Cross Cultural Adaptation and Validation of Hindi Version of WHOQOL-BREF in Patients With Chronic Low Back Pain

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Abstract

Aim of the study was to validate Hindi version of WHOQOL-BREF in chronic low back pain patients (CLBP). In this cross-sectional study, 111 patients with CLBP were recruited. In addition to demographic information, two questionnaires Hi WHOQOL-BREF and SF-36 (Reference scale) were administered at day 0 and day 3. NRS was used for pain evaluation. Cronbach's alpha coefficient was used for scale reliability. Construct validity was analysed using Pearson correlation coefficient. Confirmatory factor analysis was performed to determine the relationships between the eight domains of SF-36 and four domains of the WHOQOL-BREF.

Cronbach's alpha coefficients were acceptable for all domains of both Hi WHOQOL-BREF (0.869 - 0.938) and SF-36 (0.752 - 0.943) questionnaires. Pearson correlation coefficients of both instruments were partly to strongly correlate with most domains (r \geq 0.40). Correlations for domains with similar constructs were stronger than those measuring varied constructs. Confirmatory factor analysis recommended approximately good relationships among the SF-36 and WHOQOL-BREF domains. Our study suggests that WHOQOL-BREF Hindi version is a reliable and valid tool for clinical and research use in CLBP.

Introduction

Low back pain is a common health problem worldwide with considerable impact on financial and socioeconomic status. It is the most common cause of absenteeism and job-related disability. Disease remains as one of the top two contributors of global disability for over two decades with a total cost of around billions of dollars annually. In India, nearly 60% of people suffer from low back pain in their life at some point or another.

Chronic pain impacts multiple life domains such as physical and mental wellbeing, social relationship and functional ability thus impacting the quality of life (QOL). Assessing this health related quality of life (HRQoL) can provide an estimate of how the disease influences people's lives and how people manage to live with chronic back pain. Several questionnaires are available for assessing QoL. These questionnaires help define patient's disability and impairment, degree of change of condition over time and the appropriate choice of therapy. World Health Organization QOL-BREF (WHOQOL-BREF) questionnaire is one of the best known instruments that has been developed for cross-cultural comparisons of QoL and is available in more than 40 languages making between countries comparison feasible. Questionnaire has been extensively used to assess QoL in various conditions including bronchial asthma, visceral leshmaniasis, mental illness and many more.

Hindi is a widely used language in the second most populous country in the world i.e. India. WHO BRIEF questionnaire is short and is easy to use in busy outpatient departments of developing countries. A generic Hindi version has been developed in India as a part of multi country initiative by WHO. Though the questionnaire appears suited for Hindi population, the Hindi version has not been tested for construct in patients with chronic low back pain (CLBP). Thus, aim of this study was to perform a cross cultural
adaptation and validation of Hindi (Hi) version of WHOQOL-BREF health questionnaire in patients with CLBP.

Methodology

Procedure

Initial permission was sought from Dolores Campanario World Health Organization (Permissions Management, Reprint Rights and Licensing) to reproduce, reprint and/or re-translate WHOQOL-BREF Hindi version cross-culturally and validate it for use in CLBP patients. The study was approved by the Institute Ethics Committee, PGIMER, Chandigarh, India (INT/IEC/2021/SPL-403 dated 12th March, 2021) and registered with Central trial registry India vide no CTRI/2021/04/033034. Written informed consent was obtained from all participants before participating in the study. All methods were performed in accordance with the relevant guidelines and regulations.

Patients of either gender with CLBP duration of >3 months, aged 18-65 years who were able to read and speak native Hindi language, attending Pain Clinic in the Department of Anaesthesia, PGIMER, Chandigarh were recruited in the present study. Patients with any other pain conditions, chronic disorders, or the presence of “red flags” were excluded from the study.

