



Quality of Life among Moroccan Women Undergoing Treatment of Breast Cancer

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Authors' contributions

This work was carried out in collaboration between all authors. Authors BHR, AM, KER jointly developed the structure and arguments for the paper. Author BHR collected data, performed the data analysis and wrote the first draft. Authors BHR, KER and SA contributed to the manuscript results and conclusions. Authors AM, KER, ZH, BB, SA and FO performed critical reviews for important intellectual content of the manuscript. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2017/33772

Editor(s):

(1) Sevgul Donmez, Faculty of Health Sciences, Gaziantep University, Turkey.

Reviewers:

(1) Mohamed Najimudeen, Melaka Manipal medical college, Malaysia.

(2) Ana Joaquim, Centro Hospitalar de Vila Nova de Gaia/Espinho, Portugal.

(3) Ana Fátima Carvalho Fernandes, Universidade Federal do Ceará, Brazil.

Complete Peer review History: <http://www.sciedomain.org/review-history/19122>

Original Research Article

Received 28th April 2017

Accepted 14th May 2017

Published 18th May 2017

ABSTRACT

Introduction: The aim of this study was to evaluate quality of life of Moroccan women with breast cancer and studied its association with clinical and demographic characteristics.

Methods: A cross-sectional study was carried out from July 2014 to July 2015 at the National Institute of Oncology in Rabat. The sample consisted of 400 patients with breast cancer recruited

for face-to-face interviews. Data were collected using a questionnaire addressing personal and clinical characteristics and Moroccan versions of EORTC QLQ C30 and BR 23 to measure quality of life.

Results: The mean age of participants was 48.2years \pm 10.2. Most of them were married (61%), illiterate (65%) and the majority (86%) were housewives. Participants scored fairly well on global health status/QOL scale (Mean 53.4; SD 17.7).Cognitive functioning scored the highest with a mean of 64.6 on a scale of 100. Whereas role functioning scored the lowest (25.5). For the BR-23, all functional scales received scores below 50. Regression analyses showed that age, marital status, chemotherapy, surgery and radiotherapy were statistically significant in predicting patient's quality of life.

Conclusions: Our finding highlighted functional, psychological and social difficulties with which live Moroccan patients with breast cancer.

Keywords: Breast cancer; quality of life; predictors; Moroccan women.

ABBREVIATIONS

QOL: Quality of Life; EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Core quality of life questionnaire; EORTC QLQ-BR23: European Organization for Research and Treatment of Cancer breast cancer- specific quality of life questionnaire; GHS-QOL: Global Health Status- Quality of Life.

1. INTRODUCTION

For many years in oncology, treatment efficacy was assessed in terms of response rate and prolongation of survival. Nevertheless, the benefits associated with increased survival of patients cannot reasonably be considered without regard to the quality of their life.

Quality of life (QOL) has been defined as the subjective evaluation of life as a whole or the patient's appraisal and satisfaction with their current level of functioning compared with what they perceive to be possible or ideal [1]. It is a multidimensional construct that refers to a person's perceived quality of her/his physical, psychological, social, and existential functioning [2]. It focuses on how disease and its treatment affect the individual.

Understanding the effect of breast cancer and its treatment on a patient's QOL has been a central clinical and research question [3]. This is due firstly to the increased incidence of this disease which is the second highest of all cancers with approximately 1.67 million new cases diagnosed worldwide in 2012 [4], and secondly to the early detection and treatment leading to survival rates up to 10 years after diagnosis [5].

Studies have shown that breast cancer and its treatment processes affect the QOL of patients in the physical, psychological and social domain [3]. Patients with breast cancer are faced with treatment side effects undermining their QOL because they tend to receive multimodal

treatment including surgery, chemotherapy, and/or radiotherapy over an extended period of time [6]. Side effects may include pain, fatigue, pulmonary symptoms, radiation burns, nausea, vomiting, insomnia, infertility, and sexual dysfunction among others [7]. In addition, patients are at risk of experiencing anxiety and depression [8]. Determinants such as disease stage, type of treatment and socio-demographic characteristics have been studied extensively and researchers have demonstrated a strong association between these factors and QOL of patients [1,9].

According to the overall statistics of Morocco, breast cancer is the most common cancer in women with an incidence of 39.9 per 100,000 women in 2007 [10]. Numerous efforts have been made to prevent and control this disease as part of a plan developed by the Ministry of Health in partnership with Lalla Salma Foundation [11]. Actions have been taken in terms of infrastructure, medication access and early detection [12]. Moreover, the Lalla Salma Foundation created temporary accommodation spaces near each cancer center called "house of life" [12], to encourage adherence to treatment and support patients and their relatives.

