Detecting Response Shift in Health-related Quality of Life Measurement among Patients with Hypertension Using Structural Equation Modeling.

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Abstract

Background: Outcomes derived from longitudinal self-reported health-related quality of life measures can be confounded by response shift. This study was aimed to detect response shift phenomena among patients with hypertension attending a community-based disease management program.

Methods: 240 consecutive consulting or followed up patients with diagnosed hypertension were recruited. The SF-36 instruments were self-administered at 12 community health service stations and four weeks after attending the program. RS was assessed by the 4-step structural equation modeling approach.

Results: Data from 203 (84.6%) patients were eligible for analyses (mean age 65.9±10.8 years, 46.3% female). The results showed uniform recalibration of social functioning ($\chi^2_{SBdiff}(1)=22.98$, $P<0.001$), and non-uniform recalibration of role limitations due to physical problems ($\chi^2_{SBdiff}(1)=8.84$, $P=0.003$), and bodily pain ($\chi^2_{SBdiff}(1)=17.41$, $P<0.001$). The effects of response shift were calculated as “small”, but the influence on the measurement results was noticeable. After accounting for the response shift effect, the general physical health of participants was improved (+0.234, $P<0.001$), while a deterioration of general mental health (-0.165, $P=0.025$) was also found.

Conclusions: Recalibration existed among patients with hypertension attending the disease management program. The adaptation to chronic illness might act as a catalyst that induced the response shift. We concluded that response shift should be considered in hypertension researches with longitudinal health-related quality of life data, and linking with measurement of the appraisal process was recommended.

Key words: Health-related quality of life, Response shift, Structural equation modeling, Hypertension, SF-36

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Health-related quality of life (HRQOL), representing people’s subjective assessment of their sense of health-specific well-being, has been frequently used as a health indicator in medical interventions or health surveys. However, the measurement of change in HRQOL may be affected by the fact that individuals’ frame of reference (or standard) or the concept and meaning of HRQOL can differ over time, known as Response Shift (RS) [1-2]. A theoretical model of RS have been proposed by Sprangers and Schwartz who postulated a dynamic feedback loop, where “catalyst”, “antecedents”, “mechanisms” and “RS” interacted and eventually maintained or led to changes in HRQOL [1], among which, RS was defined as three different types: (a) recalibration: a change in the respondent’s internal standards of measurement; (b) reprioritization: a change in the respondent's values; and (c) reconceptualization: a redefinition of the target construct. With existence of RS, individual experience of improvement or deterioration over time will be modified. In other word, substantial change of HRQOL can be over- or under-estimated without adjusting for RS [3-5]. Therefore, it is important to consider RS effect when measuring changes in HRQOL [6].

A variety of methodological methods are available to detect and adjust RS [2]. Based on the latent variable measurement modeling, Oort and colleagues [7-8] have proposed a 4-step RS detecting procedure for longitudinal measurement occasions, named the Oort’s structural equation modeling (SEM) approach. The invariance of the
patterns or magnitude of the corresponding parameters across occasions were associated with the interpretation of all three types of RS. Due to its versatility, the Oort’s SEM approach has become the most widely used statistical method in RS detection [9].

Hypertension is a common chronic disease and a major risk factor for cardiovascular chronic diseases [10]. A copious number of studies have confirmed that hypertension has been an influencing factor for deterioration of HRQOL [11-14]. Previous researches have provided evidences that recalibration type of RS existed among hypertensive male subjects [15] and hypertensive patients with coronary artery disease (CAD). Whereas there is still dearth of records that address RS phenomena against general hypertensive patients.

The adaptation of patients to their chronic illness could induce RS, because the process where patients coping with their chronic condition may alter their perceptions of quality of life [17]. For example, patients with multiple chronic diseases changed perspective of their health status after attending self-management courses [18].

The community disease management program is a component of the national essential public health services in China, providing disease screening, drug therapy, long-term follow up, and health education services to improve hypertension care [19]. Theoretically, individuals undergo the program will experience RS as they changed the way understanding or coping with the disease. The objective of this study was to detect effects of RS on HRQOL changes in patients with hypertension involved in the community disease management program.
Methods

Study design and samples

The study cohort recruited 240 patients with hypertension in the community disease management program from a community health service center in Hangzhou, China. On given week chosen by the study, all visiting or followed up patients in the belonged 12 community health service stations were invited to self-administer a health status survey before consultation until the quota for each station (n=20) was met. Four weeks later, the participants were asked to complete the survey once again. Patients who had cognitive or visual problems, or were unable to complete the questionnaires independently, were not included. The protocol was approved by the Ethics Committee of Zhejiang University School of Medicine and all participants provided written informed consent. Two hundred and eleven (87.9%) patients completed the questionnaire twice, while eight patients with missing data were excluded, resulting in a data set of 203 (84.6%) patients used for analyses.