Phases of the Study

The present study was performed in two phases: (a) cognitive debriefing of Hi-WHOQOL-BREF (b) cross-cultural validation of the resulting adapted Hi-WHOQOL-BREF

Cognitive debriefing

In order to assess the comprehensibility of the Hindi version provided by WHO, cognitive debriefing, a method to test and validate a questionnaire, was administered to 10 CLBP patients of either gender as per study inclusion criteria. Along with completing the Hi-WHOQOL-BREF, all the patients described understanding of the items of the scale in their own verbatim. They were also asked to suggest alternate words for the words that they found difficult to understand. The responses were summarized, including the suggestions indicated by the participants.

Cross-Cultural Validation

All the recruited patients completed the Hi-WHOQOL-BREF together with socio-demographic information and other reference scales (36-Item Short Form Survey: SF-36 and Numeric Rating Scale: NRS). To assess test-retest reliability, the Hi-WHOQOL-BREF was re-administered to these patients 3 days after they completed the baseline questionnaire. E-version (Google forms) of both questionnaires were shared with the patients on Day 3 via WhatsApp. This was done to avoid unnecessary visit of patients to outpatient department during COVID pandemic and this was a suitable alternative to the paper version as well.11 (Figure 1)
Instruments

Numeric Rating Scale (NRS)

Pain severity was assessed using a 0 to 100 NRS. In the survey, patients were asked, “On a scale from 0 to 100, mark/tell your level of CLBP, with 0 being none and 100 being unbearable.”

SF-36 (36-Item Short Form Survey)

It is a multicultural scale consisting of 36 questions and categorized into eight-domain profile of scores: physical functioning (PF; 10 items), general health (GH; 5 items), role physical (i.e., role limitations due to the physical health problems, RP; 4 items), bodily pain (BP; 2 items), social functioning (SF; 2 items), vitality (VT; 4 items), role emotional (i.e., role limitations due to emotional problems, RE; 3 items), and mental health (MH; 5 items). For each domain, a score ranging from 0 to 100 was assessed with a higher score indicating better health. Scoring was done using PRO-CoRE scoring software provided by QualityMetric Incorporated, LLC. Score were represented both as individual components as well as two final domains: PCS (physical component score) and MCS (mental component score). Higher the score better the QOL. Considerable evidence has been found for the reliability of the SF-36 (Cronbach's alpha greater than 0.85, reliability coefficient greater than 0.75 and for construct validity in terms of distinguishing between groups with expected health differences.

World Health Organization QOL-BREF (WHOQOL-BREF)

The questionnaire contains two items from the overall QOL and GH and 24 items of patient satisfaction that are divided into four domains: Physical health with 7 items (Domain 1), psychological health with 6 items (Domain 2), social relationships with 3 items (Domain 3) and environmental health with 8 items (Domain 4). Each item is rated on a 5-point Likert scale. Raw domain scores were transformed to a 0-100 score according to WHO guidelines.

Sample size calculation

According to HinkinTR, the sample size required to perform exploratory factor analysis is a sample size to number of items ratio of no lower than 4:1. As Hi-Hi-WHOQOL-BREF has 26 items (26*4=104), minimum of 104 patients were required. Assuming an attrition of about 5%, 111 cases were enrolled.

STATISTICAL ANALYSIS

The statistical analysis was carried out using IBM SPSS (Statistical Package for Social Sciences) statistical version 20. All quantitative variables were estimated using measures of central location (mean) and measures of dispersion (standard deviation). Normality of data was checked by Skewness and Kurtosis. For normally distributed data, mean were compared for follow-up using the paired t-test. Internal consistency of the domains was assessed by using Cronbach's alpha coefficient for the entire scale, each construct and each factor. A value of >0.70 was considered sufficient. Test re-test reliability was assessed using Intra-class correlation coefficient [ICC]. To evaluate the convergence and discriminant
validity, correlations among the SF-36 and the Hi-WHOQOL-BREF were examined applying Pearson correlation coefficient. It was hypothesized that those domains that are conceptually related would be more strongly correlated, but those domains in the two instruments with less in common would demonstrate weaker correlations. Therefore, we assumed moderate to high correlations (Pearson correlation coefficient significant at two-tailed level of significance \( p \leq 0.01 \) and \( p \leq 0.05 \)) between all domains of the Hi-WHOQOL-BREF and all domains of the SF-36. Confirmatory factor analysis (CFA) was done to examine the relationships between the eight domains of SF-36 and four domains of Hi-WHOQOL-BREF. Extent to which variance in each domain was explained by other domains in both instruments was tested. We used the goodness-of-fit index (GFI), incremental fit index (IFI), the comparative fit index (CFI), the Tucker–Lewis Index (TLI) and the root-mean-square error of approximation (RMSEA) in order to assess model fit. P<0.05 was considered as statistically significant.

