Evaluation of osteoarthritis knee and hip quality of life (OAKHQoL): adaptation and validation of the questionnaire in the Hungarian population

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Abstract

Background: At least 17% of the population suffers from osteoarthritis (OA) in Hungary, according to the European Health Interview Survey. In Hungary, until now there was no OA-specific questionnaire available for the lower limb, in order to monitor the health-related quality of life (HRQoL). This gap gave the relevance of this research. The aim of the study was to perform the Hungarian cross-cultural adaptation and validation of the French-developed Osteoarthritis Knee and Hip Quality of Life (OAKHQoL) questionnaire.

Methods: The five-step translation procedure of the original OAKHQoL was performed by the expert panel and the translators. The created Hungarian version (OAKHQoL-HUN) was tested in six different geographical areas of Hungary. The validity and the reliability of this adapted tool was analyzed by our research group.

Results: A total of 99 patients completed the questionnaires (78 women and 21 men), with the average age of 66.6 years (standard deviation (SD) 12.1), living with OA for more than 10 years. Excellent internal consistency was observed in the following domains: physical activity ($\alpha = 0.93$), mental health ($\alpha = 0.91$) and pain ($\alpha = 0.89$). Good correlation was determined between physical subscales ($r = 0.615$–0.676) and mental subscales ($r = 0.633$–0.643) compared to generic quality of life instruments (World Health Organization Quality of life – BREF questionnaire and EQ-5D-3L).

Conclusion: The OAKHQoL-HUN is the first valid and reliable tool for measuring the Hungarian lower limb OA patients' quality of life.

Trial Registration: This study is registered (24950-3/2016/EKU) by the National Ethics Committee: the Hungarian Medical Research Council.

Keywords: adaptation, osteoarthritis, osteoarthritis knee and hip quality of life questionnaire, patient-reported outcome, quality of life, validation

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Background

Osteoarthritis (OA), including coxarthrosis and gonarthrosis, is a major cause of severe pain, limited mobility and disability resulting in a significant reduction in quality of life.[1–3] It means increasing costs for the individuals and for the society as well.[4–7] According to the Global Burden of Disease 2010 Study, OA accounts for 17.1 million of the total global years lived with disability (YLDs), which supposedly means the 11th leading cause of disability in the world.[8,9] The affected patients have incapacity for work, difficulty in applying for a job or early retirement.[10] An estimated 9.6% of men and 18% of women aged over

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60 years are affected worldwide and this prevalence increases with age.[1,11–14] According to the European Health Interview Survey, made by the Hungarian Central Statistical Office, an estimated 17% of the Hungarian population is affected by OA.[15] The Global Burden of Disease 2015 Study stated that the prevalence (thousands) of OA was increased from 178,665 (2005) to 237,369 (2015).[16]

Generic and disease-specific questionnaires are part of the Patient Reported Outcome Measurements (PROMs). PROMs are useful tools to evaluate patients' perceptions about their health status, their current treatments, or their health-related quality of life (HRQoL). HRQoL questionnaires are promising tools for the evaluation of the burden of illness, the diagnosis or the treatment options. Measuring the quality of life is used to evaluate the patients' perception of their own general wellbeing.[17–20] For a complex and valid evaluation, besides generic questionnaires such as the World Health Organization Quality of life – BREF (WHOQoL-BREF), there is a need to use a disease-specific instrument as well.[21–25] The Osteoarthritis Knee and Hip Quality of Life questionnaire (OAKHQoL), developed by French researchers, is multidimensional and covers all the dimensions which are highlighted for patients affected by lower limb OA.[26–29] The OAKHQoL disease-specific questionnaire has been translated into different languages and has proved to be a successful instrument for measuring quality of life in the case of knee and hip OA patients.[30–36]

The aim of this study was to develop a cross-cultural adaptation of the OAKHQoL questionnaire, set to the Hungarian population and to validate the adapted Hungarian version (named OAKHQoL-HUN) in terms of its psychometric properties of validity and reliability.

Methods

Study design

This prospective study was performed among patients diagnosed by the doctors, acting as the expert panel of this study – with OA of the lower limb. The recruitment was performed between June 2017 and November 2017, in six hospitals situated in six different geographical regions of Hungary. The participating hospitals were selected in a way to represent different geographical and cultural areas of the country; the patients were selected randomly by the doctors of the given sites after evaluating the inclusion criteria, which were as follows: age over 18 years, clinically/doctor diagnosed knee and/or hip OA, native Hungarian language, the ability of self-filling and completely filled patient data sheet. Exclusion criteria were age under 18 years, other type of OA, psychiatric disorders and those who had surgeries within 1 month, or who were incapable of filling the forms.

This research was evaluated and approved by the Hungarian Medical Research Council, acting as the National Ethics Committee, its registration number is: 24950-3/2016/EKU. A printed patient information sheet was provided to each participating patient, patients had enough time to think over the participation, and had the opportunity to ask questions and the questions were answered, then the participating patients provided verbal informed consent.

