

Measuring the Quality of Life among Head-and/or-Neck Cancer Patients with Oral Mucositis Using the Functional Assessment of Cancer Therapy-General in Jordan

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ABSTRACT

Objective: Quality of life (QOL) in cancer patients can be influenced by the presence of medical conditions, such as oral mucositis (OM). There is still limited knowledge about this issue among patients in Jordan, and this could be related to the absence of research instruments testing QOL among cancer patients with OM. This study measured the QOL among cancer patients using the Functional Assessment of Cancer Therapy-General (FACT-G), Arabic version. **Methods:** This was a cross-sectional study on 118 head-and/or-neck cancer patients with OM in Jordan. Data were submitted to measures of normality, reliability, and validity using exploratory factor analysis. The study also measured QOL among the study sample. **Results:** FACT-G demonstrated good internal

consistency reliability and validity. Factor analysis indicated the presence of four factors explained by 24 items representing a valid FACT-G, Arabic version. Scores reflected low QOL compared to reported normative values in the literature. The values used to compare findings from this study were extracted from international literature; no similar values were present in published literature.

Conclusions: FACT-G, Arabic version, is valid and reliable when applied to this study population. Further testing is recommended, which would include the establishment of normative values.

Key words: Cancer patients, Functional Assessment of Cancer Therapy-General, Jordan, oral mucositis, quality of life

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Introduction

Oral mucositis (OM) remains the most common side effect of chemotherapy and radiotherapy for patients with head-and-neck cancers, causing additional suffering among patients.^[1] OM is an inflammation that occurs in the mucous membranes of the oral cavity and the upper gastrointestinal tract, ranging from mild symptoms of discomfort to severe, continuous pain.^[2] Almost all patients with combined treatment of chemo- and radiotherapy develop OM at some stage during head-and-neck treatment,^[3] influencing their quality of life (QOL) due to pain attacks and its effect on food intake.^[4,5] It is also associated with a high rate of hospitalization and interferes with therapy.^[6] However, limited information is available on the impact of OM on head-and-neck cancer patients in Jordan. This could be due, in part, to the absence of valid research instruments to measure the impact of OM on QOL.

In OM, chemo- and radiotherapy causes damage to the DNA, resulting in the death of the basal epithelial cells with the generation of reactive oxygen species causing further damage to the connective tissue.^[7] This damage activates several transcription factors, such as nuclear factor-kappa B and p53, amplified through positive feedback loops to cause thinning of the mucosal lining, resulting in the development of ulcerated mucositis. OM takes approximately 5–10 days to develop from the initiation of chemotherapy.^[1,8] Clinically, patients with OM usually present with generalized erythema, pseudomembranous degeneration, dysphagia, ulceration, and hemorrhage.^[9]

It has been well documented in literature that OM significantly influences QOL in cancer patients.^[10,11] However, the main obstacle remains in reporting the incidence of OM and the severity of symptoms.^[12] This study highlights the problem and raises awareness to improve the reporting and management of OM. There is a scarcity in the literature reporting the prevalence of OM, which might be related to patients and their carers viewing this issue as minor compared to the general health condition of the patient (i.e., head and/or neck cancer).^[11,12] There is a scarcity of literature examining OM among neck-and/or-head cancer patients in Jordan. Therefore, this study aimed to validate the Functional Assessment of Cancer Therapy-General Questionnaire (FACT-G) and to measure the QOL among head-and/or-neck cancer patients suffering from various degrees of OM.

Methods

Research design

This study was a cross-sectional study on non-probability and a convenience sample of patients

with OM secondary to treatment of head-and/or-neck cancer in Jordan.

Settings and sample

Patients were recruited from three public oncology units in Amman, Jordan (both in and outpatients). The required sample size was 96 patients, estimated using G power (medium effect size 0.05, alpha 0.05, and power 0.95).^[13] Patients were selected based on information from their medical records. One of the researchers explained the study purpose and procedure fully to the candidate patients. Patients then completed the study questionnaire and dropped it into a box designed for this purpose at their unit.