Measures

We used a validated Chinese (mainland) version of the Short-Form Health Survey (SF-36) to evaluate HRQOL of patients with hypertension in this study [20]. The SF-36 instrument consists of 36 items which measure eight scales: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to...
emotional problems (RE), and mental health (MH). All original scales were linearly transformed to a scale from 0 to 100, with a higher score indicating better HRQOL [21]. The demographic and disease information, including age, gender, marital status, employment status, educational attainment, health insurance, self-reported severe illness experience, duration of disease, blood pressure, high risk level, and medicine taken were also collected.

Analyses

Structural Equation Modeling

The Oort’s SEM approach was applied to detect RS in a 4-step procedure [7-8]: (1) establishing a decent measurement model; (2) forming a no RS model; (3) detecting RS; (4) evaluating adjusted change.

Step 1: in the first step, we established a longitudinal measurement model (Model 1) based on the result of exploratory factor analyses (EFA) for baseline data and the theoretical considerations. In this model, all parameters could be estimated freely across occasions, except for the common factors means and variances that were constrained at zero and one respectively as the scales and origins for the unobserved variables. Only when the model 1 shows good fit, could further analyses be conducted.

Step 2: the invariance constrains on all RS parameters (residual variances, intercepts, factor loadings) across occasions were placed, forming the no RS model (Model 2). By using the \( \chi^2 \) difference test, overall existence of RS could be detected. If the
model fit of the model 2 was significantly worse than the model 1, we could conclude that RS existed.

Step 3: in the third step, the invariance constrains that had been proved untenable by the $\chi^2$ difference test were released individually, leading to a model (Model 3) where no modification index of RS parameters indicated a significantly better fitting (i.e. all RS was taken into account). Different types of RS were operationalized by the following parameters that varied across occasions: reconceptualization (factor patterns); reprioritization (factor loadings); uniform recalibration (intercepts); ununiform recalibration (residual variances). Given the backward approach could result in over identification of RS, a Bonferroni-adjusted critical value of 0.05/8 was used to control type I error [16,22-23].

Step 4: as the final step, the tenable constrains of means, variances and correlations of common factors were placed to the final model (Model 4). In this model, the adjusted change was assessed by testing the invariant hypothesis of common factor means across occasions after account for all RS. The estimated parameters in the model 4 were used to calculate the effect-sizes of RS and the adjusted change.

Statistical analyses

Mplus (version 7.4) was used for the SEM analyses. Given our data deviated from multivariate normality, the Robust Maximum Likelihood Estimator (MLR) was employed as the estimator [24]. When conducting the $\chi^2$ difference tests in Mplus with the MLR estimator, it was essential to adjust the $\chi^2$ using the Satorra-Bentler scaling correction [25]. A variety of alternative fit indexes were used to assess the
appropriateness of model fit. Those include the comparative fit index (CFI), the Tucker-Lewis index (TLI), the standardized root mean square residual (SRMR) and the root mean square error of approximation (RMSEA). With CFI, TLI>0.9, SRMR<0.1, and RMSEA<0.08 indicate acceptable model fit [26-27].

Results

Participants' characteristics and health information

The initial cohort included 240 patients. 203(84.6%) patients with eligible data were used for analyses, among which 94 were female (46.3%), and the mean age was 65.9 years (range 35-86, SD 10.8). About one fifth (19.2%) participants had college or above education. Four fifth (75.4%) participants were unemployed or retired. More than four fifths (83.7%) participants had an annual household income no more than 60,000 RMB. Seven (3.3%) participants did not have any health insurance (Table 1).

About one third participants reported own or family member serious diseases experience. Sixteen (7.8%) participants had hypertension no more than six months. More than half (54.2%) of participants had average blood pressure lower than 140/90mmHg. About three fourths (74.4%) participants had low or medium level of health risks. Sixteen (7.9%) participants did not take any medicine (Table 2).

