

Development and Validation of Quality of Life Tool among Chemotherapy Patients: A Pilot Trial

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ABSTRACT

Introduction: Quality of Life (QoL) is a main alarm of patients with life-threatening cancer. Symptoms have an effect on their QoL. There are many standardised tools which measure the QoL among cancer patients. But there is no specific questionnaire or tool available to evaluate the chemotherapy patients in Indian context.

Aim: To develop and validate a QoL tool for chemotherapy patients.

Materials and Methods: This mixed method pilot study with sequential exploratory design was led at Outpatient Department (OPD) and Inpatient Department (IPD) of S. N. Shah Cancer Hospital, Nadiad city, Gujarat, India, from April to May 2020. In qualitative stage, the data was gathered by involving in detail interview of 15 chemotherapy patients. Interview data were analysed by utilising conventional content analysis method and themes and subthemes were formed. Based on it, a pool of items for the questionnaire was prepared. In quantitative stage, psychometric properties of the questionnaire were assessed by

using face, content and construct validity. The reliability of the tool was evaluated by internal consistency and Cronbach's alpha. Overall 15 patients participated in qualitative and quantitative phase separately.

Results: At the end of phase I, a draft of 104 questionnaires was formed. In phase 2, a specialist panel reviewed 84 items relevant with the domains and 20 items were erased on the basis of expert opinion, Item Content Validity Index (I-CVI) and Scale Content Validity Index (S-CVI). At this time, 84 item tool were given to 15 chemotherapy patients. In view of the patient's opinion, researcher drew a screen plot based on eigen value of above 1. These four domains showed 53.846% of the total variance. Last 84 items were scrutinised as per specific domain. The end draft had a Cronbach's alpha value of 0.932.

Conclusion: The newly develop tool will help the chemotherapy patients and healthcare team to evaluate the QoL. This QoL tool will also impact the cancer treatment and implement strategies accordingly.

Keywords: Item pool generation, Mix method, Psychometric property, Sequential exploratory, Tool development

INTRODUCTION

There are numerous factors which affect the health status of a person and society. The key components of health include physical, mental, social, emotional and spiritual well-being [1,2]. Cancer is a leading reason of death. People living with cancer experience a diversity of symptoms. QoL cares with "the degree to which an individual enjoys the important possibilities of life". Health Related Quality of Life (HRQoL) depicts an individual's view of how well-being impacts a person's life quality and overall well-being. QoL is a significant measurable result of care for conditions that do not threaten life [3]. The QoL is an individual observation. It may vary from person to person as per his life goal and expectation. A healthy person is considered to have a good QoL [4]. QoL can be dignified with the help of qualitative and quantitative approach. Mixed method is the best approach to collect the detailed information from the participants [5]. Mixed method is a way to gather information under various domains. It also recognises the theme and subthemes from subject's statement [6]. Evaluating the QoL tool among the chemotherapy patient it assists with perceiving their neglected necessities, individual issues, physical needs and so forth.

Many tools have been developed to assess the QoL of cancer patient in India and globally and there are few remedial modalities for cancer treatment such as surgery (curative, palliative), radiation therapy and chemotherapy. This tool might be utilised for cancer patients. But the present study revealed that the newly developed tool (84 items) covered all the domains of health (physical, social, psychological and spiritual). This tool also covered various important questions like awareness about disease, lack of knowledge about government

health scheme, Non Government Organisation (NGO) for cancer, poor socialisation, social aspects (stigma, non acceptance in family), spiritual aspects, traditional beliefs and superstition etc. Therefore, the newly developed tool (84 items) is a useful tool in measuring QoL among the chemotherapy patients. It can be used to observe the patient's QoL improving during the chemotherapy cycle. It is simple to use and not cumbersome.

MATERIALS AND METHODS

This mixed method pilot study with sequential exploratory design was led at Outpatient Department (OPD) and Inpatient Department (IPD) of S. N. Shah Cancer Hospital, Nadiad city, Gujarat, India, from April to May 2020. The study was endorsed by the Institutional Ethics Committee board of CHARUSAT (ARIP/IEC/19/08).

Inclusion criteria: Patient diagnosed with cancer (irrespective of site) and those who were receiving chemotherapy, atleast had 2 or more cycles, age above 20 years, free at the time of enrolment were included in the study.

Exclusion criteria: Cancer patient receiving chemotherapy along with radiation and other adjuvant treatment and refusal to give assent were excluded from the study.

