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Original Article

Quality of Life in Taiwanese Breast Cancer Survivors With Breast-conserving Therapy

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Background/Purpose: Breast cancer is the most common female malignancy in Taiwan; however, quality of life (QOL) following breast cancer therapy remains rarely studied. The aim of the present study was to evaluate QOL among Taiwanese breast cancer patients with and without breast-conserving therapy.

Methods: A total of 130 women with breast cancer (37 with breast-conserving therapy and 93 with modified radical mastectomy) were enrolled between August, 2004 and December, 2007 in a single center. Patients who underwent breast-conserving therapy were younger, less likely to be married, had a higher educational level, and were at an earlier clinical stage than those who underwent modified radical mastectomy. The traditional Chinese version of the European Organization for Research and Treatment of Cancer QLQ-C30 and QLQ-BR23 questionnaires were used as measuring instruments. Structural equation modeling with mean structural analysis, which evaluates configuration invariance and compares groups for latent functional/symptomatic factors, was constructed using a multi-indicators approach.

Results: Patients with breast-conserving therapy reported worse global QOL status and role function scores and higher symptomatic scores for fatigue, pain, dyspnea, insomnia, appetite loss, breast and arm problem subscales than those without conserving therapy. In addition, age, marital status, hormone manipulation and postoperative adjuvant therapy were significant confounders for QOL. Measurement invariance was ascertained and the same QOL construct could be applied to Taiwanese subjects with and without breast-conserving therapy.

Conclusion: Our study suggests that breast-conserving therapy might be associated with worse perceived QOL for Taiwanese breast cancer survivors.

Key Words: breast-conserving therapy, EORTC QLQ-BR23, EORTC QLQ-C30, quality of life, structural equation modeling

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Breast cancer is the leading cause of female malignancy in Taiwan according to the 2003 Taiwan Cancer Registry Annual Report;[1] 5325 incident cases were diagnosed, and this number was roughly one-fifth of all female malignancies. Evidence has accumulated about psychosocial consequences of breast cancer therapy, and quality of life (QOL) is regarded as one of the clinical outcomes.[2–7] Breast-conserving therapy (partial mastectomy with postoperative irradiation) has been advocated as an alternative to the standard procedure of modified radical mastectomy, for comparable long-term clinical outcomes and cosmetic consideration.[8,9] However, most Taiwanese women with breast cancer prefer modified radical mastectomy rather than breast-conserving therapy, despite the shortcoming of body image destruction. Complications and QOL status following breast surgery have rarely been investigated in Taiwan. Most postoperative breast cancer QOL studies have been conducted among western women,[10] but cross-cultural differences might hinder applying the conclusions to Taiwanese women. Furthermore, in the limited number of surveys of QOL of breast cancer patients in Taiwan, there is no information on QOL after breast-conserving therapy because of the low use of this treatment strategy, even though it is designed to improve body image.[11,12]

The objective of this study was to evaluate the effects of breast-conserving therapy on QOL of Taiwanese women, with adjustment for other confounders. The approach was based on structure equation modeling, with an emphasis on a means model. Group means/intercepts on latent exogenous/endogenous QOL factors were evaluated accordingly. Our work represents the continuous effort to apply structural equation modeling to QOL research, with the highlight of latent functional/symptomatic domain variables. Implicated relationships between observed (questionnaire items) and latent variables (functional/symptomatic domain subscales or higher-order factors) were evaluated using confirmatory factor analysis to generate a comprehensive and global speculation of a health-related QOL construct. The impact of breast-conserving therapy upon subjective QOL perception by breast cancer survivors was elucidated using structural modeling.

Patients and Methods

Study design

Study subjects were breast cancer patients who had completed surgery and/or adjuvant therapy, if indicated, and were undergoing regular follow-up. All subjects must have completed surgery or their final course of adjuvant therapy (except oral hormone manipulation therapy) for at least 9 months when QOL scores were measured. Outcomes were health-related QOL scores. The whole study design was approved by the Institute Review Board of the Cathay General Hospital. Eligible patients were well informed of the objectives and confidentiality policy of this study and informed consent was obtained from all participants.

