

Validation of EORTC QLQ-C30 questionnaire in its Tunisian version

Validation du questionnaire QLQ-C30 de EORTC dans sa version tunisienne

Soraya Fenniche, Nidhal Belloumi, Chaima Habouria, Imen Bachouch, Fatma Chermiti

University of Tunis El manar, Faculty of medicine of Tunis, Abderrahmen Mami hospital Ariana 2080, Pulmonology department Pavilion 4

Abstract

Objective: To test the validity and reliability of The European Organization for Research and Treatment of Cancer (EORTC) core (QLQ-C30) in its Tunisian dialectal version for lung cancer patients.

Methods: A total of 300 patients under a chemotherapy regimen for lung cancer were enrolled in this cross-sectional study. Participants had to answer EORTC QLQ-C30 auto-questionnaire in the Tunisian version, then in the Arabic version 15 days later. Statistical analyses were performed by SPSS 22.

Results: The Tunisian version was found reliable and valid for Tunisian cancer patients. Seven of the 8 multi-item scales of QLQ-C30 had high reliability (Cronbach's α >0.7). In our analysis, the most determinative subscales of QLQ-C30 on global health were physical functioning, cognitive functioning, fatigue, and dyspnea. Correlation with the Arabic version was nearly a perfect mismatching; all sub-scale mean scores were statistically correlated. The inter-class correlations confirmed the external convergent validity. Discriminant validity was supported since the correlation value of a symptom scale score with other similar scales was higher than any functional scale, and inversely.

Conclusions: The Tunisian version of EORTC QLQ-C30, recently written is a reliable and valid tool to assess the quality of life of Tunisian lung cancer patients.

Key words: Non small cell lung carcinoma - Quality of life - Validation - EORTC QLQ-C30

Résumé

Objectif: Tester la validité et la fiabilité du QLQ-C30 de l'EORTC dans sa version dialectale tunisienne pour les patients atteints de cancer du poumon.

Méthodes: Un total de 300 patients sous chimiothérapie pour un cancer du poumon ont été inclus dans cette étude transversale. Les participants ont répondu à l'auto-questionnaire QLQ-C30 dans la version tunisienne, puis dans la version arabe, 15 jours plus tard. Les analyses statistiques ont été réalisées par SPSS 22.

Résultats: La version tunisienne s'est avérée fiable et valide pour les patients tunisiens atteints de cancer. Sept parmi les huit dimensions du QLQ-C30 présentaient une fiabilité élevée (α de Cronbach >0,7). Dans notre analyse, les dimensions du QLQ-C30 les plus déterminantes pour la santé globale étaient le fonctionnement physique, le fonctionnement cognitif, la fatigue et la dyspnée. La corrélation avec la version arabe était presque parfaite ; les scores moyens des différentes dimensions étaient statistiquement corrélés. Les corrélations interclasses ont confirmé la validité convergente externe. La validité discriminante a été confirmée puisque la valeur de corrélation du score des échelles des symptomes entre elles était plus élevée que celle avec toute échelle fonctionnelle, et inversement..

Conclusions: La version tunisienne du QLQ-C30, récemment rédigée, est un outil fiable et valide pour évaluer la qualité de vie des patients tunisiens atteints de cancer du poumon.

Mots clés: Carcinome bronchique non à petites cellules - Qualité de vie - Validation - EORTC QLQ-C30

Correspondance

Nidhal Belloumi

University of Tunis El manar, Faculty of medicine of Tunis, Abderrahmen Mami hospital Ariana 2080, Pulmonology department Pavilion 4 Email: nidhalbelloumi@gmail.com

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NTRODUCTION

Quality of life (QoL) is a variable and very complex concept, which includes many indicators such as satisfaction, chief complaints if there are any, intensity of complaints, liberty of choice, lifestyle, and mental behavior (1). Since the quality of life follows the subjective evaluation of the patient rather than the objective evaluation of the physician, patient-oriented questionnaires were developed to better understand the quality of life. Several scales have been used to measure different QoL domains in specific pathologies. The European Organization for Research and Treatment of Cancer (EORTC) developed a cancer-specific core questionnaire (QLQ-C30) which was proven to have good reliability and validity and has gained widespread use in many countries (2-7). It is one of the generic QoL measuring tools which can be used in clinical practice and research, to evaluate, follow and supervise cancer-carrying population health status. Researchers appreciate it as a brief self-administered questionnaire that generates scores across various dimensions of health. It has proved useful in monitoring population health, estimating the burden of different diseases or impairments, monitoring outcomes in clinical practice, and evaluating treatment effects. The scale is easy to administrate and to quote which permits the calculation of QoL profile. It is frequently used in investigations and surveys because it is short, has a high standard of reliability and validity, and has good sensitivity to health status change (8-10).

Health-related Qol assessment is a real burden for such patients. EORTC came out with suitable versions for each sphere and each cancer location. Those questionnaires are meant to be used with the gold standard QLQ-C30.

Tunisia is a multicultural African country. People of the Maghreb countries are fluent in a dialectal Arabic language and have difficulty using and understanding the fine details and terminology of the literal Arabic language. Hence the interest to validate a Tunisian dialectal Arabic version allowing to explore, evaluate and monitor the quality of life by a validated tool in cancer patients.