Study Procedure

It is sequential exploratory, since first qualitative information and secondly quantitative information has been collected [Table/Fig-1]. In stage I, qualitative data were assembled from the 15 chemotherapy patient's those were diagnosed with cancer. In stage II, information was gathered from the same 15 chemotherapy patients. Each interview lasted for 15-20 minutes. The responses were noted and

| Steps | Phase | Output |
|--|------------------------|---|
| Detailed interview of participant till information immersion (n=15) | Qualitative phase | Seeking information |
| Coding and thematic analysis by conventional content analysis method | Qualitative phase | Convert information into 101 questions |
| Convert data into scaling | Quantitative phase | Likert scale of 1-5 point where 1=Always, 5=Never |
| Data collection (n=15) | Quantitative phase | Collect raw score of each item |
| Exploratory data analysis, internal consistency and reliability | Quantitative phase | Descriptive and analytic statistics |
| Integration of quantitative and qualitative data | Final tool development | 84 items in tool Includes |

[Table/Fig-1]: Phase of mix method study.

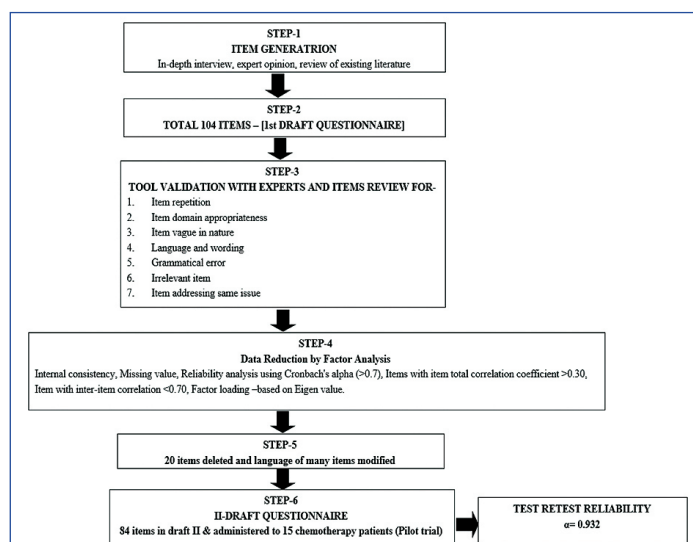
analysed using conventional content analysis. Here a researcher extracts contextual category, themes and significant statement. Data were gathered and analysed through Colaizzi method [7]. A written informed consent was taken from the patients before their cooperation in two phases. Baseline information including participants age, gender, educational status, religion, occupation, income of the family per month in rupees, financial support for chemotherapy, duration of illness, cancer affected region or organ, total number of cycle, type of care and type of chemotherapy administered.

STATISTICAL ANALYSIS

The statistical analysis was coordinated by using Statistical Package for the Social Sciences (SPSS) programming. Reliability, factor analysis, internal consistency, scree plot, inter item correlation, item total correlation was determined. The reliability was calculated through Cronbach's alpha.

RESULTS

Schematic representation of research methodology and process of tool development [Table/Fig-2]: Total 104 items were developed at the end of primary phase. Many of the items



[Table/Fig-2]: Schematic representation of research methodology and process of tool development.

were deleted from the pool, due to item repetition, item domain appropriateness, item vague in nature, correction in language and wording, few grammatical error, irrelevant item to cancer, item addressing same issue. Further, Factor Analysis (FA) was run to reduce the number items. Based on FA, 20 items were removed. The second draft consisted of 84 items which were further administered to the participants. The test retest reliability was found 0.932.

Phase-I (Qualitative)

The process of interview continued till the data saturation. In the interview questions were asked to patients on how the disease was diagnosed, experience of chemotherapy cycle and its affect, impact on day to day life, support from family members and society, financial crisis, employment issue, psychological impact, impact of spiritual activities etc. Patient's responses were noted. The responses were analysed using conventional content analysis. Result of participant's interview was discussed among the oncologist and nurse. The oncologist reviewed the interview and developed a questionnaire and suggested fitting the items as per appropriate domain. Nurses suggested including item related to patient behaviour, psychosocial well-being, financial aspect, family aspect and communication. Toward the finish of this phase-1, a pool of 104 items through categories four domains was developed. The back translation of questionnaire in local language (Gujarati) was initiated.

Phase-II (Quantitative Phase)

Validity of Tool: I-CVI (content validity of individual items) and S-CVI (content validity of the overall scale) were calculated for content validity. In this phase, 16 experts were involved (Onco-physician, Onco-surgeon, physician, psychologist, bio-statistician, pharmacologist, Onco-nurse, PhD nursing faculty) for the content validation of tool. The experts were asked to give their perspectives and rate on the very items produced during phase-I. A scale with excellent content validity ought to be made out of I-CVIs of 0.78 or higher and S-CVI Average of 0.8 and 0.9 or higher, individually [8]. The I-CVI reached the level of acceptance, that is, 0.869. The S-CVI was likewise more than 0.813 which is adequate in range.

