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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

**Медицинские новости Грузии**

საქართველოს სამედიცინო სიახლენი

**GEORGIAN MEDICAL NEWS**

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**GMN: Georgian Medical News** is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

**GMN: Медицинские новости Грузии -** ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНИТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

**GMN: Georgian Medical News –** საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНИТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებიდან.

**WEBSITE**

www.geomednews.com

## К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman** (**Кириллица**), для текста на грузинском языке следует использовать **AcadNusx.** Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи**. Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - http://www.spinesurgery.ru/files/publish.pdf и http://www.nlm.nih.gov/bsd/uniform_requirements.html
В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректура авторам не высылается, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

**При нарушении указанных правил статьи не рассматриваются**.

## REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or compu-ter-printed on a single side of standard typing paper, with the left margin of **3** centimeters width, and **1.5** spacing between the lines, typeface - **Times New Roman** (**Cyrillic**), print size - **12** (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf
In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

**Articles that Fail to Meet the Aforementioned Requirements are not Assigned to be Reviewed.**

## ავტორთა საყურადღებოდ!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე,დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx.** შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შეღებვის ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფჩხილებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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# FACTORS AFFECTING HEALTH RELATED QUALITY OF LIFE IN ADULT PATIENTS WITH BETA-THALASSEMIA MAJOR

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## Abstract.

**Background:** Health related quality of life (HRQoL) is a remarkable and powerful tool to decide the patient's perspective of their disease and its effect on their lives. Its application in thalassemia may have an impact on treatment option and may help predict mortality and morbidity. **Method:** This case control study included a total of 62 adult patients registered as β-thalassemia major at the Jin pediatric hematology-oncology center (Duhok city) in addition to 50 age and sex matched healthy controls. The RAND Short Form 36 (SF-36) Questionnaire was used to evaluate HR-QoL score, and data were analyzed using Statistical Package for Social Sciences software (SPSS).

**Result:** The HRQoL mean scores were significantly lower in adults with thalassemia major when compared to their matched controls (66.35% Vs. 84.32% with P-value <0.0005). Among the eight domains of Short Form-36, all except role emotional were significantly reduced as compared to their respective scores in the controls. Among the patient's group, the most affected domain was the general health, while the least affected was the social function. Lower mean HRQoL scores were seen in those with female gender which was clinically significant only in the pain domain (p-value =0.004). Significantly lower scores were recorded for physical function, role limitation physical, energy/ fatigue and general health domains in those with heart failure. **Conclusion:** The study documented that thalassemia major had lower HRQoL compared to their healthy counterparts. Further multicenter studies are needed to assess better the predictors of lower HRQoL in this population, since it would provide important insights for improving the management of the disease and the choices of the treatment.

**Key words.** β-Thalassemia major, Quality of life, Blood transfusion.

## Introduction.

Thalassemia is one of the most common inherited hemoglobinopathies with an autosomal recessive pattern, characterized by anemia and small-sized red blood cells [1]. HBB gene is located on the short arm of chromosome 11, consisting of three exons encoding for 146 different amino acids [2].

It is well known that the highest prevalence of β-thalassemia is recorded in the Middle East, Mediterranean countries, India, Central Asia, Southern China and the Far East in addition to countries along the north coast of Africa and in South America [3]. In the Duhok province of Iraq, which includes a population mostly consisting of ethnic Kurds, the prevalence rate of beta thalassemia carrier state is 3.7%, which is going with national average of around 4% and more than 500 symptomatic patients with thalassemia are registered at its main thalassemia center [4]. Thalassemia major patients often require lifelong red blood cell transfusions to survive, which can lead to iron overload and potential organ damage, predominantly of the hepatic tissue [5]. Patients with β-thalassemia major, usually present between 6 and 24 months of age, due to Hb production switching off from fetal to adult. Clinical features include severe pallor due to severe anemia, failure to thrive, and hepatosplenomegaly, feeding problems, jaundice, irritability or insomnia, diarrhea and gallstones [6].