The present study aimed to test reliability and validity of the Tunisian dialectal version of QLQ-C30 questionnaire for lung cancer patients, and evaluate its applicability in the local setting.

Methods

Study design and sample

This was a cross-sectional descriptive study. It was conducted at Pavilion 4 Pulmonology Department in Abderrahmen Mami teaching hospital, from September 2021 to September 2022. A total of 300 lung cancer patients in their first year of follow-up, were recruited in the study (A minimum sample size of 175 would be required to achieve an effect size leading to a confidence interval of 95% with a margin error of 1%). We included all non-small cell lung cancer (NSCLC) patients in stages II to IV of the disease according to the 8th edition of TNM classification (11,12). The sampling strategy used to recruit participants for this study was as follows :

Inclusion Criteria = patients who were 18 years and older, a confirmed NSCLC with histological proof, stage II to IV of the disease, patients still getting or already got an anti-mitotic treatment, and written informed consent to participate in the study.

Illiterate patients who can not read were also included.

Non-Inclusion Criteria = patients with pulmonary tumors but no histological proof, incidentally discovered asymptomatic NSCLC, Diagnosis not yet announced, Tumors surgically treated with no peri-operative chemotherapy, Patients with two synchronous tumors, severe psychological impairment, and inability to give consent.

Exclusion Criteria = inappropriately answered or incomplete reply form, missing items with no answers.

Practical details

Enrollment and data gathering took place at the day hospital cancer clinic. All the participants were voluntarily sequentially enrolled in the study. Participants answered the QLQ-C30 auto-questionnaire in its Tunisian dialectal version. When a participant was unable to read the reply form, a researcher carried out the face-to-face interview in a separate private room and filled out the questionnaire on his behalf. During the interview, all the questionnaire was read to the participant and if needed re-read carefully, no further explanations were provided. If the participant was coming to receive his chemotherapy session, researchers proposed the questionnaire after performing routine blood tests and before the session began.

Further data about gender, age, marital or social status, histological type of the tumor, stage of the disease, and ongoing treatment was directly taken from the patient's record.

One or two weeks later, patients took the Arabic version of the QLQ-C30 to answer it. It is a version written in 2013, already validated and adopted by the EORTC (13).

Instrument used in the study

The EORTC QLQ-C30 is a 30-item core cancer-specific questionnaire-integrating system. This tool assesses the health-related Qol of cancer patients participating in international clinical trials (14,15). The questionnaire incorporates five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, nausea and vomiting), and a global health and Qol scale. It also contains single items dedicated to additional symptoms commonly reported by cancer patients (dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea), as well as the perceived financial impact of the disease (14).

All items are scored on 4-point Likert scales, ranging from 1 ('not at all') to 4 ('very much'), except for two items in the global health/QOL scale which use modified 7-point linear analog scales. Scores of subscales are calculated based on the scoring manual of the instrument (15). All subscale scores range from 0 to 100, where high scores represent better levels of functioning, in contrast to symptom scales where higher scores indicate higher levels of problems.

Translation / Redaction of the Tunisian dialectal version of QLQ-C30

The Tunisian dialectal version of EORTC QLQ-C30 was developed using a rigorous translation and backtranslation process. We recruited and involved three linguistic experts and one sociological expert. The group initially worked separately to produce three independent versions of the questionnaire. Then, after careful rereading, a single representative version was produced. A linguistics expert carried out the back-translation blindly, without consulting the original version beforehand. The next step is carried out by a committee of lung specialists and oncologists to check that the original version corresponds perfectly to the back-translated version. In order to identify and solve potential problems in the translation, the Tunisian dialectal version was subsequently pilot tested by 15 patients recruited for this purpose. All comments of experts and patients led to appropriate modifications to the questions.

Statistical analysis

Data management and analyses were done using statistical analysis software SPSS version 21. Frequencies and percentages, as well as means and standard deviations (SD), were used to describe categorical and continuous variables respectively. The reliability (internal consistency) of multi-item scales was tested by Cronbach's alpha coefficient. Internal consistency of magnitude more than 0.70 was considered rigorous (16,17). Multitrait scaling analysis was employed to test for item discriminant and convergent validity based on item-scale correlations (18). Convergent validity was supported when the correlation coefficient between an item and its scale was higher than 0,40 (corrected for overlap). Discriminant validity was supported when the correlation value of an item with its corresponding scale was higher than other scales.

Construct validity was evaluated by principal component factor analysis or using interscale correlations in terms of the magnitude and direction of the correlation. Correlation coefficients between 0.40 and 0.70 provide solid evidence of being conceptually related; with no criticism about the distinctiveness of concepts being measured.

External validity between the scale's scores of the QLQ-C30 in their Arabic and Tunisian versions were examined using Pearson's correlation coefficient. It was expected that the scales that were conceptually related would correlate with one another, and their correlation coefficient r would be more than 0.4 (19). Test–retest reliability of the QLQ-C30 in its Arabic and Tunisian versions was assessed using Interclass Correlations (ICC) between baseline and retest, two weeks later. A correlation of >0.80 was considered "trustworthy" (19). The significance level was Belloumi & al. QLQ-C30 in its Tunisian version

set at p < 0.05. We hypothesized that the functioning scales of the questionnaire should correlate better with one another, but not with the symptom scales and vice versa.

