

Quality of Life for Patients with Heart Disease: Limitations and Remedial Actions

Satyendra Nath Chakrabartty

Indian Statistical Institute, Indian Ports Association, New Delhi, Delhi, INDIA.

ABSTRACT

Background: Various generic and disease-specific scales used for assessment of Health-Related-Quality of Life (HRQOL) in patients with Coronary Heart Disease (CHD) consider items which differ in formats, chosen domains, scoring systems. Discrete scores generated by such scales fail to satisfy equidistant property for addition. Analyses do not consider distributions of item scores or scale scores. **Materials and Methods:** The methodological paper provides an assumption-free method to convert discrete, ordinal item scores to continuous equidistant scores following normal distribution in the score-range 1 to 100 to ensure non-negative scores. Sum of normally distributed transformed item scores are taken to find Domain scores and scale scores, each following normal. **Results:** The proposed scores result in meaningful arithmetic aggregation and avoid major limitations of getting test scores as sum of raw item scores and facilitate parametric analysis, meaningful comparisons, ranking and classification, responsiveness of the scale i.e. assessment of changes across time at individual level or for a sample of individuals and helps to draw progress-paths. Normality also helps to estimate population parameters, finding equivalent scores of scales and psychometric features like factorial validity, discriminating value and reliability. **Conclusion:** Normally distributed scores improve scoring of instruments relating to health outcomes of surviving-patients with CHD. Health care professionals and researchers can take advantages of the proposed method satisfying desired properties, including detection of changes by longitudinal data and evaluating psychometric parameters at population level.

Keywords: Cardiovascular diseases, Quality of Life, Normal distribution, Transformation, Assessment of progress, Population estimates.

Correspondence:

Prof. Satyendra Nath Chakrabartty,
Indian Statistical Institute,
Indian Ports Association, New Delhi,
Delhi-110003, INDIA.
Email: chakrabarttysatyendra3139@gmail.com

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INTRODUCTION

Heart Failure (HF) is common to heart diseases and often results in problems like dyspnea, chest pain, fatigue, swollen ankles, exercise intolerance, neurohormonal dysfunctions, depression etc. and deteriorated Quality of Life (QoL). Major purposes of evaluation in the context of Cardiovascular Diseases (CVD) and Coronary Heart Disease (CHD) include assessment of outcomes, disease severity, impact of implemented interventions or effectiveness of treatment plan, improvement or deterioration of health status pre-and post-treatment, etc.

Accordingly, large numbers of scales have been developed consisting of binary items (Yes-No type) or k -point Likert items

[$k = 3, 4, 5, 6...$] or combination of both. Health-Related Quality of Life (HRQoL) with more focus on patients' perceptions of their physical and mental health and their correlates is preferred over QoL. Assessments by HRQoL instruments provide important information on evaluation of prognosis and also help in screening and diagnosis.

Common generic HRQoL instruments for patients surviving HF are SF 36, Sickness Impact Profile (SIP), etc. Disease-specific instruments include Cardiovascular Limitations and Symptoms Profile (CLASP), Minnesota Living with Heart Failure questionnaire (MLHF), Seattle Angina Questionnaire (SAQ), Quality of life after Myocardial Infarction questionnaire (QLMI/MacNew), Myocardial Infarction Dimensional Assessment Scale (MIDAS), etc. Each scale has strengths and weaknesses. Combined use of generic measure and disease-specific measure is common.¹ However, the scales differ with respect to length (number of items), width (number of response-categories), number of dimensions, scoring system, measurement properties and psychometric properties, etc.² Five stroke scales were compared and impairments of patients who survived strokes



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are not adequately described by the scales.³ Barthel Index as standard measure of disability and Rankin Scale as global measures of disability⁴ have limitations especially at the higher levels of physical functioning.⁵

The paper provides an assumption-free method to transfer ordinal item scores to proposed scores (P_i) following normal distribution in the score-range 1 to 100 and finding dimension scores and scale scores as sum of P_i 's irrespective of length of scale and width of items. Normally distributed proposed scale scores satisfy desired properties of measurement and also help in better computation of reliability, validity, assessment of responsiveness (changes over time), finding equivalent scores of two tests, etc.