Results

Results of cognitive debriefing were reviewed by one of the investigators (RS). No item caused difficulties in comprehension for more than three participants. Hence, no modifications were suggested and the final translated original Hi-WHOQOL-BREF was locked down and entered for the cross-cultural validation phase in CLBP patients. These 10 patients were not enrolled in the final sample.

Demographic Data

The mean age of participants was 40.71±12.92 years. 57(51.4%) patients were males and 54(48.6%) were females, Majority were married 92(82.9%). The mean (SD) duration of back pain is 25(33) months. The average weight of patients was 65 (10) kg. (Table-1) Score distribution of all subscales of SF-36 and Hi-WHOQOL-BREF are presented in Table 2.

Reliability

a) Internal Consistency

Internal consistency of the clinical measure of Hi-WHOQOL-BREF was assessed for total and sub-scales by using Cronbach’s-\( \alpha \). Value obtained in the study ranged between 0.753 to 0.971 for items (Table 3) and 0.869 - 0.938 for domains (Table 2) for Hi-WHOQOL-BREF. Value obtained for SF-36 ranged between 0.752 - 0.943 for domains. (Table 2) The results show good internal coherence between these specific items within each domain in population studied.

b) Test–Retest Reliability between Baseline and Day 3

All the patients screened at baseline were re-administered the Hi-WHOQOL-BREF after 3 days. ICC was calculated from the data of patients who responded for both observations. Retest was successfully administered after three days in 93.6% patients. Seven patients did not respond at day 3. Any patient responding thereafter was not included. Test re-test was found to be good for all four components of Hi-WHOQOL-BREF (ICC 0.768 - 0.883) (Table 2). Significant difference between Day 0 and Day 3 was
observed only in two items; item-15 of domain 1 (PH) with p-value of .000 and item 5 of domain 2 (PS) with p-value of .023. All other items were comparable. Item wise description of Hi-WHOQOL-BREF ICC is presented in Table-3.

c) Bland-Altman Plot

A scatter plot was created for total baseline and total retest scores for all above mentioned scales and plotted against difference of two set of scores. The plots for Hi-WHOQOL-BREF showed good test retest reliability. (Figure 2)

Construct validity

Statistically significant positive correlation was found between all conceptually expected domains of Hi-WHOQOL-BREF and SF-36. Domains assessing similar constructs were moderately to highly correlated (r=0.40–0.60), while domains assessing varied constructs were weakly correlated (r < 0.40). Correlation values ranged from 0.206 to 0.599 on day 0. For example, maximum correlation was found between domain 2 (PS) and vitality (VT), minimum correlation was found between domain 2 (PS) and physical functioning (PF). Correlation values range from 0.257 to 0.702 on day 3 with maximum correlation between domain 1 (PH) and general health (GH) and minimum between domain 4 (EH) and physical functioning (PF). Domains in the SF-36 and Hi-WHOQOL-BREF that did not match to one another were similarly associated. No statistically significant correlation was seen on day 0 for SH with PF and RE components of SF-36. (0.120 and 0.009 respectively), EH with PF and RE components of SF-36. (0.169 and 0.108 respectively). On day 3 no statistically significant correlation was seen for SH and EH with RE components of SF-36. (0.155 and 0.176 respectively) (Table-4)