Floor & ceiling effects of the QLQ-C30 were analyzed and a cut-off value of 20% was considered as the presence of a floor or ceiling effect (20).

Clinical validity was assessed using known group comparisons. This assesses if the questionnaires were able to discriminate between subgroups of patients differing in clinical status. The known groups used in this study were age, educational level, disease stage, and treatment type (curative intention vs. palliative). Differences between groups were tested with t-test or Mann-Whitney test as appropriate.

Independent sample t-test and one-way analysis of variance (ANOVA) were used to test the statistical significance of group differences or to confirm the absence of any significant difference between results withdrawn from the analysis of the Arabic or Tunisian versions of the QLQ-C30.

Ethical settings

Prior to the study, two requests via mail were written to the EORTC Quality of life department and its executive committee. We asked for permission to use already validated versions of QLQ-C30 and permission to conduct a study aiming to create and validate a new Tunisian dialectal version. For those two requests, we had a positive answer. Informed consent was obtained from all patients prior to participation in the study.

RESULTS

No patients rejected taking part in the study. All 326 patients answered the QLQ-C30. Eight patients didn't give back the paper filled with answers and 18 patients filled it inappropriately or incompletely (Figure 1).



Study population

The study population consisted of 300 NSCLC male patients. Socio-demographical features of the patients were analyzed. Mean age was 64 years old (median of 66 years, standard deviation of 10.92, and range from 49 to 75). More than half of the patients (58.3% of the

group) reached a secondary education level or higher and 87 patients (88%) were urban residents (Table 1).

Table 1. Patients' Demographical and Clinical Data

| Parameter | Mean | SD |
|--|------|-------|
| Age (years) | 66 | 10.92 |
| Educational level | n | % |
| Illiterate | 33 | 11 |
| Primary level, School | 89 | 29.7 |
| Secondary level, High school | 127 | 42.3 |
| University | 42 | 16 |
| Stage of the disease | n | % |
| I | 0 | 0 |
| lla | 10 | 3.3 |
| IIb | 44 | 14.7 |
| IIIa | 14 | 4.7 |
| IIIb | 51 | 17 |
| IIIc | 48 | 16 |
| IV | 133 | 44.3 |
| Protocol of treatment | n | % |
| Neoadjuvant chemotherapy | 12 | 4 |
| Adjuvant chemotherapy | 54 | 18 |
| Concomitant chemoradiation therapy | 10 | 3.3 |
| Sequential chemoradiation therapy | 78 | 26 |
| Two drugs Platinum based palliative chemotherapy | 113 | 37.7 |
| One drug palliative chemotherapy | 33 | 11 |

Treatment

Nearly half of the participants (48.7%) were receiving a first-line palliative chemotherapy regimen at enrollment. Therapeutic protocols were as follows = sequential chemoradiation therapy (78 patients; 26%), concomitant chemoradiation therapy (10 patients; 3.3%), neoadjuvant chemotherapy (12 patients; 4%) or adjuvant chemotherapy (54 patients; 18%). Most of the participants had stage IV (44.3%), followed by stage III (37.7%) then stage II (18%) upon diagnosis.

QLQ-C30 mean scores analysis

The best mean scores reflecting the preserved functional scales were attributed to: Role functioning, Emotional functioning, and cognitive functioning. Social functioning was the scale with the worst mean score (Table 2).

Symptom scales with the highest mean scores were: Appetite loss, Dyspnea, and Fatigue. They were, so, the chief complaints of our patients during chemotherapy administration (Table 2). The mean scores of symptom scales were found to be < 50 thus indicating less symptomatology and problems from classic avoidable and treatable symptoms. Otherwise, patients mentioned a great burden of financial difficulties.

Inter Class Correlations between the Arabic version and the Tunisian version of QLQ-C30

Statistical analysis comparing the Arabic version with the dialectal version had shown that most of the items and scales' mean scores were correlated (Table 3). No correlation was found between mean scores of the following scales = Cognitive functioning, Insomnia, Diarrhea, and Financial difficulties.

 Table 2. Overall Qol, Functional and Symptom Scales values extracted

 from QLQ-C30 answers (Tunisian version)