Illustrative generic scales

Sickness Impact Profile (SIP)

SIP with 136 items of “Yes–No” type covering 12 health domains (mobility, ambulation, social-interaction, behaviour, communication, recreation, domestic-affairs, work, eating, sleep, emotions and self-care),⁶ is a commonly used generic measure based on observable behavior of patients' health status with respect to their disease impact. It was also used in angina, Myocardial Infarction (MI) patients to evaluate physical and emotional functioning including changes using longitudinal data.⁷

Generic SIP is quite lengthy and difficult to administer among stroke patients. Disease-specific stroke adapted 30-item SIP version (SA-SIP30) with 30 items in 8 subscales was developed with more homogeneity of items.⁷ However, it excludes assessment of domains like recreation, energy, general health perceptions, pain, overall quality of life or stroke symptoms.⁸ Both SIP and SA-SIP30 consider observable behavior and not subjective health perceptions, and thus can better be taken as measures of disability and not a HRQoL measure.⁹

Medical Outcomes Study 36-Item Short Form Health Survey (SF-36)

The SF-36¹⁰ covering eight domains/sub-classes by 36 items has also been used in patients with MI, angina, ischemic heart failure, etc.¹¹ SF-12, shorter version of SF-36 was preferred for HRQoL assessment of patients with Coronary Heart Disease (CHD).¹²

Items of SF 36 are in different formats and subclasses differ in number of items. Scores of an item are rescaled to range between 0 to 100. A high score indicate higher favorable health state, unlike SIP scores.

Major issues of SF-36 are:

- Distributions of items are different. Addition of two variables following two different distributions (mostly unknown) is problematic.
- Does not provide a single measure, due to several dimensions being measured.

Disease-specific instruments

SAQ

For patients with Coronary Artery Disease (CAD), SAQ with 19 items distributed in five dimensions viz. physical limitation, anginal stability, anginal frequency, treatment satisfaction and disease perception/quality of life, measures functional status.¹³ It is used as a HRQoL measure since 36.84% (7 out of 19 items) items correspond to emotional health. Like SF 36, SAQ does not provide a single summary score reflecting overall health status. Shortened version SAQ-7 with 7 items, each in 6-point scale with provision of single summary score was derived.¹⁴

Disadvantage with SAQ

- (i) Less precision than the diary reports. For example, 3 versus 4 episodes/week may be detected in angina diary but, the SAQ fails to detect such difference.
- (ii) SAQ is zero for a patient with extremely frequent angina and having 20 episodes of angina/d and the same SAQ score is continued even if it is reduced to 10 episodes/d, indicating ≥ 4 episodes/d.¹⁵ Thus, method of deciding class-boundary points needs to be re-visited.

QLMI/MacNew questionnaire

It evaluates emotional, physical, and social dimensions which are affected by CHD with 26 number of 7-point items.¹⁶ The 27-item version of the instrument with three subscales¹⁷ is a modification of the original QLMI questionnaire, originally developed for acute MI patients.¹⁸

MLHF questionnaire

With 21 number of 6-point items (0 to 5), MLHF gives scores for physical and emotional dimensions and total score (assuming unidimensionality).¹⁹ Summative total score ranges between 0 to 105. Higher total score indicates more impairment. However, researchers differed in factor structure of MLHF. The third factor was confirmed.²⁰

MIDAS

35 items of MIDAS are arranged in a hierarchy order²¹ to measure seven health-status dimensions (physical activity, insecurity, emotional reaction, dependency, diet, concerns

over medications and side effects) and is designed specifically for those who have suffered MI. Each dimension is scored separately using Mokken Scaling Procedure, a computer program that reflects relationship between MIDAS items and measurement of QoL after MI.

