scores of both scales using SSPS version 21.

Table 7

Pearson correlation between scores of BPTSSTP and Symptom Checklist (N=100)

	M	*SD*	*R*
Bio-psychosocial problems scale	104.69	23.10	.63**
Symptom Checklist-90-	238.59	48.11	

***p*< .01, *M*=Mean, *SD*=Standard Deviation, *r*= correlation

Table 6 showed the results of relationship between scales, BPSSTP and symptom Checklist. The value of reliability coefficient was .63 which indicated that there was a positive relationship between scores of both scales. This result confirmed the hypothesis that both scales are highly correlated and confirmed the convergent validity of BPSSTP.

Discriminative Validity

Discriminative validity of BPSSTP was assessed by determining the relationship between Quality of life scale SF-36 and Bio-psychosocial Problems Scale for Thalassemia patients (BPSSTP). Patients with blood transfusion diseases have less life quality (Muazzam & Javed, 2013) so QOL was chosen as an opposite construct to check this type of Validity.

Table 8

Pearson correlation between scores of BPSSTP and SF-36 (N=100)

Scales	*M*	*SD*	*R*
BPSSTP	*104.69*	*13.40*	*-.42***
Quality of Life Scale SF-36	*61.26*	*6.26*	

***P< .01,M*=Mean, *SD*=Standard Deviation, *r*= correlation

Table 8 shows significant negative correlation between BPSSTP and SF-36. So, it is concluded that indigenously developed scale BPSSTP has good discriminant validity.

Discussion

Thalassemia is largely considered to be a much neglected population in terms of assessment of their problems because the patients do not tend to live long and are not considered as much useful members of society in Pakistan (Ansari. et al, 2011). Our aim was to assess problems of thalassemia patients so that some attention could be paid to them. The items for the bio-psychosocial problems of thalassemia scale were constructed using empirical method. Factors were explored. Findings showed 20 clear items with three factors. Reliability of bio-psychosocial problems of thalassemia scale was .93. Furthermore, all items were found highly internally consistent (most of the items total correlation > .3). Furthermore, CFA on 349 patients was conducted. CFA model depicted good model fit. Three distinct factors (viz., social, biological, and psychological problems) emerged. The biological problems included pain in body, fatigue, nausea due to blood transfusion and medication, problems due to iron deficiency, difficult to walk and work etc. In previous literature, Hoppe (2013) also found all such symptoms very much in thalassemia patients. Previous researches conducted on psychological issues of these patients extracted the problems such as depression, anxiety and concern about body image (Smith, 2015). In our study seven items were extracted as psychological problems. In Western (Galanello & Origa, 2010) and Asian (Hossain, Raheem, & Sultana, 2017) cultures several studies were also conducted on social and other factors such as financial issues for treatment, social problems of patients, problems related to collect blood for blood transfusion and social support from the society. In Pakistan where the average daily income in 1.25 U.S dollars per person, it becomes very difficult to afford the financial cost of treatment where the Government provide minimum or almost no support to this population. This increase the psychological trauma as well. Six items extracted in the present study were related to social problems including awareness about the procedure of blood transfusion, blood arrangement by themselves for transfusion, inferiority complex in participating different social functions, and financial problems for treatment of patients to their parents.

In addition, to find out the psychometric properties of this scale convergent and discriminative validities were established. Results of Cronbach's alpha and Pearson correlation on both convergent and discriminative validities indicated that presently developed scale is highly reliable and valid.

Implications and suggestions

The present research could be beneficial not only for patients and their families but also for practitioners to assess problems of thalassemia patients comprehensively and to take good intervention decision. Size of sample was main limitation. Participants were selected from one city with sample age ranging from 12 to almost 50 So, for more reliable findings large sample should be collected from different cities. However these limitations can be ignored considering this a preliminary study which is opening a new horizon for researcher to further explore the strategies to reduce the physical psychological and financial burden of this population.

Conclusion

Despite its limitations, a newly developed bio-psychosocial problems scale for thalassemia patients have good reliability. This tool will measure problems of thalassemia major. Using the findings of this study some better intervention strategies could be suggested by practitioners as well social workers to reduce the psychological and financial trauma of thalassemia patients if not their physical burden.

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