| Scale (number of items) | Mean score ±SD | Best correlations |
|----------------------------|----------------|--|
| Global health status (2) | 37.44 ±21.55 | Physical functioning* |
| | | Cognitive functioning* |
| | | Fatigue (inversely proportional) ** |
| | | Dyspnea (inversely proportional) * |
| Functional scales | | |
| Physical functioning (5) | 65.54 ±30.32 | Global health status * |
| | | Role functioning * |
| Role functioning (2) | 69.01 ±28.44 | Physical functioning * |
| Emotional functioning (4) | 67.02 ±35.71 | Pain (inversely proportional) * |
| Cognitive functioning (2) | 68.08 ±30.92 | Global health status * |
| Social functioning (2) | 50.70 ±36.78 | No correlation |
| Symptom scales | | |
| Fatigue (3) | 35.05 ±27.14 | Global health status (inversely proportional) ** |
| Nausea and vomiting (2) | 17.37 ±13.59 | Appetite loss * |
| Pain (2) | 16.67 ±11.13 | Emotional functioning (inversely proportional) * |
| Dyspnea (1) | 38.50 ±20.54 | Global health status (inversely proportional) * |
| Insomnia (1) | 28.17 ±20.12 | No correlation |
| Appetite loss (1) | 42.72 ±18.22 | Nausea and vomiting * |
| Constipation (1) | 9.86 ±7.82 | No correlation |
| Diarrhea (1) | 0.47 ±6.44 | No correlation |
| Financial difficulties (1) | 50.23 ±26.04 | No correlation |

* Strong reliable correlation ** Strong reliable correlation with a coefficient r > 0.7 meaning a superposition of concepts

 Table 3. Qol Scales values extracted from QLQ-C30 answers (Arabic version) and correlation with the dialectal Tunisian version

| Scale | Mean score ±SD | Correlation with scales from the Tunisian version QLQ-C30 (r and p) |
|-------------------------------|------------------------|---|
| Global health status | 38.18 ±19.55 | (0.601 and 0.028) * |
| Functional scales | | |
| Physical functioning | 66.16 ±31.06 | (0.557 and 0.000) * |
| Role functioning | 67.14 ±23.47 | (0.816 and 0.001) ** |
| Emotional functioning | 69.75 ±35.18 | (0.638 and 0.031) * |
| Cognitive functioning | 55.08 ±28.28 | (0.553 and 0.249) *** |
| Social functioning | 47.65 ±24.94 | (0.715 and 0.017) * |
| Symptom scales | | |
| Fatigue | 36.15 ±22.77 | (0.473 and 0.013) * |
| Nausea and vomiting | 21.57 ±13.66 | (0.454 and 0.042) * |
| Pain | 19.96 ±10.53 | (0.722 and 0.001) * |
| Dyspnea | 40.15 ±20.11 | (0.658 and 0.041) * |
| Insomnia | 32.17 ±16.12 | (0.291 and 0.097) *** |
| Appetite loss | 37.72 ±17.29 | (0.926 and 0.000) ** |
| Constipation | 9.86 ±7.82 | (0.580 and 0.007) * |
| Diarrhea | 8.70 ±4.51 | (0.198 and 0.30) *** |
| Financial difficulties | 41.93 ±21.97 | (0.294 and 0.163) *** |
| * Strong correlation ** Stron | g reliable correlation | with a coefficient $r > 0.8$ meaning a |

* Strong correlation ** Strong reliable correlation with a coefficient r > 0.8 meaning a superposition of concepts *** No correlation found

Internal consistency / Reliability

Table 4 presents the Cronbach's alpha coefficients of all symptom and functional subscales. Eight subscales out of the nine met the standards of reliability with coefficients ranging from 0.72 to 0.86. Cognitive functioning scale had the lowest alpha value of 0.55, indicating a lack of internal consistency.

Ceiling & Floor effects / Reliability

In the QLQ-C30 functional scales, the ceiling effect was present in three out of five (role, cognitive and social functioning) whereas there was no floor effect (Table 4). Instead, there was floor effect in almost all symptom scales (7 out of 9, excluding fatigue and appetite loss). Ceiling effect was only noted with Financial difficulties and Appetite loss scales (Table 4).

Table 4. Cronbach's Alpha coefficients, Floor and Ceiling effects ofeach subscale in the Tunisian version of the EORTC QLQ-C30

| QLQ-C30 scales | Item No * | Cronbach's Alpha coefficients | Ceiling effect (%) | Floor effect (%) |
|------------------------|------------|-------------------------------------|-----------------------|------------------------|
| Global health status | 29, 30 | 0.81 | 8.7 | 3.1 |
| Functional scales | | | | |
| Physical functioning | 1 - 5 | 0.83 | 5.5 | 0.0 |
| Role functioning | 6, 7 | 0.86 | 52.3 | 1.6 |
| Emotional functioning | 21 - 24 | 0.76 | 8.7 | 3.1 |
| Cognitive functioning | 20, 25 | 0.55 | 24.2 | 1.6 |
| Social functioning | 26, 27 | 0.72 | 30.1 | 3.1 |
| Symptom scales | | | | |
| Fatigue | 10, 12, 18 | 0.85 | 1.6 | 9.4 |
| Nausea and vomiting | 14, 15 | 0.79 | 4.8 | 45.7 |
| Pain | 9, 19 | 0.72 | 0.0 | 33.1 |
| Dyspnea | 8 | Single item | 6.6 | 77.1 |
| Insomnia | 11 | Single item | 25.1 | 48.4 |
| Appetite loss | 13 | Single item | 38.2 | 13.5 |
| Constipation | 16 | Single item | 4.8 | 21.1 |
| Diarrhea | 17 | Single item | 3.3 | 79.4 |
| Financial difficulties | 28 | Single item | 58.9 | 14.9 |
| | | | | |