Item analysis: According to [Table/Fig-3], each of the 84 items was organise into four domains factors as per factor analysis matrix. These four domains (named physical domain, social domain, psychological domain, spiritual domains) covered 53.846% of variance. The [Table/Fig-4] shows scree plot viewing factors on the based on eigen value for all 84 items, according to statistical analysis.

Item reduction (Principal component analysis): Data from draft of 84 items was statistical assessed. Items were removed on the basis of item total correlation and inter item correlation matrix. The [Table/Fig-5] showing the range of score considered as acceptable.

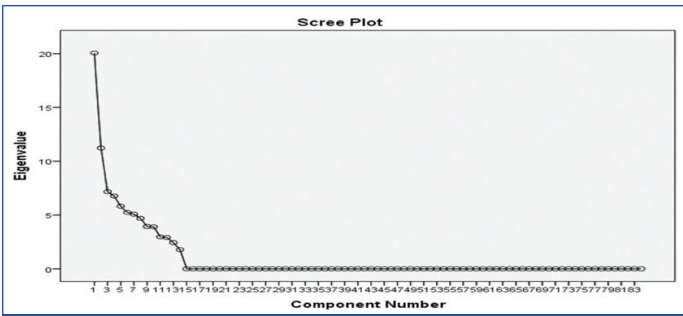
Reliability analysis: The internal consistency, i.e., Cronbach's alpha was 0.932.

Inter item correlation: As per inter item correlation, 11 items which had item total correlation coefficient of <0.3 were expelled while nine items were excluded as they showed an inter item correlation of >0.7. So 20 items were deleted.

Reliability-Internal consistency reliability (Cronbach's alpha): Cronbach alpha value of each component was satisfactory (>0.7). The final draft of the tool had four components (84 items) [Table/Fig-6].

| Component | Total variance explained | | | | | | | | |
|-----------|--------------------------|---------------|--------------|-------------------------------------|---------------|--------------|-----------------------------------|---------------|--------------|
| | Initial eigen values | | | Extraction dums of squared loadings | | | Rotation sums of squared loadings | | |
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 20.064 | 23.886 | 23.886 | 20.064 | 23.886 | 23.886 | 18.293 | 21.777 | 21.777 |
| 2 | 11.226 | 13.365 | 37.251 | 11.226 | 13.365 | 37.251 | 10.368 | 12.343 | 34.121 |
| 3 | 7.173 | 8.540 | 45.791 | 7.173 | 8.540 | 45.791 | 9.421 | 11.215 | 45.336 |
| 4 | 6.766 | 8.055 | 53.846 | 6.766 | 8.055 | 53.846 | 7.148 | 8.510 | 53.846 |

[Table/Fig-3]: Factor analysis (extraction method: principal component analysis).



[Table/Fig-4]: Scree plot showing various factors.

| Analysis | Acceptable value | | |
|-------------------------------------|---|--------------------|--------------------|
| Cronbach's alpha | 0.932 | | |
| Intra class Correlation Coefficient | | | |
| | Intra class correlation 95% confidence interval | | |
| Single measures | 0.141 | Lower value | Upper value |
| | | 0.076 | 0.300 |

[Table/Fig-5]: Intra class correlation coefficient.

| Domains | Cronbach's alpha value |
|---------------|------------------------|
| Physical | 0.868 |
| Social | 0.895 |
| Psychological | 0.811 |
| Spiritual | 0.902 |

[Table/Fig-6]: Cronbach's alpha value.

Every item estimated the response in five point Likert scale. Each item can have a minimum score of '1' and a maximum score of '5' [Table/Fig-7].

| Component as per domain | No. of items | Min. | Max. |
|-------------------------|--------------|------|------|
| 1. Physical domain | 27 | 27 | 65 |
| 2. Social domain | 18 | 18 | 90 |
| 3. Psychological domain | 22 | 22 | 110 |
| 4. Spiritual domain | 17 | 17 | 85 |
| Total | 84 | 84 | 350 |

[Table/Fig-7]: Maximum and minimum score of 84 items.

Factor analysis of the four domains: Component I (physical domain) had 27 items related to routine life style, lack of sleep and activity of daily life. The reliability of this domain was 0.868. The inter item total

correlation as per matrix was acceptable, which differed from -0.371 to 1.000. The Cronbach's alpha of physical endurance was 0.868 and corrected item total correlation varied from -0.022 to 0.692.