Table 1: Demographic characteristics of study participants

| Variable                  | N   | n (%)   |
|---------------------------|-----|---------|
| Gender                    | 203 |         |
| Female                    | 94  | 46.3    |
| Male                      | 109 | 53.7    |
| Marital status            | 201 |         |
| Married/co-habiting       | 181 | 89.2    |
| Variable                                      | N   | n (%)   |
|-----------------------------------------------|-----|---------|
| Experienced severe illness                    | 202 | 71(35.0)|
| Family members experienced severe illness     | 201 | 68(33.5)|
| Duration of hypertension                      | 202 |         |
| < 6 months                                     |     | 16(7.8) |
| ≥6 months                                     |     | 186(92.2)|
| Last month blood pressure                     | 200 |         |
| < 140/90mmHg                                  |     | 110(54.2)|
| ≥140/90mmHg                                  |     | 90(45.8) |
| Health risk level a                           | 186 |         |
| Low                                           |     | 51(25.1)|
| Medium                                        |     | 100(49.3)|
| High                                          |     | 26(12.8)|
| Very high                                     |     | 9(4.4)  |
| Anti-hypertensive medications                 | 202 |         |
| 0                                             |     | 16(7.9) |
| 1                                             |     | 134(66.0)|
| 2                                             |     | 44(21.7)|

*a other insurances include new cooperative medical scheme, commercial medical insurance, free medical service, etc.*
health risk was assessed based on blood pressure, risk factors, and target organ damage/diabetes mellitus, and multi-morbidities [19].

**Structural Equation Modeling**

**Measurement Model**

According to the guideline [7], we developed a measurement model based on the result of EFA and the theoretical consideration (Figure 1). The ovals worded as GenPHYS (General physical health) and GenMENT (General mental health) represented two latent variables. The GenPHYS were measured by PF, RP, BP, RE, while the GenMENT were measured by GH, SF, VT, MH. The eight scales were represented by the rectangles. The circles below represented residual terms. We found out the residual factors for RP and RE should be correlated, as both scales have close questions and wording expression about social roles, which were agreed by several corresponding RS studies with the SF-36 [8,16,28].

Fig 1 The measurement model used in RS detection.

Details for model fit are given in Table 3.

Step 1: all fit indexes for the model 1 were in an acceptable range, indicating an appropriate unconstrained measurement model was established.

Step 2: in the model 2, all RS parameters were constrained to be invariant across
occasions. Fit of the model 2 was still acceptable, but was significantly worse than the model 1 ($\chi^2_{SBdiff}(20)=69.53, P<0.001$), indicating overall existence of RS.

Step 3: after controlling for Type I error (Bonferroni-adjusted critical value=0.006), constrains of the residual variances of RP ($\chi^2_{SBdiff}(1)=8.84, P=0.003$) and BP ($\chi^2_{SBdiff}(1)=17.41, P<0.001$), the intercept of SF ($\chi^2_{SBdiff}(1)=22.98, P<0.001$) were removed, indicating non-uniform recalibration of RP and BP, uniform recalibration of SF.

Step 4: all the tenable constrains were placed on common factor means, variances and correlations, forming the model 4. Difference of means of both common factors were significant, indicating significant adjusted change in both common factors. The GenPHYS improved (+0.234, $P<0.001$), whereas the GenMENT deteriorated (-0.165, $P=0.025$), with effect-sizes all considered “small” (effect-sizes=0.37, -0.21 respectively). Estimated parameters of the model 4 are presented in Table 4.

Table 5 shows significant test of RS, and the effect-sizes of observed change, RS and adjusted change. RS in the SF, RP, and BP scale were all significant. The effect was calculated as “small” for uniform recalibration of SF (effect-size=0.35). The effect-sizes of RP and BP were zero at the group level, since the non-uniform recalibration indicated changes of individual internal standard in different directions.

After accounting for the RS effect, all scales except for the PF scale were stable. The PF scale of the participants improved slightly (effect-size=0.21).