The most common clinical features of poorly transfused or untreated patient are pallor, jaundice, growth retardation, and skeletal changes that result from the bone marrow expansion [7,8]. Iron chelation therapy also is necessary to reduce the toxic effects of transfusion-related iron overload, which can impact the endocrine system (e.g., gonads, thyroid gland and blood glucose levels), heart, liver and bones. Health-related quality of life (HRQoL) may be adversely affected by the burden of Transfusion-dependent thalassemia (TDT) as well as the frequency and invasiveness of its treatments [9]. Management typically includes routine transfusions and iron chelation therapy to prevent iron overload; however, newer approaches including gene therapy and bone marrow transplantation are becoming viable options [10].

HRQoL focuses on the individual's subjective evaluation of how healthcare and health care inspire their health status and their capacity to achieve a performance level that allows them to continue accomplishing those activities that are critical to them and affect their well-being [11]. Recent evidences highlight the significance of enhancing quality of life in the treatment of patients with chronic diseases like thalassemia and in managing their symptoms [12]. The current study aimed to assess the quality of life in adult's patients with thalassemia major, also to determine the frequency, significance of various complications and the correlation of clinical and hematological parameters with HRQoL in this population.

## Subjects and Methods.

**Patients' selection:** A case control study was conducted at Jeen pediatric hematology-oncology center in Duhok city located in North of Iraqi, in the period between April 2024 and August 2024. Total of (62) patients aged ≥ 18 years old with confirmed diagnoses as thalassemia major by clinical /hematological and/

or molecular study and registered at the thalassemia center in Duhok were recruited. Patients with normal cognitive function and those who have not underwent bone marrow transplantation, and fifty apparently healthy individuals above or 18 years old, age and sex matched to the patients recruited were as controls from Azadi hospital visitors.

**Clinical assessment:** A distinct sheet was created to collect the required data from the medical record of all enrolled patients regarding the following: age, sex, education, job of the patient, marital status, monthly income, age of diagnosis, age of starting 1st transfusion, date of last transfusion, pre-transfusion hemoglobin level, frequency of transfusion in the last year and any other feature or comorbidity that may be of relevance in the history, then checked for height and weight, the following features were particularly scrutinized (physical examination): Facial skeletal changes, splenectomy and splenomegaly/ hepatomegaly. Under completely a septic venipuncture process blood sample was taken from each patient for complete blood count, biochemical analysis and virology screening. Forty-five patients had echocardiography arranged at the time of enrollment by using a VIVID 3 (GE) echocardiography machine in cardiac center in Azadi teaching hospital.

**Quality of life:** This study evaluated health-related quality of life (HRQoL) using the SF-36 (Short Form 36) questionnaire in accordance with standard procedures (13). The English and Arabic versions of SF-36 tool was used to assess HRQoL outcomes. This was administered either by self-reporting or by an interview (if illiterate or unable to complete by self-administration), The survey generates eight health status scales namely: physical functioning, role-limitation due to physical health, role-limitation due to emotional problem, vitality (energy/fatigue), emotion well-being, bodily pain, social functioning and general health.

**Ethical Consideration:** This study was approved by an official permission by the ethics committee at Iraqi board medical Specialties' commission and by the directorate of health of Duhok. Informed consent was obtained from all recruited patients.

**Statistical analysis:** All Statistical analyses were done using the Statistical Package for Social Sciences software, version 24 (SPSS Inc., Chicago, IL, USA). The results were reported as mean values ± standard deviations. The independent samples t-test, Pearson correlation and ANOVA test were used to make comparisons between the scores in different groups of patients relating number of complications, P values < 0.05 were considered as statistically significant.

## Results.

This case control study included 33 males and 29 females (M: F ratio 1.13:1). the mean age of the patients was 22.7 years (SD 5.07), while the mean age of the controls was 23.3 years (SD 5.4) and included 25 males and 25 females (M: F ratio 1:1). There were no significant differences in age or in gender between patients and controls (p value 0.52 and 0.73 respectively). Majority of the patients were literate 44/62 (70.1%), and with low socioeconomic states 37/62 (59.6%). Only 2 patients were married and only one of whom had children (3 children). The remaining patients were unmarried.