Study population

Between August, 2004 and December, 2007, 130 women with incidental breast cancers were diagnosed and treated in the Cathay General Hospital. Patients presented with curable diseases (no distant metastasis) and were offered counseling for the surgical options of breast-conserving therapy or modified radical mastectomy. Table 1 summarizes the demographic and clinical features of the study population. Patients who chose breast-conserving therapy rather than modified radical mastectomy tended to be younger and single, and to have a higher education level and earlier clinical stage of cancer. There was no difference regarding postoperative adjuvant therapy between these two groups. Hormone manipulation therapy such as tamoxifen or aromatase inhibitor was prescribed less frequently for the breast-conserving therapy group.

Measuring instruments

The European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-BR23 questionnaires were used to assess QOL of breast cancer patients. EORTC QLQ-C30 is a

Table 1. Demographic and clinical features of study population*

	Breast conserving therapy ($n=37$)	Modified radical mastectomy ($n=93$)	$p^{\dagger}$
Age (yr)	51.1 (22–78)	55.1 (32–77)	0.04
Married	31 (83.8)	89 (95.7)	0.02
Education			
High school	13	52	<0.01
University	9	38	
Graduate school	15	3	
Stage			
0	7	3	<0.01
I	15	24	
II	10	49	
III	5	17	
Adjuvant therapy	30 (81.1)	68 (73.1)	0.34
Chemotherapy only	6	55	
Radiotherapy only	15	1	
Chemo-radiotherapy	9	12	
Hormone manipulation therapy	22 (59.5)	76 (81.7)	<0.01

**Data presented as median (range) or n (%); $^{\dagger}\chi^2$ test for categorical and t test for continuous variables.*

generic QOL measuring instrument for cancer patients. It comprises a global health status/QOL, five multi-item functional subscales and several single/multi-item symptomatic subscales. Four-to-seven-level Likert scales (seven for global health status/QOL and four for the others) are linearly transformed to a 0–100 score, with higher scores indicating better functional status or worse symptomatic problems.[13] EORTC QLQ-BR23 is a 23-item breast cancer site-specific supplemental module for QLQ-C30 to enhance the sensitivity and specificity for breast cancer QOL measures. The original English version comprises five multi-item subscales and three single-item subscales, with higher scores for better functional or worse symptomatic QOL conditions.[14,15] The Taiwan Chinese version of EORTC QLQ-C30 has been validated for breast, lung, head and neck, and gastric cancer,[12,15–17] and that of EORTC QLQ-BR23 has been validated for breast cancer in Taiwan.[12] The questionnaires were self-administered during the predefined time frame, 9–12 months after completion of surgery or postoperative adjuvant therapy, at the scheduled follow-up visits.

Statistical analysis

The Wilcoxon rank sum test was used for univariate between-group comparisons. A p value < 0.01 was considered statistically significant in each QOL subscale. QOL scores with significant between-group differences were further evaluated by multivariate regression to adjust for confounders. All statistical analyses were conducted using SAS/STAT version 9.1 with procedures, NPAR1WAY and GLM (SAS Institute Inc., Cary, NC, USA).

QOL subscales, either functional or symptomatic, with scores predictable by breast-conserving therapy, along with relevant confounders, were selected for structural equation modeling. Functional and symptomatic domains were evaluated by EORTC QLQ-C30 and QLQ-BR23; therefore, two latent variables, functional and symptomatic status factors, were constructed and realized by observable QOL subscale scores in functional and symptomatic domains, respectively. The cause–effect relationship between latent symptomatic and functional factors was quantified by regression weight. The rationale for such an arrangement came from the hypothesis that worse symptoms

might cause QOL function deterioration, as suggested by Fayes et al in their causal-indicators model.[18,19] QOL scores and potential confounders were treated as endogenous and exogenous observed variables in this construct.