| Table 3: Goodness of fit of models in the 4-step detection procedure |
|-----------------|-----|-------|-----|------|-----------------|-----|
| Model           | Df  | CHISQ | CFI | TLI  | RMSEA (90%CI)   | SRMR|
| Model 1         | 88  | 151.6 | 0.951 | 0.934 | 0.060 (0.043,0.075) | 0.050 |
| Model 2         | 108 | 222.6 | 0.912 | 0.903 | 0.072 (0.059,0.086) | 0.067 |
| Model 3         | 105 | 178.5 | 0.944 | 0.936 | 0.059 (0.044,0.073) | 0.059 |
| Model 4         | 106 | 179.7 | 0.944 | 0.936 | 0.059 (0.043,0.073) | 0.060 |
Table 4: Parameters estimated in the model 4

| Pre-test          | Post-test         |
|-------------------|-------------------|
| GenPHYS<sub>1</sub> | Gen-MENT<sub>1</sub> | GenPHYS<sub>2</sub> | Gen-MENT<sub>2</sub> |
| **PF**            | 17.557            | 17.557              |
| **RP**            | 29.074            | 29.074              |
| **BP**            | 13.761            | 13.761              |
| **RE**            | 18.159            | 18.159              |
| **GH**            | 14.339            | 14.339              |
| **SF**            | 12.508            | 12.508              |
| **VT**            | 12.664            | 12.664              |
| **MH**            | 13.713            | 13.713              |

Factor loadings

| Pre-test          | Post-test         |
|-------------------|-------------------|
| **PF**            | PF                | PF                |
| **RP**            | RP                | RP                |
| **BP**            | BP                | BP                |
| **RE**            | RE                | RE                |
| **GH**            | GH                | GH                |
| **SF**            | SF                | SF                |
| **VT**            | VT                | VT                |
| **MH**            | MH                | MH                |

Intercepts

| Pre-test          | Post-test         |
|-------------------|-------------------|
| **PF**            | 74.214            | 72.804            |
| **RP**            | 78.853            | 83.962            |
| **BP**            | 83.962            | 54.656            |
| **RE**            | 80.049            | 55.038            |
| **GH**            | 69.664            | 69.664            |
| **SF**            | 67.002            | 67.002            |
| **VT**            | 243.002           | 243.002           |
| **MH**            | 282.521           | 282.521           |

Residual variance

| Pre-test          | Post-test         |
|-------------------|-------------------|
| **ResPF**         | 236.00            | 236.00            |
| **ResRP**         | 777.51            | 777.51            |
| **ResBP**         | 255.96            | 255.96            |
| **ResRE**         | 670.02            | 670.02            |
| **ResGH**         | 141.12            | 141.12            |
| **ResSF**         | 243.06            | 243.06            |
| **ResVT**         | 169.46            | 169.46            |
| **ResMH**         | 282.521           | 282.521           |

Common factor variances

| Pre-test          | Post-test         |
|-------------------|-------------------|
| GenPHYS<sub>1</sub> | 1.00              | 1.00              |
| Gen-MENT<sub>1</sub> | 1.00              | 1.00              |
| GenPHYS<sub>2</sub> | 1.136             | 0.781             |
| Gen-MENT<sub>2</sub> | 1.136             | 0.781             |

Common factor correlations

| Pre-test          | Post-test         |
|-------------------|-------------------|
| GenPHYS<sub>1</sub> | 1.00              | 1.00              |
| Gen-MENT<sub>1</sub> | 0.840             | 1.00              |
| GenPHYS<sub>2</sub> | 0.871             | 0.685             |
| Gen-MENT<sub>2</sub> | 0.561             | 0.583             |

Common factor means

| Pre-test          | Post-test         |
|-------------------|-------------------|
| GenPHYS            | 0.00              | 0.00              |
| Gen-MENT           | 0.234             | -0.165            |

Parameters of factor loadings are unstandardized; Results indicating across-measurement variance are printed in bold.
| Scale | RS                      | Significance test | Effect-sizes*       |
|-------|-------------------------|------------------|---------------------|
|       | $\chi^2_{\text{SBdiff}}$ (df=1) | Prob. | observed change | RS | adjusted change |
| PF    |                         | 0.21             | 0.21                |
| RP    | Non-unif. recalibration | 8.84             | 0.003               | 0.19 | 0.00 | 0.19 |
| BP    | Non-unif. recalibration | 17.41            | <0.001              | 0.16 | 0.00 | 0.16 |
| RE    |                         | 0.12             | 0.13                |
| GH    |                         | -0.13            | -0.13               |
| SF    | Uniform recalibration   | 22.98            | <0.001              | 0.25 | 0.35 | -0.10 |
| VT    |                         | -0.12            | -0.11               |
| MH    |                         | -0.10            | -0.10               |

*Effect-sizes were calculated as corresponding parameters difference in model 4 divided by the estimated standard deviation; Values of 0.2, 0.5, 0.8 indicate “small”, “medium”, and “large” effect-sizes. Values less than 0.2 are considered “negligible”; Bonferroni-adjusted critical value=0.006.

