Original Article

Health-related Quality of Life in Thalassemia Treated with Iron Chelation

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Background : *Thalassemia is a chronic hereditary disease in which patients with severe disease present with anemia in their first year of life. In Thailand, there are limited means to treat cases using stem cell transplantation. Supportive treatments such as blood transfusion and iron chelation have been demonstrated to improve both patient survival and quality of life. However, little data exists on the Health Related Quality of Life (HRQoL) of these patients. We conducted a study on the four dimensions of quality of life - physical, emotional, social, and role (school) functioning - using the PedsQL™ 4.0 Generic Core Scale to measure the patients' HRQoL. This study aims to evaluate the quality of life in thalassemic patients treated with three iron-chelating agents.* ***Methods :*** *A descriptive study was conducted, using the PedsQL™ 4.0 Generic Core Scale questionnaires (Thai version), among thalassemic patients at the Hematology Unit, Department of Pediatrics, Phramongkutklao Hospital, during December 1, 2006 - November 30, 2007.* ***Results :*** *Forty-nine thalassemic patients were enrolled and treated with iron-chelating agents. Their mean (SD) age was 10.61 (4.33). Fifteen thalassemic patients were treated with desferrioxamine, 18 with deferiprone and 16 with deferasirox. The results of the quality of life (QOL) show that the mean (SD) total summary score was 74.35 (12.42). For the psychosocial health summary score, the social and school functioning scores were 85.40 (16.67) and 62.14 (15.84), respectively. The QOL of the patients who received desferrioxamine, deferiprone and deferasirox were 75.29 (9.09), 73.91 (15.25) and 73.98 (12.32), respectively (p = 0.94). The QOL showed no significant differences in age, gender, type of thalassemia, and serum ferritin. Multivariate regression analysis showed no significant differences in clinical severity, age onset, and pre-transfusion hematocrit level.* ***Conclusions :*** *The quality of life in thalassemic children shows improvement of psychosocial health, especially social functioning. The three iron-chelating agents had no difference in impact on health-related quality of life.*

Key words: ● *HRQoL* ● *Thalassemia* ● *Iron chelation* ● *Quality of life* ● *Severe thalassemia*

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Background

Thalassemia is an inherited blood disorder characterized by a defect in globin chain synthesis in red blood cells. This defect results in red blood cell destruction leading to chronic anemia. Thalassemia is a global public health problem, with an estimated 900,000 babies with this disorder expected to be born in the next 20 years. The incidence of hemoglobin (Hb) E approaches 60% of the population in many regions of Southeast Asia[1]. In Thailand, about 30-40% of the population are carriers of alpha- or beta-thalassemia. One percent of the Thai population

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are affected with thalassemic diseases. The combination of thalassemia and any of the various hemoglobinopathy genes results in more than 60 thalassemic syndromes, with varying clinical severity[2]. The disorders can be classified by severity of clinical signs and degree of anemia. Hematopoietic stem cell transplantation is a curative treatment for severe thalassemia, but is limited to human leukocyte antigen (HLA)-identical donors[3]. Blood transfusion and chelation are necessary in severe patients, especially during childhood, in order to promote growth and prevent bone deformities[4]. Beta-thalassemia major patients successfully treated with transfusion and who have good compliance with iron-chelation therapy have long-term survival prospects[5-6]. Patients who receive oral chelation therapy, i.e. deferasirox, have satisfactory results[7] and a positive impact on their daily lives[8]. Oral iron chelators such as deferiprone and deferasirox are now available in Thailand. However there is little available data on the Health Related Quality of Life (HRQoL) in thalassemic children. Thus this study aims to assess the HRQoL of thalassemic children who are receiving blood transfusion and iron chelation.

