A Study on Health Utility Mapping Model of the Generalized Quality of Life Measurement Scale with Chinese Medicine Characteristics

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Abstract

Background and Objective: The lack of traditional Chinese medicine (TCM)-related health utility measurement tools has hindered the expansion and research of TCM in China. The Chinese Health Status (CHS) scale, a general health status assessment scale developed in conjunction with the TCM theory, finds wide applications in clinical practice; however, it cannot be directly used to measure the patient's health state because it lacks a utility score system. Here, we developed a utility mapping model of the CHS Scale, based on the Chinese cultural background as well as the theory and connotation of TCM, to obtain the health utility values. This study provides a methodological basis for future research on the pharmacoeconomics of Chinese medicine using cost-utility analysis.

Methods:Based on real data from medical institutions in Hunan, alternative mapping models from the CHS scale to the EQ-5D-3L were constructed using ordinary least squares, Tobit models, generalised linear models and quantile regression methods, and the mapping model with the best explanatory and predictive power was selected for further analysis.

Results: The 1200 cases included in this study were randomly divided into the construction set and the validation set based on their size. In the construction set, 24 alternative models were constructed using four econometric methods and six model types. In the validation set, these 24 alternative models were evaluated using the following evaluation indexes: model fit superiority, mean absolute error, and root mean square error. The highest prediction accuracy was found for regression fitting with ordinary least squares and model 6. Spearman rank correlation test showed that the observed and predicted values in the high correlation, with indicators MAE = 0.0590, RMSE = 0.1045, ME = 4.64e-09, AE > 0.05 (37.83%), and AE > 0.1 (17.33%) were within the acceptable range and at a better level.

Conclusions: The final mapping model predicted the utility values and were compared them with the observed values. The distributions were found to be similar, and the observed values were highly correlated with the predicted values in the medium. The fit was significantly accurate, acceptable and could be applied to the pharmacoeconomic evaluation of TCM in the future to obtain the health utility values of patients through the CHS mapping scale.

Contributions To The Literature

To better clarify the clinical value of TCM and the economic and social benefits it brings, and to bring into play the important role of pharmacoeconomic evaluation evidence of TCM in pharmaceutical and health decision-making, it becomes necessary and urgent to improve the pharmacoeconomic evaluation system of TCM.

There is currently no authoritative or widely accepted universal quality of life measurement scale in China based on the preferences of the Chinese population with Chinese medicine characteristics.

This study investigates the construction of a Chinese TCM health utility scale based on Chinese population preferences to facilitate pharmacoeconomic evaluation studies of TCM.

1. Introduction

The European five-dimensional three-level (EQ-5D-3L), and six-dimensional health measurement scales, which were developed based on the modern Western medical theory, cannot accurately reflect the theoretical characteristics and advantages of the holistic view of the traditional Chinese medicine (TCM)-based treatment. The existing quality of life (QoL) measurement scales constructed based on the TCM theory, such as the Chinese Quality of Survival Scale [1], the TCM Quality of Survival Self-Assessment Scale [2], and the Chinese Health Status (CHS) Scale [3], are nonpreference-based developed scales that cannot construct a utility score system to measure the health utility values. Thus, there is a lack of TCM-specific health utility measurement tools. In this study, we used the CHS Scale [3], which has been developed based on the theory and connotation of TCM. It is widely used in clinical practice and can effectively measure the efficacy of TCM and reflect the health status of respondents of TCM. It uses econometric methods to construct alternative mapping models between the CHS Scale and the generic utility scale EQ-5D-3L. Then, it evaluates the constructed alternative models based on the various indicators of prediction accuracy to identify the best alternative model type. Finally, the final mapping model is constructed based on the best model type, and the validity of this final mapping model is evaluated. Based on the final mapping model, the health utility values could be obtained using the CHS Scale, which provides methodological guidance for the pharmacoeconomic evaluation of TCM, as well as helps in the development and improvement of health utility measurement tools for TCM analysis.

