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Original Article

Validity and reliability of the Turkish version of the Canadian Haemophilia Outcomes-Kids' Life Assessment Tool (The CHO-KLAT)

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ABSTRACT

Objective: The evaluation of health-related quality of life (HRQoL) is encouraged to assess the multidimensional impact of treatments and disease and to improve care in boys with hemophilia (BwH). However, validated HRQoL tools for BwH are not yet available for Turkish. The purpose of this study was to assess the validity and reliability of the Canadian Hemophilia Outcomes-Kids' Life Assessment Tool (CHO-KLAT), version 2.0, which is multilingual valid tool, in Turkish.

Methods: The procedure included 4 steps: linguistic translation, content validity, validity evaluation with the Pediatric Quality of Life (PedsQL), finally test-retest analysis for reliability assessment. The participants were questioned for the type and severity of hemophilia, medical treatment, and inhibitor status.

Results: The primary Turkish version of the CHO-KLAT evolved with the cooperation of the Canadian and Turkish teams. Content validity was performed with 9 experts and latest version of Turkish CHO-KLAT was produced. This multicenter study was conducted with 53 BwH aged 4-18 for validity assessment, 52 BwH for test-retest reliability. The mean age of BwH was 11.6 (standard deviation (SD): 4.2). The means of CHO-KLAT and PedsQL were 64.1 (SD: 4.2) and 66.7 (SD: 15.3). As a result of the validity evaluation, a strong correlation was found between CHO-KLAT and PedsQL ($r = 0.603$; $P < .001$). The interclass correlation coefficient was 0.887 in the test-retest reliability.

Conclusion: The Turkish version of CHO-KLAT 2.0 was validated. It is now available to be used in clinical studies for HRQoL assessment of Turkish BwH.

Keywords: Hemophilia, children, quality of life, validity and reliability

Introduction

Hemophilia is an inherited clotting disorder that results from low levels of factor VIII (hemophilia A) or factor IX (hemophilia B) and usually only affects males. It is reported that hemophilia A constitutes 80%-85% of all hemophilia cases, and hemophilia B 15%-20%.[1] In severe hemophilia, which is common clinical type and life-threatening, individuals usually experience in the joints, muscle tissues, and internal organs. Musculoskeletal bleeding is a specific feature of severe hemophilia, with 70%-80% of all bleeding occurring in the joints and 10%-20% in the muscles.[1] Recurrent musculoskeletal bleeding can lead to complications such as chronic pain, arthropathy, and disability. Modern hemophilia maintenance requires versatility. Prevention of hemorrhage and musculoskeletal damage is primary. Musculoskeletal health should be restored with physiotherapy approaches and rehabilitation in the period following joint bleeding. Approaches for chronic musculoskeletal pain, which greatly reduces the quality of life, are important. Treatment of inhibitor and musculoskeletal complications can be complicated. Additionally, psycho-social support and quality-of-life assessments are essential components of care.[1-3] As seen in the text, improving the health-related quality of life (HRQoL) of people with hemophilia is only possible with a multidisciplinary approach. Since hemophilia is a life-long disease with various complications, HRQoL is observed as a critical assessment tool in clinical.[4]

The Canadian Hemophilia Outcomes-Kids' Life Assessment Tool (CHO-KLAT) is a child-centric, specific to hemophilia HRQoL instrument. The CHO-KLAT is valid.[5-6] It is handled on issues related to hemophilia and susceptible to major alteration.[5] The CHO-KLAT only assesses boys 4-18 years.

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The CHO-KLAT has a parents or surrogate type for 4-8 years children, and self-report type for 8-18 years. It is formed with 35 items and gives a total point (0-100). The CHO-KLAT was developed in Canadian (English) and then was updated to version 2.0.[7-8] Also, the French-Canadian version was validated.[9] It was validated in several countries such as China, 5 European countries, Brazil, and Ivory Coast.[10-13] Factor concentrates have been used in the treatment of hemophilia in Türkiye since the early 90s. However, any questionnaire evaluating the HRQoL of boys with hemophilia (BwH) has not been validated for Turkish. Therefore, it is not possible to evaluate the effect of the disease and the interventions on the HRQoL. The purpose of this study was to assess the validity and reliability of the CHO-KLAT version 2.0 in Turkish for clinical studies evaluating the HRQoL of BwH.