Relations among Domains of both SF-36 and Hi-WHOQOL-BREF

The eight domains of SF-36 and four domains of Hi-WHOQOL-BREF were also subjected to the CFA to test the fitness of a model. This model fits the relationships among all domains of the SF-36 and Hi-WHOQOL-BREF. Covariance matrixes were applied and fit indexes were calculated. The relative chi-square (χ2) for models 1, 2, and 3 was equal to 1.535, 0.882, 1.25 respectively, and showing the goodness of fit for the model 2 (P<0.05). The RMSEA of all models were presenting good fit. Additionally, the RMSEA for models 2 was 0.0001. All comparative indices of the 3-model including GFI, CFI, IFI, and TLI were more than 0.90 (0.947, 0.975, 0.976 and 0.959 for model 1, 0.996, 1, 1.001 and 1.004 for model 2, and 0.913, 0.981, 0.981 and 0.974 for model 3, respectively) of which fall in the acceptable range. The results obtained from the CFA are shown in Figures 3 and Table 5. Comparing all three figures showed that weights of subscales were not statistically different with weights in separate models except role emotion (RE) component of SF-36 (p-value 0.01).
Table 1
Baseline characteristics of patients with CLBP (N=111)

| Age (years) Mean(SD) | 40.71±12.92 |
|----------------------|-------------|
| Gender M:F n(%)      | 57:54 (51.4/48.6%) |
| Marital status Married: Unmarried n(%) | 92:19 (82.9/17.1%) |
| Duration of back pain (months) Mean(SD) | 25(33) |
| Weight (Kg) Mean(SD)  | 65(10) |
| BMI (Kg/m^2) Mean(SD) | 25(3) |
| NRS Mean (SD)*       | 63(22) |
| Day 0                | 61(23) |
| Day 3                |            |
Table 2
Domain wise mean comparison of baseline and day 3 observations of Hi-WHOQOL-BREF, SF-36 and NRS

| Domains | Observations | Mean(SD) | Skewness | Kurtosis | T-Value | p-Value | α Value | ICC |
|---------|--------------|----------|----------|----------|----------|---------|---------|-----|
|         |              |          |          |          |          |         |         |     |
| Hi-WHOQOL-BREF |              |          |          |          |          |         |         |     |
| PH      | Day 0        | 38.69(18.13) | .000     | -.727    | 1.713    | .090    | .933    | .874 |
|         | Day 3        | 40.23(18.37) | -.251    | -.345    |          |         |         |     |
| PS      | Day 0        | 48.22(17.70) | .055     | -.699    | -549     | .584    | .938    | .882 |
|         | Day 3        | 48.67(17.00) | .174     | -.447    |          |         |         |     |
| SR      | Day 0        | 59.28(19.05) | -.509    | .653     | .569     | .570    | .869    | .768 |
|         | Day 3        | 58.56(18.85) | -.393    | .922     |          |         |         |     |
| EH      | Day 0        | 51.62(18.72) | -.191    | -.471    | .123     | .902    | .918    | .848 |
|         | Day 3        | 51.75(18.83) | -.389    | -.132    |          |         |         |     |
| SF-36   |              |          |          |          |          |         |         |     |
| PF      | Day 0        | 38.00(9.11)  | .061     | -.801    | 1.496    | .144    | .882    | .790 |
|         | Day 3        | 36.57(9.80)  | -.082    | -.950    |          |         |         |     |
| RP      | Day 0        | 34.80(7.16)  | .169     | -.449    | .229     | .819    | .877    | .781 |
|         | Day 3        | 34.80(7.37)  | .040     | -.484    |          |         |         |     |
| BP      | Day 0        | 33.97(7.57)  | .604     | -.654    | 1.391    | .167    | .860    | .755 |
|         | Day 3        | 34.68(8.79)  | 632      | -.143    |          |         |         |     |
| GH      | Day 0        | 39.81(7.79)  | .373     | -.026    | .086     | .931    | .863    | .758 |
|         | Day 3        | 39.87(8.70)  | .028     | .007     |          |         |         |     |
| VT      | Day 0        | 39.23(10.87) | .535     | -.322    | 1.457    | .148    | .943    | .891 |
|         | Day 3        | 39.71(11.14) | .377     | -.652    |          |         |         |     |
| SF      | Day 0        | 37.28(10.29) | .303     | -.898    | 1.556    | .123    | .855    | .747 |
|         | Day 3        | 36.03(11.76) | .146     | -.994    |          |         |         |     |
| RE      | Day 0        | 36.11(8.49)  | .516     | -.269    | 1.732    | .092    | .752    | .690 |
|         | Day 3        | 34.92(9.58)  | .059     | -.570    |          |         |         |     |
| MH      | Day 0        | 39.18(10.20) | .269     | -.624    | .538     | .592    | .863    | .759 |
|         | Day 3        | 38.56(11.29) | -.023    | -.275    |          |         |         |     |
| Domains | Observations | Mean(SD)       | Skewness | Kurtosis | T-Value | p-Value | α Value | ICC  |
|---------|--------------|----------------|----------|----------|---------|---------|---------|------|
| PCS     | Day 0        | 36.96(7.28)    | .046     | -.686    | .627    | .532    | .931    | .871 |
|         | Day 3        | 37.20(7.75)    | -.121    | -.605    | .627    | .532    | .931    | .871 |
| MCS     | Day 0        | 37.97(10.44)   | .536     | -.502    | .919    | .360    | .898    | .815 |
|         | Day 3        | 37.41(10.12)   | .241     | -.203    | .919    | .360    | .898    | .815 |
| NRS     | Day 0        | 63.38(21.89)   | .009     | -.988    | 1.140   | .257    | .870    | .770 |
|         | Day 3        | 61.67(23.19)   | -.081    | -.709    | 1.140   | .257    | .870    | .770 |
Table 3
Item wise scores of patients with chronic low back on Hi-WHOQOL-BREF

