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Systematic Review (Pages: 8483-8494)

Health-Related Quality of Life in Iranian Patients with Thalassemia Major: A Systematic Review and Meta-Analysis

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Abstract

Background: Thalassemia is the most common genetic disorder in Iran. High treatment costs, the use of iron chelators, comorbidities and periodic visits affect the quality of life in these patients. The present study was conducted to assess the quality of life, according to the Short healthy survey (SF-36), in Iranian patients with thalassemia major.

Materials and Methods: In this meta-analysis, search was done in national and international databases, including SID, MagIran, Google Scholar, Web of Science, Medline (via PubMed), and Scopus until March 2018. The searched papers were screened and summarized by two independent reviewers. Based on the heterogeneity among the studies, the data were analyzed using the random effects model. Data were analyzed using STATA version 14.0.

***Results*:** Data from 18 studies, including 2,897 patients (age group 12-45 years old); were entered in the final analysis. The mean mental component scale in patients with thalassemia major (57.30; 95% confidence interval: 50.31-64.30) was lower than the mean physical component scale (62.77, 95% CI: 52.63-70.91). The mental component scale increased significantly between 2009 and 2017 (as the year of publication increased) (P = 0.043). The highest (74.77), and lowest (60.94) subscale scores of quality of life were related to physical functioning and general health, respectively.

Conclusion

Patients with thalassemia major have a relatively low quality of life. Providing strategies for improving the quality of life in this group of patients (particularly in terms of mental components) seems necessary.

Key Words: Children, Iran, Thalassemia Major, Meta-analysis, Quality of Life.

*Please cite this article as: Mitra Goli, Shahin Salarvand, Fazel Dehvan, Houshyar Ghafouri, Sahar Dalvand, Reza Ghanei Gheshlagh, et al. Health-Related Quality of Life in Iranian Patients with Thalassemia Major: A Systematic Review and Meta-Analysis. Int J Pediatr 2018; 6(11): 8483-94. DOI: **10.22038/ijp.2018.32565.2869**

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Received date: May.17, 2018; Accepted date: Jun.22, 2018

1- INTRODUCTION

Thalassemia is a genetic blood disorder that may be fatal, if not properly treated. The alpha or beta globin chain is a part of the hemoglobin structure in the red blood cells that is either not produced or produced in small amounts in this disease (1). Disruption in hemoglobin production and high rates of red blood cell destruction impose lifelong transfusions on the patients (2). There are about 300 million patients with thalassemia in the world, 55 million of which live in Southeast Asia. Thalassemia is the most common genetic disease in Iran. About three million people (four percent of the total population) are carriers of thalassemia, and 25,000 are suffering from thalassemia major, with an annual increase of about 800 people (3).

The global prevalence of thalassemia in the world is two per 1,000 births, but it is four to eight per 1000 births in Iran. Children with thalassemia seem to be fine at birth, but they gradually develop anemia due to partial or total absence of hemoglobin, which may lead to early death if left untreated (1). High costs of treatment, iron chelators, blood tests, treatment of the side effects, and periodic visits affect the quality of life in these patients (2). Due to medical advances, regular and safe transfusions and iron chelation therapy, the life expectancy and survival of these patients have increased dramatically compared with previous decades (2, 4).

Although the advancements in medical knowledge has led to an increase in the lifespan of these patients, the main goal of the researchers is not simply to increase their lifespan, but the challenge of the new century is the quality of life of people, as chronic diseases have adverse effects on the quality of life (5, 6). Health-related quality of life (HRQoL) is a multidimensional concept that focuses on the impact of disease and treatment on patients. This measure evaluates the patients' view of disease and treatment, their perceived needs for healthcare providers and their preferences for treatment and outcomes of the disease (1). These patients suffer from chronic comorbidities such as heart failure, cardiac arrhythmias, liver disease, endocrine complications and infection, which may have adverse effects on their quality of life (7). On the other hand, the diagnosis of this chronic disease during childhood imposes a lot of mental shock and stress on the child and the family (2).