Methods

This was conducted as a multicenter study that included Van Yüzüncü Yıl University, Gaziantep University and Adana Acıbadem Hospital. Ethical approval was acquired from Van Yüzüncü Yıl University Non-Interventional Clinical Research Ethics Committee (Approval no: 2022/05-05, Date: May 5, 2022). In addition, this study was registered in the International Registry (NCT05439642). Permission to use the CHO-KLAT survey was obtained from the Canadian team that prepared the original survey.

Linguistic Translation

The forward translation was done by individuals whose first language was Turkish, and the back translation was done by a professional translation service in Canada. The back translations were reviewed by both English- and Turkish-speaking Canadian colleagues to ensure the compromise of the version and to address the hemophilia-specific terminology. The final translated version was confirmed by consensus of the translation teams.

Content Validity

Nine specialists (hematologist and hemophilia specialist physiotherapists) were interviewed to test the content validity of the CHO-KLAT. The content validity index (CVI) was computed using the Davis technique. The specialists evaluated each question of CHO-KLAT separately and rated from 1 to 4. One point was given if not related, 2 point if revision is required, 3 points if relevant but minor change, and 4 point if well related.[14] Content validity is said to be sufficient when the CVI point is above 0.80. In this study, the CVI point of 2 questions was below 0.80. These questions reviewed and re-translated changed by specialists. Latest version of Turkish version was send to the developer of the original scale.

Validity and Reliability

The validation of the Turkish version of CHO-KLAT was evaluated by comparison to the Pediatric Quality of Life (PedsQL), which was also used as a comparator in the first CHO-KLAT study (5). Therefore, a Pearson correlation coefficient was used to assess the relationship between the CHO-KLAT and the PedsQL.[15] The PedsQL is a generic measure of HRQoL and contains 23 questions about health-activity, feelings, and school.[16] Turkish version of PedsQL was validated.[17,18] Reliability was assessed for the summary scores using a random-effects intra-class correlation coefficient (ICC).[19] CHO-KLAT measurements were repeated 1-2 weeks after the first measurement for the reliability test, and the ICC between these measurements was calculated.

Data Collection

In this study, the inclusion criteria were having hemophilia A or B and being 4-18 years old. Exclusion criteria were having any neurological or psychiatric disease that would affect mental perception. Power analysis was performed to calculate the minimum sample size to participate in the study. The number of subjects was found to be at least 42 with $\alpha = 0.05$, $\beta = 0.20$, and 80% power.[9] Totally 53 BwH who met the criteria were included the study. Demographic data (age, type and severity of hemophilia, treatment regimen, and inhibitor status) were obtained from parents of BwH, and information about the disease were confirmed by the responsible hematologist. In addition, verbal and written informed consent was obtained from the parents of the children who participated in this study. Boys with hemophilia aged 8-18 completed child self-report versions of CHO-KLAT and PedsQL. For BwH aged 4-8, their parents fulfilled parent-proxy versions of CHO-KLAT and PedsQL. Participants were individually taken to the clinic and a quiet environment was provided for the measurements. Canadian Hemophilia Outcomes-Kids' Life Assessment Tool measurement was repeated after 1-2 weeks. In addition, participants were asked about the presence of serious bleeding between the first (T1) and second (T2) CHO-KLAT measurement, and those without serious bleeding were included in the test–retest analysis.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for Social Sciences version 22.0 software (IBM Corp.; Armonk, NY, USA) for validity and reliability analyses and AMOS version 22 for CVI at a significance level of 0.05. Summary scores of PedsQL and CHO-KLAT were calculated according to the questionnaires' manuals. Both HRQoL measurements are scored from 0 to 100, with 100 indicating the best HRQoL. The validation of the Turkish version of CHO-KLAT was determined using the Pearson correlation coefficient between CHO-KLAT and PedsQL. For the reliability assessment of the Turkish CHO-KLAT, the test–retest reliability between the T1 and T2 scores of CHO-KLAT was determined using an ICC.

Results

The validation assessment process of the Turkish CHO-KLAT was completed with 53 BwH. The mean age of validation samples was 11.6 (SD: 4.2, range: 4-18 years). The clinical characteristics and questionnaire scores of the participants are given in Table 1. Two patients had inhibitor, and one of them was severely physically disabled. All patients were receiving prophylaxis treatment. The mean of questionnaires was that CHO-KLAT 64.1 (SD: 4.2, range: 40.7-87.5), PedsQL 66.7 (SD: 15.3, range: 31.52-98). In addition, BwH were divided into 2 groups as severe (35 boys) and mild/moderate (18 boys). There was no significant difference between the groups for CHO-KLAT ($P = .11$) and PedsQL ($P = .08$) results (Table 2).