Methods

The cross-sectional study was conducted among children and adolescents with thalassemia at Phramongkutklao Hospital from December 2006 to November 2007. In this institution, desferrioxamine had been the standard iron chelation method. The oral iron chelators deferasirox and deferiprone were introduced for thalassemia patients in May and November 2006, respectively. Patients were approached as they came in for their blood transfusion. Written parental informed consent and the child's assent were obtained prior to their participating in the study. The study was approved by the Hospital Ethics Committee. Inclusion criteria were thalassemic patients 6-18 years of age, who regularly received blood transfusion, had serum ferritin > 1,000 ng/mL, and were being treated with iron chelation.

Research instruments

A quality of life assessment was performed using the Pediatric Quality of Life Inventory™ (PedsQL™) 4.0 Generic Core Scale (Thai version). The PedsQL 4.0 includes parallel child self-reports (age ranges 5-7, 8-12 and 13-18 years) and parent proxy reports (age ranges 2-4, 5-7, 8-12 and 13-18 years). This instrument has 23 items - consisting of 8 items on physical functioning, 5 items on emotional functioning, 5 items on social functioning and 5 items on school functioning - yielding a total score and summary scores (i.e. physical health, and psychosocial health). Each scale has a score ranging from 0-100, with a higher score indicating higher QOL.

Data analysis

Data were analyzed by Microsoft Excel 2003 and SPSS (Statistical Package for the Social Sciences) program version 13.0. Clinical characteristics of the patients, total HRQoL score, and summary scores were reported as means and standard deviations (SD). Pearson's correlation, chi-square, ANOVA, and t-test were used to examine the relationship between HRQoL and clinical data. Factors influencing the quality of life were later examined by multiple regression analysis. For this study, a patient was classified as having a severe condition if any of the following applied: 1) his/her age at onset of anemia was less than 2 years, and age at first transfusion was less than 4 years; 2) a pre-transfusion hematocrit (Hct) level < 20%; or 3) having been diagnosed with homozygous β-thalassemia. With respect to pre-transfusion Hct level, Hct < 20% was classified as a low blood transfusion regimen and Hct > 20% as a high transfusion regimen.

Results

Demographic and clinical characteristic of the 49 patients are presented in Table 1. The mean age was

Table 1 Patient characteristics

Clinical characteristics of thalassemia patients	N = 49
Age (years)[+]	10.61 (4.33)
Gender*	
Male	30 (61.2)
Female	19 (38.8)
Age range*	
2 – 4 years	4 (8.2)
5 – 7 years	8 (16.3)
8 – 12 years	17 (34.7)
13 – 18 years	20 (40.8)
Diagnosis*	
β-thalassemia/Hb E	37 (75.5)
Homozygous β-thalassemia	7 (14.3)
Hemoglobin H disease	5 (10.2)
Age at onset of anemia (months)[+]	35.45 (29.81)
Age at first transfusion (years)[+]	3.22 (2.38)
Type of blood transfusion*	
Low transfusion regimen (Hct < 20%)	9 (18.4)
High transfusion regimen (Hct > 20%)	40 (81.6)
Pre-transfusion Hct level[+]	24.67 (2.59)
Serum ferritin level[+] **(ng/mL)**	2,473.92 (1247.38)
Iron chelation treatment*	
Desferrioxamine	15 (30.6)
Deferiprone	18 (36.7)
Deferasirox	16 (32.7)
Severity*	
Yes	30 (61.2)
No	19 (38.8)
Education level*	
Kindergarten	5 (10.2)
Primary school	19 (38.8)
Secondary school	20 (40.8)
Higher than secondary school	5 (10.2)
Type of payment*	
Out-of-pocket	9 (18.4)
Civil Servant Medical Benefit Scheme	14 (28.6)
Universal Coverage	26 (53.1)

*Values are presented as number (percentage); [+]Data given as mean (SD)

10.6 years; 30 patients (61%) were male; and 39 patients (80%) were in primary and secondary school. Patients were more likely to have β-thalassemia/Hb E (75%). Eighty-one percent of patients received a high transfusion regimen, and the mean (SD) of serum ferritin was 2,473.92 (1,247.38) ng/mL. There were 15 thalassemic patients treated with desferrioxamine, 18 with deferiprone and 16 with deferasirox. Thirty patients (61%) were classified as having a severe type.