Exclusion criteria included complicated conditions with metastasis, neck or mouth surgery during treatment, presence of co-morbidities (such as diabetes mellitus, renal dysfunction, and hypertension), those with a psychological problem (such as depression), and those unable to read or sign the consent form. All participants had solid tumors and had been receiving chemotherapy for at least 14 days or had finished neck or head irradiation 1 week from data collection, which is considered to be the peak phase of OM.^[14]

Instrument

OM severity was assessed using the World Health Organization scale, which combines objective mucosal changes (redness and ulceration) with functional outcomes (ability to eat) to arrive at a score.^[15] This instrument is widely used in clinical settings and research.^[16] It utilizes a 5-grade classification of OM severity and reads as follows; Grade 0: No changes (to the oral mucosa); Grade 1: Soreness, erythema; Grade 2: Soreness, erythema, ulceration, and can eat solid foods; Grade 3: Soreness, erythema, ulceration, and can consume a liquid diet only; and Grade 4: Soreness, erythema, ulceration, and oral alimentation is not possible.^[15]

FACT-G was used to assess QOL.^[17] This instrument was developed originally to measure QOL among head-and-neck adult cancer patients.^[18] The FACT-G version 4 has been used in many clinical trials as it is easy to complete and demonstrates sensitivity to the performance status and the extent of disease.^[18,19] The participant rates the 27 items on the scale where each item is scored from 0 to 4 anchored from “not at all” to “very much.” The scale produces separate subscale scores for the dimensions of well-being. The physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), and functional well-being (7 items) subscales all have potential ranges of 0–28, 0–28, 0–24, and 0–28, respectively. The highest possible score of the complete FACT-G is 108 points with the higher scores indicating better QOL.

Versions of the FACT-G questionnaire are available in 45 different languages, permitting cross-cultural comparisons of people from diverse backgrounds, adopting translation methodology developed for the Functional Assessment of Chronic Illness Therapy (FACIT) project into European, Asian, and African languages (www.facit.org). The internal consistency values ranged between 0.71 and 0.82 and the test–retest reliability within 24–48 h was 0.80.^[17] No Arabic form of FACIT-G existed until the commencement of the present study.

Content validity

Content validity of the FACT-G was evaluated using the content validity ratio in previous studies and the results indicated acceptable values (CVR 12; $\alpha \geq 0.57$).^[18] There were no reports on using FACT-G in the Middle East in Arabic when conducting this study.

Translating the scale

The translation process was carefully managed to ensure that FACT-G statements were translated accurately reflecting the meaning of the source version:

- FACT-G English version was translated into Arabic by two bilingual nursing researchers with PhD degrees
- These two translations into Arabic were revised by the researchers for accuracy to combine the best and most appropriate translation resulting in a single Arabic copy (selected language for use)
- This new Arabic copy was sent to another bilingual researcher for back-translation into English
- The back-translated copy and the English version were compared by the researchers who found no discrepancies
- The Arabic version was ready for use after it was grammatically checked.

Pilot testing

FACT-G-Arabic was pilot-tested on 14 patients (6 males and 8 females). Patients were instructed to complete the study questionnaire and write comments on the questionnaire readability, and whether they felt any statement was inappropriate or offensive. No comments were reported and the Cronbach's alpha coefficients range in this pilot test was 0.649–0.864. Results from the pilot study were not included in the study report.

Data analysis

Data analysis was performed using SPSS version 21 (SPSS@IBM, Armonk, NY: IBM Corp.). Descriptive analyses were performed to describe the characteristics of the participants, to calculate mean scores on the study scale, and to examine the normality of the mean scores obtained. This study used the exploratory factor analysis (EFA)

adopting a maximum likelihood method for data extraction and varimax rotation to validate the Arabic version of the instrument. The cutoff point used in this study was 0.40. Cronbach's alpha was used to measure internal consistency and Pearson's *r* was used to assess the correlation of normally distributed scores. Questionnaires with missing data were not included in this analysis as factor analysis is sensitive to missing data.

Ethical considerations

Patients signed the consent form to participate in the study after acknowledging that participation was voluntary and that they could withdraw at any time during the study without any effect on their treatment.