Even though these actions give hope to more and more women in terms of prognosis and access to treatment, it is important to make sense of and look at QOL of these women. Indeed, limited data exist on quality of life of women with breast cancer in Morocco [13].

Therefore, the present study aimed to evaluate QOL and studied its association with certain clinical and demographic characteristics of Moroccan women with breast cancer under treatment in Oncology hospital of Rabat, Morocco.

2. MATERIALS AND METHODS

We use the term quality of life to be synonymous with the expression "health-related quality of life" [14].

2.1 Study Design

We used a cross-sectional quantitative study. We targeted 400 patients diagnosed with breast cancer recruited consecutively for face-to-face interviews. All patients were recruited as outpatients within National Institute of Oncology in Rabat in period June 2014 to June 2015. The study was conducted on the gynecological and breast cancers department. It is the most Moroccan's cancer referring center and receive patients from all parts of the country.

2.2 Simple Size

The sample size was calculated based on an estimate of 50% for prevalence of outcomes and a precision of 5% for a 95% confidence interval; the required sample size was calculated to be 384. We recruited 400 patients.

2.3 Eligibility Criteria

Were being able to attend the interview, a Moroccan female breast cancer patients aged 18 years old and above with a pathological first diagnosis of primary breast cancer and who just received surgery for the disease or undergoing chemotherapy or radiation therapy.

Patients with pre-existing cancer and those who had a known history of psychiatric disorder or dementia were excluded from the study. Moreover, women with proven recurring breast cancer were excluded also, since it is known that recurrence of breast cancer has a profound negative effect on QOL [15] and would therefore compromise our results.

2.4 Questionnaires

In order to collect data, three instruments were used; the first part was related to clinical and demographic characteristics, the second was the European Organization for Research and

Treatment of Cancer Quality of Life Questionnaire Core 30 version 3.0 (EORTC-QLQ-C30) [16] and the third instrument was the Breast Cancer-Specific Module (EORTC QLQ-BR23) [17].

To assess QOL we used the EORTC-QLQ-C30. This questionnaire is a valid and reliable questionnaire for evaluation of QOL in Morocco [18]. The EORTC-QLQ-C30 [16] is a self-reporting cancer-specific measure of QOL. It comprises a global health status/QOL (GHS-QOL) scale and five multi-item functional scales that evaluate physical, role, emotional, cognitive and social function. Six single items measure symptoms (dyspnea, insomnia, appetite loss, constipation and diarrhea), and three multi-item symptom scales assess fatigue, pain and nausea/vomiting. Of the 30 items, 28 are scored on four-point Likert scales and the remaining two items for the global health status/QOL scales are scored on seven-point scales. All scales were linearly transformed to a score from 0 to 100, with 100 representing the best global health status/ QOL or functional status, or the worst symptom status [16,19,20].

The EORTC QLQ breast cancer-specific module (EORTC QLQ-BR23) is used to enhance the sensitivity and specificity of the QOL measurement of patients with breast cancer. This questionnaire is a valid and reliable questionnaire for evaluation of quality of life in Morocco [13]. It is composed of 23 questions assessing functional scales (body image, sexual activity and future perspective) and symptom scales related to treatment (systemic therapy side effects, breast symptoms, arm symptoms and upset by hair loss) [17]. Scoring and interpreting methods are also included in the EORTC QLQ-C30 scoring manual [19,20].

Socio-demographic data included age, residential areas, marital status, education level, occupation and social security. Clinical characteristics included time since diagnosis, stage, current treatment, status of menopause and family history of breast cancer. Information on socio-demographic variables were collected for face-to-face interview while the clinical variables were obtained from patients' medical records.

2.5 Statistical Analysis

The collected data were coded, entered and analyzed using the statistical package SPSS version 13.0. The scale scores of the QLQ – C30

and BR-23 were computed as recommended [20]. A higher score represents a “better” level of functioning, or a “worse” level of symptoms.

We defined subjects with problematic functioning as those who scored <33.3%, while subjects in good condition scored \geq 66.7%. For symptom scales, subjects scoring <33.3% were judged as having less severe symptoms, while those scoring \geq 66.7% had more intense symptoms. This categorization was suggested from an empirical general population study [21].