HRQoL scores based on child-self reports compared to proxy reports are presented in Table 2. Mean (SD) of the total summary score of the child self-reports and proxy

Table 2 Quality of life scores, child self-report vs. proxy

Quality of life domain	Child self-report (N = 49)	Proxy (N = 49)	p-value
	Mean ± SD	Mean ± SD	
Total summary score	74.35 ± 12.42	68.41 ± 13.67	0.001
Physical Functioning	72.32 ± 17.24	66.07 ± 18.50	0.004
Psychosocial Health	75.44 ± 13.78	69.65 ± 13.25	0.005
Emotional Functioning	78.77 ± 18.35	75.30 ± 17.89	0.200
Social Functioning	85.40 ± 16.67	76.02 ± 18.02	0.001
School Functioning	62.14 ± 15.84	57.65 ± 17.20	0.087

reports were 74.35 (12.42) and 68.41 (13.67), respectively ($p = 0.001$). When looking at the two summary scores, it was found that the means (SD) of physical functioning and psychological health were 72.32 (17.24) and 75.44 (13.78), respectively. For the subscale of psychosocial health, the study revealed that social functioning scored the highest (mean = 85.40; SD = 16.67), followed by emotional functioning (mean = 78.77; SD = 18.35) and school functioning, which scored the lowest (mean = 62.14; SD = 15.84).

Table 3 presents HRQoL scores from the child self-report, classified by patients' characteristics. It was found that younger patients were more likely to have higher total summary scores, as compared to their older age counterparts. When looking at each summary score, the results showed that gender, age, diagnosis, severity, iron chelation treatment, serum ferritin level, type of payment and education level were not significantly related to each other ($p > 0.05$).

Relationships between HRQoL score and patient's characteristics are presented in Table 4, in terms of Pearson's correlation coefficient. It was found that serum ferritin, pre-transfusion Hct level, age, diagnosis, type of iron chelation and type of payment were not significant predictors of HRQoL.

Table 5 presents the results of multivariate regression analysis in examining factors associated with the total summary score. It is shown that severity, age and pre-transfusion Hct level were not significant predictors of HRQoL (i.e. total summary score).

Discussion

The assessment of HRQoL of thalassemia patients in this study showed that psychosocial health had a higher score than physical health, especially emotional functioning, which differents from the findings in a previous study[9-10]. It was concluded that medical therapy of these patients should be supported with psychological aid and psychiatric treatment[10]. The recognition and management of the psychological problems that accompany chronic physical illnesses including thalassemia would optimize treatment outcomes and HRQoL[11].

Ismail et al.[12] used the PedsQL 4.0 Generic Core Scaes to assess the HRQoL of thalassemia patients and healthy children. The results showed that the mean (SD) of total summary score in thalassemia and healthy children were 68.91 (12.12) and 79.76 (11.60), respectively. HRQoL scores obtained from the present study were somewhat higher. This could be due to differences in country-specific characteristics. Another reason that could account for the difference in HRQoL scores between the previous study[12] and this study is that most of the patients were thalassemia intermedia. About 75% and 10% were diagnosed with β-thalassemia/

Table 3 Quality of life scores, child self-report classified by patient's characteristics