Questionnaire translation and the cross-cultural adaptation process

The adaptation process of the OAKHQoL questionnaire was conducted according to the published guidelines, based on the instructions and cooperation with the researchers of the original questionnaire.[37–39] The committee of the procedure was composed of: (a) translation committee (4 members); (b) team of University of Szeged, as moderator (4 members); (c) expert panel (6 doctors of the study sites: orthopedists, rheumatologists, musculoskeletal rehabilitation doctors).

Step 1: The original French questionnaire's English version was translated into the Hungarian language by two translators independently of each other. The use of the English version of the original questionnaire for the adaptation process was recommended by the developer as it is equivalent to the French one. One of them was a healthcare professional and the other one was a professional bilingual translator based on the guideline.

Step 2: The two created versions – TH1 and TH2 (translated-Hungarian) – were merged into one (named: TH1.2.) by the expert panel, based on their experience with the Hungarian patients.

Step 3: The expert panel suggested some changes which made the questionnaire fit to national characteristics. Hungarian language limitations justified to merge the two questions. This was approved by the developers of the questionnaire and the local professional panel too.

Step 4: The TH1.2. pre-final version's content validity was tested within a focus group by interviewing 34 patients. This formed the pre-testing procedure. This TH1.2. version was translated backward by two native English-speaking persons independently (backward-English – BE1 and BE2), and then this was synthetized by the research group to form the final OAKHQoL-HUN version. (The TH1.2. version and OAKHQoL-HUN are the same, the former is in Hungarian and the latter is in English).

Step 5: This step was the pilot testing procedure in order to evaluate the psychometric properties of the questionnaire. In total, 99 questionnaires – from the initial 125 – met the requirements of complete filling. From the 125 questionnaire 26 were excluded as they did not meet one of the inclusion criteria, namely in these cases the patient data sheets were not completely filled in.

Questionnaire validation process: applied tools

OAKHQoL. The original OAKHQoL questionnaire contains 43 items; in which 40 items are divided into five domains: physical activity,[16] mental health,[13] pain,[4] social support,[4] social activity[3] and three independent items about professional life, sexual activity and relationships.[26,27] Each question was responded to by a 0–10 response scale, in which 0 determined the worst status and 10 determined the best status. The score of each dimension is standardized to a 0 (worst level of quality of life) to 100 scale (best level of quality of life). In accordance with the guideline, if missing items are below 5% within a domain, the domain is evaluable. Missing items code number was determined as "99".

WHOQoL-BREF. WHOQoL-BREF is the abbreviated version of the World Health Organization's generic health-related quality of life (HRQoL) questionnaire, available in the Hungarian language.[40] This tool is made up of 26 items, divided into four domains: physical health,[7] psychological health,[6] social relationship,[3] environment[8] and two independent items – one about the individual's overall perception of quality of life and one item about the individual's overall perception of his/her own health. The Likert response scale was used with the range from 1 (worst status) to 5 (best status). Domain scores are scaled in a positive direction – higher score reflecting higher quality of life. Within each domain the mean score of items was used to calculate the domain score. Based on the guideline the domain score's result was transformed to a 0–100 scale. The evaluation was constructed according to the WHOQoL-BREF instruction guideline.[22–23]

EQ-5D-3L. EQ-5D-3L is a generic HRQoL measurement tool as well, also available in the Hungarian language. This questionnaire is divided into five dimensions, each with one item: mobility, usual activities, self-care, pain/discomfort and anxiety/depression, resulting in a simple descriptive profile about the individual's perceptions of the health status, ranging from 0 (bad health value) to 1 (good health value). However, the range is understandable between 0 and 1, the calculation could result in a value under 0, which means that there are several health statuses which affect the patients harder than death. Within each dimension there is a three-level response option: level 1: no problem; level 2: moderate problem; level 3: severe problem; $3^5 = 243$ health status could be stated by calculating the EQ-5D index. Based on the given responses, an official online calculator considers the EQ-5D index number with regard to visual analogue scale (VAS) and time trade of method (TTO). Several countries in Eastern and Central Europe have no individual national value set for calculation, neither has Hungary. In this case for the Hungarian calculation the British value set is recommended to be used according to the practical proposals in the concerning literature. The VAS is part of the EQ-5D, mentioned as a health status thermometer, ranging from 0 to 100 for the patients to evaluate their current general health status; 0 represents the possible worst health status and the 100 represents the best possible health status.[41–45]

Patient data sheet. Each participating patient received the patient data sheet. The patient data sheet contains questions with regard to patients' demographic characteristics: gender, year of birth, height and weight – to calculate the body mass index (BMI), residence type (urban or rural), education level, marital status, OA duration, income level, type of OA (knee, hip, both). In accordance with the reviewed international and national literature and the evaluated parameters the research team made the following hypothesis: Participants with higher ages will have suffered from OA more, and more women will be affected.