Validation Findings

The correlation between CHO-KLAT and PedsQL was analyzed for the validation assessment of the Turkish CHO-KLAT (Table 3). There was a strong correlation between CHO-KLAT and PedsQL total outcomes ($r = 0.603$; $P < .001$) (Figure 1). This result is similar to results of the CHO-KLAT version 2.0 study ($r = 0.62$; $P < .001$)(8). In addition, self-reported and proxy-reported outcomes of CHO-KLAT and PedsQL were examined, and it was seen that there is a strong correlation between self-reports ($r = 0.612$; $P < .001$) and moderate correlation between proxy-reports ($r = 0.565$; $P < .001$).

Reliability Findings

The reliability assessment of the Turkish CHO-KLAT was performed by examining the consistency between the first and second CHO-KLAT total outcome of 52 BwH. One BwH was excluded from the test–retest analysis because of major hematomas in the quadriceps muscle. In addition to the total score, self-reported (40 BwH) and proxy-reported (12 BwH) scores were also examined separately. In this study, total, self-reported, and proxy-reported ICC scores were

Table 1. Clinical Features and Scores of Participants

	Total (N = 53) Mean ± SD or n (%)	Self-Reported Outcome (N = 41) Mean ± SD or n (%)	Proxy-Reported Outcome (N = 12) Mean ± SD or n (%)
Age (years)	11.6 ± 4.2		
4-7.9 aged	10 (19.0)	0 (0.0)	10 (83.3)
7.9-17.9 aged	43 (81.0)	41 (100.0)	2 (16.7)
Type of hemophilia			
Hemophilia A	48 (90.6)	26 (63.4)	8 (66.6)
Hemophilia B	5 (9.4)	15 (36.6)	4 (33.3)
Clinical severity			
Mild	1 (1.9)	0 (0.0)	1 (8.3)
Moderate	17 (32)	14 (34.2)	3 (3.6)
Severe	35 (66.1)	27 (65.8)	8 (66.6)
CHO-KLAT score	64.1 ± 10.8	65.4 ± 10.3	60 ± 12
Score of moderate BwH	60.8 ± 10.3	61.1 ± 10	59.9 ± 12.7
Score of severe BwH	65.8 ± 10.8	67.6 ± 9.8	60 ± 12.5
PedsQL score	66.7 ± 15.3	68.3 ± 16.4	61 ± 9.4
Score of moderate BwH	61.7 ± 18.2	62.8 ± 19.9	57.9 ± 11.4
Score of severe BwH	69.2 ± 13.1	71.2 ± 13.7	62.6 ± 8.6

CHO-KLAT, Canadian Hemophilia Outcomes–Kids' Life Assessment Tool; BwH, boys with hemophilia; PedsQL, Pediatric Quality of Life; SD, standard deviation.

Table 2. Canadian Hemophilia Outcomes–Kids' Life Assessment Tool and Pediatric Quality of Life Scores of Severe and Mild/Moderate Hemophilia Groups

	Severe (*N* = 35) (Mean ± SD)	Mild/Moderate *N* = 18 (1/17) (Mean ± SD)	*t*	*P*
CHO-KLAT (0-100)	65.8 ± 10.8	60.8 ± 10.3	1.62	.11
PedsQL (0-100)	69.2 ± 13.1	61.7 ± 18.2	1.73	.08

CHO-KLAT, Canadian Hemophilia Outcomes–Kids' Life Assessment Tool; BwH, boys with hemophilia; PedsQL, Pediatric Quality of Life; SD, standard deviation.
Independent sample *t-t*est, $P > .05$.