| Item No. | Day 0 Mean (SD) | Day3 Mean (SD) | p-Value | α-value | ICC  |
|----------|-----------------|----------------|---------|---------|------|
|          | α-value | ICC  |          |         |      |
| PH       |        |      |          |         |      |
| Item 3   | 2.10 (0.58) | 2.14 (0.65) | .396    | .843    | .729 |
| Item 4   | 2.72 (1.02) | 2.71 (1.04) | .863    | .920    | .852 |
| Item 10  | 2.39 (1.10) | 2.43 (1.11) | .608    | .867    | .765 |
| Item 15  | 2.45 (1.01) | 2.69 (1.08) | .000    | .918    | .849 |
| Item 16  | 2.82 (1.10) | 2.88 (1.12) | .408    | .889    | .799 |
| Item 17  | 2.64 (1.06) | 2.74 (0.97) | .213    | .827    | .705 |
| Item 18  | 2.58 (1.00) | 2.59 (0.97) | .894    | .841    | .725 |
| Domain 1 | 38.69 (18.13)| 40.23 (18.37)| .090    | 0.933   | 0.874|
| PS       |        |      |          |         |      |
| Item 5   | 2.42 (1.03) | 2.57 (1.10) | .023    | .888    | .799 |
| Item 6   | 2.59 (0.95) | 2.63 (0.91) | .519    | .882    | .789 |
| Item 7   | 2.65 (0.98) | 2.57 (0.95) | .184    | .899    | .817 |
| Item 11  | 3.20 (1.41) | 3.20 (1.38) | 1.000   | .903    | .823 |
| Item 19  | 2.78 (1.01) | 2.80 (1.02) | .783    | .861    | .757 |
| Item 26  | 3.88 (.62) | 3.86 (.62) | .726    | .753    | .604 |
| Domain 2 | 48.22 (17.70)| 48.67 (17.00)| .584    | 0.938   | 0.883|
| SR       |        |      |          |         |      |
| Item 20  | 3.25 (0.95) | 3.29 (0.96) | .574    | .849    | .737 |
| Item 21  | 3.37 (0.94) | 3.34 (0.93) | .614    | .891    | .804 |
| Item 22  | 3.44 (0.94) | 3.34 (0.97) | .183    | .830    | .709 |
| Domain 3 | 59.28 (19.05) | 58.56 (18.85) | .570 | 0.869 | 0.768 |
| EH       |        |      |          |         |      |
| Item 8   | 2.77 (1.06) | 2.83 (1.06) | .389    | .887    | .796 |
| Item 9   | 3.01 (0.92) | 3.05 (0.93) | .540    | .866    | .764 |
| Item 12  | 2.57 (1.03) | 2.66 (1.02) | .243    | .846    | .734 |
| Item No. | Day 0 Mean (SD) | Day3 Mean (SD) | p-Value | α-value | ICC  |
|---------|----------------|----------------|---------|---------|------|
| Item 13 | 3.01 (1.03)    | 2.98 (1.01)    | .595    | .851    | .741 |
| Item 14 | 2.66 (0.95)    | 2.65 (0.90)    | 1.000   | .779    | .639 |
| Item 23 | 3.51 (1.15)    | 3.51 (1.09)    | 1.000   | .971    | .871 |
| Item 24 | 3.05 (1.18)    | 3.01 (1.19)    | .589    | .898    | .815 |
| Item 25 | 3.35 (1.16)    | 3.30 (1.14)    | .468    | .907    | .829 |
| Domain 4 | 51.62 (18.72)  | 51.75 (18.83)  | .902    | 0.918   | 0.848 |
Table 4
Correlation between Hi-WHOQOL-BREF and Hi-SF-36 baseline and Day 3