Statistical analysis. The statistical evaluation of data was made by means of the 23.0 version of the SPSS program. The adapted OAKHQoL-HUN

questionnaire items were grouped into the five dimensions and three independent questions, then the standardized scores (0–100) were calculated in case of each dimension based on the scoring sheet. The descriptive analysis was determined by mean, standard deviation (SD), missing items, and the observed and theoretical range. Validity and reliability were evaluated as well.[46,47]

Validity assessment. Content validity was performed by the doctors forming the expert panel. The doctors evaluated how understandable the questionnaire was. This process represented Step 4. The construct validity and the discriminant validity (other way known-group validity, henceforth known-group validity) was evaluated as well. Construct validity is used when the different measurement tools' similar dimensions are measured with the same construct (convergent validity).[46–49] In this way, the OAKHQoL-HUN five domains were compared to the two generic quality of life questionnaires' domains (WHOQoL-BREF and EQ-5D). Correlation to other musculoskeletal tools was not possible due to the fact that at the time of the practical part of this research (2017) there was no OA-specific questionnaire available in Hungary. The determination of the correlation was calculated by using Pearson's correlation coefficients (r). The correlation was evaluated as poor (0–0.2), fair (0.2–0.4), moderate (0.4–0.6), very good (0.6–0.8) and excellent (0.8–1.0).[48,49] To determine known-group validity, the OAKHQoL-HUN 5 dimensions' values were evaluated in connection with the gender, age groups and OA duration. The Mann–Whitney test was used to analyze known-group validity.[50,51]

Due to the content validity, it was assumed that patients will understand the items and the content of the questionnaire. The basis of this assumption was that the terminology of the items is simple, clear, they are not too long, and no difficult sentences applied. Regarding the construct validity, the next hypothesis was that the items related to the physical, pain, mental and social parameters could be measured dependably. In these cases, at least good correlation ($p = 0.6$–0.8) was assumed. However, there were doubts regarding the comparability of the independent questions of the questionnaire. The team predicted significant difference (significance level $p = 0.05$) regarding the patients with higher age and higher duration of OA in comparison to physical conditions as described by known-group validity.

Reliability assessment. Reliability was evaluated with the following methods: the internal consistency was analyzed by means of Cronbach's alpha ($\alpha > 0.7$, acceptable; $\alpha > 0.8$, good; $\alpha > 0.9$, excellent).[46–49] The intraclass correlation coefficient (ICC) was derived from a two-way analysis of variance with a random effect.[52] In accordance with the 95% confidence interval (CI) of the ICC estimate, values <0.5 (poor), between 0.5 and 0.75 (moderate), between 0.75 and 0.9 (good) and >0.90 (excellent) reliability.

The reliability was measured by two methods, first by determining the Cronbach alpha and by ICC. The internal consistency was hypothesized to be at least good ($\alpha > 0.8$) in connection with all five domains. The ICC was assumed to be found at least good (by 95% CI above 0.7).

Results

Translation and content validity

After reviewing the first two translated versions (TH1 + TH2), the expert panel made the following modifications: questions 13 and 14 ("I need to pace myself" and "It takes me longer to do things") sound the same way in the Hungarian language, therefore they were merged. The new question in English is the following: "I have slowed down my usual pace, so it takes me more time to complete my tasks".

Questions 19 and 20 ("I am anxious" and "I am depressed") had almost the same meaning in the Hungarian language, so they were also merged. The suggested question by the expert panel: "I often feel anxious, sometimes I am even depressed". Based on the expert panel's opinion, two new questions were included. The first one in the physical domain: "I must use knee support (e.g.: orthresis) to avoid pain", the second one in the mental health domain: "I have difficulty practising my treatment". Finally, the expert panel also suggested some changes in the order of the items, while the items' number within the domains was not changed. The back-translated and synthetized final version, named OAKHQoL-HUN met the requirements of the back-translation procedure.[26] As the final step, the expert panel evaluated the results of the interviews of 34 patients, performed during focus group and accepted the content and face validity of the adapted questionnaire.

Sample

Ninety-nine questionnaires were completed properly (78 women and 21 men). The average age of the sample was 66.6 years (SD 12.1), they were mostly obese (48.5%), low educated (47.5%), with a low level of income (53.5%) and married (55.6%). The average duration of the OA was more than 10 years (59.6%). The results proved the previous hypothesis, based on the average age of the evaluated population and number of the participating women. Detailed information is presented in Table 1.

Each recruited participant completed the patient data sheet. The questions of the patient data sheet were addressed to the general demographic labels. The BMI categories were classified by using WHO determined classification. Based on these: ⩽18.5 were underweight; 18.51–24.9 were normal weight; 25.0–29.99 were overweight (other words pre-obese) and ⩾30.00 were obese (obese I.II.III.). The income level was determined with the following process: low income: calculated by using the living/minimum wage, and the average retired pay in Hungary in the year the evaluation was performed. Middle income: calculated by using the average income which could be earned. If somebody has at least high school graduation – these fees are determined by Hungarian government every year. High income was calculated above middle income. Education level was determined in accordance with the following: low education: below eight elementary class; medium education: at least secondary school and/or vocational school; high education: high school and/or university degree. Each factor in the patient data sheet was measured by using the scale method. The data were analyzed in total and also by gender, numerically and by percentage as well.