2. Data Sources And Research Methods

The data information collected in this study was real-world data. The data were collected between August 2020 and March 2021, and the collection sites were the Department of Traditional Chinese Medicine, Xiangya Second Hospital of Central South University, and the First Hospital of Hunan University of Traditional Chinese Medicine. The survey methods were face-to-face and online web surveys, where the investigators first explained the purpose of the survey to the respondents in person or online and then conducted the survey through conversation, questionnaire filling, and email.

2.1 Data Collection Subjects

We collected information and data from study subjects who met the following inclusion and exclusion criteria for data study analysis.

Inclusion criteria: (1) age ≥ 18 years; (2) Chinese nationals; (3 living in mainland China for the past 5 years; (4) normal mental status, no cognitive impairment, or mental disorders, no serious hearing or vision problems; (5) could independently read the questionnaire, use WeChat, use Chinese for normal communication, and express their opinions clearly; (6) understood the purpose of the study and agreed to cooperate with the survey. Exclusion criteria: (1) did not meet the inclusion criteria; (2) did not understand the task of the questionnaire; (3) could not provide correct health information, such as those who graded severe health status as lower than the mild status; (4) patients treated with a combination of Chinese and Western medicine.

2.2 Data collection content

The data collection in this study was conducted by administering questionnaires to study subjects who met the criteria (**Appendix 1 of the Supplementary Material for sample questionnaires**) using the following three main components: (1) a questionnaire on basic patient information; (2) the CHS Scale, a universal measurement scale developed by combining Chinese culture and TCM theory, which reflects both Chinese cultural characteristics and TCM health connotations and effectively measures the efficacy of TCM and assess the health status of the respondents from the perspective of TCM [3]; (3) the EQ-5D-3L [4], a highly standardized set of measurement scales, pioneered by the European QoL Group, with the three-level scale as the initial development version. It is now widely used for the measurement of health utility in health care. The scale includes a multidimensional health state measurement system and a VisualAnalogue Scale (VAS). This study used the 2014 version of the Chinese utility point system (**Supplementary Material Spreadsheet 1 for a detailed table of the point system**), which better fits the health preference profile of the Chinese population, enabling the calculation of accurate health utility values.

3. Mapping Model Types And Selection Methods

3.1 Econometric methods

Ordinary Least Squares (OLS), truncated regression model (Tobit model), generalized linear model (GLM), and quantile regression (QR) were used to study the economic methods.

3.2 Model Type

In the regression model of this study, the dependent variable Y was the health utility value measured by the EQ-5D-3L scale, and the independent variable represented the data of the CHS Scale, while the demographic information, health behavior information, and health status information were considered as the covariates. The more comprehensive and detailed was the basic information of patients included in the model, the more robust was the model obtained from the regression, and the more accurate were the prediction results. However, in this study, only seven indicators (gender, age, smoking status, alcohol consumption, exercise status, diet control status, and BMI) were selected as covariates to obtain more generalized results. There were six alternative model types for this study (**Appendix 2 in the Supplementary Material**).

3.3. Selection of the optimal model

3.3.1 Steps for selecting the optimal model

First, the total sample was divided into two sub-sample sets based on two-thirds and one-third of the total sample capacity, which were used as the construction set and the validation set, respectively. The construction set was used to construct the alternative regression models with different model types using the different econometric methods mentioned above. The validation set was used to construct the alternative regression models to predict the corresponding utility values. Then the alternative models were evaluated based on various indicators to select the best mapping model type. Finally, based on the total sample, the best mapping model was used to solve the values of the respective variable coefficients of the final mapping model.

3.3.2 Validation of alternative models and selection of indicators

The alternative models were selected based on two indicators: fitting ability and predictive ability.