Various studies have assessed the quality of life in patients with thalassemia in Iran and reported varied results. The SF-36 quality of life questionnaire measures two distinct physical and mental scales, each scale from four subscales. The physical component scale of quality of life includes four subscales of physical functioning, physical role limitation, physical pain and general health, and the mental component scale includes subscales of vitality, social functioning, mental role limitations and mental health (8). Unlike specific questionnaires that are limited to a specific group and are always criticized in this regard, this questionnaire measures all the important aspects of patient's health and is able to compare similar patients or patients with different conditions and diseases (9).

This questionnaire was translated and revised by Montazeri et al. in Iran in the years 2005. Reliability was estimated using the internal consistency and validity was assessed using known groups' comparison and convergent validity. The internal consistency (to test reliability) showed that all eight SF-36 scales met the minimum reliability standard, the Cronbach's a coefficients ranging from 0.77 to 0.90 with the exception of the vitality scale ($\alpha = 0.65$). Known groups comparison showed that in all scales the SF-36 discriminated between men and women, and old and the young

respondents as anticipated (all p values less than 0.05). (10). Reviewing the literatures exhibited the various studies have been reported different results on the quality of life of patients with thalassemia; furthermore, the necessity of combining the results of these. Studies appeared so necessary to examine the overall quality of life of these patients. According to the lack of comprehensive studies in this field, the current study was conducted with the following objectives: (1) estimate the physical and mental components of health-related quality of life in patients with thalassemia major in Iranian society, and (2) collective estimation of the eight subscales of quality of life in patients with thalassemia major using SF-36 questionnaire, so that we can use its result to make the healthcare policy-makers and decision-makers more aware of the quality of life in this group of patients and to provide the basis for evidence-based decision making.

2- MATERIALS AND METHODS

2-1. Systematic review methods

This systematic review and meta-analysis reviews the quality of life in Iranian patients with thalassemia major according to PRISMA guidelines based on articles published in national and international journals (11). To search related articles, two independent researchers searched the Persian and English databases.

2-2. Persian and English databases

The searched Persian databases in the study were scientific information database (SID), Magiran, and Persian Google Scholar. The searched English databases in the study were Google Scholar, Web of Science, Medline (via PubMed), and Scopus. Searching the Persian and English database was done without any time limit and language of the papers; moreover, selecting the Persian and English databases were according to the comprehensively, popularity, and availability of the databases, then Cochrane library wasn't searched. The references of the reviewed articles were also reviewed to access other articles. The articles were searched using the following keywords: ("Quality of Life" OR "Health-Related Quality of Life" OR "QOL" OR "HRQoL") AND ("Short form questionnaire 36" OR "SF-36") AND ("Thalassemia") AND "Iran".

The search strategy in PubMed database was as follows: ((("Quality of Life" [Title/Abstract] OR "Health-Related Quality of Life" [Title/Abstract] OR "QOL" [Title/Abstract] OR "HRQoL" [Title/Abstract] OR "Short form questionnaire 36" [Title/Abstract] OR "SF-36"[Title/Abstract])) AND "Thalassemia" [Title/Abstract]) AND "Iran" [Title/Abstract]).

2-3. Study Selection and Data Extraction

First, all articles that referred to the quality of life of patients with thalassemia were collected. The inclusion criteria were as follows: studies that were conducted exclusively among patients with thalassemia major, observational (non-interventional) study, assessment of quality of life using SF-36 questionnaire and providing adequate information related to the research objectives. Both Persian and English papers if included the inclusion criteria were reviewed. The exclusion criteria were: being irrelevant to the subject, duplicate studies, and lack of access to the full text of the articles. Considering the inclusion and exclusion criteria, the abstracts of the articles were reviewed by the researchers and related items were extracted. For extracting data from selected articles, a checklist was used that included variables such as the first author of the article, the year of publication, the location of the study, the