Score distribution

In accordance with OAKHQoL domains, lower values were predicted, so lower HRQoL to physical activities and pain and higher HRQoL value to social domains were expected. The mean values of the domains are presented in Table 3. The lowest value belongs to the domain "physical activity" (38.39), as it was predicted. This means severe physical dysfunction as in the evaluating score between 0 and 100, the 0 means the worst possible health status. The best quality of life (74.15) was observed in case of "social support". Previously, higher quality of life was predicted to social domains, which was partially proved by results of social support's domain. The other three domains had values around the average. Missing items were detected under 5% regarding the five domains. On average, 30–50% of the participants did not give evaluable answers in the case of the three independent items (38.4% in case of "professional activity", 37.4% in case of "spouse relation" and 48.5% on sexual activity). Neither a floor nor ceiling effect was detected among the domains "physical activity" and "mental health". The range floor and ceiling effects were detected between 0% and 6.06%.

Table 2 shows floor-ceiling effects and missing data of the items. The research team feared that most of the missing items will belong to the independent questions which affected the patient's private life. Missing data ranged between 0% and 48.5%, the average rate for items was 4.70%. The items with more than 5% missing data were in connection with "using public transport" (19.2%), "completing work tasks" (38.4%), "condition affects relationships" (37.4%) and "condition affects sexual life" (48.5%). High missing data were predicted to items which affect the private life. As per our results, the highest missing data were observed in case of relationship and sexual life. Relatively high floor and ceiling effects were observed in some cases; namely the highest floor effect for the item "knee support" (47.5%); 20% was the floor effect in case of items 33, 36, 37 and 38. Analyzing ceiling effects, the highest value was observed in the case of item 42 "feel support from those close to me" (51.5%). Also, a relatively high ceiling effect belongs to items 15, 16, 40, 41 and 43.

Reliability

The reliability results are presented in Table 3. The questionnaire has good or excellent internal consistency based on the values of Cronbach alpha in case of physical activity (0.93), mental health (0.91) and pain (0.89). Lower values (0.62 and 0.57) were observed in the case of social support and social activities. The hypothesis in the case of three domains were proved but the 0.8 internal consistency was not observed by social support and social activities domains. The results of test–retest reliability were evaluated, by 95% CI, and found excellent in the case of physical activity (0.908), good in the case of two domains: mental health (0.892) and pain (0.881). Moderate values were observed in the case of the other two

Table 1. Sociodemographic and clinical characteristics of patients with knee and hip osteoarthritis participating in the study.

Characteristics	Total sample (n^a = 99)	Men (n = 21)	Women (n = 78)
Age (years; mean ± SD[b])	66.6 (12.1)	62.1 (9.9)	67.8 (12.4)
Range	28–99	38–81	28–99
Age groups; number (%)			
⩽55	18 (18.2%)	3 (14.3%)	15 (19.2%)
56–65	26 (26.3%)	10 (47.6%)	16 (20.5%)
66–75	30 (30.3%)	6 (28.6%)	24 (30.8%)
⩾76	25 (25.3%)	2 (9.5%)	23 (29.5%)
BMI[c] (kg/m^2; mean ± SD)	29.5 (4.9)	31.3 (4.4)	29.0 (4.9)
Range	17.1–43.1	24.4–42.3	17.1–43.1
BMI groups (kg/m^2; number (%)			
⩽18.5 (underweight)	1 (1.0%)	0 (0%)	1 (1.3%)
18.51–24.99 (normal)	19 (19.2%)	1 (4.8%)	18 (23.1%)
25.00–29.99 (overweight)	31 (31.3%)	8 (38.1%)	23 (29.5%)
⩾30.00 (obese)	48 (48.5%)	12 (57.1%)	36 (46.2%)
Residence; number (%)			
Urban	61 (61.6%)	10 (47.6%)	51 (65.4%)
Rural	38 (38.4%)	11 (52.4%)	27 (34.6%)
Education level; number (%)			
Low	47 (47.5%)	9 (42.9%)	38 (48.7%)
Medium	35 (35.4%)	9 (42.9%)	26 (33.3%)
High	17 (17.2%)	3 (14.3%)	14 (17.9%)
Family status; number (%)			
Single	9 (9.1%)	1 (4.8%)	8 (10.3%)
Married	55 (55.6%)	17 (81.0%)	38 (48.7%)
Widowed	25 (25.3%)	2 (9.5%)	23 (29.5%)
Divorced	10 (10.1%)	1 (4.8%)	9 (11.5%)
Income level; number (%)			
Low	53 (53.5%)	7 (33.3%)	46 (59.0%)
Medium	42 (42.4%)	13 (61.9%)	29 (37.2%)
High	4 (4.0%)	1 (4.8%)	3 (3.8%)

(Continued)

Table 1. (Continued)

Characteristics	Total sample ($n^a = 99$)	Men ($n = 21$)	Women ($n = 78$)
OA[d] duration (years; number (%)			
<5 years	17 (17.2%)	3 (14.3%)	14 (17.9%)
5–10 years	23 (23.2%)	8 (38.1%)	15 (19.2%)
>10 years	59 (59.6%)	10 (47.6%)	49 (62.8%)
OA involvement (body area; number (%)			
Knee	15 (15.15%)	5 (33.33%)	10 (66.67%)
Hip	9 (9.09%)	2 (22.22%)	7 (77.78%)
Both	75 (75.76%)	14 (18.67%)	61 (81.33%)

[a]Number of the sample.
[b]Standard deviation.
[c]Body mass index.
[d]Osteoarthritis (OA).