Patients' mean age at diagnosis and at first transfusion were both at 1.0 year (SD 1.1). Spleen was palpable in 9/62 (14.5%), while the remaining patients had been splenectomised. Hepatomegaly was detected in 16/62 (25.8%). Thalassemic faces were noted in 47/62 (75.9%), including 33/62 (53.1%) with moderate or severe changes. All patients as expected were on regular transfusion therapy with a mean frequency of 18.5 (SD 3.7) annually (Range 12-27). Their mean pre-transfusion hemoglobin was maintained at a mean of 8.55 g/dl (SD 0.8), with 17/62 (27.4%) with Hb > 9 g/dl. All patients were on regular chelation therapy, most with the oral deferasirox 50/62 (80.6%), 9/62 (14.5%) on Deferoxamine, while the remaining 3/62 (4.8%) were on combined therapy, most patients were compliant with therapy 50/62(80.6%). Thirty-seven (59.6%) of the patients were HCV antibody positive, while none were HIV or HBsAg positive at the time of enrolment. Serum ferritin mean (SD) was used to evaluate the iron status of our enrollees and its median was 2495 ug/L (Range 370-12000) among the studied patients at the time of enrolment. S Ferritin was in excess of 2500 ug/L in 48.3%.

Forty-five patients had echocardiography arranged at the time of enrolment and out of these, 7/62 (15.5%) had TRV >2.8 m/s with associated exertional dyspnea, so pulmonary hypertension was diagnosed; five patients were already diagnosed as heart failure at the time of enrolment and were receiving anti-failure therapy. Among the 45 patients who were subjected to echocardiography an extra patient was diagnosed as heart failure with an ejection fraction ≤ 55%.

The overall frequency of hypogonadism (male +female) is 27/62 (43.5%). Fourteen of the 33 males (42.4%) and 13 of the 29 females (44.8%) were diagnosed with this complication based on the criteria proposed by references and as described [14].

Six patients (9.6%) were already diagnosed as DM at the time of enrolment and all were on insulin. Although random blood sugar was done on all remaining patients, no new case was documented at the time of enrolment.

## Health Related quality of Life.

### HRQoL in Patients versus Controls:

By using SF36 score the overall mean HRQoL score in the 62 enrolled adults with thalassemia major was 66.35% (SD 14.54%), which was significantly lower than that among 50 age and matched controls (Mean ±SD = 84.32% ± 7.38%) (P value < 0.0005). The most affected domain of the eight SF36 domains was the general health at 46.29% and the energy fatigue at 46.67%. While the least affected was the social function at 84.21% (Table 1).

### Correlations of mean HRQoL to the gender, various clinical and socioeconomic parameters:

Gender differences in the mean overall HRQoL and in seven of its domains were insignificant, except for pain which was significantly lower among females (P value =0.004) (Table 2), however, no significant differences in HRQoL, overall or in any of the eight domains, relevant to educational background or the economic status was seen (Table 2).

Table 1. HRQoL (SF36) score (%) comparison between adult patients with thalassemia major and healthy controls.

| Cate gory | HRQoL (Mean±SD) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | age | Phys ical function | Role of physical | Role of emotional | Ene rgy fatigue | Soci al function | pain | Gen eral Health | Emoti onal well being | Overall mean |
| Patie nt | 22.73 ± 5.07 | 73.38 ± 18.30 | 62.30 ± 28.53 | 81.70 ± 28.75 | 46.67 ± 16.28 | 84.21 ± 22.1 | 75.76 ± 26.36 | 46.29 ± 17.94 | 61.54 ± 15.09 | 66.35 ± 14.54 |
| Contr ol | 23.36 ± 5.46 | 88.40 ± 12.22 | 85.00 ± 16.75 | 86.98 ± 16.26 | 77.50 ± 11.35 | 92.25 ± 14.26 | 88.90 ± 15.55 | 78.10 ± 9.94 | 77.6 ± 11.08 | 84.32 ± 7.38 |
| p value | 0.527 | <0.0005 | <0.0005 | 0.249 | <0.0005 | 0.028 | 0.002 | <0.0005 | <0.0005 | <0.0005 |