| Day 0 | PCS | MCS | | PCS | MCS |
|-------|-----|-----|-----|-----|-----|
| **PH** | .298** | .395** | .476** | .532** | .570** | .477** | .226* | .442** | .457** | .496** |
| | .002 | .000 | .000 | .000 | .000 | .017 | .000 | .000 | .000 | .000 |
| **PS** | .206* | .348** | .369** | .522** | .599** | .455** | .312** | .522** | .278** | .566** |
| | .030 | .000 | .000 | .000 | .000 | .001 | .000 | .000 | .003 | .000 |
| **SR** | .120 | .226* | .366** | .349** | .442** | .363** | .009 | .372** | .327** | .313** |
| | .211 | .017 | .000 | .000 | .000 | .929 | .000 | .000 | .001 | .000 |
| **EH** | .169 | .215* | .358** | .366** | .482** | .328** | .108 | .368** | .300** | .340** |
| | .075 | .023 | .000 | .000 | .000 | .261 | .000 | .001 | .000 | .000 |
| **PH** | .395** | .522** | .525** | .702** | .638** | .662** | .340** | .445** | .582** | .558** |
| | .000 | .000 | .000 | .000 | .000 | .000 | .000 | .000 | .000 | .000 |
| **PS** | .359** | .439** | .396** | .589** | .647** | .615** | .281** | .635** | .404** | .657** |
| | .000 | .000 | .000 | .000 | .000 | .000 | .004 | .000 | .000 | .000 |
| **SR** | .279** | .329** | .323** | .280** | .370** | .354** | .155 | .381** | .309** | .361** |
| | .004 | .001 | .001 | .004 | .000 | .000 | .117 | .000 | .001 | .000 |
| **EH** | .257** | .394** | .340** | .463** | .509** | .470** | .176 | .485** | .344** | .494** |
| | .008 | .000 | .000 | .000 | .000 | .074 | .000 | .000 | .000 | .000 |

Table 5 Three used models and the fitness of models
| Measure       | Model-I | Model-II | Model-III |
|--------------|---------|----------|-----------|
| DF           | 17      | 1        | 49        |
| Chi-Square   | 1.535   | 0.882    | 1.25      |
| GFI          | 0.947   | 0.996    | 0.913     |
| CFI          | 0.975   | 1        | 0.981     |
| IFI          | 0.976   | 1.001    | 0.981     |
| TLI          | 0.959   | 1.004    | 0.974     |
| RMSEA        | 0.07    | 0.0001   | 0.048     |