Table 2. Floor effect, ceiling effect and missing data of the items of the OAKHQoL-HUN.

Items of OAKHQoL-HUN	Floor effect[a] *n* (%)	Ceiling effect[b] *n* (%)	Missing data *n* (%)
I1 Dressing	4 (4.04)	6 (6.06)	2 (2.02)
I2 Bending and standing	4 (4.04)	10 (10.10)	1 (1.01)
I3 Walking	2 (2.02)	11 (11.11)	1 (1.01)
I4 Orthresis	19 (19.19)	19 (19.19)	1 (1.01)
I5 Knee support	47 (47.47)	6 (6.06)	2 (2.02)
I6 Going down stairs	6 (6.06)	19 (19.19)	2 (2.02)
I7 Going up stairs	4 (4.04)	21 (21.21)	0 (0.00)
I8 Taking bath	15 (15.15)	8 (8.08)	2 (2.02)
I9 Cutting toenails	4 (4.04)	29 (29.29)	2 (2.02)
I10 Start moving	3 (3.03)	15 (15.15)	1 (1.01)
I11 Staying same position	2 (2.02)	15 (15.15)	0 (0.00)
I12 Difficulty falling asleep	6 (6.06)	10 (10.10)	2 (2.02)
I13 Waking up because of pain	10 (10.10)	8 (8.08)	1 (1.01)
I14 Getting in and out of car	4 (4.04)	14 (14.14)	1 (1.01)
I15 Using public transport	4 (4.04)	23 (23.23)	19 (19.19)
I16 Difficulty carrying heavy packages	1 (1.01)	33 (33.33)	0 (0.00)

(Continued)

Table 2. (Continued)

Items of OAKHQoL-HUN	Floor effect[a] *n* (%)	Ceiling effect[b] *n* (%)	Missing data *n* (%)
I17 Completing work tasks	10 (10.10)	12 (12.12)	38 (38.38)
I18 Completing role within family	5 (5.05)	12 (12.12)	2 (2.02)
I19 Have to slow down. More time to complete tasks	1 (1.01)	22 (22.22)	0 (0.00)
I20 Help with the everyday actions	13 (13.13)	15 (15.15)	2 (2.02)
I21 Visitors in the house	10 (10.10)	14 (14.14)	1 (1.01)
I22 Leaving house	11 (11.11)	17 (17.17)	2 (2.02)
I23 Depression because of pain	5 (5.05)	11 (11.11)	0 (0.00)
I24 Anxiety sometimes even depressed	18 (18.18)	5 (5.05)	4 (4.04)
I25 Irritable and grumpy	5 (5.05)	5 (5.05)	2 (2.02)
I26 Annoying friends and family	19 (19.19)	2 (2.02)	4 (4.04)
I27 Chronic pain (frequency)	2 (2.02)	11 (11.11)	1 (1.01)
I28 Acute pain (strength)	7 (7.07)	5 (5.05)	1 (1.01)
I29 Feeling older than actual age	27 (27.27)	5 (5.05)	4 (4.04)
I30 Afraid of becoming handicapped	18 (18.18)	18 (18.18)	0 (0.00)
I31 Ability to plan for long term	11 (11.11)	4 (4.04)	2 (2.02)
I32 Wondering what the future holds	7 (7.07)	17 (17.17)	1 (1.01)
I33 Feeling self-conscious	26 (26.26)	4 (4.04)	0 (0.00)
I34 Worrying about being dependent on others	7 (7.07)	18 (18.18)	1 (1.01)
I35 Feeling embarrassed to ask for help	8 (8.08)	17 (17.17)	2 (2.02)
I36 Difficulty practising treatment	20 (20.20)	5 (5.05)	1 (1.01)
I37 Wary of side effects	25 (25.25)	4 (4.04)	3 (3.03)
I38 Condition affects relationship	24 (24.24)	4 (4.04)	37 (37.37)
I39 Condition affects sexual life	7 (7.07)	7 (7.07)	48 (48.48)
I40 Capability of talking to others about difficulties	2 (2.02)	22 (22.22)	1 (1.01)
I41 Others understand my difficulties	2 (2.02)	28 (28.28)	2 (2.02)
I42 Feel support from those close to me	1 (1.01)	51 (51.52)	1 (1.01)
I43 Feel support from my social circles	7 (7.07)	26 (26.26)	2 (2.02)

[a]Number and percentage of the lowest modality.
[b]Number and percentage of the highest modality.

dimensions: social support (0.579) and social activities (0.551). These results proved our prediction partially, because similar to internal consistency, the ICC was not observed above 0.7 in the case of the social domains.