**Table 2.** HRQoL and its relevance to patient's gender, some clinical and socioeconomic parameters.

| Parameters | HRQoL Scores (Mean±SD) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Physical function | Role of Physical health | Role of emotional problem | Energy fatigue | Emotionalwell being | Social function | Pain | General Health | Mean |
| Male | 75.30± 19.07 | 60.60± 27.26 | 79.78± 32.22 | 48.44± 17.55 | 63.2± 14.9 | 85.59± 25.61 | 84.69± 23.02 | 46.97± 18.95 | 67.94± 15.80 |
| Female | 71.20± 17.45 | 63.79± 30.31 | 83.86± 24.60 | 44.65± 14.75 | 59.5± 15.2 | 82.65± 17.62 | 65.59± 26.60 | 45.51± 17.02 | 64.55± 13.01 |
| P value | 0.384 | 0.665 | 0.579 | 0.365 | 0.341 | 0.605 | 0.004 | 0.753 | 0.364 |
| Education | | | | | | | | | |
| - Literate | 74.7±18.2 | 64.2±30.6 | 79.5±29.8 | 48.1±17.7 | 61.6±16.5 | 83.4±22.2 | 76.8±27 | 46.2±20 | 66.7±16 |
| - Illiterate | 70±18.5 | 56.9±22.3 | 81.7±25 | 43.05±11.5 | 61.3±11.2 | 86±22.2 | 73±25.1 | 46.3±0.97 | 65.4±10.2 |
| P-value | 0.35 | 0.36 | 0.33 | 0.26 | 0.94 | 0.67 | 0.6 | 0.97 | 0.76 |
| Economic status | | | | | | | | | |
| Low economic (37) | 72.16±18.8 | 64.18±29.7 | 78.3±29.6 | 45.6±16.1 | 61.2±16 | 84.0±23 | 75.2±24.8 | 46.2±14.3 | 65.7±15.1 |
| Intermediate and high (25) | 75.2±17.7 | 59.7±26.8 | 86.6±27.2 | 48.1±16.7 | 61.9±13.7 | 84.5±21.1 | 76.4±20.8 | 46.4±22.6 | 67.3±13.8 |
| P-value | 0.52 | 0.48 | 0.26 | 0.56 | 0.87 | 0.93 | 0.86 | 0.96 | 0.67 |
| Hepatomegaly | | | | | | | | | |
| Not detected (43) | 73.7±17.8 | 63.9±24.5 | 83.7±25.6 | 47.9±16.9 | 61.8±16.2 | 83.7±22.7 | 78.4±22.5 | 49.7±17.2 | 67.7±13.9 |
| Detected (19) | 72.6±19.9 | 70.8±36.3 | 77.1±33.2 | 43.6±14.6 | 60.8±12.3 | 85.3±21.1 | 69.6±33.3 | 38.4±17.4 | 63.1±15.7 |
| P-value | 0.8 | 0.4 | 0.4 | 0.34 | 0.8 | 0.78 | 0.22 | 0.02 | 0.25 |
| Spleen | | | | | | | | | |
| -Splenomegaly (9) | 81.1±19 | 77.7±15.2 | 81.4±33.8 | 47.7±8.7 | 66.6±11.4 | 91.6±10.3 | 75.2±26.5 | 50.8±8.6 | 71.4±11.0 |
| -Splenectomy (53) | 72±18 | 59.4±29.5 | 81.7±28.1 | 46.4±17.2 | 60.6±15.5 | 82.9±23.2 | 75.8±26.5 | 45.6±19 | 65.4±14.9 |
| P-value | 0.17 | 0.07 | 0.97 | 0.82 | 0.27 | 0.27 | 0.95 | 0.5 | 0.26 |
| Hb concentration | | | | | | | | | |
| ≥9 n=17 | 72.1±18.7 | 69.1±31.2 | 74.4±32.3 | 47.6±16.4 | 62.1±14.6 | 89.5±16.3 | 67.7±32 | 48.8±20.8 | 66.4±14.1 |
| < 9 n=45 | 73.5±18.3 | 59.4.7±27.3 | 83.6±27.1 | 46.3±16.3 | 61.3±15.4 | 82.2±23.7 | 78.7±23.6 | 45.3±16.9 | 66.2±4.7 |
| P-value | 0.95 | 0.23 | 0.26 | 0.77 | 0.85 | 0.24 | 0.14 | 0.49 | 0.94 |
| S. Ferritin | | | | | | | | | |
| < 2500 ug/L | 75.49±13.2 | 63.83±25.38 | 88.5±26.2 | 46.05±16.9 | 62.7±75 | 83.8±21.5 | 74.8±26 | 48.5±17 | 67.9±13.3 |
| > 2500ug/L | 71.16±20.3 | 60.83±31.9 | 74.4±29.9 | 47.3±15.8 | 60.2±14.6 | 84.5±23.1 | 76.75±27.8 | 43.8±18.4 | 64.6±15.7 |
| P value | 0.35 | 0.73 | 0.053 | 0.76 | 0.52 | 0.9 | 0.77 | 0.3 | 0.38 |
| Thalassemic Faces | | | | | | | | | |
| Not Severe N=54 | 75.9±16.3 | 64.35±28.1 | 81.46±29.4 | 47.5±16.9 | 61.25±15.4 | 86±21.1 | 76.7±24.5 | 46.75±43.1 | 67.39±14.2 |
| Severe N=8 | 56.2±22.6 | 46.8±28.1 | 83.3±25.2 | 40.62±9.7 | 63.5±12.9 | 71.8±25.6 | 69.3±38 | 43.12±11.6 | 59.3±15.8 |
| P value | 0.004 | 0.1 | 0.86 | 0.26 | 0.69 | 0.09 | 0.46 | 0.59 | 0.14 |