Table 3. Correlation Between Canadian Hemophilia Outcomes–Kids' Life Assessment Tool and Pediatric Quality of Life Total, Self-Reported, and Proxy-Reported Scores

	CHO-KLAT (Mean ± SD)	PedsQL (Mean ± SD)	*R*
Total (N = 53)	64.1 ± 10.8	66.7 ± 15.3	0.603*
Self-reported outcome (N = 41)	65.4 ± 10.3	68.3 ± 16.4	0.612*
Proxy-reported outcome (N = 12)	59.95 ± 11.96	61 ± 9.4	0.565*

R, Pearson correlation coefficient; CHO-KLAT, Canadian Hemophilia Outcomes–Kids' Life Assessment Tool; PedsQL, Pediatric Quality of Life.
*$P < .001$.

respectively 0.887, 0.886, and 0.889 (Table 4). These findings show that the Turkish version of the CHO-KLAT is reliable with a compliance near excellence.

Discussion

The purpose of this study was to produce the Turkish version of CHO-KLAT, version 2.0, by completing linguistic translation, content validity, validation, and reliability phases. The Turkish validity and reliability of a hemophilia-specific questionnaire was conducted with this study, for the first time. As a result, CHO-KLAT, version 2.0, was shown to be valid and reliable in Turkish.

The HRQoL assessment can be an important parameter for monitoring the effects of treatments and disease, and quality of care provided in haemophilia.[20] Prophylaxis therapy improves HRQoL in adult hemophilia patients.[21] In our study, all hemophilia patients were receiving prophylaxis therapy and the mean of CHO-KLAT scores was 64.1 ± 4.2. In an international study conducted in European countries, the mean ± SD score of the CHO-KLAT was found to be 76.7 ± 9.7 in France, 71.5 ± 13.3 in Germany, 82.8 ± 8.4 in Netherlands, 78.4 ± 10.8 in England.[11] In the study conducted in Canada, the CHO-KLAT scores (75.4 ± 12.0) were higher than in our study.[8] In a study performed in China, the mean ± SD score was found to be 63.7 ± 10.6, similar to our study.[10] In many countries, hemophilia patients do not have access to prophylaxis treatment due to economic constraints. In the study performed in Ivory Coast, the CHO-KLAT scores of boys with hemophilia (mean ± SD: 52.3 ± 9.4) were found to be lower than in countries with prophylaxis treatment.[13] The relationship between the level of

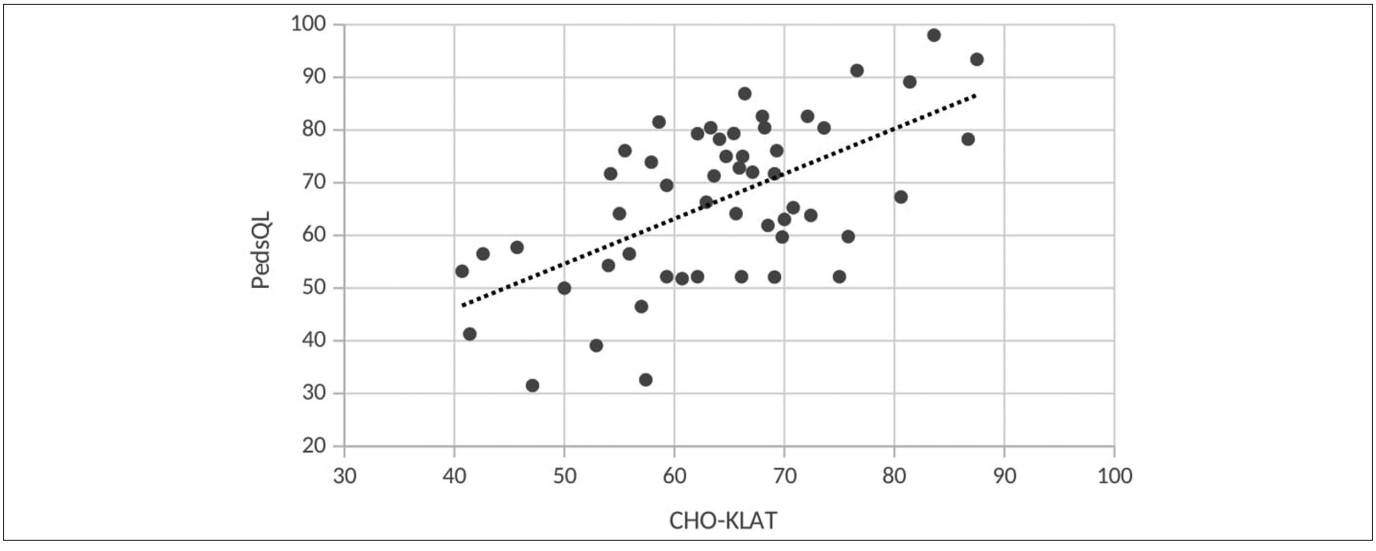

Figure 1. Correlation between the Canadian Hemophilia Outcomes-Kids Life Assessment Tool (CHO-KLAT) and the Pediatric Quality of Life Inventory (PedsQL) total scores.