CLASP

Distribution of 37 items of widely used CLASP are as follows: Physical activity (12 items); insecurity (9 items); emotional reaction (4 items); dependency (3 items); diet (3 items); concerns about medications (2 items); side effects (2 items); four symptom subscales namely angina, breathing problems, swelling of ankle and tiredness) and five functional limitation subscales (mobility, social life and leisure activities, activities within the home, concerns and worries and gender).²² Symptoms subscales reflect mild, moderate, and severe where lower scores are better. However, like SF-36, CLASP does not provide total score.

EQ-5D-5L

EQ-5D-5L scales are increasingly being used to assess HRQoL for heart patients. It considers five dimensions (items) each having five levels (1 to 5) and shows health-status or value-set using permutations of digits 1, 2, 3, 4, 5. The worst health state is equivalent to 5-5-5-5-5 and 1-1-1-1-1 represents no problem in any of the chosen dimensions. For a patient, such pattern helps to know the dimension in order of importance where he/she is suffering and helps to have patient-centric economic evaluation and HRQoL assessment. Area Under the Curve (AUC) method was used for scoring of EQ-5D-5L.²³ EQ-5D-5L is an extension of EQ-3D-3L. However, EQ-5D-5L with higher number of health-states due to higher number of response options than EQ-3D-3L showed better measurement properties in terms of improved discriminatory power and convergent validity.²⁴ A mapping algorithm for scoring of EQ-5D-5L is available.²⁵

Observations and emerging questions/ suggestions

Disadvantages of summative Likert scores are: (i) Addition is not meaningful²⁶ since they do not satisfy equidistant property.²⁷ In addition, the respondents may fail to perceive that levels are equidistant²⁸ (ii) Equal importance to the items for summative scores may not be in order despite different contributions of items to total score, different correlations between item and total score, different factor loadings, etc.²⁹ (iii) Unknown and different distributions of item scores. Interpretation of $X \pm Y$ and further use of $X \pm Y$, finding the joint distribution of item scores are problematic when distributions of X and Y are different, that too unknown, (iv) Distribution of summative Likert scores is skewed and do not follow symmetric normal distribution, which is the

basic assumption of analysis like *t*-test, AVOVA, PCA, FA, and estimation and testing of population parameters, etc.

Question1: Can we transform ordinal discrete item scores to continuous scores following Normal distribution facilitating better admissibility of arithmetic aggregation and find domain scores and scale scores as sum of the normally distributed item scores?

Scales have different length (number of items) and width (number of response-categories), scoring system, dimensions chosen, measurement properties, etc.

Question2: Whether transformation of original item scores to normally distributed scores could be done irrespective of length and width?

Score of an individual reflecting overall assessment of patients' health status is taken as a summative Likert scores (MLHF, SAQ 7) unlike SF-36, SAQ, CLASP. Domain score of MacNew is average of the responses to the items in that domain. CLASP scores are transformed to find subscale scores. Each dimension of MIDAS is scored separately. Such dimension scores create difficulties in meaningful computation of mean, variance, distribution of the scale for meaningful comparisons, ranking, classifying individuals, and statistical inferences.

Question 3: Can we transfer each item score to follow same distribution say Normal to facilitate arithmetic aggregation and find joint distribution of sum of item scores?

Score direction: Interpretation of high score is different for SIP and SF-36.

Suggestion: Follow the same convention say, higher score \leftrightarrow higher health status. This may require inverse scoring of items that does not follow the convention.

Anchor values: Zero value in scale tends to lower mean and variance. Over 40% of the patients had zero score in 10 subscales of SIP and in one sub-class of SF-36.³⁰ Frequent zero responses to an item reduces value of the covariance and correlation with that item. Expected values (score * corresponding probability) is not meaningful when zero is used as an anchor value. If each respondent of a sub-group selects the response category with zero value to an item, then computation of between group variance will be difficult since mean = variance = 0 for the sub-group and correlation with that item is undefined.