Table 3. Some complications of thalassemia major and relevance to HRQoL as individual parameters.

| Parameters | HRQoL Scores (Mean±SD) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Physical function** | **Role of Physical health** | **Role of emotional problem** | **Energy fatigue** | **Emotionalwell being** | **Social function** | **pain** | **General Health** | **Mean** |
| **Diabetes Mellitus** | | | | | | | | | |
| Non-Diabetic (56) | 74.5±17.7 | 62.9±28.9 | 81.5±29 | 47.1±16.4 | 61.7±15.6 | 83.8±22.7 | 76.6±26.2 | 47±18.4 | 66.8±14.7 |
| Diabetic (6) | 62.5±21.1 | 54.1±29.2 | 83.3±27.9 | 42.5±15.4 | 60±9.7 | 87.4±15.9 | 65.5±28.8 | 39.1±10.6 | 62±13.2 |
| P-value | **0.12** | **0.4** | **0.88** | **0.5** | **0.79** | **0.71** | **0.42** | **0.3** | **0.45** |
| **Heart Failure** | | | | | | | | | |
| Present (6) | 55.8±17.7 | 37.5±34.4 | 94.4±13.6 | 32.5±5.2 | 59.3±11.14 | 79.1±28.1 | 72.9±29.3 | 30.8±12 | 57.7±13.8 |
| Absent (56) | 75.2±17.4 | 64.7±26.8 | 79.7±29.6 | 48.1±16.3 | 61.7±15.5 | 84.7±21.6 | 76±26.2 | 47.9±17.7 | 67.2±14.3 |
| P-value | **0.012** | **0.025** | **0.23** | **0.024** | **0.70** | **0.55** | **0.78** | **0.025** | **0.132** |
| **Pulmonary Hypertenison** | | | | | | | | | |
| Absent (38/45) | 72.7±19.1 | 61.1±26.4 | 82.4±30.7 | 48±14.3 | 61.7±13 | 87±17.4 | 75.4±25.6 | 42.8±18.4 | 66.4±12.4 |
| Present (7/45) | 72.1±20.3 | 67.8±40 | 80.9±26.2 | 44.1±27.5 | 62.2±20.6 | 82.1±28.7 | 82.1±27.9 | 56.4±24.4 | 68.5±20.2 |
| P-value | **0.93** | **0.57** | **0.9** | **0.57** | **0.9** | **0.53** | **0.53** | **0.09** | **0.7** |
| **Hypogonadism** | | | | | | | | | |
| Absent | 75.0±18.7 | 67.1±24.8 | 83.7±28.4 | 47.5±15.9 | 60.6±13.5 | 85±21.6 | 81.8±14.8 | 43.4±19 | 68±13.3 |
| Present | 71.2±17.7 | 55.5±32 | 78.9±29.4 | 45.5±16.8 | 62.6±17 | 83.2±23.1 | 67.8±31.6 | 50±15 | 64.1±15.9 |
| P-value | **0.43** | **0.114** | **0.5** | **0.6** | **0.61** | **0.7** | **0.037** | **0.15** | **0.3** |
| **Compliance for Chelation** | | | | | | | | | |
| Good (50) | 74.1±18.3 | 65±27.1 | 82.6±25.4 | 47±17.2 | 62±15.5 | 83.4±23.1 | 80.7±23.7 | 47±18.3 | 67.6±14.4 |
| Poor (12) | 70.4±18.7 | 50±31.9 | 77±41.03 | 45±12.06 | 59.6±13.6 | 87.5±27.4 | 55±27.4 | 43±16.4 | 61.07±14.3 |