For structural equation modeling, goodness of fit was evaluated by χ^2 and the ratio of χ^2 to the degree of freedom. A ratio of < 3 indicated a good fit of the hypothesized model to the experimental data. Other fit indexes included: goodness of fix index (GFI) > 0.90, adjusted GFI > 0.80; standardized root mean square residual (RMR) < 0.1; comparative fit index (CFI) > 0.9; root mean square error of approximation (RMSEA) < 0.08; normed fix index (NFI) > 0.9; non-normed fix index (NNFI) > 0.9; and incremental fix index (IFI) > 0.9.[20–25] Global model fitness of the structural equation modeling construct was tested and indicated by absolute (χ^2, GFI, adjusted GFI, standardized RMR, and RMSEA), incremental (NFI and NNFI) and parsimonious (CFI and IFI) fit measures.[26] Statistical works with structural equation modeling were performed with AMOS version 6.0 (SPSS Inc., Chicago, IL, USA).

Measurement invariance

Measurement invariance was guaranteed in two steps. First, multi-group structural equation modeling was performed and factor loadings for each group were estimated separately. Configuration or pattern invariance across groups was ascertained and pair-wise comparisons of factor loading of each QOL domain/subscale were performed. Factorial invariance was claimed when factor loadings for different groups were the same for most QOL subscales. Second, after assuring factor and structure homogeneity across groups with equal values, latent variables (intercepts for endogenous and means for exogenous variables) were allowed to be estimated separately for each group, as were regression weights between latent variables within each group. Generally, mean structural analysis was based on the prerequisite of structural equation modeling with equal factor loadings in most measurement domains for all groups, but allowed latent variables to change across groups in intercept/mean and distinct estimation of regression weights for each group if multiple latent variables were included in the model.

Results

QOL in patients with and without breast-conserving therapy

Univariate analysis revealed that the breast-conserving therapy group experienced worse global health status/QOL and role function, as well as more fatigue, pain, dyspnea, insomnia, appetite loss, breast and arm symptoms, than the modified radical mastectomy group. In general, patients with breast-conserving therapy reported lower functional domain QOL scores and worse (higher) symptomatic domain QOL scores. The only exception was the sex enjoyment subscale of EORTC QLQ-BR23, for which, more satisfaction was observed for the breast-conserving therapy group (Table 2).

Multivariate analysis

Table 3 shows regression weights when multiple linear regression analysis was performed with QOL subscale scores as dependent variables. Breast-conserving therapy inevitably exerted a negative impact upon functional domain subscales and worsened symptomatic domain subscales. When

Table 2. Mean quality of life score of study population

Quality of life subscale	Breast conserving therapy	Modified radical mastectomy
Global health status/QOL	56.3	68.1
Role function	73.9	89.7
Fatigue	37.2	22.5
Pain	34.7	15.4
Dyspnea	17.1	6.2
Insomnia	45.9	22.2
Appetite loss	21.6	8.1
Sex enjoyment	52.8	35.7
Breast symptoms	27.2	20.0
Arm symptoms	31.2	18.1

QOL = Quality of life.

Table 3. Regression weights of multiple linear regression analysis

QOL subscale	Confounder				
	Breast conserving therapy	Age	Married status	Adjuvant therapy	Hormone manipulation therapy
Global health status/QOL	–9.7	–	–	–	–
Role function	–15.0	–	–16.3	–	–
Fatigue	13.3	–	–	–	–
Pain	18.4	–	–	–	–
Dyspnea	10.8	0.4	–	–	–
Insomnia	22.4	–	–	12.1	12.0
Appetite loss	11.1	–	–	–	–9.2
Sex enjoyment	–	–	–	–	–
Breast symptoms	11.4	–	9.4	8.3	–
Arm symptoms	12.2	–	–	11.5	–

QOL = Quality of life.

age was treated as a continuous variable, every 10-year gain in age was associated with a four-point increase in dyspnea score. Marital status had an adverse effect on role function and breast symptoms. Adjuvant therapy, as expected, caused deterioration in insomnia, breast and arm symptoms. Hormone manipulation therapy, however, showed contradictory effects with worse insomnia but fewer appetite loss problems. Neither education level nor clinical staging was predictive of QOL. It should be noted that sex enjoyment was no longer predictable by breast-conserving therapy after multivariate adjustment.