Suggestion: Assign values 1, 2, 3,..... and so on as the anchor values of an item, without disturbing the data structure.

Skewed distribution: SA-SIP-30 scores are less skewed:

Question 6: Can we transfer the scores to follow Normal distribution with zero skew value?

Equivalent scores: Cut off points for total score of SA-SIP30 and SIP136 are 33 and 22 respectively, each indicating poor health profiles:

Question 7: How to ensure that SIP30 score of 33 is equivalent to SIP136 score of 22 in the sense that area up to 33 of distribution of SIP30 score is equal to the same for SIP136 score of 22?

Regression analysis done as $SIP-136 = \alpha + \beta(SA-SIP30)$ assuming linearity between the variables. However, high correlation \nrightarrow linearity. For example, X and X² are not linear but $r_{X,X^2} = 0.93$ when X = 1, 2, 3, 30. Factor structures were found for almost each scale using Principal Component Analysis (PCA), Factor Analysis (FA).

Question 8: Whether SIP30 score is linearly related with SIP136 score? How to ensure satisfaction of the assumption of normality for PCA, FA?

Most studies are sample based and do not address what is happening in the population. Cronbach alpha of same scale varied among samples.

Question 9: Can we estimate population parameters including scale variance and also variance for each item and obtain population estimate of Cronbach alpha?

Proposed methods

For solution to the above said problem areas,³¹ proposed angular similarity (Method-1) considering cosine of the angle between the score vector of a patient and the target vector, reflecting “no symptoms” status.³² gave method of arithmetic aggregation (Method-2) by converting raw item score \rightarrow equidistant scores using different weights to different levels of different items \rightarrow standardization to follow $N(0, 1)$ transformation to [1, 100] so that the transformed item-score follow Normal distribution.

Both the methods satisfy desired properties of measurement. But normality needs to test for Method 1 and thus Method 2 is preferred. Method 2 is presented below.

Let X_{ij} denote the raw score of a respondent in the i -th item if he/she chooses the j -th response-category. If the item is 5-point, weighted score (WS) = $W_{ij} X_{ij}$ where W_{ij} 's are different for different levels of the i -th item satisfying $W_{ij} > 0$ and $\sum_{j=1}^5 W_{ij} = 1$. Scores of the i -th item will be equidistant and monotonic if $W_{i1}, 2W_{i2}, 3W_{i3}, 4W_{i4}$ and $5W_{i5}$ forms an arithmetic progression(AP) with common difference > 0 .

For the i -th item, find maximum ($f_{i \max}$) and minimum frequency ($f_{i \min}$) of the levels. Find initial weights $\omega_{ij} = \frac{f_{ij}}{n}$.

Arrange the ω_{ij} 's so that $\omega_{i1} < \omega_{i2} < \omega_{i3} < \omega_{i4} < \omega_{i5}$ where $\omega_{i1} = \frac{f_{i \min}}{n}$ and $\omega_{i5} = \frac{f_{i \max}}{n}$. Let intermediate weight $W_{i1} = \omega_{i1}$

The common difference α can be found as $\alpha = \frac{5f_{i \max} - f_{i \min}}{4n}$ since $W_{i1} + 4\alpha = 5W_{i5}$

Define other intermediate weights as $W_{i2} = \frac{\omega_{i1} + \alpha}{2}$, $W_{i3} = \frac{\omega_{i1} + 2\alpha}{3}$; $W_{i4} = \frac{\omega_{i1} + 3\alpha}{4}$; and $W_{i5} = \frac{\omega_{i1} + 4\alpha}{5}$.