| P-value | **0.53** | **0.1** | **0.6** | **0.69** | **0.6** | **0.57** | **0.002** | **0.529** | **0.16** |
| **Hepatitis C Antibody** | | | | | | | | | |
| Positive (37) | 69.5±20 | 58.7±29.5 | 81.9±27.8 | 43.4±14.5 | 59.6±15.5 | 81.3±25.4 | 72.4±25.8 | 47.8±13.7 | 64.2±14.3 |
| Negative (25) | 79±13.9 | 67±26.7 | 81.3±30.5 | 51.4±17.7 | 64.3±14.1 | 88.4±15.4 | 80.6±26.9 | 44±22.9 | 69.5±15.5 |
| P-value | **0.4** | **0.27** | **0.9** | **0.06** | **0.23** | **0.22** | **0.23** | **0.4** | **0.15** |

Table 4. The association between HRQoL scores and the number of concurrent complications in individual patients.

| No. of complications | Physical function | Role of Physical health | Role of emotional problem | Energy fatigue | Emotional well being | Social function | pain | General Health | Mean |
|---|---|---|---|---|---|---|---|---|---|
| 0 n=7(11.2%) | 86.4±12.1 | 75±20.4 | 95.2±12.6 | 58.5±15.7 | 71.4±9.6 | 94.6±9.8 | 88.2±15.5 | 55.7±21.6 | 78.7±10 |
| 1 n=26(41.9%) | 76.5±17.1 | 69.2±24.8 | 73±35.3 | 45.7±15.9 | 58.6±15.4 | 82.5±22.7 | 79.4±28.4 | 42.1±17.1 | 65.8±14.7 |
| 2 n=22(35.4%) | 70.4±16.5 | 53.4±32 | 84.8±22.3 | 46.5±17.4 | 61.8±16.9 | 84±22.2 | 71.4±25.4 | 52.2±17 | 65.3±14.6 |
| 3 n=3(4.8%) | 63.3±27.5 | 66.6±14.4 | 77.7±38.5 | 46.6±5.7 | 65.3±2.3 | 87.3±21.9 | 54.1±13.7 | 33.3±10.4 | 61.8±7.8 |
| 4 n=4(6.4%) | 53.7±22.1 | 37.5±32.2 | 91.6±16.7 | 32.5±2.8 | 59±10.0 | 75±35.3 | 70±33.2 | 33.7±7.5 | 56.6±15.3 |
| p-value | 0.028 | 0.081 | 0.32 | 0.14 | 0.37 | 0.66 | 0.30 | 0.048 | 0.141 |

**Correlations between health-related Quality of Life and individual complications:**

As shown in Table 3, and although the overall mean HRQoL was lower in those with diabetes mellitus, heart failure, hypogonadism, those with hypoparathyroidism, hepatitis C antibody and those poorly-complaints with chelation therapy, none was significant. However, significantly lower scores for physical function, role limitation physical, energy/fatigue and general health domains in those with heart failure. pain domain had significantly lower scores with each of hypogonadism and poorly complaint patients with chelation therapy.