Table 4. Reliability of the Turkish Canadian Hemophilia Outcomes–Kids' Life Assessment Tool Total, Self-Reported, and Proxy-Reported Scores

	First Evaluation (T1) Mean ± SD	Second evaluation (T2) Mean ± SD	Test–Retest ICC (95% CI)
Total score (N = 52)	64.1 ± 10.8	62.7 ± 12.1	0.887 (0.805-0.935)*
Self-reported score(N = 40)	65.4 ± 10.3	63.4 ± 12.4	0.886 (0.785-0.939)*
Proxy-reported score (N = 12)	60 ± 12	60.7 ± 11.3	0.889 (0.611-0.968)*

CI, confidence interval; ICC, intraclass correlation coefficients; SD, standard deviation.
*P-value ≤ .001, to test whether the ICC was > 0.70.

development of countries and HRQoL of patients with hemophilia is remarkable.

In the current study, BwH was examined in 2 groups as mild/moderate (n = 18) and severe (n = 35). There was no statistically significant difference between the 2 groups in terms of measurement results. It may be related to the high number of patients with moderate hemophilia with a high number of bleeding and physical/psychological effects in our sample. In the validation study of Canadian–French CHO-KLAT, a slight difference was observed between mild and severe groups in summary score.[9] This finding of our study is compatible with the literature.

In this study, there was a strong correlation between CHO-KLAT and PedsQL (r = 0.603 for total), similar as first validation study of the CHO-KLAT (r = 0.59) and the CHO-KLAT, version 2.0, study (r = 0.64).[5,8] PedsQL was used as a comparator in both studies. In the validation study of European countries (England, The Netherlands, France, Germany, and Spain), CHO-KLAT showed a moderate correlation with the PedsQL (r = 0.52).[11] These findings showed that the Turkish version of CHO-KLAT 2.0 was valid.

The reliability assessment of this study showed that there is a good compliance between the first and second total assessment of CHO-KLAT with ICC score = 0.887. Measurements of BwH were also examined as self-reported and proxy-reported, and ICC scores of these were 0.886 and 0.889, respectively. In the study of Landis and Koch, ICC scores between 0.60 and 0.80 have been considered substantial reliability coefficents.[15] In the other reliability assessment, an ICC score between 0.75 and 0.90 is defined as "good" compliance, above 0.90 "excellent."[22] In the first CHO-KLAT study, ICC were found 0.74 for child-reported and 0.83 for proxy-reported.[6] In the international validation study of CHO-KLAT, ICC was 0.65 for total and 0.82 for proxy-reported.[11] The Turkish version of CHO-KLAT showed good or excellent compliance similar to other CHO-KLAT studies, and this result indicated that it was reliable.

The limitation of our study is that we could not perform the cultural adaptation study of the Turkish version of the CHO-KLAT due to the additional patient needed for this. Although our study was multicenter, the number of our patients was very limited due to the fact that hemophilia is a rare disease.

Conclusion

This study has reported that the Turkish version of CHO-KLAT 2.0 is valid and reliable. This hemophilia-specific HRQoL measurement for boys aged 4-18 is ready for use in clinical studies in Türkiye. Access to factor concentrates is quite easy in Türkiye and patients with hemophilia are generally satisfied with the treatment. However, a specific scale for hemophilia that evaluates the effects of treatments on HRQoL cannot be used because there is no Turkish validation and reliability study. The reason for this may be the difficulty in reaching the sample size. This study is expected to fill this important gap about the HRQoL assessment of Turkish boys with hemophilia. Our recommendation for future studies is to conduct Turkish validation studies of HRQoL questionnaires for adult patients with hemophilia.

Ethics Committee Approval: Ethics committee approval was received for this study from the Van Yüzüncü Yıl University Non-interventional Clinical Researches Ethics Committee (Approval no: 2022 05-05; Date:May 5, 2022).

Informed Consent: Verbal and written informed consent was obtained from the parents of the children who participated in this study.

Peer-review: Externally peer-reviewed.

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