Results

Participants

A total of 336 eligible patients were included in the study; however, only 118 (35.1%) completed the study questionnaire. Data were collected by the researchers between November 2016 and March 2017. As shown in Table 1, most patients suffered mucositis which ranged between second and third grades (22.9% and 47.5%, respectively). Female patients represented more than 72% ($n = 86$) of participants and nearly 84% ($n = 99$) were older than 41 years. Approximately one-fifth of the patients ($n = 25$) reported that they smoked during the data collection period. In addition, the majority of patients received radiotherapy (78.0%, $n = 92$), while the remaining number of patients received either

Table 1: Characteristics of the study sample ($n = 118$)

Characteristics	<i>n</i> (%)
Gender	
Male	32 (27.1)
Female	86 (72.9)
Age (years)	
18-25	2 (1.7)
26-40	17 (14.4)
41-55	45 (38.1)
>55	54 (45.8)
Grade of mucositis	
1	27 (22.9)
2	56 (47.5)
3	31 (26.3)
4	4 (3.4)
Smoking	
Yes	25 (21.2)
No	93 (78.8)
Type of treatment	
Radiotherapy	92 (78.0)
Chemotherapy	14 (11.9)
Chemoradiotherapy	12 (10.2)

chemotherapy alone or a mixed therapy of both types of treatment.

Findings of the Functional Assessment of Cancer Therapy-General

Cronbach’s alpha for the FACT-G-Arabic was 0.76, with subscales range of 0.67–0.83. The intercorrelations among items were <0.30, reflecting acceptable internal consistency. Scores in the FACT-G and its subscales represented normally distributed values [Figure 1]. Skewness and kurtosis values indicated normal distribution.^[20] The mean score for the FACT-G was above the midpoint of 54 [Table 2]. This finding also applied to the mean scores of the subscales, except for the social well-being scale, which had a mean score significantly higher than the average, indicating a favorable result of an acceptable level of social well-being.

Factor analysis

The Kaiser–Meyer–Olkin measure of sampling adequacy was 0.852, indicating a high level of intercorrelation among the items.^[21] This result was consistent with Bartlett’s test of sphericity, which showed that the correlations between the items were sufficient to perform factor analysis (approximate Chi-square: 1428.415, DF: 351, $P < 0.001$).

The correlations between the factors ranged from 0.149 to 0.542 ($P < 0.05$). The Spearman–Brown coefficient was .82 for both equal and unequal length,

skewness –0.112 (SE = 0.133), kurtosis –0.056 (SE = 0.266), Kolmogorov–Smirnov 0.076 (the lower bound of the true significance is <1.96), and Shapiro–Wilk 0.985 ($P = 0.210$). The scores of the FACT-G were normally distributed.^[22]

An EFA with varimax rotation was performed with the original FACT-G scale [Table 2]. The result showed that 24 items loaded significantly above the cutoff point of 0.40 subsumed within four factors. Therefore, three items were deleted, as they did not load above the cutoff point. This step further emphasized the construct validity of the tool when used in the study population. The first six items explained more than 52% of the total variance representing the first factor [Figure 2], social well-being, while the remaining 18 items explained nearly 47% [Table 3] of social well-being.

The community item values ranged from 0.39 to 0.71, which are considered acceptable low-to-moderate values.^[23] The goodness of fit achieved a significant value (Chi-square: 207.756, DF: 147, $P < 0.001$), leading to the acceptance of the null hypothesis, which assumes the model that does not fit significantly is worse than a model where variables correlate freely and leads to indicate a poor level of fit. However, the loading values of items in the model showed that the 24 items significantly contributed to the interpretation of the concept of QOL.^[24] Therefore, based on findings from the factor analysis in the current study, the valid Arabic version of the FACT-G is composed of 24 items distributed on four factors.

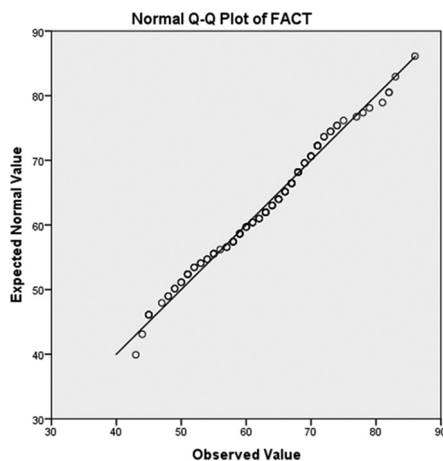


Figure 1: Q-Q plot of the Functional Assessment of Cancer Therapy-General mean scores