sample size and the quality of life score in the eight dimensions and the total score of the two main physical and mental components. Each article was reviewed independently by two researchers, and in case of controversy, the article was judged by another author who was a meta-analysis expert. In the initial search, 1065 articles were found, of which 1,065 articles were excluded due to being irrelevant to the subject. Finally, 18 Persian and English relevant articles were analyzed. The methodological quality of articles was evaluated based on a scale that was used in various national and international studies. The scale included five items of the study plan, a comparison group, a description of the characteristics of the study samples, the sample size of the study, and the scale used; each item was given a score of zero to three, and higher score indicated higher methodological quality (12-14). Some of these studies did not report the mean physical and mental component scale of quality of life, and some did not report the mean score of the eight subscales, so in each of the analyses, the articles with appropriate and adequate data were analyzed.

2-5. Statistical analysis

Considering the fact that the quality of life score had normal distribution, the variance of each study was calculated based on the variance of normal distribution according to the equation: $var(\bar{X}) = \sigma^2/n$.

The weight assigned to each study was proportional to the variance. The mean score of health-related quality of life and its components were estimated with 95% confidence interval (CI). I^2 index and Cochran's Q test were used to analyze the heterogeneity of the data. If the I^2 index was higher than 50% or the probability of the Cochran's Q test was lower than 0.05 ($P<0.05$), the random effects model was used and otherwise, the fixed effects model was used to estimate the quality of life scores. Sensitivity analysis was performed to ensure the stability of the results. The meta-regression model was used to examine the relationship between physical and mental components of quality of life and mean age, year of publication and sample size. The potential publication bias of the results was investigated using Begg's funnel plot. Data analysis was performed using STATA version 14 and the significance level was considered 0.05.

3- RESULTS

In this study, all articles published in Persian and English that assessed the quality of life in patients with thalassemia major in Iran without time limit were analyzed according to PRISMA guidelines. In the initial search, national and international databases were reviewed until March 2018, and ultimately, 18 articles entered the meta-analysis process based on the inclusion and exclusion criteria (**Figure.1**).

Sensitivity analysis was performed on the selected articles, and it showed that the absence of an article does not significantly change the estimation of the mean quality of life score in patients with thalassemia major. The biased graph was used to determine whether all studies carried out in this regard were analyzed. Based on the results of both Egger's test and Begg's test, the publication error of the physical and mental components of quality of life in patients with thalassemia major was not statistically significant (p=0.514) (**Figure.2**) and (**Table.1**) (*please see the table.1 at the end of paper*).