* Numbers corresponding to the item numbers in the QLQ-C30 questionnaire

Divergent validity

Functional scale scores were correlated to clinical variables in our patients as shown in Table 5. A better educational level may lead to a better score in "Physical functioning" and "Social functioning". Advanced stages of the disease were correlated to a decline in mean scores of "Emotional functioning", "Cognitive functioning" and "Social functioning". Patients on palliative chemotherapy had poor functional status compared to other patients. They got significantly low mean scores on four scales over five. The severity of symptoms such as fatigue, vomiting, and pain was assessed by mean scores of the corresponding scales. Those scores were correlated to the age range, stage of the disease, and treatment. Worse symptoms were noted in the elderly, in patients with advanced stages, or in patients receiving palliative chemotherapy (Table 6).

DISCUSSION

The transcultural validation of the EORTC QLQ-C30 questionnaire for cancer patients was reported previously for various countries such as Turkey, Poland, Singapore, United Emirates, and Korea (3,5,9,10,13,21,22).

The prevalence of lung cancer and thoracic malignancies worldwide and on a national Tunisian scale are increasing. There is a need for tools able to assess objectively the health-related QoL in this group of patients.

One of the key objectives of the current study was to examine the concurrent validity of the Tunisian version of EORTC QLQ-C30 (recently written) using the Arabic version (already validated) as a main referential instrument of comparison. The findings of this study support the reliability of both Qol measurement tools.

Our methodology was designed to ensure the inclusion of illiterate patients, thereby avoiding potential selection bias. Additionally, we aimed to minimize confounding bias related to investigator intervention by having the investigator read the questionnaire aloud without providing further explanations.

There was a good convergence between functional scales and between symptom scales of QLQ-C30. Test–retest inter-class correlations show good reliability and reproducibility of the Tunisian version of the QLQ-C30, as compared to the Arabic version.

A Turkish study was conducted on a group of female patients, treated for advanced-stage breast cancer. Investigators used QLQ-C30 and QLQ-BR to assess Qol. Stepwise multiple linear regression analyses were conducted to investigate the potential contributions of the scales of both of the instruments on general health. The most determinative subscales of QLQ-C30 on global health were emotional functioning followed by fatigue, role functioning, and appetite loss (3). The authors discussed hypothetically a negative impact of chemotherapy side effects on Qol and general health mean score (3). Jaiyesimi et al analyzed 35 Nigerian women receiving radiotherapy for breast cancer and indicated that the overall QoL was significantly related to physical, cognitive, and social functioning. There was also significant inverse relation between the scores of fatigue, nausea and vomiting, pain, insomnia, and financial difficulty (23). Similarly, Kootstra et al used QLQ-C30 to evaluate QoL before and after surgery for cancer. Results suggested that complications and chemotherapy had a significant negative effect on Role, Emotional, and Cognitive Functioning scales (24).

Our questionnaire managed to differentiate between subgroups of patients according to their stage of the disease and according to the ongoing therapeutic protocol. These findings are consistent with data in the medical literature (25–28). Several studies defended the utility of using questionnaires such as QLQ-C30 and QLQ-LC to predict prognosis, rapid decline of the general health status, and success or failure to finish a chemotherapy course.
 Table 5. QLQ-C30 functional scales by sociodemographic and clinical parameters

| Parameter | Physical functioning | Role functioning | Emotional functioning | Cognitive functioning | Social functioning |
|---|----------------------|------------------|-----------------------|-----------------------|--------------------|
| Educational level | | | | | |
| Illiterate (n= 33) | 60.77 ±32.81 | 66.64 ±23.37 | 71.52 ±33.86 | 55.08 ±28.28 | 42.25 ±23.94 |
| Primary level, School (n= 89) | 66.16 ±31.06 | 68.09 ±25.28 | 68.25 ±34.18 | 52.52 ±26.49 | 42.77 ±20.64 |
| Secondary level, High school (n= 127) | 69.76 ±34.22 | 65.43 ±22.39 | 69.88 ±33.91 | 56.01 ±28.44 | 47.08 ±26.17 |
| University (n= 42) | 71.33 ±28.94 | 66.16 ±25.13 | 68.64 ±32.04 | 54.62 ±27.38 | 51.12 ±24.64 |
| Ρ | 0.018 | 0.094 | 0.170 | 0.384 | 0.003 |
| Stage of the disease | | | | | |
| lla | 66.10 ±38.52 | 70.38 ±28.11 | 77.29 ±34.90 | 69.44 ±30.49 | 65.43 ±22.39 |
| llb | 69.44 ±30.49 | 64.58 ±24.17 | 76.51 ±33.79 | 67.14 ±36.92 | 68.09 ±25.28 |
| Illa | 67.14 ±36.92 | 68.47 ±24.92 | 71.52 ±33.86 | 56.01 ±28.44 | 56.61 ±27.44 |
| IIIb | 69.51 ±32.14 | 67.17 ±24.73 | 68.25 ±34.18 | 55.08 ±28.28 | 54.62 ±27.38 |
| llic | 66.48 ±33.11 | 64.16 ±23.93 | 55.08 ±28.28 | 52.52 ±26.49 | 42.25 ±23.94 |
| IV | 63.62 ±31.41 | 66.44 ±22.39 | 52.52 ±26.49 | 49.83±26.14 | 42.77 ±20.64 |
| Ρ | 0.106 | 0.178 | 0.033 | 0.002 | 0.013 |
| Ongoing treatment | | | | | |
| Adjuvant chemotherapy | 69.76 ±34.22 | 64.58 ±24.17 | 71.52 ±32.86 | 67.14 ±36.92 | 51.12 ±24.64 |
| Concomitant chemoradiation therapy | 61.73 ±30.22 | 68.47 ±24.92 | 68.75 ±34.18 | 56.01 ±28.44 | 49.12 ±24.91 |
| Chemotherapy course (Whatever was the protocol) | 51.33 ±28.94 | 67.17 ±24.73 | 52.52 ±26.49 | 49.83±26.14 | 42.77 ±20.64 |
| Р | 0.012 | 0.16 | 0.033 | 0.002 | 0.013 |