	Total score	Physical functioning	Psychological functioning	Emotional functioning	Social functioning	School functioning
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (N = 49)						
2 – 4 years (N = 4)	80.43 (2.51)	67.19 (21.88)	87.5 (9.95)	97.5 (5)	92.5 (15)	72.5 (12.58)
5 – 7 years (N = 8)	70.79 (15.28)	69.53 (15.47)	71.46 (15.72)	75 (24.49)	82.5 (17.53)	56.88 (14.38)
8 – 12 years (N = 17)	70.2 (11.64)	67.46 (19.07)	71.67 (11.09)	77.06 (12)	80.88 (19.22)	57.06 (13.24)
13 – 18 years (N = 20)	78.1 (12.05)	78.59 (14.49)	77.83 (14.63)	78 (20.55)	89 (14.01)	66.5 (17.55)
p-value	*0.147*	*0.209*	*0.130*	*0.198*	*0.379*	*0.116*
Gender (N = 49)						
Male (N = 30)	74.24 (13.43)	74.06 (17.33)	74.33 (13.6)	80.33 (16.55)	83.83 (17.8)	58.83 (15.74)
Female (N = 19)	74.54 (11)	69.57 (17.21)	77.19 (14.27)	76.32 (21.14)	87.89 (14.84)	67.37 (14.94)
p-value	*0.935*	*0.380*	*0.485*	*0.461*	*0.412*	*0.066*
Diagnosis (N = 49)						
β-thalassemia/Hb E (N = 37)	67.17 (19.99)	56.88 (17.17)	72.67 (24.31)	80 (25.74)	80 (29.37)	58 (22.53)
Homozygous β-thalassemia (N = 7)	76.47 (11.16)	76.52 (15.23)	76.44 (12.86)	80.68 (18.15)	85.54 (15.27)	63.11 (14.74)
Hemoglobin H (N = 5)	68.32 (10.4)	61.16 (18.39)	72.14 (10.44)	67.86 (10.75)	88.57 (14.64)	60 (18.48)
p-value	*0.110*	*0.008*	*0.680*	*0.239*	*0.686*	*0.746*
Severity * (N = 49)						
Yes (N = 30)	75.87 (12.87)	75.52 (16.37)	76.06 (14.61)	81 (18.77)	86 (16.53)	61.17 (16.54)
No (N = 19)	71.97 (11.6)	67.27 (17.81)	74.47 (12.71)	75.26 (17.6)	84.47 (17.31)	63.68 (14.99)
p-value	*0.289*	*0.103*	*0.700*	*0.291*	*0.758*	*0.593*
Iron-chelation treatment (N = 49)						
Desferrioxamine (N = 15)	75.29 (9.09)	71.04 (15.95)	77.56 (12.44)	83.67 (13.69)	87.67 (12.94)	61.33 (18.46)
Deferiprone (N = 18)	73.91 (15.25)	70.66 (20.11)	75.65 (15.69)	77.5 (18.41)	83.89 (19.6)	65.56 (16.53)
Deferasirox (N = 16)	73.98 (12.32)	75.39 (15.52)	73.23 (13.24)	75.63 (21.98)	85 (17.03)	59.06 (12.28)
p-value	*0.943*	*0.694*	*0.690*	*0.453*	*0.811*	*0.487*
Serum ferritin level						
< 2,500 ng/mL (N = 29)	73.01 (13.74)	70.69 (17.1)	74.25 (14.72)	78.79 (18.5)	84.14 (18.37)	59.83 (14.73)
> 2,500 ng/mL (N = 20)	76.3 (10.24)	74.69 (17.62)	77.17 (12.49)	78.75 (18.63)	87.25 (14.09)	65.5 (17.16)
p-value	*0.368*	*0.431*	*0.473*	*0.994*	*0.526*	*0.222*
Type of payment						
Out-of-pocket (N = 9)	77.29 (14.6)	72.57 (19.06)	79.81 (16.55)	86.67 (15.21)	86.67 (21.65)	66.11 (16.73)
Civil Servant Medical Benefit Scheme (N = 14)	75.47 (14.87)	72.32 (21.58)	77.14 (14.67)	78.93 (20.96)	89.29 (14.53)	63.21 (16.48)
Universal Coverage (N = 26)	72.74 (10.32)	72.24 (14.59)	73.01 (12.28)	75.96 (17.72)	82.88 (16.07)	60.19 (15.52)
p-value	*0.600*	*0.999*	*0.390*	*0.327*	*0.505*	*0.609*
Education level						
Kindergarten (N = 5)	80 (2.38)	68.75 (19.26)	86 (9.25)	96 (5.48)	94 (13.42)	68 (14.83)
Primary school (N = 19)	72.14 (13.63)	70.39 (19.39)	73.07 (13.43)	76.32 (17.31)	83.42 (18.64)	59.47 (12.9)
Secondary school (N = 20)	74.08 (10.81)	74.69 (14.01)	73.75 (13.07)	75.5 (18.27)	84.5 (16.13)	61.25 (17.98)
Higher than secondary school (N = 5)	78.26 (19.31)	73.75 (22.6)	80.67 (18.95)	84 (24.34)	88 (15.25)	70 (18.71)
p-value	0.557	0.844	0.213	0.120	0.633	0.485