Get final weights $W_{ij(Final)} = \frac{W_{ij}}{\sum_{j=1}^5 W_{ij}}$ enabling $\sum W_{ij(Final)} = 1$ and

$$j \cdot W_{j(Final)} - (j-1) \cdot W_{(j-1)(Final)} = \text{constant}$$

However, value of constant will be different for different items, when the process is repeated for each item

Observations

- i) $W_{i(Final)}$ are based on empirical probabilities.
- ii) $f_{ij} = 0$ is the zero value of the transformed scores.
- iii) Generated scores (E) as weighted sum are equidistant and continuous.
- iv) The method can be used for items with different number of response-categories including binary items.

Transform E -scores of the i -th item by

$$Z_{ij} = \frac{X_{ij} - \bar{X}_i}{SD(X_i)} \sim N(0, 1).$$

Take linear transformation of Z -scores to P -scores by:

$$P = (99) * \left[\frac{(Z_{ij} - \text{Min}(Z_{ij}))}{\text{Max}(Z_{ij}) - \text{Min}(Z_{ij})} \right] \quad (1)$$

For the i -th item, $P_i \sim N(\mu_i, \sigma_i^2)$ and $1 \leq P_i \leq 100$ where estimates of μ_i and σ_i^2 are obtained from the data. P -score of an item as per equation (1) can be obtained irrespective of length of scale and width of items.

Domain score of an individual is taken as sum of normally distributed P -score of relevant items which will follow normal with mean $\sum_i \mu_i$ and $SD = \sqrt{\sum \sigma_i^2 + 2 \sum_{i \neq j} Cov(P_i, P_j)}$. Similarly, scale score is sum of domain scores. also following normal.

Properties

1. Domain scores (D_i) and scalescores (S_i) of the i -th individual are continuous, monotonically increasing and follow normal distribution. Normality ensures meaningful computation of arithmetic average, SD, correlation, etc. and facilitates statistical analysis under parametric set up including unbiased estimates of population mean (μ), population variance (σ^2) confidence interval of μ , and testing of null hypothesis like $H_0: \mu_1 = \mu_2$ or $H_0: \sigma_1^2 = \sigma_2^2$ etc. across time and space.

2. Progress registered by the i -th person in two successive time-periods can be quantified in percentage by $\frac{S_{i(t)} - S_{i(t-1)}}{S_{i(t-1)}} \times 100$, which also quantifies responsiveness of the scale and effectiveness of a treatment plan. Deterioration is indicated if $\frac{S_{i(t)} - S_{i(t-1)}}{S_{i(t-1)}} \times 100 < 0$

Similarly, progress for a group of persons is reflected if $\overline{S_{i(t)}} > \overline{S_{i(t-1)}}$. Normality of S_i helps to test $H_0: \mu_{S_i} = \mu_{S_{i(t-1)}}$ and also $H_0: \text{Progress}_{(t+1) \text{ over } t} = 0$. Deterioration if any may be probed to find extent of deterioration in domain scores for possible corrective actions.

3. The graph of progress and/or deterioration of a patient or sample of patients at various time points can be used to compare health-status of patient(s) from the start.

4. Normally distributed scores satisfy the assumptions of PCA and enable to find factorial validity in terms of ratio of the first eigenvalue to the sum of all eigenvalues i.e. Factorial Validity = $\frac{\lambda_1}{\sum \lambda_i}$, where λ_1 is the first principal component with highest eigenvalue reflecting the main factor for which the scale was developed and accounts $\frac{\lambda_1}{\sum \lambda_i} \times 100$ for percent of overall variability. Such factorial validity avoids the problems of construct validity and selection of criterion scale.

5. Normality helps to estimate variance of subclass, scale and each item and estimated Cronbach alpha for a domain/subclass as

$$\hat{\alpha} = \left(\frac{n}{n-1} \right) \left(1 - \frac{\text{Sum of estimates of variance of items in the sub-class}}{\text{Estimate of variance of the sub-class}} \right) \quad (2)$$

Reliability of the scale (r_u) consisting of K -number of domains can be obtained as a function of domain reliabilities by

$$r_u = \frac{\sum_{j=1}^K r_{u(i)} S_{Xi} + \sum_{i=1, i \neq j}^K \sum_{j=1}^K 2COV(X_i, X_j)}{\sum_{i=1}^K S_{Xi} + \sum_{i=1, i \neq j}^K \sum_{j=1}^K 2COV(X_i, X_j)} \quad (3)$$

where ($r_{u(i)}$) and S_{xi} denote respectively reliability and SD of the i -th domain.