Table 6. QLQ-C30 symptom scales by socio-demographical and clinical parameters

| Parameter | Fatigue | Nausea and vomiting | Pain |
|---|----------------|------------------------|--------------|
| Age (years) | | | |
| 40-49 | 29.07 ±16.84 | 26.64 ±13.37 | 31.52 ±13.86 |
| 50-59 | 33.68 ±21.06 | 18.09 ±15.28 | 26.25 ±14.18 |
| 60-69 | 36.86 ±24.22 | 19.43 ±12.39 | 16.88 ±9.77 |
| 70-79 | 37.03 ±20.74 | 20.16 ±11.13 | 10.64 ±6.04 |
| Ρ | 0.008 | 0.170 | 0.004 |
| Stage of the disease | | | |
| lla | 26.10 ±18.52 | 9.38 ±6.19 | 11.33 ±5.19 |
| IIb | 29.44 ±20.49 | 8.09 ±5.28 | 10.64 ±6.04 |
| Illa | 30.14 ±22.92 | 19.43 ±12.39 | 17.52 ±11.86 |
| IIIb | 33.68 ±21.06 | 20.16 ±11.13 | 31.52 ±13.86 |
| IIIc | 36.86 ±24.22 | 24.16 ±15.93 | 26.25 ±14.18 |
| IV | 37.03 ±20.74 | 26.44 ±19.39 | 35.52 ±22.49 |
| Ρ | 0.006 | 0.008 | 0.033 |
| Ongoing treatment | | | |
| Adjuvant chemotherapy | 16.68 ±11.06 | 9.43 ±7.39 | 10.64 ±6.04 |
| Concomitant chemoradiation therapy | 36.86 ±24.22 | 20.16 ±11.13 | 17.52 ±11.86 |
| Chemotherapy course (Whatever was the protocol) | a 37.03 ±20.74 | 24.16 ±15.93 | 36.52 ±17.06 |
| Ρ | 0.038 | 0.016 | 0.023 |

Patients with advanced stage NSCLC had a significant decline in mean scores of functional scales which treat psychological integrity or communicating abilities : "Emotional functioning", "Cognitive functioning" and "Social functioning". Tan et al. found a similar phenomenon in stage III breast cancer, compared to early stages. They found also a significant negative impact of chronic osteoarthritis on physical functioning (P<0.001)

and role functioning scales (P<0.001) (9).

Interestingly, another main important finding was described among cancer survivors. Patients often struggle with their financial situation during cancer treatment due to treatment-related costs or loss of income. We tend to mention this resulting negative effect as "financial toxicity", which is known as a side effect of cancer care, all spheres included. In numerous studies, QLQ-C30 analysis had shown high financial concerns in cancer-surviving patients (29–31). The economic well-being of patients really matters and influences significantly on Qol.

Concerning educational level and income, our study revealed better mean scores of physical and social functioning, with no effect on symptom scale scores. We can hypothetically explain this fact by a correlation between educational level, monthly mean income, and ability to get access to the health care system. This hypothesis was defended already in literature (9,22,32). Nevertheless in the same analysis spectrum, Highly educated and graduated cancer patients were also found to experience higher levels of fatigue and insomnia than those who were less educated at the primary and below level (33). Other studies noted a frequent use of nonconventional therapies in those sub-groups of cancer patients (34-36). Drug-resistant symptoms and various coping techniques seem to reflect higher anxiety and disturbance affecting highly educated patients. It could be also a sign of lack of confidence even under treatment. A wider assessment for all aspects of Qol is attainable when using simultaneously QLQ-C30 and QLQ-LC, which is possible but inconvenient for the participants. So, we recommend strongly, conducting a similar study to validate a Tunisian dialectal version of QLQ-LC, to be used specifically for lung cancer patients.

The construct validity and the reliability of the multiitem QLQ-C30 auto-questionnaire (Tunisian version) was confirmed in the current study. Its utility made already no doubt.

We didn't check the external convergent validity, the gold standard test to assess validity, due mainly to the unavailability of other Tunisian QoL assessment tools already validated. So, we managed to use QLQ-C30 in its Arabic version.