Known-group validity

The questionnaire's validity was evaluated in connection with the different demographic factors (Table 4). A significant difference was predicted between the physical activity domain and

Table 3. Distribution and reliability coefficients for the five subscales of the OAKHQoL-HUN.

OAKHQoL[a] domains	No. of items	Mean	SD[b]	Missing items NO (%)[c]	Floor effect[d] (%)	Ceiling effect[e] (%)	Observed range[f]	Theoretical range[g]	Cronbach α[h]	ICC[ji] (95% CI)
Physical activity	16	38.39	19.88	2.25 (2.27)	0	0	8.00–89.38	0–100	0.93	0.908 (0.869–0.938)
Mental health	13	54.06	21.45	1.85 (1.86)	0	0	11.54–92.50	0–100	0.91	0.892 (0.851–0.924)
Pain	4	44.07	25.56	1.25 (1.26)	4.04	2.02	0–100	0–100	0.89	0.881 (0.834–0.916)
Social support	4	74.15	19.32	1.5 (1.52)	0	6.06	10–100	0–100	0.62	0.579 (0.416–0.704)
Social activities	3	50.84	19.19	1.67 (1.68)	2.02	0	0–93.33	0–100	0.57	0.551 (0.331–0.699)

[a]Osteoarthritis Knee and Hip Quality of Life Questionnaire.
[b]Standard deviation.
[c]Number and percentage of the patients with some missing items in the subscale, and this ratio in parentheses is the missing items of the questionnaire.
[e]Percentage of the lowest modality summarized by domains.
[d]Percentage of the highest modality summarized by domains.
[f]The range of the observed lowest and highest value of each subscale.
[g]The range of the possible lowest and highest value, which was determined by the evaluation guideline.
[h]The internal consistency was evaluated in case of each subscale with the use of Cronbach α coefficient.
[i]The intraclass correlation coefficient and the confidence interval (CI) (95%).

the different age groups, and also between the OA duration and the five domains. Based on the results, significant difference was detected only in mean score between physical activity and age groups ($p=0.048$). Younger patients (<55 years) have a significantly better physical status.

Construct validity: convergent validity

Good correlation ($r=0.6$–0.8, $p=0.01$) was determined between physical activity and EQ-5D-VAS ($r=0.615$), Mental health and EQ-5D-VAS/TTO ($r=0.643$, 0.633), pain and EQ-5D-VAS/TTO ($r=0.676$, 0.670) and professional activity – physical health ($r=0.621$). Moderate correlation ($r=0.4$–0.6) was observed in many cases, for example, physical activity – physical health ($r=0.599$), mental health – psychological ($r=0.594$), mental health – environment ($r=0.575$), pain – physical health ($r=0.589$) and physical activity – EQ-5D-TTO ($r=0.587$). In addition, the social dimensions weakly correlated with the WHOQoL-BREF dimensions and EQ-5D (Table 5), to reach at least moderate correlation to verify the convergence between the two different measurement tools.

Discussion

The results of our study present good content and face validity, as was observed in another adaptation study as well.[32] According to the expert panel suggestions for amending and improving items, the hypothesis was proved, and the questionnaire was found understandable by the patients. Demographic data correlate with the scientific literature (9.6% of men and 18% of women aged over 60 years are affected with OA), as in our study the percentage of women is higher (12.4%) over age 60 than men (9.9%), and other validation studies.[26,30,33,34] The mean distribution of the different domains was hypothesized that lower values belong to physical activity and pain, meaning lower HRQoL. The lowest value was observed in the case of physical activity (38.39); however, the value of the pain (44.07) domain was also very low, which means severe pain for the affected patients and 44.07 still not referred for satisfying HRQoL, similar to the Spanish validation study.[30] Besides probably the value could be higher due to patients who participated in rehabilitation procedures at the time of completing the questionnaire and they had a lot of useful treatments which reduced their pain. Social domains were predicted to be high, which was observed by the social support (74.15) – similar results were found as Ouédraogo *et al.*[33] in their research and also Gonzalez Sáenz de Tejada *et al.*;[30] but it was only around the average value in the case of social activity (50.84), similar to a Chinese study.[34] This value could be explained by the following: three questions belonged to this domain and as it was predictable, one of the items (22) was easy to misunderstand for the patients. Further examination is needed to prove this, because based on the focus

Table 4. Known-group validity analysis of the OAKHQoL-HUN.

