Study of Quality of Life for Uterine Cervical Cancer : Preliminary Study for Development of a QOL Scale.

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Preliminary Study for Development of a QOL Scale.

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Abstract

In uterine cervical cancer，the outcome of treatment has been evaluated by survival or response rate for anticancer drugs．Recently，evaluating subjective quality of life（QOL）has become one of the most important parameter of evaluating patient outcome． The purpose of this study is to make scales for evaluating subjective QOL common to patients with uterine cervical cancer and to examine the scales from a viewpoint of reliability and validity．The 124 items were collected for QOL questionnaire，and finally 28 items including femininity and sexual life domain were selected by gynecologic oncologists，gynecologic care nurses，sociologist and statistician．One hundred and seventy-six patients with cervical cancer were available for this study．Cronbach's α demonstrated good internal consistency，with the coefficient α equal to 0.85．Construct validity was assessed by correlating the CES-D self-recording type depression scale（Radloff，1977）with this QOL score using Spearman's rank coefficient．The correlation between this QOL questionnaire and the CES-D self-recording type depression scale was r=.-657（p<0.01）．Four items were deleted because of deviation of answering "yes"（more than 90%）in two by simple tabulation，and poor item-total correlation in two．Then，total of 24 items were used for factor analysis．The number of the factors whose peculiar values were 1.0 or more is 5，and the versatility of QOL was suggested．We should add new items and perform test by the revised QOL questionnaire to improve this QOL questionnaire．

Keywords：quality of life（QOL）生活の質
scale development（尺度開発）
questionnaire survey（質問紙調査）
uterine cervical cancer（子宮頸がん）

Introduction

We have developed a scale for evaluating subjective quality of life（QOL）to patients with uterine cervical cancer．In uterine cervical cancer，the outcome of treatment has been evaluated by survival or response rate for anticancer drugs．Recently，the evaluating subjective quality of life（QOL），which a patient herself feels，is one of the most important parameters of evaluating patient outcome（1）．The quality of life needed to be quantified to perform QOL evaluation objective．The investigation item used as the index had to be examined from a viewpoint of reliability and validity（2-6）．However，there is no QOL scale specific for

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the uterine cervical cancer. Now it is important to develop the QOL questionnaire specified as cervical cancer aimed at setting up the investigation item examined from a viewpoint of reliability and validity for the QOL evaluation.

Materials and Methods

The process for item generation was taken the following procedure. An initial pool of questions was generated by a critical review of literature and the previous questionnaires of WHO QOL –26 (26 items) (7), European organization for research and treatment of cancer quality of life questionnaire (EORTC QOL) (30 items) (8) and Quality of life questionnaire for cancer patients treated with anticancer drugs (QOL-ACD) (22 items) which are conventionally used for the cancer patients (9-10), and related references. Moreover, from the viewpoint of a sex and gender, the researcher of the domain concerned conducted to reference about femininity and sexual life, and proposed the investigation item. In addition, the peer interviews with gynecologic oncologists, and gynecologic care nurses were done. These questions formed the basis of a semi-structured interview. Each researcher such as gynecologic oncologists, gynecologic care nurses, a sociologist and a statistician proposed the question item reflecting each research domain using the K-J method. As an initial step, the investigators eliminated redundant items. The 124 items included physical domain (36 items), human relationship domain (13 items), psychological domain (30 items), social function domain (2 items), economic domain (2 items), medical domain (14 items), a health view (three items), an overall health view (two items), vitality (three items), and femininity and sexual life domain (19 items).

These items were extracted to a total of 28 items in process of wording. The wording is adjusting the language usage of a question. Questions were constructed to be simple, direct, clear, unbiased and closed ended. In process of repeating the work of wording, the double barrel questions and the questions with the carry-over effect were eliminated, and it strove for creation of a more suitable question item.

The 28 items are attached in Table 1.