This new questionnaire is suitable so, for measuring the Qol in cancer patients in Tunisia. We consider it as an objective measuring instrument, with good psychometric properties relevant to different cancerpatient populations. This will facilitate the translation and validation of other auto-questionnaires such as the QLQ-LC (Tunisian version).

References

- 1. Park KU. Assessment of change of quality of life in terminally ill patients under cancer pain management using the EORTC Core Quality of Life Questionnaire (QLQ-C30) in a Korean sample. Oncology. 2008;74 Suppl 1:7–12.
- Ameri H, Yousefi M, Yaseri M, Nahvijou A, Arab M, Akbari Sari A. Mapping EORTC-QLQC30 and QLQ-CR29 onto EQ-5D-5L in Colorectal Cancer Patients. J Gastrointest Cancer. 2019 Apr 12;
- Demirci S, Eser E, Ozsaran Z, Tankisi D, Aras AB, Ozaydemir G, et al. Validation of the Turkish versions of EORTC QLQ-C30 and BR23 modules in breast cancer patients. Asian Pac J Cancer Prev APJCP. 2011;12(5):1283–7.
- El ayoubi H. Comparison of Reliability and Validity of the Breast Cancer depression anxiety stress scales (DASS-21) with the Beck Depression Inventory-(BDI-II) and Hospital Anxiety and Depression Scale (HADS). Int J Behav Res Psychol. 2016;4(4):197–203.
- Gadisa DA, Gebremariam ET, Ali GY. Reliability and validity of Amharic version of EORTC QLQ-C30 and QLQ-BR23 modules for assessing health-related quality of life among breast cancer patients in Ethiopia. Health Qual Life Outcomes. 2019 Dec;17(1):182.
- Musarezaie A, Khaledi F, Esfahani HN, Ghaleghasemi TM. Factors affecting quality of life and fatigue in patients with leukemia under chemotherapy. J Educ Health Promot. 2014;3:64.
- Pompili C, Koller M, Velikova G, Franks K, Absolom K, Callister M, et al. EORTC QLQ-C30 summary score reliably detects changes in QoL three months after anatomic lung resection for Non-Small Cell Lung Cancer (NSCLC). Lung Cancer Amst Neth. 2018;123:149–54.
- Oñate-Ocaña LF, Alcántara-Pilar A, Vilar-Compte D, García-Hubard G, Rojas-Castillo E, Alvarado-Aguilar S, et al. Validation of the Mexican Spanish version of the EORTC C30 and STO22 questionnaires for the evaluation of health-related quality of life in patients with gastric cancer. Ann Surg Oncol. 2009 Jan;16(1):88–95.
- Tan ML, Idris DB, Teo LW, Loh SY, Seow GC, Chia YY, et al. Validation of EORTC QLQC30 and QLQ-BR23 questionnaires in the measurement of quality of life of breast cancer patients in Singapore. Asia-Pac J Oncol Nurs. 2014 Apr;1(1):22–32.
- Tomaszewski KA, Püsküllüoğlu M, Biesiada K, Bochenek J, Nieckula J, Krzemieniecki K. Validation of the Polish Version of the EORTC QLQ-C30 and the QLQ-OG25 for the Assessment of Health-Related Quality of Life in Patients with Esophagi-Gastric Cancer. J Psychosoc Oncol. 2013 Mar;31(2):191–203.
- Eberhardt WEE, Mitchell A, Crowley J, Kondo H, Kim YT, Turrisi A, et al. The IASLC Lung Cancer Staging Project: Proposals for the Revision of the M Descriptors in the Forthcoming Eighth Edition of the TNM Classification of Lung Cancer. J Thorac Oncol Off Publ Int Assoc Study Lung Cancer. 2015 Nov;10(11):1515–22.
- 12. Goldstraw P, Chansky K, Crowley J, Rami-Porta R, Asamura H,

Eberhardt WEE, et al. The IASLC Lung Cancer Staging Project: Proposals for Revision of the TNM Stage Groupings in the Forthcoming (Eighth) Edition of the TNM Classification for Lung Cancer. J Thorac Oncol Off Publ Int Assoc Study Lung Cancer. 2016 Jan;11(1):39–51.