	Physical activities			Mental health			Pain			Social support			Social activities		
	Mean	**SD[a]**	***p*[b]**	**Mean**	**SD**	***p***	**Mean**	**SD**	***p***	**Mean**	**SD**	***p***	**Mean**	**SD**	***p***
Gender (*n*)			0.51			0.76			0.72			0.94			0.66
Men (21)	40.90	17.01		52.79	22.61		45.87	23.23		73.85	19.95		49.21	16.69	
Women (78)	37.65	20.63		54.41	21.26		43.59	26.27		74.23	19.28		51.28	19.88	
Age (years) (*n*)	**0.048**			0.655			0.613			0.355			0.780		
⩽55 (18)	49.90	25.77		56.31	23.77		49.31	28.36		79.03	18.27		52.59	19.39	
56–65 (26)	37.62	20.23		49.82	23.58		40.47	24.82		69.74	25.06		52.69	21.91	
66–75 (30	34.85	17.16		54.03	19.74		41.75	24.94		72.58	17.51		47.89	16.50	
⩾76 (25)	34.94	15.27		56.89	19.90		46.90	25.58		77.10	14.55		51.20	19.76	
OA[c] duration (years) (*N*)	0.088			0.685			0.158			0.541			0.822		
<5 (17)	44.44	23.49		57.52	16.16		49.56	28.58		75.05	20.20		51.57	24.10	
5–10 (23)	43.06	15.12		55.18	21.92		50.43	22.07		70.22	18.49		52.75	12.50	
>10 (59)	34.74	19.89		52.63	22.73		40.01	25.53		75.42	19.50		49.89	19.99	

[a]Standard deviation.
[b]Significance level ($p = 0.05$).
[c]Osteoarthritis.

Table 5. Construct validity of the OAKHQoL-HUN with correlation of WHOQoL-BREF and EQ-5D-3L generic quality of life questionnaires.

OAKHQoL[a]								
	Physical activity	**Mental health**	**Pain**	**Social support**	**Social activities**	**Professional activity**	**Spouse relation**	**Sexual activity**
WHOQoL-BREF[b]								
Physical health	0.599**	0.502**	0.589**	0.018	0.106	**0.621****	0.284*	0.470**
Psychological	0.308**	0.594**	0.447**	0.253*	0.104	0.455**	0.182	0.378**
Social relationships	0.126	0.352**	0.241*	0.227*	0.098	0.250	0.339**	0.431**
Environment	0.448**	0.575**	0.501**	0.180	0.127	0.385**	0.313*	0.242
Overall QoL perception	0.272**	0.356**	0.272**	0.071	0.090	0.284*	0.201	0.226
Overall health perception	0.378**	0.296**	0.229*	–0.212*	–0.074	0.291*	0.060	0.134
EQ-5Dc								
EQ-5D-TTO[d]	0.587**	**0.633****	**0.670****	0.028	0.197	0.538**	0.251*	0.443**
EQ-5D-VAS[e]	**0.615****	**0.643****	**0.676****	0.037	0.177	0.588**	0.249*	0.452**
VAS[f]	0.363**	0.423**	0.377**	0.038	0.215*	0.246	0.067	0.264

**Correlation is significant at the 0.01 level.
*Correlation is significant at the 0.05 level.
[a]Osteoarthritis Knee and Hip Quality of Life Questionnaire.
[b]World Health Organization Quality of Life – BREF.
[c]EQ five dimensions three levels.
[d]EQ-5D index, calculated by using time trade off method (EQ-5D-TTO) – the UK values were used in Hungary.
[e]EQ-5D index, calculated by using visual analogue method (EQ-5D-VAS) – the UK value set was used in Hungary.
[f]Visual analogue scale.
The construct validity indicated by Pearson's correlation coefficient, *r* (*p* value) and the indicated instruments.

group analysis the items were found clear and understandable. As the research team predicted, the construct validity was detected to be good ($p = 0.6$–0.8) in the case of physical activity, mental health, pain and EQ-5D scale results, which refers to the Spanish results.[30] Comparison with WHOQoL-BREF, good correlation was found just in one case – physical health and professional activity which was not predicted previously. Weak correlation was observed among social domains; however, a good correlation was expected in this section. Regarding the independent questions, such as referring to sexual activities; they were found to be weak, which is in accordance with our prediction. The reliability was examined by two methods: one of them was the measuring of the internal consistency (based on Cronbach's alpha values), which was excellent in the case of "physical activity" ($\alpha = 0.93$), and mental health ($\alpha = 0.91$), and good in the case of the domain: "pain" ($\alpha = 0.89$). In correlation to the Spanish survey, these results are the same in the case of physical activity and pain domains and almost the same in the case of mental health.[30] The social support ($\alpha = 0.62$) and social activities ($\alpha = 0.57$) domains were below the acceptance level ($\alpha > 0.7$, acceptable). These results met partially the previously predicted results, but social factors did not reach the $\alpha > 0.8$ level. If we did not take into account item 22 ("I leave my house as often as I would like"), the Cronbach alpha value was >0.7. These results were expected, as this was also observed in the case of other adaptation processes found in the literature in the case of "physical activity" and "mental health" domains and lower values in connection with other domains. Few items belong to social dimensions of the WHOQoL-BREF and the OAKHQoL, therefore it is hard to find significant correlation.