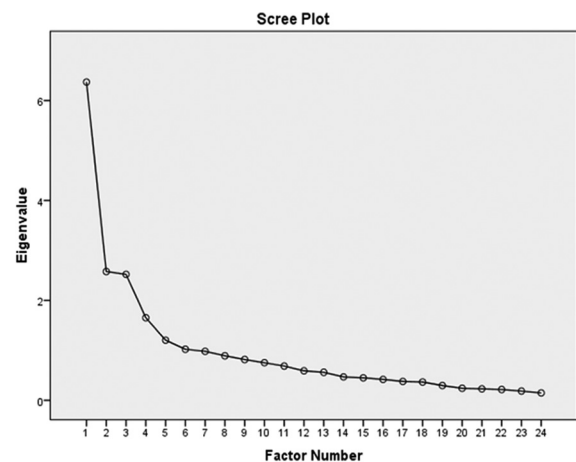


Figure 2: Scree plot representing the 24-item model

Table 2: Findings of the study sample on Functional Assessment of Cancer Therapy-General						
Item	Mean (SD)	Score range	α value	α range (items)	Skewness (SE)	Kurtosis (SE)
FACT-G	63.02 (9.04)	43-86	0.60	-	-0.07 (0.223)	-0.15 (0.442)
Social/family well-being	18.95 (5.92)	0-28	0.82	0.78-0.84	-0.90 (0.223)	0.71 (0.442)
Physical well-being	15.20 (5.18)	4-28	0.83	0.79-0.82	0.27 (0.223)	-0.19 (0.442)
Functional well-being	16.52 (5.16)	4-28	0.77	0.70-0.77	-0.06 (0.223)	-0.42 (0.442)
Emotional well-being	12.35 (4.14)	0-23	0.67	0.55-0.76	-0.10 (0.223)	0.24 (0.442)

FACT-G: Functional Assessment of Cancer Therapy-General, SD: Standard deviation, SE: Standard error

Table 3: Findings from factor analysis ($n = 118$)*

Scale items	Loading	Eigen value	Percentage explained variance
Social well-being (explained 63.94% of the variance)			
I feel close to my friends	0.744	6.371	26.545
I get emotional support from my family	0.744	2.577	10.737
I get support from my friends	0.744	2.520	10.500
My family has accepted my illness	0.570	1.652	6.883
I am satisfied with family communication about my illness	0.635	1.203	5.013
I am satisfied with my sex life	0.445	1.022	4.258
Physical well-being (explained 21.96% of the variance)			
I have a lack of energy	0.655	0.980	4.082
I have nausea	0.494	0.890	3.709
Because of my physical condition, I have trouble meeting the needs of my family	0.717	0.816	3.398
I have pain	0.690	0.752	3.133
I am bothered by side effects of treatment	0.575	0.684	2.850
I feel ill	0.608	0.589	2.456
I am forced to spend time in bed	0.581	0.560	2.332
Functional well-being (explained 9.88% of the variance)			
I am able to work (include work at home)	0.463	0.468	1.949
I am able to enjoy life	0.677	0.449	1.870
I have accepted my illness	0.445	0.417	1.738
I am sleeping well	0.425	0.376	1.569
I am enjoying the things I usually do for fun	0.490	0.365	1.521
I am content with the quality of my life right now	0.687	0.295	1.228
Emotional well-being (explained 4.23% of the variance)			
I feel sad	0.495	0.240	1.01
I am losing hope in the fight against my illness	0.593	0.228	0.952
I feel nervous	0.603	0.215	0.897
I worry about dying	0.759	0.185	0.769
I worry that my condition will get worse	0.634	0.146	0.610

*Extraction method: Maximum likelihood, Rotation method: Varimax

Impact of the sample characteristics on Functional Assessment of Cancer Therapy-General scores

There were no significant differences among the subgroups of the tested variable ($P > 0.05$) indicating that patients with different OM grades, from both sexes, age groups, and types of treatment did not have statistically significant differences on the FACT-G-Arabic [Table 4].

Discussion

The FACT-G is a widely used instrument to measure QOL among cancer patients. This study presented an evaluation of the instrument's validity and reliability of measuring the psychometric properties when applied to an Arabic-speaking population. There is wide evidence in the literature on the validity and utility of the FACT-G scale to measure QOL among head-and-neck cancer patients.^[5,25] This study, however, tested this issue in a new population (i.e., cancer patients in Jordan). The study aim was achieved in that the FACT-G demonstrated acceptable validity and reliability when used in cancer patients in Jordan.