Each question was accompanied by a 4-point Likert scale, anchored at the ends with 1= "only

Table 1. Quality of Life Scale

1. Do you experience any difficulties in performing everyday tasks (meal preparation, dressing/personal care)?*
2. Do you worry about needing other person's assistance in performing everyday tasks (ADL'S)?*
3. Do you experience any difficulty at work and with housekeeping?*
4. Are meals enjoyable and delicious?
5. Do you experience difficulty in sleeping?*
6. Does pain become a hindrance in everyday life?*
7. Are your bowel movements troublesome?*
8. Do you have any issues relating to urination?*
9. Do you feel personal relationships (family, friends) are satisfying?
10. Are you able to concentrate, absorb and devote yourself to things?
11. Do you feel you have emotional support?
12. Do you feel blue (depressive, insecure, desperate etc)?*
13. Do you feel that it is good to be alive?
14. Are home life and work life worthwhile?
15. Is illness economically burdensome?*
16. Do you feel that you are able to talk to the doctor and nurse in charge of you?
17. Do you feel satisfaction with your current medical treatment?
18. Do you find it troublesome to make frequents trips to the hospital?*
19. After experiencing sickness, do you feel that health is valuable?
20. Do you feel anxious about the course of your illness?*
21. Do you feel less feminine due to bodily changes?*
22. Do you feel uneasy about your sexual life and find sexual intercourse restrictive?*
23. Do you feel satisfied with intimate and sexual relationships with your husband or partner?
24. Do you feel satisfied with life in general?
25. Do you feel satisfied with your health on the whole?
26. Do you feel you live with confidence?
27. Do you feel there is meaning to living?
28. Are you able to respond to your illness positively?

*: reversed item

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a little", through 4="a lot". The final reduced set of questions comprised the first version of the questionnaire with 28 questions.

Then, the questionnaire for medical institutions and the questionnaire for patients were made. In the questionnaire for medical institutions, items concerning performance status, clinical stage, therapeutic procedure, presence or absence of dysuria, and so forth were selected for external standard of QOL scale. The questionnaire for patients is composed of the question item about the attribute（age, the presence of the husband or partner, the labor load, the degree of the pain） and the question item of newly developed QOL scale. Furthermore, a CES-D self-recording type depression scale（11）was adopted as an external standard of a QOL measure. The pretest of this questionnaire was carried out for 30 persons, before conducting this investigation. The investigation for new QOL scale was performed at three major general hospitals in Fukuoka city. The questionnaires were distributed and collected after explanation of this study to the outpatients with the uterine cervical cancer. Data was statistically analyzed by using SPSS10.0J. The simple tabulation, Spearman's rank coefficient and t-test were used as the statistics procedure. Moreover, the internal consistency reliability was assessed by Cronbach's α coefficient which is a measure of the extent to which items within a scale correlate with each other to constitute a multi-item scale（12）. A Cronbach's a coefficient of 0.70 or greater is considered acceptable. Construct validity was assessed by correlating this QOL questionnaire with external standard of QOL scale using Spearman's rank coefficient. Good － poor （GP）analysis, item-total（IT）correlation analysis and factor analysis were done to select appropriate items.

This research observed the "ethics indicator about epidemiology research" notified from the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labor and Welfare on June 17, 2002, and was carried out. About investigation, we obtained consent from each patient, and had her enter. Although obtained from each medical facility about consent of patient information offer, for protection of personal information, the information was collected only in an assignment researcher and a research cooperator. After it performed disposal which transposes all patient names to a number, and forms them into connection impossible anonymity, it processed by inputting data.

Results

One hundred and seventy-six patients with cervical cancer were available for this study. One hundred sixty patients（91%）were performance status 0, and sixteen（9%）were performance status 1. One hundred fourteen（65%）were clinical stage I, 32（18%）were stage II, 25（14%）were stage III and 5（3%）were stage IV. One hundred and thirty patients（74%）underwent at least a total hysterectomy, and in 111 of these 130, radical hysterectomy was performed. Eighty-eight patients （50%）were treated by radiation, and 61（35%）had chemotherapy. Fifty-one patients（29%）had dysuria and 44（25%）had dyschezia（disturbance of bowel movement）. The average age of the 176 patients was 53（ ± 14）. One hundred and nineteen（69%）had is a husband or a partner. One hundred and forty-four patients（84%）had one or more children. In 127 patients（73%）, it took less than one hour from their home to the hospital. Concerning labor load, 100 patients（60%）were doing mostly or relatively standing work. Sixty-six patients（38%）complained of pain.

Cronbach's α demonstrated good internal consistency, with the coefficient α equal to 0.85. The questionnaire was tested for construct validity. Construct validity was assessed by correlating the CES-D self-recording type depression scale

(11) with this QOL score using Spearman's rank coefficient. The correlation between this QOL questionnaire and the CES-D self-recording type depression scale was r=.-657 (p<0.01).