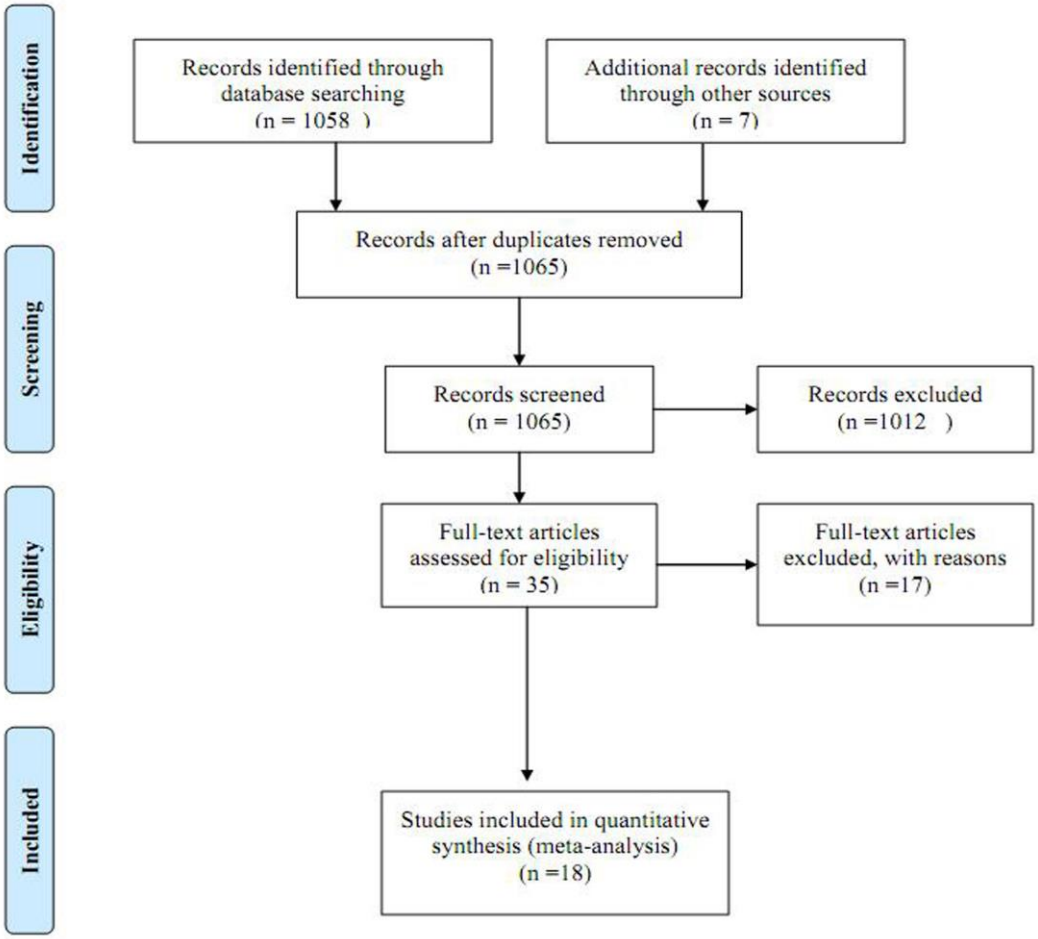

Fig.1: PRISMA flowchart of present study.

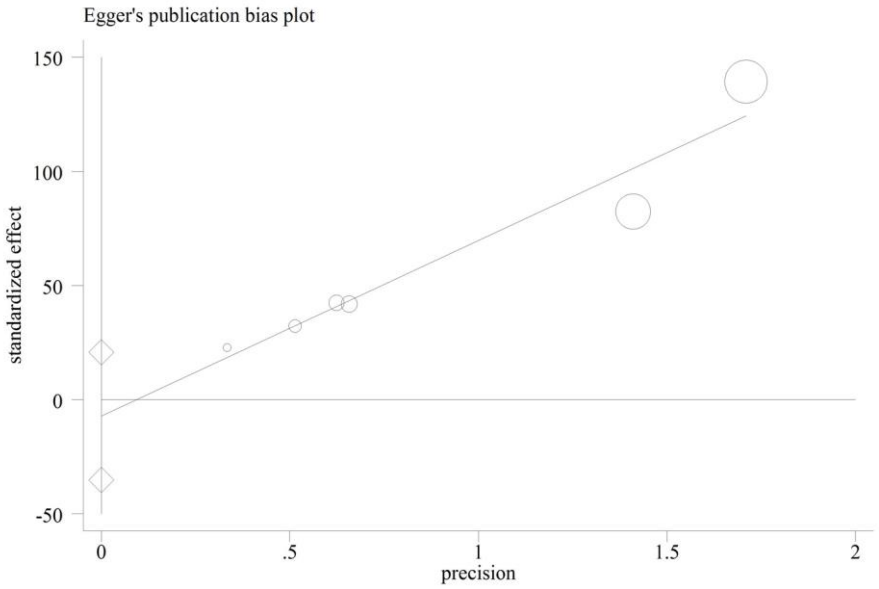

Fig.2: Egger's regression test to assess publication bias.

In this study, 18 articles with a sample size of 2,922 patients and an average of 163 patients per article were analyzed. The mean mental component scale in patients with thalassemia major (57.30; 95% CI: 50.31-64.30) was lower than the mean physical component scale (62.77, 95% CI: 52.63-70.91)(**Figure.3, 4**).