## Discussion.

Our study showed that thalassemic adults had much lower mean HRQoL scores than their healthy peers, which was

encountered in all 8 domains assessed, and was significant in all except for role emotional domain. The most reduced domains compared to healthy controls were General Health and energy/ fatigue at around 46% each. Such results were also encountered in earlier studies on TDT, where General health was the most reduced domain in Iranian [15,16] Italian, American TDT patients; [17,18] and collection of 26 study from different countries performed in Cochrane Library [19], while energy fatigue was the most reduced in a study from Saudi Arabian TDT patients [20]. Other studies reported other domains as the most affected such as the mental domain in some other Iranian studies [21,22] and Role-emotional & Physical Functioning in one Italian study [23].

The highest score was in the social functioning domain, which is similar to the observations reported in Iranian and Saudi TDT patients (20,21), but is in contrast to other Iranian and Italian studies which reported the highest scores for physical functioning [15,16,22].

Since the concept of health-related quality of life was introduced several decades ago, it emerged as a better tool to recognize the disease burden from the patient's perspective, and was quite informative to the attending physicians, families as well as the patients themselves. Using HRQoL has been shown to improve patient provider communication and thus deliver a more patient-centered environment [24]. Among the several tools used to determine the HRQoL we chose SF-36 since it is the most common method used to measure the HRQoL in adults with hemoglobinopathies, and allowed the comparison with healthy controls and with other chronic disorders with proven validity [25].

There was no correlation of HRQoL with age, which is consistent with the results of Iranian and Omani TDT [26,27], but is in contrast to one American/British Study which revealed that older age was associated with lower HRQoL in TDT [18]. The latter study also showed that females had a lower HRQoL compared to males, and this is to some extent similar to our observation that female participants had lower HRQoL than males, though it was not significant in our series. The reduction in HRQoL was mainly due to reductions in five of the eight domains. When the domains were looked at in isolation, it was found that it was the pain domain which was the main contributor to reduction in mean and it was significantly lower in females compared to males. Such an observation is similar to reports from Saudia Arabia, USA and Iran [18,20,22], where pain scores were significantly lower in females. Contrary to the bulk of literature, another Iranian study reported a better quality of life in females in all domains except bodily pain with significant differences in General health and Physical functioning [27].

The current study also showed no significant differences in HRQoL, overall or in any of the eight domains relevant to educational background, the economic status, hematological and clinical parameters. Regarding hemoglobin and ferritin our results were the same as those in Iranian and American/British TDT adult patients [18,27], though they are contrary to those reported in children/adolescents with symptomatic thalassemia from northern and Southern Iraq [28] where S. ferritin was significantly associated with lower HRQoL scores.

All patients in the current study were receiving regular blood transfusion and chelation therapy. Regular life-long blood transfusions carry with it the risk of transmission of viral infections, and iron overload-related complications. Such complications tend to increase with age, as the cumulative number of transfusions and its associated iron burden increase [29].

Hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) are the most frequent infectious agents that patients with TDT may acquire as a consequence of their regular exposure to packed red cells [30]. Among our TDT patients, HCV antibodies were the most frequent documented complication seen in nearly 60% of our enrollees. This is most probably due to transfusion of blood which was screened by less than adequately sensitive tests and/or the unavailability of screening at certain times at the blood bank/hospital laboratories prior to 2004. As anticipated the hepatitis C virus antibody frequency increases with increasing age, and that is why its frequency in an earlier study from the same center in children is lower [28]. Similar figures were reported among TDT from central Iraq [31]. Variable figures for HCV antibodies in TDT have been reported in Western countries, ranging 34% in French patients with thalassemia who were older than 15 years to 42% in those above 16 years from North America [32]. Human immunodeficiency virus antibodies were also undetected in our sample, which is likely to be due to extremely low frequency of the virus in the Iraqi population and was documented by previous national study [33].