**Discussion**

We in this study aimed to evaluate internal consistency of transculturally adapted WHOQOL-BREF questionnaire in patients with CLBP. Results of our study suggest that Hi-WHOQOL-BREF is reliable and valid tool for assessing QOL in Hindi speaking patients with CLBP. Hi-WHOQOL-BREF in our study showed excellent internal consistency. (Cronbach-α 0.869 - 0.938) The test retest reliability was good (ICC 0.768-0.883). Maximum positive correlation was found between domain 2 (PS) of and vitality (VT) of SF-36. Confirmatory factor analysis showed that approximately all three models were fitted well and similarly.

The WHOQOL-100 allows detailed assessment of each individual facet relating to QOL. In certain instances however, the WHOQOL-100 may be too lengthy for practical use. The WHOQOL-BREF Field Trial Version has therefore been developed to provide a short form of QOL assessment questionnaire that looks at domain level profiles. WHOQOL-BREF has been widely translated and validated in several languages and in many chronic disorders. Hindi version used in the present study was obtained from WHO organisation online.

Previous literature suggests that Hindi version of the questionnaire possess good internal consistency with high Cronbach alpha range in different settings. Hi-WHOQOL-BREF in our study showed excellent internal consistency with cronbach's-α reaching 0.869 and 0.938 in patients of CLBP. This is more than all other versions validated for respective populations in other languages: Krio 0.55-0.72, Amharic >0.7, Kazakh 0.7-0.78, Chichewa >0.7, Libras 0.6-0.873, Odia 0.65-0.7, and Malayalam 0.28-0.48.

Lower internal consistency was found in social domain. This can be attributed to the small number of questions (3 items) in social relationships domain. Further, domain enquires into the sexual life and social support which are perceived and answered in a different way in Indian society. This domain showed similar results in validation studies in different countries.

The correlation between the SF-36 and Hi-WHOQOL-BREF has been examined previously in different fields with contradictory results. While some studies have shown strong correlation between both questionnaires, others have reported weak correlation. This suggests that the reliability and validity of
these two questionnaires for the evaluation of QoL may be different. In a national survey on 11,440 civilian residents of Taiwan, Huang et al indicated that the correlations were weak among the subscales of both instruments and concluded that both SF-36 and WHOQOL-BREF appeared to measure different constructs.27 Another study by Hsiung et al on patients with HIV infection reported that both the questionnaires were reliable and valid health-related QoL instruments.28 Our study found good construct validity of WHOQOL-BREF in patients with CLBP. (Pearson coefficient 0.206 - 0.702).

93.6% patients completed the questionnaires on day 3 indicating good acceptability. There was no confusion in reporting of any of the domains. The scale was easily understandable and acceptable, and could be completed by patients in about 8 (1.4) minutes. This confirms that the meaning of the original items was not changed during translation done by WHO.

In our study there was a significant difference in response to item 15 of physical health (p-value 0.000) “Aap kitni achi tarah idhar udhar aa ja pate hain” (How well are you able to get around?) and item 5 of psychological domain (p value 0.023) “Aap jeevan mai kitna aanand lete hain” (How much do you enjoy life?) between day 0 and day 3. CLBP is a dynamic state and variation in mobility is dependent on pain. This might have led to variation in response creating a bias in reporting of this question. Overall state of the person, especially when in pain can be a confounding factor while filling the questionnaire.

CFA done in our study showed that the proposed model 2 captured the covariance between all the items in the model 1. WHOQOL-BREF is an acceptable model as seen by the absolute indices, where RMSEA value of .06 or less and GFI value of over .9 is indicative of acceptable model fit. The relative fit indices (also called “incremental fit indices” and “comparative fit indices” too ensured that misspecified models are deemed acceptable by achieving a value greater than .90.

Though there are many published QOL measures, there is still a lack of consensus amongst researchers about its definition as seen in the choice of items for their instruments while assessing QOL. SF-36 is a sufficient measure of health status and functioning of patients with LBP29 and hence we decided to use it as a reference scale. However, it is a more objective questionnaire when compared to WHOQOL-BREF and requires more time to fill. On the other hand, WHOQOL-BREF is a completely subjective questionnaire.