**Discussion**

This study explored the occurrence of RS in patients with hypertension attending the community disease management program by using the Oort’s SEM approach. In our sample, we detect recalibration type of RS in the SF, RP, and BP scale. The effects of RS in the SF scale were calculated as “small”, but the influence of RS on the measurement results was noticeable, which, emphasized the importance of adjustment of RS impact in longitudinal HRQOL studies against patients with hypertension. Further, the RS could be recognized as an important effectiveness consequence in clinical interventions.

After accounting for all RS effects, we also found slight improvement in the general physical health (GenPHYS), and slight deterioration in the general mental health (GenMENT) of participants. The physical functioning (PF) of patients was significantly improved during the program. The community disease management
program in this study was more effective in physical dimensions than mental.

Four weeks after the program, the meaning of the response scale anchors of the SF scale has changed. A possible explanation for this result could be that when obtained more information about the illness, or compared themselves with other patients, the participants felt actual limitations in their social functioning, or the gaps between their current status and ideal criterion. Therefore, they recalibrated their internal standards of the SF scale, so that their functioning improved less than would be expected on account of the interventions.

Prior researches have explored the mechanisms where RS produced. Sprangers and Schwartz [1] have proposed several such mechanisms, including social comparisons, and coping strategies. Empirical evidences have provided that social comparison acted as a mediator between life events and RS [29], and that patients who considered themselves better off than others tend to be able to maintain their quality of life even with a worsening functioning [30]. Oort inferred that learning how to cope with illness could induced RS in patients’ physical functioning [14]. By integrating appraisal process into the theoretical model of RS, Rapkin and Schwartz proposed the concepts and methods for direct measurements of individual psychological process involved in rating a QOL item [31], which provided a deep sight into how and when RS occurred.

The then-test method was used to detect RS for this cohort in our previous work [32]. The group level results were deviate in the PF scale, where the recalibration has been found by the then-test. Then-test approach was susceptible to inaccurate recall [33].
especially among elderly participants (mean age=65.9) [34], while the SEM approach was immune to recall issues. However, one thing should be noted, the RS interpreted by the model-based methods including the SEM approach are not unambiguous [35].

The group level model-based methods identify RS in terms of the variances of model patterns or parameters, but RS may not the only reason that arise these differences. This explained why the direct measurement of individual appraisal process is necessary. As mentioned by Rapkin and Schwartz [35], linking these group-level statistical methods to appraisal is central to the (RS research) field, which is the direction for our future researches.

**Conclusions**

This study detected RS in HRQOL measurement among patients with hypertension attending the community-based disease management program by using the 4-step SEM approach. The existence of recalibration had been detected, and the influence on the SF scale was noticeable. We deduced that by initiating the social comparisons and learning a better coping strategy in the program, the participants recalibrated their internal standards of social functioning, so that it improved less than would be expected on account of the intervention effects. We concluded that response shift should be considered in longitudinal health-related quality of life researches among patients with hypertension, and could be recognized as an effectiveness consequence in clinical interventions. We recommended direct measurement of the appraisal process in the future researches to explore the nature of RS.
Abbreviations

RS: Response Shift; SEM: Structural Equation Modeling; HRQOL: Health-Related Quality of Life; CAD: Coronary Artery Disease; SF-36: 36-item Short Form Health Survey; PF: Physical Functioning; RP: Role limitations due to Physical problems; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role limitations due to Emotional problems; MH: Mental Health; SD: Standard Deviation; EFA: Exploratory Factor Analysis; MLR: Robust Maximum Likelihood Estimator; CFI: Comparative Fit Index; TLI: Tucker-Lewis Index; SRMR: Standardized Root Mean Square Residual; RMSEA: Root Mean Square Error of Approximation; GenPHYS: General Physical Health; GenMENT: General Mental Health

Declarations

Ethics approval and consent to participate

All patients provided written informed consent to participate in the study. The protocol was approved by the Ethics Committee of Zhejiang University School of Medicine.

Consent for publication

Not applicable.

Availability of data and materials

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

Competing interests

The authors declare that they have no competing interests.

Authors’ contributions

HC performed statistical analysis, interpreted the data. HC and LZ wrote the first draft. HW, PL, and HC designed the study. HW, RZ, XL, DLP, and TCE contributed to the writing of the final version of manuscript. All authors have read and approved the final version of the manuscript and its conclusions.

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