According to the expert panel's opinion, changes should be made in the case of item 22 (social

activities domain), and an alteration of the sentence and the answer dimension from "never – always" to "not at all – severely" is needed. After these changes, a higher Cronbach alpha and ICC values could be expected, but further examination needs to be performed to evaluate this fact. In addition, the reliability was measured by the evaluation of the ICC. The results found in this case were satisfying as ICC values above 0.7 were detected in the case of physical activity, mental health and pain. These results correlate with results of Moroccan – Arabic and Chinese adaptation surveys.[31,34] A significant difference was detected only between the age and the physical activity domain ($p = 0.048$), but this analysis did not meet the team's prediction. The significant difference was not proved between physical activity and BMI, and OA duration.

Average missing data were 4.70%. The highest impact was detected in connection with the item aimed at work habit, the explanation for this result could be that most of the patients who had taken part in this survey are retired (age above 65 years: 55.6%, Table 1). Relatively high missing data belonged to items that focused on private life relationships, which was hypothesized. The highest ceiling effect was observed with family support (51.52%), meaning that the patients can count on their families.

The strengths of our study are that: (a) the unmet need for a Hungarian OA-specific questionnaire was satisfied by constructing this one, based on an international guideline, making the results comparable with the findings of other countries; (b) our findings had very good or excellent construct validity and good reliability in the case of the domains: "physical activity", "mental health" and "pain"; and also that (c) the recruited patients covered all relevant parts of Hungary, so we have information about the Hungarian patients' characteristics. However, several limitations of this study also have to be noted, such as: (a) our findings in the domains: "social support" and "social activities" and in the case of the three independent items had moderate results. That requires further examination, possibly it will be needed to make a revision of the items within these domains. (b) There was a high percentage of missing data in the case of the independent items, limitation could have occurred in the patients' moderated intention to speak about their private life. Limitations were observed with regard to floor and ceiling effects in connection with "using public transport", "completing tasks", "condition affects relationship" and "condition affects sexual life". The highest percentage of missing data was detected in these cases. It should be taken into consideration that the participating patient group was mostly retired and seniors. Due to this fact, the "not applicable" option should be inserted into these items as a possible response. Completing this amendment, missing data would not be as high as was observed and the highest missing data would be 4.04%. (c) The test–retest analysis was not constructible into this survey, therefore it should be analyzed separately for a better understanding. It is required to perform further statistical analysis to prove psychometric properties of the adaptation and validation process, regarding the reliability and reproductivity of the adapted questionnaire. Further statistical analysis is needed to prove structural validity of the adapted tool and is required to evaluate the responsiveness of the questionnaire in order to measure the change over a predetermined time frame. The adaptation process is continuously going on from this aspect.

Conclusion

The OAKHQoL questionnaire was found to be an adequate tool to measure the quality of life of Hungarian patients with lower limb OA, and thr OAKHQoL-HUN is the first lower limb OA-specific questionnaire in Hungary, giving the basis for conducting international comparisons and evaluations. However, the statistical analysis drew the attention to several limitations with regard to the performed examination. At the time of the research work there was no other complex adaptation and validation survey with regard to Hungarian arthritis patients which would establish the characteristics of the population in question and therefore could help to predict the critical aspects. Otherwise, this unmet need was satisfied with this study, and made this adaptation and validation process necessary, in order to be able to evaluate and monitor the health status of Hungarian OA patients not only with generic, but also with a disease-specific tool.

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Author contributions

The research team of the University of Szeged, Faculty of Pharmacy, Doctoral School of Pharmaceutical Sciences and the Institute of Pharmaceutical Technology and Regulatory Affairs formed the main frame for this study. The six different hospitals provided the location of the research, the doctors formed the expert panel. The translators took part in the adaptation procedure according to the relevant guideline. Based on the literature search of HF, ICS built the cooperation with FG in order to get the permission for using the original OAKHQoL questionnaire in order to adapt it to the Hungarian version and validate it as well. FG gave the licence for using this questionnaire and made all relevant documents and guidelines to manage the procedure. FG designated AV to support the process in case of any kind of technical questions. AV shared all the information to manage the statistical analysis and the scaling score. HF and ICS performed the design of the study. HF performed the documentation for the ethical approval. HF and ICS established the contact with the study sites and discussed the study design with the professionals. RF, ZL, FL, IT, KT, CV supported the possible participants for the randomization and for the pre-testing procedure and coordinated the technical staff at the given site. HF conducted the interviews with all the participants personally (verbal information, patient information sheet and filling the questionnaires). HF evaluated the data and made the statistical analysis. HF wrote the manuscript, which was revised by ICS and by EP. All authors approved the final version for publication.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

The authors declare that there is no conflict of interest.

Ethics and consent to participate

Based on the Hungarian Health Care Act (Act CLIV of 1997), Decree no. 23/2002 of the Ministry of Health, and Governmental Decree no. 235/2009, the non-interventional study was evaluated by the Hungarian Medical Research Council, as the official National Ethics Committee. All relevant documents (questionnaires, patient information sheets) together with the detailed study protocol were evaluated by the council. Based on the council's decision, the study received the permission and a registration number (24950-3/2016/EKU). The authors stated that the research work was conducted in accordance with the Declaration of Helsinki.

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