QOL construct with structural equation modeling

QOL subscales with significant differences in scores between breast-conserving therapy and modified radical mastectomy were treated as observed endogenous variables, and QOL confounders as observed exogenous variables. Two latent variables, one for functional and the other for symptomatic domains, were constructed and the cause–effect relationship was expressed by regression weight (symptomatic status factor → functional status factor, Figure). As a result of missing values in some questionnaire items, there were 117 subjects (35 in the breast-conserving therapy group) available for structural equation modeling analysis.

Multi-group model with mean/intercept fixed to zero was tested first for measurement invariance, and factor loadings for each group were estimated separately. Pair-wise comparisons revealed between-group differences in factor loadings: functional status factor → role function, symptomatic status factor → breast symptoms, and regression weight: adjuvant therapy → breast symptoms, all of which had exceeded the critical ratio of 1.96 at an α level of 0.05. Point estimates of standardized regression weights were: 0.820 versus 0.575 (functional status factor → role function); 0.428 versus 0.709 (symptomatic status factor → breast symptom); and 0.357 versus 0.102 (adjuvant therapy → breast symptom) for breast-conserving therapy and modified radical mastectomy. Other parameters showed no significant between-group differences. A revised model with equal factor loadings across groups (factorial invariance) was constructed and model fitness parameters revealed a significant χ^2 difference of 28.505 (df = 15, $p = 0.015$), which indicated a slightly compromised model fit if measurement invariance was assumed for the breast-conserving therapy and modified radical mastectomy groups.

Based on factorial invariance assumption, a means model with different means/intercepts across groups was constructed. The mean of latent exogenous symptomatic status factor, intercept of latent endogenous functional status factor, and

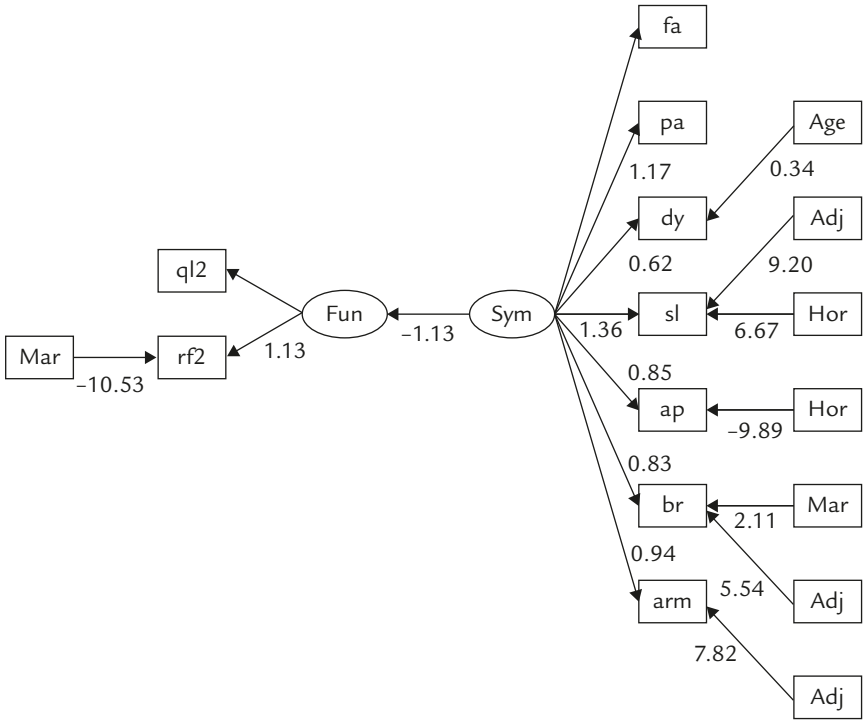

Figure. Quality of life construct with structural equation modeling. Two regression weights (fun → ql2 and sym → fa) were set to unity as baseline. fun = Functional status factor; sym = symptomatic status factor; ql2 = global health status/quality of life; rf2 = role function; fa = fatigue; pa = pain; dy = dyspnea; sl = insomnia; ap = appetite loss; br = breast symptom; arm = arm symptom; mar = marital status; adj = adjuvant therapy; hor = hormone manipulation therapy.