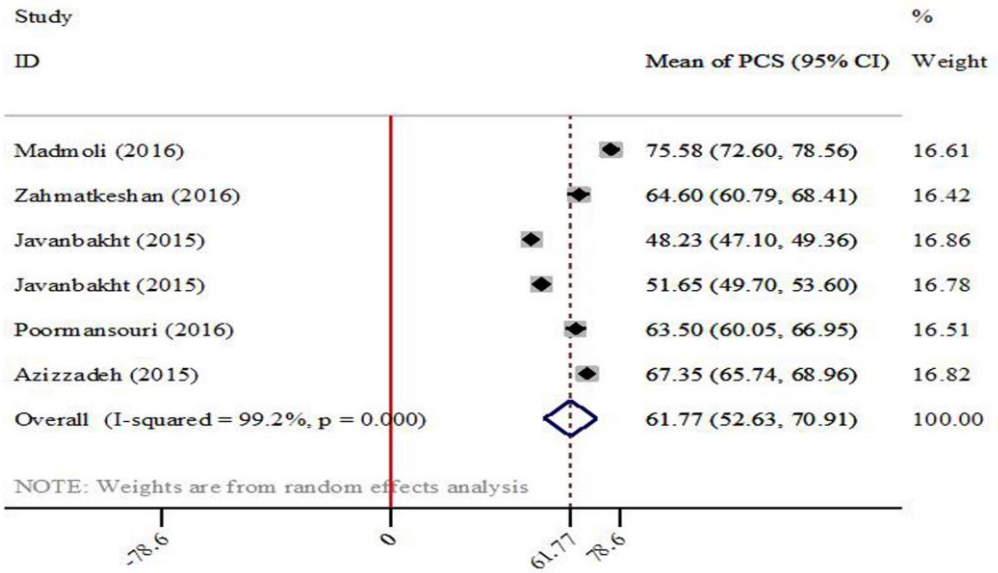

Fig.3: The mean scores for the physical dimension of HRQoL among patients with thalassemia. CI of 95% of each article is represented as horizontal lines near the main mean line; dashed line at the mid represents an estimate of the total mean score; and the rhomboid represents CI of the mean score of physical dimension.

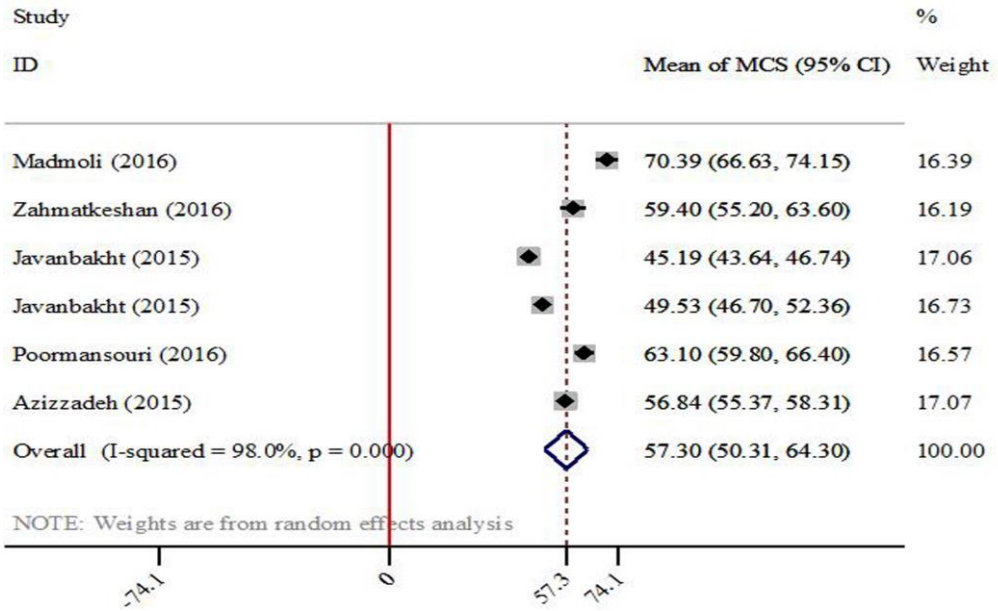

Fig.4: The mean scores for the mental dimension of HRQoL among patients with thalassemia. CI of 95% of each article is represented as horizontal lines near the main mean line; dashed line at the mid represents an estimate of the total mean score; and the rhomboid represents CI of the mean score of mental dimension.