The QOL measure item considered correlation between items etc. Question 1 and 2 were deleted because of deviation of answering "yes" (more than 90%) by simple tabulation. The correlation between question 4 and 19, and total score were r=0.218 and 0.193, respectively, and these two questions were deleted because of poor item-total correlation. Question 19 had also no significant differences by good-poor analysis. In this way, four items, namely 1, 2, 4, and 19 were deleted, and a total of 24 items were used for factor analysis. The result of factor analysis indicated five subscales of QOL. These are, 1) "Feel satisfied with life", 2)" Feel life worth living", 3) "Feel no emotional disturbance", 4) "Feel no hindrance in daily life", 5)" Feel no troubles in performing". The QOL outcomes of the patients are shown in Table 2.

Discussion

At present, there is no QOL questionnaire specific for uterine cervical cancer. The questionnaire in consideration of the specificity of the disease is necessary to evaluate patient's QOL. This QOL questionnaire was created also fully in consideration of the sexual life and femininity relevant to the female genitals, medical economy, medical access

Table 2. Result of Factor Anasysis of QOL

	1	2	3	4	5
16. Do you feel that you are able to talk to the doctor and nurse in charge of you?	.609				
17. Do you feel satisfaction with your current medical treatment?	.648				
24. Do you feel satisfied with life in general?	.739				
25. Do you feel satisfied with your health on the whole?	.615				
26. Do you feel you live with confidence?	.741				
27. Do you feel there is meaning to living?	.779				
28. Are you able to respond to your illness positively?	.648				
9. Do you feel personal relationships (family, friends) are satisfying?		.776			
10. Are you able to concentrate, absorb and devote yourself to things?		.702			
11. Do you feel you have emotional support?		.794			
13. Do you feel that it is good to be alive?		.769			
14. Are home life and work life worthwhile?		.570			
23. Do you feel satisfied with intimate and sexual relationships with your husband or partner?		.335			
5. Do you experience difficulty in sleeping?			.418		
12. Do you feel blue (depressive, insecure, desperate etc)?			.637		
15. Is illness economically burdensome.			.540		
20. Do you feel anxious about the course of your illness?			.679		
21. Do you feel less feminine due to bodily changes?			.590		
22. Do you feel uneasy about your sex life and find sexual intercourse restrictive?			.680		
3. Do you experience any difficulty at work and with housekeeping?				.763	
6. Does pain become a hindrance in everyday life.				.768	
7. Are your bowel movements troublesome?				.750	
1. Do you have any issues relating to urination?					-.531
18. Do you find it troublesome to make frequents trips to the hospital?					.729
cumulation of percentage	16.6	30.3	41.1	51.6	57.2

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and a mental side.

When evaluating QOL, it is a big subject how to evaluate subjective QOL objectively. It is important for quality quantifying what method is taken and whether it becomes the index with which the method had reliability and validity (1-6).

The internal consistency reliability was measured by Cronbach's α coefficients, which is a measure of the extent to which items within a scale correlate with each other to constitute a multi-item scale (12). A Cronbach's α coefficient of 0.70 or greater is considered accepted. In this study, the Cronbach's α coefficient shows high value with 0.85, and it is thought that there is sufficient internal consistency about this scale.

Examination of standard related validity is performed as examination of validity (1-3). It is common to investigate the relation between the characteristic and an external standard through calculation of a correlation coefficient. In this investigation item, performance status of a patient and depression measure (11) were set up as an external standard, and the correlation coefficient with a QOL investigation item was computed. A strong correlation between a depression measure and QOL questionnaire was shown and standard related validity was accepted. Moreover, the gynecologists and special nurses of the gynecology selected the item. Small-scale investigation is conducted also to patients, and the contents-validity of an investigation item is guaranteed

As an appraisal method to a cancer patient, the QOL questionnaire (22 items) in WHO QOL-26 (26 items) (7), EORTC (30 items) (8), and the cancer medication of the Ministry of Health and Welfare (9-10), with which examination of reliability or validity is fully made is often used for QOL evaluation.

These questionnaires were generally accepted by patients with nonspecific cancer (7-10), but not created to specific cancer such as cervical cancer.

There were several points which should be corrected in some respects for evaluating a patient's QOL with cervical cancers.

The specificity of cervical cancer was considered and the item about the sexual life and femininity in relation to female genitals, the item about postoperative urination / defecation disturbance, medical economy and medical access, and the item about a mental side were also added.