regression weight (symptomatic status factor → functional status factor) were estimated separately for patients with and without breast-conserving therapy. Regression weight (symptomatic status factor → functional status factor) was −1.127 ($p < 0.001$), which was compatible with a causal relationship between these two latent variables, and showed no difference between the breast-conserving therapy and modified radical mastectomy groups. The mean symptomatic status factor for the breast-conserving therapy group was 15.917 higher than for the modified radical mastectomy group, and was highly significant at the $p < 0.001$ level. The intercept of functional status factor was 4.425 higher for breast-conserving therapy but was not statistically significant ($p = 0.138$).

Discussion

We conducted a cross-sectional QOL survey in Taiwanese breast cancer patients who underwent curative surgery with or without breast-conserving therapy. For eastern countries where the incidence of breast cancer is around half that in western countries, the impact of relevant clinical factors and demographic features upon QOL following breast cancer surgery should be evaluated independently and thoroughly.[1,10] We found that patients who received breast-conserving therapy rather than modified radical mastectomy reported worse function and more symptoms, even after adjusting for other confounders.

Many previous studies have emphasized the benefits of functional preservation, and limited breast resection, such as breast-conserving therapy, might bring favorable cosmetic results and subsequent better QOL, especially with regard to body image, femininity, sexual function and other dimensions.[2–6] For example, Engel et al[7] demonstrated that breast-conserving therapy outperforms modified radical mastectomy for better body image, role and sex function scores in the EORTC QLQ-C30 questionnaire. Optimistic outcomes for

breast-conserving therapy using other measuring tools have also been reported in the Asia–Pacific region, such as India and Australia.[27,28] Janz et al[29] found that patients treated with breast-conserving therapy experience subjectively better body image than those treated with modified radical mastectomy and reconstruction, whereas age and education have been identified as QOL predictors. In contrast, Shimozuma et al[30] argued that there is no association between type of surgery and QOL 1 year after breast cancer surgery.

Most QOL studies regarding postoperative functional and symptomatic status have been performed with standard and valid measuring instruments, and have compared QOL scores between groups with different treatment modalities or other potential confounders. Usually, the same study subjects have been tested several times for each QOL subscale dimension. However, none has investigated in depth the whole QOL construct, including functional and symptomatic domains simultaneously, and the correlation between these two domains across multiple QOL subscales. To overcome the problem of multiple tests in the same study population, and to treat the QOL construct as a whole with underlying factor/pathway structure incorporated into model fitness, structural equation modeling with multiple indicators was performed and acted as the main analytical strategy in the current study.

The advantages of structural equation modeling rather than direct QOL scores comparison include simultaneous parameter estimation and serial model fitness evaluation. Relationships between the observed variables (QOL scores) and latent variables (functional and symptomatic status factors) are evaluated in a hierarchical manner. Measurement and equation errors are estimated separately. Structural equation modeling has been adopted for generic instruments such as the Short Form-36 (SF-36) Health Survey[31,32] and cancer-tailored EORTC questionnaires.[33] The initial effort of using structural equation modeling for EORTC QLQ-C30 (version 1.0) was proposed by Fayers et al,[18] by separating the causal variables (symptoms) from the effect indicator variables (QOL domains). In 2006, Boehmer et al[34] expanded the concept of causal and indicator variables to evaluate fully the multifactorial structure of QLQ-C30, except items that measure global health status/QOL (Q29 and Q30). They named the causal-indicator variables approach the "multiple indicator multiple cause" (MIMIC) method. In the current study, the causal relationship between symptomatology and QOL functionality was quantified by regression weight, with the latter regressed on the former.

For structural equation modeling with multiple study populations, such as in the current study, there are two levels of measurement invariance. The first is configuration or pattern invariance, to guarantee that the factor/pathway structure remains the same across multiple groups. The second is that when factor loadings are equal across groups (factorial invariance), underlying latent factor means and intercepts are relaxed for estimation. As already mentioned, mean/intercept estimation (structure mean modeling) is based on the prerequisite that factor loadings are equal across all groups to guarantee the comparability of latent factors.