WHO-QOL assessment scale is a valuable tool for patients with CLBP where prognosis is likely to involve only partial recovery or remission. Countries where no validated QoL measures currently exist can be confident that data yielded by work involving the WHOQOL assessments will be genuinely sensitive to their setting. This study shall make multi-centre QoL research possible and comparable.

One of the advantages of this study is the use of a sample from one of the largest government hospitals in North India for the validation of the Hindi version of a patient satisfaction questionnaire. This sample may overcome any cultural and environmental factors that could lead to differences in the instrument’s ability to measure an object of interest. The high response rate to the questionnaire can be explained by its design, which takes into consideration the deficiencies observed in other questionnaires, such as a
large number of questions, including all the activities performed in daily living of a common person, which may discourage participants from completing the questionnaire.

STUDY LIMITATIONS

The present study has certain limitations. Even though explained, an intention to aggravate one's condition for the above reason and thus creating a test retest reliability bias cannot be ruled out. Also, investigators did not undergo any formal training to conduct cognitive debriefing. Another limitation was the short test–retest time interval (3 days). This was selected assuming no change in disease state within such a short span of time. However, the chance of the memory effect for an observed effect of good test–retest reliability cannot be ruled out. Finally, the generalizability of the Hi-WHOQOL-BREF to other musculoskeletal disorders apart from CLBP cannot be assured from the results of the present study.

Conclusion

Hi-WHOQOL-BREF showed good internal consistency with a statistically significant component analysis of CLBP patients with Hindi version of SF-36 indicating desirable construct validity. Correlation matrix showed satisfactory results in all related domains. Thus making it well suited questionnaire for Hindi speaking patients. To conclude the item and scale level analyses supports the validity and reliability of the translated and adapted version of Hi-WHOQOL-BREF for use in India in patients with CLBP.

Declarations

Conflict of Interest: None

Acknowledgement- None

Authors' contributions:

JKM: Study design, literature search, data collection, manuscript writing, and critical revision.

AG: Literature search, data collection, data analysis, data interpretation, manuscript writing, and critical revision.

RS: Data analysis, data interpretation, and critical revision.

VK: Data collection, and critical revision.

BG: Literature search, data interpretation, and critical revision.

SP: Data interpretation, and critical revision.
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**Figures**
Figure 1

Consort

Figure-1: Consort

Total no. of patients screened (n: 135)

Excluded: 24
Not meeting inclusion criteria: 15
Consent not given: 9

Cases enrolled (n: 111)

Loss to follow up (n: 7)

Analysis
(n: 104)
Figure 2: Test-retest reliability of the Hindi version of the Hi-WHOQOL-BREF as shown by Bland-Altman plot.

a) Domain 1
b) Domain 2
c) Domain 3
d) Domain 4

Test-retest reliability of the Hindi version of the Hi-WHOQOL-BREF as shown by Bland-Altman plot.

Average of test and retest scores of Hi-WHOQOL-BREF is plotted against the difference of these two scores. Note: Continuous horizontal centre line is of mean difference and the line above and below represent limits of agreement (the mean difference ± 1.96 times the SD of the differences).
A) Model 1: CFA for the eight domains of the SF-36.

B) Model 2: CFA for the four domains of the Hi-WHOQOL-BREF (n =104)

C) Model 3: CFA for the eight domains of the SF-36 in correlation to four domains of the WHOQOL-BREF (n =104)

Abbreviations: SF-36, Short Form 36 Health Survey; WHOQOL-BREF, World Health Organization Quality of Life Scale Brief Version; PF, Physical Functioning; GH, General Health; RP, Role Physical; BP, Bodily Pain; SF, Social Functioning; VT, Vitality; RE, Role Emotional; MH, Mental Health; PH, Physical Health; PS, Psychological well-being; SR, Social Relationships; EH, Environment Health.