In WHO QOL-26 (7) and EORTC (8) which were translated into Japanese, the investigation item is created on the basis of the European and American view, some investigation items had the difference in the view of Japanese people and Europeans and Americans, and there were some which are considered to be inapplicable to Japanese people as it is. Moreover, the problem of wording was also seen in part. As for the QOL questionnaire from the former, emphasis is put on evaluation of the effect of intervention of medical treatment (7-10).

Researchers, in fields of medicine, the science of nursing, sociology, and statistics, cooperated in creation of this investigation item, and it aimed at creating the questionnaire which fully reflected how the patient felt and the life style itself.

In question 1 and 2, the majority of patients in this study were going to outpatient clinic with relatively good performance status and more than 90% of patients answered yes. These two questions should be deleted because of deviation of answer. Question 4 was inadequate by item-total correlation analysis, and work of wording may be necessary. Question 19 was the double barrel one.

In conclusion, this research aimed at the setup of the investigation item for the QOL evaluation about uterine cervical cancer. The questionnaire carried out in fixed evaluation from the former was made reference. Paying attention to the feature of a disease, the item about sexual life, the item about postoperative urination / defecation disturbance, and the item about femininity were added further,

and the questionnaire was created. In order to examine the internal consistency, Cronbach's α coefficients was computed（12）. Correlation with the degree of depression（11）used as an external standard for evaluating standard related validity was found. Reliability and validity are checked and the investigation item about QOL for patients with cervical cancer created this time is considered for usefulness to be relatively high. In this study, 24 items were adequate for QOL questionnaire, but 4 items were deleted for various reasons. We should add new items and perform test by the revised QOL questionnaire to improve this QOL questionnaire. From now on, QOL evaluation will be investigated with time and across boundaries to patients with cervical cancer using this questionnaire. Evaluation of the QOL which the patient itself feels is taken in to evaluation of outcome of medical treatment for patients with cervical cancer. The effect of medical treatment can be caught on many sides by this, and the evaluation of the QOL is expected to be important issue for the future cancer treatment

Acknowledgements

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ー要　旨ー

　子宮頸癌患者の治療成績は生存率や薬物療法に対する治療効果により評価されてきたが，患者自身が感じる生活の質（Quality of Life）も合わせて評価することが重要視されてきた。

　医学・助産学・看護学等各研究者が集まってK-J法を用い，性生活に関する項目や，術後の排尿・排便障害に関する項目，さらに女性らしさに関する項目に従来から一定の評価をされている調査票も参考にして身体機能，人間関係，心理，社会機能，経済，医療，健康観，全体的健康観，活力を加えた124尺度項目を抽出した。

　これらの項目は，wordingの過程で計28項目に絞られた。QOL尺度の外的基準を測定する項目はPerformance Status，臨床進行期，治療方法，排泄障害の有無であった。データはSPSS10.0Jで単純集計，スピアマンの順位相関係数を用いた。また，信頼性係数にはアルファを用いた。本研究は文部科学省，厚生労働省から告示された「疫学研究に関する倫理指針」（平成14年6月17日）を遵守して遂行された。QOL27項目の内的整合性を検討するためにCronbachのα係数を算出したところ，$\alpha = .85$であり，内的整合性が高かった。

　次に，QOL項目の基準関連妥当性を検討するために，それぞれ外的基準としての設問項目との相関をみた。その結果，CES-D自記式抑うつ尺度との間に強い負の相関（r=.−657，p<0.01）があった。

　QOL尺度項目は，項目間の相関などを加味し，一定の方向性の見られない4項目を削除し，計24項目を採用した。24項目の因子分析の結果，因子の数は5であり，QOLの多面性が示唆された。

　子宮頸癌に関してのQOL評価のための調査項目の設定を目標とした本研究では疾患の特徴に注目し，性生活に関する項目や，術後の排尿・排便障害に関する項目，さらに女性らしさに関する項目を加え調査票を作成した。今回作成した子宮頸癌患者のQOLに関する調査項目は信頼性と妥当性をクリアし有用性が高いと思われるが，さらに新たな調査項目を加え再調査し，より完成度の高い調査票を作成して，子宮頸癌患者に対して経時的，横断的にQOL評価の調査を行って，患者自身が感じる生活の質（Quality of Life）の評価も子宮頸癌患者の治療効果の評価に取り入れていくことにより，治療効果をより多角的に捉え，今後の癌治療に活かされることが望まれる。