Despite the fact that all patients were on regular chelation therapy, and most were compliant with such therapy, the median S. ferritin was high at 2495 ng/ml (slightly less than half of the patients had a ferritin in excess of 2500 ng/ml). Such figures are similar to that in one Turkish study [34-36] but are higher than result from United Arab of Emirates [37]. Though the lower ferritin levels in the UAE study may be due to enrolment of adults as well as children, so it is expected that they would have lower ferritin than the current studies, since iron overload increases with age [28].

A multitude of complications arise from iron overload in various organs and the most frequent are endocrinopathies, which affected 61% of our patients, which is similar to rates of 60.5% reported in patients with TDT in Turkey [34]. The most frequent of endocrinopathies is hypogonadism, with an overall frequency of 43.5% which is higher than reported in Turkey [34] and Italy [4] ranging from 36.3-36.8% but is lower than reports on Omani and Lebanese at 73.3% and 80% respectively [35,36].

In the present study the frequency of diabetes mellitus was 9.6%, which is going with figures reported from UAE, Italy at 8.6-10.5% [37,38], though they are higher than other reports from countries Turkey and southeast of Iran of 0-7.8% [39,40], and lower than reports from countries including Egypt, Iran and another Turkish study of 12.5-20% [34,41,42]. Interestingly, it appears that the routine screening and its timing for Diabetes mellitus at our center is quite appropriate, since we failed to document any unidentified cases by blood sugar screening.

In the present study the prevalence of cardiac complications was 21%, which is similar to some Iranian and Egyptian reports

putting the rates between 22 and 23% [41,42]. The cardiac complications in our study included heart failure, pulmonary hypertension and arrhythmia, while thrombotic events were not documented in any of our TDT patients.

The frequency of heart failure in our study was 9.6%, which is similar to that reported among some other TDT populations e.g. Lebanese and French at 9.7-10% [32,36], while it was lower than those reported from Italian patients at 19% [38]. In relevance to arrhythmia, it was reported in only one patient, which is slightly higher than a report from UAE 0.6% [43], but is lower than reports from France of 8%. [32]. Though it since our study is not a longitudinal one, transient arrhythmias may have been missed or went un-noticed and undocumented.

Pulmonary hypertension was the commonest cardiovascular complication in current study at 15.5%, which is consistent with an earlier report from our center on TDT [44]. Studies on pulmonary hypertension in TDT from other parts of the world reported variable rates ranging from 11.9-18% [45,46]. The importance of early detection and proper management of this important complication should underscore, since it may remain unnoticed unless echocardiography is performed, particularly in adults with TDT.

It was interesting to note that with increasing cumulative number of complications in individual patients the health-related quality of life scores deteriorates progressively, and this was evident with domains like physical functioning, Role physical, general health which were significant. Clearly the mean score also decreased gradually with increasing complications though this did not reach significance due to small subgroup number in the studied sample. Such observation is logical and is not unique, previous studies on symptomatic adult thalassemia patients from the USA and Lebanon documented similar observations [14,18].

The limitation of the present study includes unicentre study and small sample size, limiting the generalizability of findings. Being cross-sectional, changes in HRQoL over time were not captures. Patients based reported parameters of the quality of life are subjective and influenced by mood changes. Positive associations may be overreported, while non-significant findings may be underreported.

## Conclusion.

This study documented for the first time that TDT Kurdish adults have lower HRQoL compared to their healthy counterparts. The reduction in SF-36 scores were in almost all domains, but it was particularly more prominent in general health and energy fatigue domains, the most frequently documented complications were HCV infection, Hypogonadism, cardiac complications and diabetes mellitus.

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