Among the 27 statements of the original questionnaire, this study found 24 items to represent the valid Arabic version

of the questionnaire grouped together into four factors: Social well-being, physical well-being, functional well-being, and emotional well-being. Only three statements from the original English version of the FACT-G were rejected, namely, "I feel close to my partner (or the person who is my main support);" "my work (including work at home) is fulfilling;" and "I am satisfied with how I am coping with my illness." One could argue that the use of another tool to check for the convergent validity would have added to this study. However, there are no similar scales translated and validated which could be compared against the findings from the FACT-G. In addition, there is enough evidence for the construct and content validity of the FACT-G in the literature.^[26,27]

Reliability and validity are essential characteristics of any research instrument. Reliability was measured using the internal consistency of the FACT-G, Arabic version, by item analyses. The internal consistency of the questionnaire was found to be acceptable. The validity of the scale was examined using factor analysis to determine factors and items explaining the QOL among the participants.

Based on the study findings, the FACT-G total mean score was lower than the reported mean score in the USA^[28]

Table 4: The impact of patient characteristics on the Functional Assessment of Cancer Therapy-General mean scores

Characteristics	FACT-G mean	SD	F	P
Gender				
Male	61.87	8.310	0.784	0.378
Female	63.55	9.303		
Age group (years)				
18-25	58.50	0.707	0.847	0.498
26-40	63.88	8.616		
41-55	62.96	9.902		
>55	62.87	8.543		
Smoking status				
Yes	62.46	9.537	0.153	0.697
No	63.27	8.957		
Type of treatment				
Radiotherapy	63.08	9.378	0.255	0.857
Chemotherapy	64.70	6.750		
Chemoradiotherapy	61.77	8.795		

FACT-G: Functional Assessment of Cancer Therapy-General, SD: Standard deviation

of 80.10 and other studies from China^[29] of 66.10, indicating that Jordanian patients with OM were perceived as having low QOL. Furthermore, results showed that mean scores on the subscales were also lower than those reported in the literature.^[5,28-30] For instance, in a study in the USA that investigated QOL among patients with advanced cancers who were on palliative treatment, higher mean scores were reported compared with the present study.^[31] In addition, other researchers^[27] examined QOL in patients postautologous hematopoietic cell transplantation with moderate or severe OM and reported high mean scores on the well-being subscales and the FACT-G scale. On the other hand, Cheng^[19] reported lower mean scores in a study on 38 inpatients and 50 outpatients with OM from Hong Kong, China. Cheng's study reported that the mean scores of physical, social/family, emotional, and functional subscales were 15.1 (SD: 5.9), 16.3 (SD: 4.1), 15.7 (SD: 4.5), and 11.9 (SD: 6.8), respectively.^[19] Another study reported initial baseline mean scores similar to this study; however, these were in cancer patients with no OM.^[31] Bush *et al.* reported a FACT-G mean score of 65 for 218 cancer patients who did not experience OM or any other acute condition.^[32] Another study in Italy^[5] reported a FACT-G mean score of 73.91 (SD 14.16) 2 weeks after the treatment. Possible reasons for these low QOL findings could not be determined in this study. However, low QOL of life among cancer patients with OM is usually associated with the unpleasant feelings related to decreased ability to perform the usual activities of daily living without experiencing pain and discomfort, loss of appetite, and fatigue.^[33]

There are no normative values reported for the FACT-G scale. A study by Brucker *et al.*^[33] adopted values^[34] reported on adult cancer patients in the USA as a reference. These

values are significantly higher than the mean scores obtained in the present study for the FACT-G. Therefore, our findings might be interpreted as indicative of low QOL among the study sample. However, it is too early to conclude that the normative scores reported in the literature^[33,35] could apply to our sample. The FACT-G Arabic version comprising of the valid 24 items needs further testing to ensure that the findings of this study are valid, and furthermore, to test the stability of the instrument over greater use among other samples of cancer patients.

This study was cross-sectional and adopted a non-probability convenience sampling, which might have resulted in limited representation and a threat to external validity. Data were collected in three settings and were specifically addressing patients with head-and-neck cancers. It is recommended to conduct similar studies on other cancer patients. In addition, it is difficult at this stage to assume that the reported mean scores are mainly related to the presence of OM. Therefore, a study comparing QOL for patients with and without OM could be beneficial.

Conclusion

The Arabic version of the FACT-G is valid and reliable when used in this study population. Normative values and cutoff points still need to be determined in the future studies. Further testing of this instrument is required to ensure stability over time and use.

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Conflicts of interest

There are no conflicts of interest.

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