3.3.3 Final mapping model determination and effectiveness evaluation

The alternative models were evaluated and screened according to the above steps, and the regression model and regression method with the best predictive ability were selected. The respective variable coefficients were obtained by using the total sample set, and this regression equation was the final mapping model. The effectiveness of the model was evaluated based on the following three points: (1) the difference between the observed and the predicted values. The main evaluation was the distribution of the observed values and the predicted values of the model; (2) correlation between the observed values and the predicted values; (3) the accuracy of the model prediction. Thus, mainly the distribution of prediction error, positive and negative situations, and prediction accuracy index were evaluated. The accuracy index referred to the above prediction ability index, i.e., the sample size ratio of mean absolute error (MAE), root mean square error (RMSE), and absolute error (AE) > 0.05 and sample size ratio of 0.10.

4. Results

4.1 The research subjects

Based on the data sources and the purpose of this study, the finalized total sample size for this study was 1200 cases. **Supplementary Material Spreadsheet 2-4 provide** information on the overall demographic characteristics, health behavior characteristics, and related health status of the study population.

4.2 CHS Scale measurement results

The theoretical structure of the CHS Scale consists of nine aspects: energy, pain, diet, stool, urine, sleep, body mass, emotion, and health evaluation. The CHS Scale consists of 33 entries, and each entry contains four levels. Post-analysis, the highest CHS Scale scores of the subjects in this study was 19.43 with a mean (standard deviation) of 2.72 (0.12) (**Supplementary Material Spreadsheet 5-6**).

4.3 EQ-5D Measurement Results

4.3.1 Distribution of health status levels in each dimension of EQ-5D

We found that 8.2%, 5.5%, 8%, 19.7%, and 16.7% of the 1200 subjects in this study had problems related to the mobility dimension, self-care dimension, daily activities dimension, pain or discomfort dimension, and anxiety or depression dimension, respectively. Compared to the five dimensions, the highest percentage of problems was in pain/discomfort dimension, followed by anxiety/depression. The highest percentage of all three levels compared to all five dimensions was the no difficulty level, followed by some distress level (**Supplementary Material Spreadsheet 7**). The results showed that the main aspects of the study's overall health status that were problematic were pain/discomfort and anxiety/depression.

4.3.2 EQ-5D health utility value results

We used the Chinese version of the integral system for calculating EQ-5D health utility values, which was jointly designed and developed by our scholars Wu Hongyan and Liu Guoen. Its theoretical range was -0.149 to 1. The maximum and minimum values of EQ-5D health utility values in the total sample of this study were 1 and -0.03, respectively; the mean (standard deviation) was 0.923 (0.158); the median (interquartile) was 1 (0.875, 1) (**Supplementary Material Spreadsheet 8**). When the results of the EQ-5D health utility values were analyzed, the percentage of health utility values such as 1 ranked first, at 67.0%. The next highest distribution of health utility values was in the range of 0.8-1, at 19.8%. The lowest percentage of health utility values less than 0 was 0.2% (**Supplementary Material Spreadsheet 9**).

4.3.3 Sample Diversity Results

The total sample was divided into two subsets, the construction set (Derivation set) and the validation set (Validation set), in a ratio of 2/3 and 1/3. The stratified randomization method was used for creating the subset, and the demographic index (age) was used as the stratification factor to stratify the population according to their age groups in the dataset; each level was randomized in a ratio of 2:1. The final result was 800 cases in the construction set and 400 cases in the validation set, with an overall ratio of 2:1. The relative ratios of men and women in the construction and validation sets were 63% and 55%, respectively. Next, the four-compartment table X^2 test was performed, with the statistic $X^2 = 0.600$, $P > 0.05$, which indicated that there was no statistical difference in the distribution of men and women. The median age of the construction and validation sets were 41 and 43 years, respectively, and the statistic Z= -0.128, $P >$ 0.05, by rank-sum test, can be considered as a balanced age factor for both groups. The median BMI of the construct and validation sets were 22.86 and 23.13, respectively. Based on the rank-sum test, the statistic Z = -0.592, $P > 0.05$, it could be considered that the two groups achieved equilibrium on this factor. Thus, both the construction and validation sets were balanced regarding the gender, age, and BMI factors. In addition, the concentration trends of the total scale scores and EQ-5D health utility values in the construction and validation sets were analyzed and the hypotheses of variance were tested. The results showed that the construction and validation sets were not statistically different between the two groups for these indicators at $P > 0.05$ (**Supplementary Material Spreadsheet 10**). Thus, the construction and validation sets were well representative of the total sample.