- Huijer HAS, Sagherian K, Tamim H. Validation of the Arabic version of the EORTC quality of life questionnaire among cancer patients in Lebanon. Qual Life Res. 2013 Aug;22(6):1473–81.
- Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst. 1993 Mar 3;85(5):365– 76.
- Fayer P, Aaronson NK, Bjordal K, Sullian M. EORTC QLQ-C30 Scoring Manual. [Internet]. EORTC Quality of Life Group, Bressels; 1995. Available from: https://www.eortc.org/app/uploads/ sites/2/2018/02/SCmanual.pdf
- Nunnally JC, Bernstein IH. Psychometric theory. 3rd ed. New York: McGraw-Hill; 1994. 752 p. (McGraw-Hill series in psychology).
- 17. DeVellis RF. Scale development: theory and applications. Fourth edition. Los Angeles: SAGE; 2017. 262 p.
- Hays RD, Hayashi T. Beyond internal consistency reliability: Rationale and user"s guide for Multitrait Analysis Program on the microcomputer. Behav Res Methods Instrum Comput. 1990 Mar 1;22(2):167–75.
- Fayers PM, Machin D. Quality of life: The assessment, analysis, and reporting of patient reported outcomes. Third edition. Chichester, West Sussex, UK ; Hoboken, NJ: John Wiley & Sons Inc; 2016.
- 20. Everitt B. The Cambridge dictionary of statistics. 2nd ed. Cambridge, UK ; New York: Cambridge University Press; 2002. 410 p.
- Yun YH, Park YS, Lee ES, Bang SM, Heo DS, Park SY, et al. Validation of the Korean version of the EORTC QLQ-C30. Qual Life Res Int J Qual Life Asp Treat Care Rehabil. 2004 May;13(4):863–8.
- Shih CL, Chen CH, Sheu CF, Lang HC, Hsieh CL. Validating and Improving the Reliability of the EORTC QLQ-C30 Using a Multidimensional Rasch Model. Value Health. 2013 Jul;16(5):848– 54.
- Jaiyesimi AO, Sofela EA, Rufai AA. Health related quality of life and its determinants in Nigerian breast cancer patients. Afr J Med Med Sci. 2007 Sep;36(3):259–65.
- Kootstra J, Hoekstra-Weebers JEHM, Rietman H, de Vries J, Baas P, Geertzen JHB, et al. Quality of life after sentinel lymph node biopsy or axillary lymph node dissection in stage I/II breast cancer patients: a prospective longitudinal study. Ann Surg Oncol. 2008 Sep;15(9):2533–41.
- Cocks K, Wells JR, Johnson C, Schmidt H, Koller M, Oerlemans S, et al. Content validity of the EORTC quality of life questionnaire QLQ-C30 for use in cancer. Eur J Cancer Oxf Engl 1990. 2023 Jan;178:128–38.
- Daroszewski C, Stasiewicz M, Jaźwińska-Tarnawska E, Rachwalik A, Mura E, LubochKowal J, et al. Quality of Life in Patients with Advanced Non-Small-Cell Lung Cancer Receiving Palliative Chemotherapy. Adv Exp Med Biol. 2019;1160:11–8.
- Chie WC, Yang CH, Hsu C, Yang PC. Quality of life of lung cancer patients: validation of the Taiwan Chinese version of the EORTC QLQ-C30 and QLQ-LC13. Qual Life Res Int J Qual Life Asp Treat Care Rehabil. 2004 Feb;13(1):257–62.
- Dean GE, Abu Sabbah E, Yingrengreung S, Ziegler P, Chen H, Steinbrenner LM, et al. Sleeping with the enemy: sleep and quality of life in patients with lung cancer. Cancer Nurs. 2015 Feb;38(1):60– 70.
- 29. Brown ML, Lipscomb J, Snyder C. The burden of illness of cancer: economic cost and quality of life. Annu Rev Public Health. 2001;22:91–113.
- Kajimoto Y, Honda K, Suzuki S, Mori M, Tsubouchi H, Nakao K, et al. Association between financial toxicity and health-related quality of life of patients with gynecologic cancer. Int J Clin Oncol. 2023 Mar;28(3):454–67.
- Shim S, Kang D, Kim N, Han G, Lim J, Kim H, et al. Validation of Korean Version of the COmprehensive Score for financial Toxicity (COST) Among Breast Cancer Survivors. Cancer Res Treat. 2022

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Jul;54(3):834-41.

- 32. Dar MA, Chauhan R, Trivedi V, Kumar R, Dhingra S. Assessing the Prevalence of Financial Toxicity, its Predictors and Association with Health- Related Quality of Life Among Radiation Oncology Patients in India: A Cross-Sectional Patient Reported Outcome Study. Int J Radiat Oncol Biol Phys. 2023 May 1;116(1):157–65.
- Belloumi N, Maalej Bellaj S, Bachouche I, Chermiti Ben Abdallah F, Fenniche S. Comparison of Sleep Quality before and after Chemotherapy in Locally Advanced Nonsmall Cell Lung Cancer Patients: A Prospective Study. Sleep Disord. 2020 Jul 20;2020:1–8.
- 34. Asiimwe JB, Nagendrappa PB, Atukunda EC, Kamatenesi MM, Nambozi G, Tolo CU, et al. Prevalence of the Use of Herbal Medicines among Patients with Cancer: A Systematic Review and Meta-Analysis. Evid-Based Complement Altern Med ECAM. 2021;2021:9963038.
- Molassiotis A, Fernández-Ortega P, Pud D, Ozden G, Scott JA, Panteli V, et al. Use of complementary and alternative medicine in cancer patients: a European survey. Ann Oncol Off J Eur Soc Med Oncol. 2005 Apr;16(4):655–63.
- Wode K, Henriksson R, Sharp L, Stoltenberg A, Hök Nordberg J. Cancer patients" use of complementary and alternative medicine in Sweden: a cross-sectional study. BMC Complement Altern Med. 2019 Mar 13;19(1):62.