Component II (social domain) had 18 items which included relationship with relatives, friends and society. The reliability of this domain was 0.895. The inter item total correlation as per matrix was also satisfactory which range variety from -0.264 to 0.568. The Cronbach's alpha of this domain was 0.895.

Component III (psychological/mental domain) had 22 items associated to assurance, distrustful life, fears and career prospect. The reliability of this domain was 0.811. The inter item total correlation as per matrix was acceptable and ranged from -0.257 to 0.361. The Cronbach's alpha of this domain was 0.811 and corrected item total correlation differed from -0.143 to 0.746.

Component IV (spiritual domain) had 17 items associated with spirituality, self-confidence and achievement. The reliability of this domain was 0.902. The inter item total correlation as per matrix was satisfactory and ranged from -0.499 to 0.134. The Cronbach's alpha of this domain was 0.902 and corrected item total correlation variety from -0.390 to 0.643.

DISCUSSION

The QoL refers to "global well-being," including physical, emotional, mental, social and behavioural factors. Prolonged cancer may harm multiple organs for long duration and affecting patients' health and subjective perceived QoL. There are particular difficulties in patients' life including the physical impairment, yet in addition change in psychological and social domain. Many QoL assessment tools and questionnaires have come into utilisation throughout the past 10 years. The most commonly tools to measure the QoL in cancer patients are the EORTC QLQ-C30, SF-36, FACT-G, and the Rotterdam Symptom Checklist (RSCL) [9-11]. But due to geographical limitations and cultural differences, a common resolution may not be pertinent and thus there is a need to formed a local based tool and validate (standardise) the similar tool [Table/Fig-8] [9-12].

A standardised tool with excellent content validity ought to be made out of I-CVIs of 0.78 or higher and S-CVI average of 0.8 and 0.9 or higher, individually. In this way, the current study showed that "I-CVI arrived the level of acceptance, that is, 0.869. The S-CVI was also more than 0.813" which show a newly developed tool is valid and reliable tool which measures the QOL among chemotherapy patients. The present study developed and validated 84 items which cover four domains as per factor analysis which are physical domain (27), social domain (18), psychological/mental domain (22), and spiritual domain

| Patient identified issues | Information available in existing tools Yes/No | | | | |
|---|--|-------|--------|--|---|
| | EORTC QLQ-C30 | SF-36 | FACT-G | The Rotterdam Symptom Checklist (RSCL) | Quality of life index Cancer version- iii |
| Have you been dissatisfied with your body image | No | No | No | No | No |
| How much has your treatment cost been a burden to you? | Yes | No | No | No | Yes |
| Has your physical condition/medical treatment interfered with your sex life? | No | No | Yes | Yes | Yes |
| Are you aware about govt. health scheme on cancer diseases? | No | No | No | No | No |
| Do you feel, you are restricted from attending social functions? | No | No | No | No | No |
| Do you feel, you are isolated from family? | No | No | No | No | No |
| Does your family have any stigma due to this disease condition? | No | No | No | No | No |
| Did you feel you are ignoring by society? | No | No | No | No | No |
| Do you have fear of recurrence or spread cancer. | No | No | No | No | No |
| Did you believe that god gives me strength to move forward? | No | No | No | No | No |
| Discourage by relatives and neighbours. | No | Yes | Yes | No | Yes |
| Did you feel, your expectation, ambition fulfil by family? | No | No | No | No | No |
| Do you know about new treatment modalities available for cancer diseases? | No | No | No | No | No |
| Do you know chemotherapy is essential treatment to recover from cancer disease? | Yes | No | No | Yes | Yes |

[Table/Fig-8]: Existing QoL tool and participant information [9-12].

1. EORTC QLQ-C30: European Organisation for Research and Treatment of Cancer, Quality of life, 30; 2. SF-36: Short Form Health Survey; 3. FACT-G: The Functional Assessment of Cancer Therapy - General; 4. The Rotterdam Symptom Checklist (RSCL); 5. Quality of life index, Cancer version-iii

(17). All these domains and items had high internal consistency (Cronbach's alpha 0.932). The QoL assessments are recommended to be used one week after chemotherapy administration when patients are at home. Tool score may help out to optimise preventive, curative and supportive care during chemotherapy.

Limitation(s)

The study sample was restricted to Charotar region (Kheda-Anand District) of Gujarat, India. Samples were chosen based on non probability sampling technique and age of patients above 20 years and data collected from OPD and IPD of cancer hospital.

CONCLUSION(S)

This newly developed QoL tool, comprising of 84 items is a reliable and valid instrument for the evaluation of QoL among the chemotherapy patient. More exploration studies are expected to validate the tool for application in other clinical areas, and wider socio-economic community settings. Linguistic validation is also required to manage in various languages with more number of participants.

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