4.3.4 Alternative model construction

(1) Construction of the alternative model

Six model types were constructed using the EQ-5D-3L health utility values as the dependent variable (**Appendix 3 of the Supplementary Material**). Five econometric methods, OLS, Tobit, GLM, QR, and CLAD, were used to construct a set of 800 samples, respectively. The regressions were fitted using the constructed set of 800 samples. The **spreadsheet 11 in the Supplementary Materia**l shows the variables involved in the model types and their characteristics.

(2) Alternative model construction results

Regression fits were performed based on the construction set sample using EQ-5D-3L health utility values as the dependent variables of the models. The **Appendix 4 and Spreadsheet 12 in Supplementary Material** show the results of the regression fit. The six models were ranked in descending order of the goodness of fit: model 1 < model 2 < model 3 < model 4 < model 5 < model 6. The model types were ranked in descending order of RMSE: model 6 < model 5 < model 4 < model 3 < model 2 < model 1. Therefore, model type 6 was the best in terms of goodness of fit. The Tobit model 6 with a pseudo R^2 = 0.52, > 0.5, indicating that the nine aspect scores and covariates explained more than 50% of the dependent variable health utility value (U). Thus, this model type was used to build the regression equation in this model.

4.3.5 Optimal model type testing and selection

(1) Alternative model prediction results

The 24 alternative models constructed based on the validation set samples were used to predict the EQ-5D-3L utility values using the observed values. The observed values and the predicted values were analyzed as follows: of the 24 models, only six models had the mean values lower than the observed mean values; only two models had the upper quartile values lower than the observed values; only six models had higher median values than the observed median values. . Only five models had lower minimum values than the observed values and seven models had lower maximum values than the observed maximum values. In terms of absolute error (AE), model 4 of the QR method accounted for the least number of cases with AE > 0.05 and AE > 0.1, with 62 cases (31%) and 31 cases(15.5%). The number of cases with AE > 0.05 and AE > 0.1 was the highest in Model 1 of the Tobit method, with 194 (97%) and 175 (87.5%) cases, respectively (**Supplementary Material Spreadsheet 13**).

(2) Comparison of prediction accuracy of alternative models

Among the OLS, Tobit, and QR regression methods, the MAE and RMSE values of model 4, model 5, and model 6 were smaller than those of model 1, model 2, and model 3, i.e., the prediction accuracy of the regression fit using the CHS Scale score as the main effect of the independent variable was higher than that of the model using the CHS Scale total scores as the main effects of the independent variables. The overall MAE was ranked from Tobit < GLM < OLS < QR, with model 4 in the QR method being the best. Model 6 was optimal, and the addition of demographic information (e.g., age, gender, and BMI) or health behavior information (e.g., smoking status, alcohol consumption, etc.) as covariates in each method further reduced the RMSE values and improved the prediction accuracy. The combined MAE metrics and RMSE metrics showed that the prediction accuracy from highest to lowest was as follows: OLS > QR > GLM > Tobit (**Supplementary Material spreadsheet 14**). Thus, the OLS model and model 6 (OLS6) for regression fitting had the highest accuracy, followed by QR and model 6 (QR6) for regression fitting. The final mapping model was constructed based on the total sample data set using the model form of OLS6.

4.3.6 Final mapping model and effectiveness evaluation

(1) Final mapping model construction

First, the OLS method was used to fit the model based on the total sample data set with the main effect of each aspect of the CHS Scale as the independent variable. This is step 3, Finally based on step 3, the independent variables, including age, BMI, gender, smoking status, alcohol consumption, physical exercise status, and diet control status were used as covariates to adjust the model, and this is step 4. The **Supplementary Material Spreadsheet 15** shows the fit of each step.