* Age at onset < 24 months and age at first transfusion < 4 years

Table 4 Relationship between HRQOL score and patients' characteristics by Pearson's correlation coefficient

	Pearson's correlation coefficient					
	Total summary score	**Physical functioning**	**Psychological functioning**	**Emotional functioning**	**Social functioning**	**School functioning**
Serum ferritin level (ng/mL)	0.091	0.126	0.041	-0.061	-0.009	0.189
Pre-transfusion Hct level (%)	0.154	0.159	0.106	0.097	-0.031	0.197
Age (years)	0.083	0.204	-0.021	-0.141	0.056	0.049
Diagnosis	-0.021	-0.002	-0.028	-0.188	0.123	0.015
Type of iron chelator	-0.042	0.103	-0.126	-0.175	-0.063	-0.061

* $p < 0.05$; + $p < 0.1$

Table 5 Multivariate regression analysis result

	β	SE (β)	p-value
Constant	57.295	17.780	0.002
Severity*	-3.566	3.685	0.338
Age (years)	0.177	0.419	0.675
Pre-transfusion Hct level (%)	0.671	0.700	0.343

$R^2 = 0.048$; Y = Ln (total summary score);

*Age at onset <24 months and age at first transfusion <4 years

Hb E and Hb H disease, respectively, and 80% of them received a high transfusion regimen.

When looking at subdomains of HRQoL, it was found that the school functioning subscale scored the lowest. This could be explained by the fact that frequently missing school for hospital visits, and a lack of energy when performing academic activities, had a significant negative impact on the children's HRQoL.

From a previous study, iron chelation therapy (ICT), with Desferrioxamine and Deferiprone appers to negatively impact HRQoL[13]. The HRQoL of oral administration of an iron-chelating agets such as deferasirox, a once-daily oral treatment, was high when compared with subcutaneous infusion of desferrioxamine[14]. In the present study, 2% of the patients receiving ICT were covered by the Civil Servant Medical Benefit Schemd or Universal Coverage, while 18% paid out-of-pocket; but the HRQoL scores of each of the ICT groups were not different (p = 0.94). Higher scores were found in social and emotional functioning while school functioning was the lowest.

One limitation of this study, as previously mentioned, is the absence of HRQoL scores of healthy children in Thailand. As a result, the true magnitude of thalassemia's impact on HRQoL is difficult to estimate. Another limitation is that purposive sampling of the settings might limit the extent to which the results could be extrapolated to patients in other settings. Further research is warranted to continue the qualitative and quantitative study of HRQoL using validated instruments in patients receiving iron-chelating therapy to further understand the issues and improve the patients' HRQoL[15].

Conclusions

The quality of life in thalassemic children shows improvement of psychosocial health, especially social functioning. The three iron-chelating agents have no difference in impact on health-related quality of life.