6. Discriminating value of a scale is poorly defined or not defined. Mere observation that average HRQoL score for a group of healthy adults was higher than the group of patients suffering from CVD is not sufficient to quantify discriminating value of the scale. Discriminating value of a scale indicates ability of the scale to distinguish between individuals that have different degrees of the underlying construct (e.g. more or less severe CVD). Discriminating value of Likert item (Disc_i) and test ($\text{Disc}_{\text{rest}}$)

can be computed by Coefficient of Variation (CV) where

$$\text{Disc}_i = \frac{SD_i}{\text{mean}_i} \text{ and } \text{Disc}_{\text{rest}} = \frac{SD_{\text{rest}}}{\text{mean}_{\text{rest}}}$$

$\text{Disc}_{\text{Test}}$ (with m -items) are related by

$$\alpha = \left(\frac{m}{m-1} \right) \left(1 - \frac{\sum_{i=1}^m \bar{X}_i^2 \cdot \text{Disc}_i^2}{\bar{X}^2 \cdot \text{Disc}_T^2} \right) \quad (4)$$

Since, variance of the i -th item

$$S_{X_i}^2 = \bar{X}_i^2 \cdot \text{Disc}_i^2 \quad \forall i = 1, 2, \dots,$$

$$m \Rightarrow \sum_{i=1}^m S_{X_i}^2 = \sum_{i=1}^m \bar{X}_i^2 \cdot \text{Disc}_i^2 \text{ and Test variance}$$

$$S_X^2 = \bar{X}^2 \cdot \text{Disc}_T^2.$$

It can be proved that $(\text{Disc}_{\text{Test}})^2 = \frac{CV_{\text{True scores}^2}}{r_u}$ where

$$r_u = \frac{S_T^2}{S_X^2} \quad (5)$$

Thus, test reliability and are related by a negative non-linear relationship.

7. Classifications of individuals need to ensure small within group variance and high between group variance. Quartile clustering helps in classification of a group of individuals in four mutually-exclusive classes Q_1, Q_2, Q_3, Q_4 . Quartile clustering of scale scores following normal distribution may be adopted because it is simple, appealing, adds clear meaning to the clusters, provides well-defined cut-off scores for the four mutually exclusive classes and assigns equal probability to each quartile/class.

8. If, each scale score is transformed to follow normal distribution, then a given score of X_0 in Scale-1 will be equivalent

to a score of Y_0 in Scale-2 if $\int_{-\infty}^{X_0} f(x)dx = \int_{-\infty}^{Y_0} g(y)dy$ (6)

where $f(X)$ and $g(Y)$ denote normal probability density function (pdf) of transformed scores of Scale-1 and Scale-2 respectively. The equation (6) can be solved using Standard Normal probability table. It helps to find all combinations of $\{X_0, Y_0\}$ including cut off scores of two scales.

CONCLUSION

The proposed method following normal distribution contributes to improve scoring of instruments relating to health outcome in patients with CHD. Proposed scores avoid limitations of ordinal scores and facilitate parametric analysis for meaningful comparisons, classification, and integration of various scales used in cardiovascular diseases. Health care professionals and researchers can take advantages of the proposed method to convert ordinal scores to normally distributed P -scores with desired properties, including detection of changes by longitudinal data and evaluating psychometric parameters at population level. Future studies with multi-data set involving longitudinal data may be undertaken for generalization of findings along with psychometric properties of the proposed transformation and to stimulate approach leading to improved patient care and clinical outcomes.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

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