Initially non-parametric univariate analysis revealed that role function, global health status/QOL, sex enjoyment and problems such as fatigue, pain, dyspnea, insomnia, appetite loss, breast and arm symptoms were QOL subscales that showed significant score differences between breast-conserving therapy and modified radical mastectomy patients. Other QOL confounders, including age, education level, clinical stage, marital status, adjuvant therapy, and hormone manipulation therapy, were incorporated into linear regression models, and their impacts upon QOL were evaluated as regression weights in multiple linear regression analysis. It should be noted that our study did not have a randomized controlled design. It was not easy to allocate subjects to different surgical modalities without bias, such as personal preference, prior knowledge and value judgment on breast-conserving therapy, financial affordability, body image perception and other factors. The choice of breast-conserving therapy or traditional modified radical mastectomy is

complex, while some confounders are observable and others might not be. However, we tried to collect as many QOL confounders as possible to reduce the bias to a minimum. Besides, only significant QOL subscales were enrolled as dependent variables in multiple linear regression and the structural equation modeling construct. The variables selection strategy was to keep the model parsimonious and avoid potential co-linearity problems from highly correlated QOL data.

Adjuvant therapy aggravated insomnia, breast and arm symptoms. This finding is in consistency with previous studies.[35–37] Hormone manipulation therapy remained a conflicting QOL predictor because it had both a positive and negative effect on appetite loss and insomnia. In general, few side effects are now widely acknowledged for hormone therapy in terms of health-related QOL.[38,39] A positive impact of breast-conserving therapy on sex enjoyment has been reported elsewhere.[10,40,41] The impact of breast-conserving therapy upon sex enjoyment, however, became insignificant after multivariate adjustment and was abandoned from structural equation modeling analysis.

QOL subscales with significant between-group difference and relevant confounders were selected from univariate analysis and multivariate analysis, and entered for structural equation modeling. For configuration/pattern invariability, the equal factor loadings assumption was tested by pair-wise comparisons: three (functional status factor → role function, symptomatic status factor → breast symptom, and adjuvant therapy → breast symptom) were violations of between-group factorial equality. Despite this and slightly compromised model fitness indexes, measurement invariance was grossly satisfied, and the mean structural model with endogenous latent intercepts and exogenous latent means that were allowed to vary across groups was constructed. Regression weight (symptomatic status factor → functional status factor) was –1.127 and remained constant for breast-conserving therapy and modified radical mastectomy. The causal and negative effect of symptomatic status factor upon functional status factor was self-evident here. The mean of latent symptomatic status factor, in contrast, was 15.917 higher for breast-conserving therapy. The null hypothesis of equal intercept of latent functional status factor was not rejected, which meant that underlying functional status level was the same for breast-conserving therapy and modified radical mastectomy, after expelling the effect of the exogenous symptomatic status factor and its regression power.

Our study demonstrated that compromised functional and worse symptomatic scores reported by breast-conserving therapy patients were mainly attributed to the much higher mean latent symptomatic status factor. Breast-conserving therapy is understood to have better cosmetic effects than modified radical mastectomy, at the expense of postoperative adjuvant radiotherapy and more frequent follow-up to detect recurrence. After adjusting for multiple QOL confounders, we found that the breast-conserving therapy group suffered from a higher mean latent symptomatic status factor, which in turn, was manifest as higher QOL scores in multiple symptomatic domain subscales.

Our study showed that clinical staging had little impact upon QOL. Our data also indicated that, early stage or late stage breast cancer, once cured, might enjoy similar levels of QOL. The same phenomenon has been observed for Taiwanese gastric cancer patients.[42] Subjective perception of health-related QOL might not necessarily be in accordance with relevant clinical factors, such as clinical stage, which predict long-term survival. In conclusion, we found that breast-conserving therapy had a negative impact on some aspects of patients' subjective QOL and more preoperative communications with patients about the benefits and pitfalls of breast conserving therapy are necessary.

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