The results of the regression fitting showed that after adding the squared term in step 2, although the scores of each aspect became less significant, the new squared term was actually significant, and the goodness of fit R^2 increased to 0.4901 (the positive R^2 was 0.4743), and the MAE decreased to 0.0622. After adding the interaction term in step 3, the physical fitness and health evaluation aspects became significant, and the explanatory power of the model further improved, with R^2 and positive R^2 of 0.5603 and 0.5203, respectively, while the MAE decreased to 0.059 again. After adding the covariates of demographic information and health behavior information in step 4, the goodness of fit of the model decreased, with $R^2 = 0.5325$, positive $R^2 = 0.5078$, and MAE value = 0.0617135, which indicated that the addition of covariates did not improve the predictive power and predictive accuracy of the model. Therefore, step 3 was finally identified as the optimal model and used as the final mapping model for the overall sample.

$$EQ-5D-3L = 0.9879 + 0.053 \times EnT - 0.0199 \times PaT + 0.0263 \times DiT + 0.0384 \times StT - 0.0718 \times PiT - 0.0251 \times SlT - 0.106 \times PhT - 0.0215 \times MoT + 0.0437 \times GhT - 0.0759 \times EnT2 - 0.0357 \times PaT2 - 0.0380 \times StT2 + 0.165 \times EnTPhT - 0.0729 EnTGhT - 0.0829 \times DiTGhT - 0.0809 \times StTPhT + 0.1111 \times PhTGht.$$

The regression coefficients of PhT and GhT in the main effects of this regression model were significant, and the *P*-value of PiT was 0.063, which was more significant. The squared terms EnT2, PaT2, and StT2 were significant, and the interaction terms EnTPhT, EnTGhT, DiTGhT, StTPhT, and PhTGhT showed significant performance. The **Supplementary Material Spreadsheet 16** shows the results of regression coefficients, *P*-values and test statistics for each independent variable.

4.3.7 Final mapping model effectiveness evaluation

(1) Results of the distribution of observed values and predicted values

The final model predicted values ranged from 0.1 to 1.045, with a mean of 0.923, an upper quartile of 0.902, a median of 0.962, and a lower quartile of 0.988. A comparative analysis of the distribution of the observed and predicted values shows that both the observed and predicted values were mostly distributed in the greater than 0.8 fraction band, accounting for 86.83% and 89.50%, respectively. The observed values and predicted values were mostly distributed in the 0.6-0.8 score range, accounting for 86.83% and 89.50%, respectively, followed by the 0.6-0.8 score range, accounting for 8.83% and 7.83%, respectively (**Supplementary Material Spreadsheet 17-18**).

(2) Correlation analysis between observed and predicted values

The Spearman's rank correlation test was performed since the observed values and predicted values did not conform to the normal distribution. The test results showed r = 0.6181, $P < 0.0001$, $P < 0.05$, rejecting the original hypothesis that the observed values were correlated with the predicted values, showing a medium to high correlation.

(3) Analysis of prediction error sign direction

In the full sample, there were more cases of underestimation (e < 0) than overestimation (e > 0), with 397 cases (66.16%) and 203 cases (33.83%) showing both cases, respectively. Stratified analysis of the observations showed that underestimation was more severe in the group with observed utility values > 0.8. In the full health state, more than half of the cases (57%) showed underestimation (**Supplementary Material Spreadsheet 19**).

(4)Analysis of prediction accuracy indicators

Previous studies have shown that MAE, RMSE, and ME at [0.0011, 0.19], [0.084, 0.2] and [0.0007, 0.042], respectively, were more common mapping models [5]. In this study, MAE = 0.0590, RMSE = 0.1045, ME = 4.64e-09, proportion of AE > 0.05 = 37.83% and proportion of AE > 0.1 = 17.33% in the total sample of 1200 cases. These results were all within the above-mentioned range and were all at a superior level. Therefore, the model prediction accuracy was good and the model fit was acceptable.