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คุณภาพชีวิตของผู้ป่วยธาลัสซีเมียที่รับยาขับเหล็ก

กิตติ ต่อจรัส และ ธิดารัตน์ พันธุ์แก้ว

กองกุมารเวชกรรม โรงพยาบาลพระมงกุฎเกล้า

บทคัดย่อ : *โรคโลหิตจางธาลัสซีเมียเป็นโรคที่ถ่ายทอดทางพันธุกรรม ในกลุ่มที่มีอาการซีดรุนแรงจะมีอาการตั้งแต่อายุขวบปีแรก เนื่องจากการรักษาที่หายขาดของโรคธาลัสซีเมียคือการปลูกถ่ายเซลล์ต้นกำเนิดเม็ดเลือดแต่ไม่สามารถทำได้ทุกคนเนื่องจากมีข้อจำกัดของผู้บริจาคเซลล์ต้นกำเนิดไม่ตรงกับผู้ป่วย ดังนั้นการรักษาโดยการให้เลือดและยาขับเหล็กจึงมีความจำเป็นเพื่อให้ผู้ป่วยมีอายุที่ยืนยาวและมีคุณภาพชีวิตที่ดีขึ้น ปัจจุบันมีข้อมูลไม่มากที่เกี่ยวข้องกับคุณภาพชีวิตของผู้ป่วย การศึกษานี้ได้ออกแบบการวิจัยเกี่ยวกับคุณภาพชีวิตในผู้ป่วยธาลัสซีเมียที่ได้รับยาขับเหล็กใน 4 มิติ ประกอบด้วย ด้านกายภาพ อารมณ์ สังคมและบทบาทที่โรงเรียน* ***วัตถุประสงค์ :*** *เพื่อศึกษาคุณภาพชีวิตของผู้ป่วยธาลัสซีเมียที่ได้รับยาขับเหล็ก* ***วิธีการศึกษา :*** *ใช้แบบสอบถาม PedsQL™ 4.0 Generic Core Scale เพื่อวัดคุณภาพชีวิตในผู้ป่วยธาลัสซีเมียที่มารับการรักษาที่หน่วยโลหิตวิทยา กองกุมารเวชกรรม โรงพยาบาลพระมงกุฎเกล้า ตั้งแต่เดือน ธันวาคม พ.ศ.2549 – พฤศจิกายน พ.ศ.2550* ***ผลการศึกษา :*** *ผู้ป่วยทั้งหมด 49 ราย อายุเฉลี่ย 10.61 ± 4.33 ปี ผู้ป่วยได้รับยา Desferrioxamine, Deferiprone และ Deferaxirox จำนวน 15, 18 และ 16 ราย ตามลำดับ คุณภาพชีวิตโดยรวมเท่ากับ 74.35 ± 12.42 คุณภาพชีวิตด้านสังคมและบทบาทที่โรงเรียนเท่ากับ 85.40 ± 16.67 และ 62.14 ± 15.84 ตามลำดับ คุณภาพชีวิตของผู้ป่วยที่ได้รับยา Desferrioxamine, Deferiprone และ Deferasirox เท่ากับ 75.29 ± 9.09, 73.91 ± 15.25 และ 73.98 ± 12.32 ตามลำดับ (p = 0.94) อายุ เพศ ชนิดของโรคธาลัสซีเมีย และระดับ serum ferritin ไม่มีความแตกต่างทางสถิติ และการศึกษาโดย Multivariate regression ของปัจจัยที่เกี่ยวข้องได้แก่ ความรุนแรงของโรค อายุที่เริ่มมีอาการ และระดับ Hct พบว่าไม่เป็นปัจจัยที่เกี่ยวข้องคุณภาพชีวิตอย่างมีความสำคัญทางสถิติ* ***สรุป :*** *คุณภาพชีวิตของผู้ป่วยธาลัสซีเมียดีขึ้นในด้านจิตสังคมโดยเฉพาะในด้านสังคม และการได้รับยาขับเหล็กทั้ง 3 ชนิด ไม่มีผลทำให้คุณภาพชีวิตของผู้ป่วยแตกต่างกัน*

Key Words: ● *คุณภาพชีวิต* ● *ธาลัสซีเมีย* ● *ยาขับเหล็ก* ● *ธาลัสซีเมียชนิดรุนแรง*

เวชสารแพทย์ทหารบก 2554;64:3-10.