The results of analyzing the meta-regression showed that there was no significant correlation between the physical component of quality of life and the sample size (P = 0.612), the mean age of the patients (p = 0.841), and the methodological quality of the articles (P = 518), and also between the mental component of quality of life and sample size (P = 0.622), mean age of patients (p = 0.622), and methodological quality of the articles (P = 0.564). The physical component scale (p = 0.161), and mental component scale (p = 0.043) increased between 2009 and 2017 (as the year of publication increased), which was only significant regarding the mental component scale (**Figure.5**).

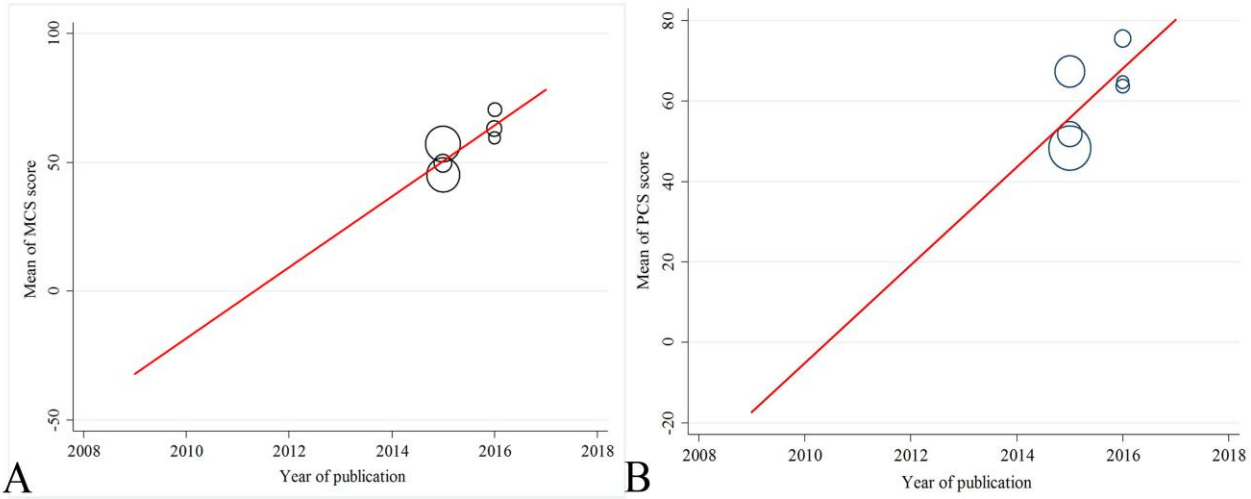

Fig.5: The results of meta-regression analysis regarding the mental (A) and physical (B) components of the quality of life based on the year of publication of the articles.

Results showed that the mean score of physical component (68.83 vs. 54.54), and mental component (63.30 vs. 51.13) of the quality of life in articles published in Persian were higher than those published in English (**Figure.6**) and (**Table.2**).