A stratified analysis of the actual observations showed that the three indicators ME, MAE, and RMSE were largest in the (0.2, 0.40] range with 0.40557, 0.40557, and 0.44547, respectively, followed by the interval of measured utility values ≤ 0.2. AE > 0.05 and AE > 0.1 were also largest in the (0.2, 0.40] range, followed by the interval of measured utility ≤ 0.2 (**Supplementary Material Spreadsheet 20**).

5. Discussion

Currently, there are relatively few studies on the cost-utility analysis of TCM in China, and there are no reference cases of classical studies. There is also a lack of authoritative or widely recognized TCM-specific generic QoL measurement scales relevant to the Chinese population, which makes it difficult to conduct cost-utility analysis of TCM. This study explored the construction of a mapping model for the conversion of the CHS Scale to the EQ-5D-3L, providing a preliminary methodological basis and research experience for the establishment of a standardized and quantifiable evaluation index based on the efficacy of TCM evidence. However, this study had several limitations, such as the relative lack of external validity of the study results and the use of direct mapping method without considering the application of indirect mapping method. Therefore, this study should be used as a basis for in-depth exploration and development of preference-based, large-sample, TCM-specific universal scales or disease-specific scales to standardize the pharmacoeconomic evaluation of TCM and promote the development and application of the cost-utility method in the pharmacoeconomic evaluation of TCM to fully reflect the clinical, economic value, and advantages of TCM.

6. Limitations

The final mapping model constructed in this study had good explanatory and predictive power along with the following two limitations: One, no external validation was conducted in this study. The final mapping model was still validated using the total sample of 1200 cases collected in this study, and no other independent data sets were used for validation; thus, the external validity was relatively insufficient. Therefore, future studies should use independent sample data for external validation of the final mapping model constructed in this study to improve the external validity and further enhance the credibility and generalizability of this study. Second, only the direct mapping method was used for the mapping of the scales. The four econometric methods and six model types used in this study all started from a direct mapping approach, i.e., the observed measured health utility values of the EQ-5D-3L were used as the dependent variable. This study did not use the indirect mapping approach, which uses three levels of the five dimensions of the EQ-5D-3L as the dependent variable, and then indirectly finds the health utility values using the integral utility system of the EQ-5D-3L. Therefore, future studies should use both the direct and indirect mapping methods for scale mapping model construction to further broaden the available options for mapping models.

7. Conclusion

The final mapping model was fitted by applying ordinary least squares and model 6 regression as follows: EQ − 5D − 3L = 0.9879 + 0.053 × EnT − 0.0199 × PaT + 0.0263 × DiT + 0.0384 × StT − 0.0718 × PiT − 0.0251 × SlT − 0.106 × PhT − 0.0215 × MoT + 0.0437 × GhT − 0.0759 × EnT2 − 0.0357 × PaT2 − 0.0380 × StT2 + 0.165 ×× $EnTPhT$ − 0.0729$EnTGhT$ − 0.0829 ×$DiTGhT$ − 0.0809 × $StTPhT$ + 0.1111 × $PhTGh$T. This final mapping model could predict utility values and compare them with the observed values; the distributions were similar, and the observed values were highly correlated with the predicted values in the medium; the fit accuracy was good, with optimal acceptability, which could be applied to the pharmacoeconomic evaluation of TCM in the future to obtain the health utility values of patients through the CHS Scale mapping.

Declarations

Ethical Approval and Consent to participate

Approval to conduct the study was gained from the Hunan Provincial Health and Wellness Commission.

Consent for publication

All participants provided written informed consent before participating in the study, Consent to submit manuscript.

Availability of data and materials

The dataset (which includes individual transcripts) is not publicly available due to confidentiality policies.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

CiYan Peng, Jing Chen conducted the literature research and data study and drafted the manuscript. SiNi Li, JianHe Li reviewed the first draft and participated in the planning of the research project and the methods used and supported the discussion of the results. LiuBao Peng participated in the design of the method and helped draft the manuscript. CiYan Peng was involved in all of the above steps. All authors read and approved the final manuscript.

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