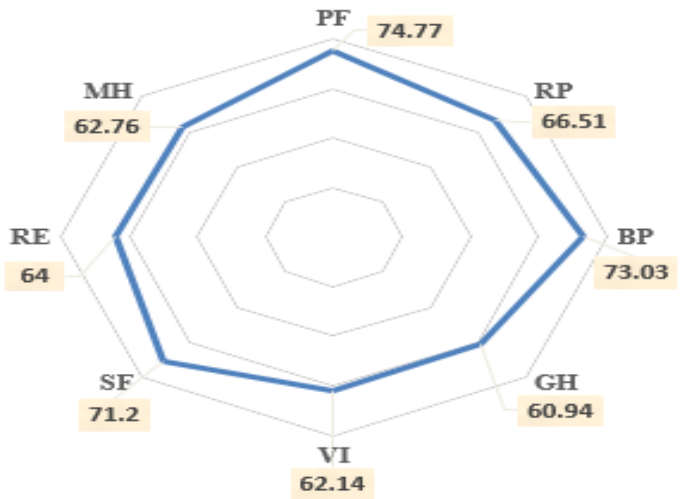

Fig.6: Comparison of the combined mean for the eight HRQoL subscales extracted from the SF-36.

Table-2: The mean score of individuals with Thalassemia on the physical and mental subscales

	Subscales	Number of studies	Mean scores	95% Confidence interval		Heterogeneity		
				Down	Up	I^2	Q	P
Physical Domain	PF	18	74.77	68.48	81.05	98.6	1189.04	0.001
	RP	18	66.51	55.95	77.07	99.3	2596.17	0.001
	BP	18	73.03	68.18	77.89	97.4	653.70	0.001
	GH	18	60.94	58.14	63.73	93.1	247.24	0.001
Mental Domain	VI	18	62.14	58.08	66.20	97.9	795.56	0.001
	SF	18	71.20	68.74	73.93	90.4	176.59	0.001
	RE	18	64.00	55.15	72.86	98.8	1416.65	0.001
	MH	18	62.76	59.33	66.20	96.2	443.48	0.001

Abbreviations: RP: role limitations; PF: physical functioning; BP: bodily pain; GH: general health; VI: Vitality; SF: social functioning; RE: role limitations; MH: mental health.

4- DISCUSSION

Paying attention to children and adolescents is an investment for the future, which may lead to the creation of a significant structure and proper social contexts (2). Health-related quality of life is a multidimensional concept that focuses on the effect of disease and treatment on patients, and by measuring this standard, the patients' view of disease and treatment, their perceived needs for health care providers and their preferences for treatment and outcomes of the disease are evaluated (1). Eighteen studies in Iran investigated the quality of life in patients with thalassemia major between 2009 and 2017, which were analyzed in this study. A review of these studies showed that the mean score of mental component in patients with thalassemia major was lower than their physical component. In other words, the adverse effects of thalassemia major on the mental component of the quality of life were more than the effects on physical component. The results of a study in Italy among patients with thalassemia major who underwent the Hematopoietic stem cells transplantation showed that the mean score of physical and mental components of the quality of life in studied patients was respectively 53 and 54.1, which is lower than the physical and mental components of the quality of life in Iranian patients(31). Sobota et al. (2011) compared the quality of life in patients with thalassemia major with American society norms. The mean score of all subscales of quality of life in patients with thalassemia major was lower than 50, which is lower than the results of the present meta-analysis (32). Repeated hospitalizations for blood transfusion, painful injections, absence of sexual development, infertility, uncertainties about the future, mental disorders, hopelessness, difficulties in social integration, language deficits, memory impairment, the problems of employment and playing a role in the community may decrease the quality of life in patients with thalassemia major (2, 4). Thalassemia is a

chronic disease that requires lifelong treatment and more than half of patients with thalassemia major suffer from depression and anxiety (33, 34). Thalassemia major impairs the appearance of patients by causing physical deformities and delayed puberty and may damage their self-image (7). The lowest score in the eight dimensions of quality of life belonged to the general health (GH) subscale. The cause of decline in the subscale of general health in these patients can be attributed to their physical problems. Patients with thalassemia major are prone to bone pain and abdominal pain due to osteopenia and hepatosplenomegaly, respectively, and the hemosiderosis in the endocrine glands leads to short stature in these patients (34).

One can briefly describe a patient with thalassemia major as "a patient who has no opportunity to have a job, get married and have children" (35). The highest score of quality of life was related to the physical functioning (PF) subscale. Contrary to the above conclusion, according to a study by Majid et al. (2012), more than one-third of patients with thalassemia major reported that their disease deprived them from normal activities such as self-care, work and leisure activities (34). Between 2009 and 2017 (with an increase in the year of publication of articles), the mental component of the quality of life increased in patients with thalassemia major, which could be due to medical advances and positive developments in the healthcare system in Iran.

Gollo et al. (2013) in Italy analyzed and compared the quality of life in patients with thalassemia major twice between 2001 and 2009. The results of their study showed that the mental component of quality of life significantly improved in these patients in this time interval (36). The strength of this study is its novelty, which offers a comprehensive overview of the health-related quality of life in these patients. In this systematic review and meta-analysis, 18 Iranian studies were combined and a general conclusion was reported, which can be used by policymakers, healthcare managers and health service providers. The results of this study showed that patients with thalassemia major have a poor quality of life and the mental component scale of quality of life was lower than physical component in these patients. Providing strategies to improve the quality of life in patients with thalassemia major (especially in mental component) seems necessary.

5- CONCLUSIONS

The results of this study showed that patients with thalassemia major have a poor quality of life, the mental dimension of quality of life questionnaire was lower than physical component in these patients. In this regards, it is stated that although the psychological dimension of the quality of life of these patients has increased in the recent years, but the physical dimension of the quality of life of these patients has not been significantly changed, which requires the adoption of health measures and interventions. According to the study results, providing strategies to improve the quality of life in patients with thalassemia major (especially in mental component) seems necessary.

6- CONFLICT OF INTEREST: None.

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Table-1: Characteristics of included studies

No	First Author	Year	Age (Mean ± SD)	Sample size	City	PCS	MSC	Quality
1	Shokri et al. (15)	2017	20 ± 4	70	Tehran	-	-	7
2	Haghpanah et al. (16)	2017	19.5 ± 4.4	101	Shirza	-	-	8
3	Emadi Dehaghi et al. (17)	2016	21.69 ± 5.74	40	Shahr-e Kord			4
4	Madmoli et al. (18)	2016	-	112	Dezful	75.58±16.11	70.39±20.30	10
5	Baraz et al. (19)	2016	15.96 ± 1.41	65	Abadan	-	-	9
6	Poormansouri et al. (20)	2016	25 ± 5.13	142	Ahvaz	63.50±20.96	63.10±20.07	6
7	Zahmatkeshan et al. (21)	2016	20 ± 4.7	72	Yasouj	64.6±16.5	59.4±18.2	5
8	Adib-Hajbaghery et al. (22)	2015	23.34 ± 5.9	173	Ahvaz	-	-	6
9	Khairkhah et al. (23)	2015	24.17 ± 7.34	150	Babol	-	-	6
10	Vafaei et al. (24)	2015	20.38 ± 7.13	40	Ardabil	-	-	5
11	Aziz-zadeh et al. (25)	2015	22.60 ± 4.5	480	Kerman	67.35±18.03	56.84±16.41	7
12	Javanbakht et al. (26)	2015	-	152	Shiraz	48.23±7.09	45.19±9.76	8
13	Javanbakht et al. (26)	2015	-	44	Shiraz	51.65±6.60	49.53±9.59	6
14	Imani et al. (27)	2013	20.94 ± 2.81	35	Bandar abbas	-	-	8
15	Imani et al. (27)	2013	21.25 ± 6.74	75	Bandar abbas	-	-	8
16	Safizadeh and Farahmandinia (28)	2012	-	209	Kerman	-	-	7
17	Khani et al. (29)	2009	21.93 ± 5.9	687	Mazandaran	-	-	6
18	Hadi et al. (30)	2009	18.44 ± 4.7	250	Shiraz	-	-	10

Abbreviations: MCS: mental component scale; PCS: physical component scale.