The descriptive statistics technique was used for the description of socio-demographic and clinical variables. All groups of quantitative data were verified using the Kolmogorov-Smirnov test in order to *evaluate their distribution*.

Multiple linear regressions were used to relate the GHS-QOL to their predictors. A stepwise selection method was used to select the best regression model. For multiple regression analysis p values \leq 0.2 were considered significant to account for multiple comparisons. The GHS-QOL score of the EORTC QLQ-C30 was treated as the dependent variable. Socio-demographic and clinical characteristics were entered as explanatory factors in the model [22]. All independent variables were categorized into two categories (no and yes) and served as predictors for the model. The differences were considered significant when P value was <0.05.

3. RESULTS AND DISCUSSION

3.1 Results

3.1.1 Characteristics of the study sample

The study enrolled 400 patients. Their mean age was 48.2 years (range 24-79, SD 10.3). Most of patients were married (61%) and 17.5% were single. Regarding the educational level 65% of participants were illiterate and only 7.3% had a university academic degree. The majority of participants (86%) were housewives, 11% were in current employment and 2% were student. Interestingly 99% of participants had social security, but it should be noted that 85.8% of them are covered by RAMED insurance, which is for people with low economic status. In terms of clinical data, 46.3% of patients were in stage III and IV. Mean time elapsed since diagnosis was 7.3 (SD \pm 3.7) months. Other socio-demographic and clinical characteristics of the study population are summarized in Table 1.

3.1.2 Quality of life assessment

The EORTC-QLQ-C30 questionnaire, showed that participants scored fairly well on GHS-QOL scale (Mean 53.4; SD 17.7). Average scores (scoring between 33.3 and 66.6) were recorded among 78.5% women. Scores on functioning scales ranged from 25.5 (SD 23.5) for role functioning to 64.6 (SD18.5) for cognitive functioning. More than half of patients (59.5%) were identified with financial problems due to disease and treatment. The most distressing symptom on the symptom scales was fatigability (Mean 60.2; SD 21.8) followed by insomnia and appetite loss (Table 2).

Using the disease specific tool (QLQ-BR23). It was found that all functional scales had means scores below 50.0. The sexual functioning scored the lowest (Mean 4.4; SD11.1), whereas body image had the higher mean score (38.4; SD36.1). On breast cancer specific symptom scales, the worst symptom was “upset from hair loss” (Mean 81.2 \pm 28.1SD). (Table 2).

3.1.3 Factors associated with QOL

Because almost all women (86%) were housewives, occupation was not included in analysis. For a similar reason, insurance was not included.

In a step wise regression analyses, the predictors which had a significant effect on GHS-QOL given the other predictors in the model were chemotherapy (β = -16.40, P <0.001), radiotherapy (β = 12.31, P <0.001), surgery (β = -12.19, P <0.001), younger age of women (β = 4.17, P = 0.002) and celibate status (β = 4.83, P =0.005) (Table 3).

3.2 Discussion

This study was positioned to evaluate the QOL of Moroccan women with breast cancer particularly during treatment. The study reported also on the importance of socio-demographic and clinical status and their impact on QOL.

Results indicate that 78.5% of patients had clinically an average Global Health Status-QOL. The role and emotional functioning had the lowest mean scores (25.5, 53.8 consecutively). The majority of Moroccan patients (85%) had average to good scores on social functioning and more than half of them (59.5%) experiencing financial problems. All functional scales had

means scores of QLQ-BR23 scales were below 50.0 indicating worse functioning.

3.2.1 Quality of life assessment

Our finding indicated that the majority of our patients (78.5%) had clinically an average GHS-QOL. The mean score of GHS-QOL in our study (Mean 53.4; SD 17.7) is close to those reported by studies conducted in Lebanon (Mean 59.6, SD 29.1) [23] and Nepal (Mean52.8, SD 24.6)[24]. Whereas it is lower than those

recorded in other Arab countries such as United Arab Emirates (Mean 74.6) [25], Tunisia (Mean 68.5) [26], Bahrain (Mean 63.9) [27] and Jordan (Mean63.7) [28]. Although, our score is higher than that reported in Kuwait (mean=45.3) [29] and Pakistan (Mean48.3) [30]. Patients with problematic functioning represented 8.3% of participants. This proportion is low than that reported in Nepal (20%) [24]. However in Kuwait and Bahrain problematic functioning was reported by only 6.2% and 5.4% consecutively [27,29].

Table 1. Socio – demographic and clinical characteristics of study population (n=400)

Variables	Effective	%
Demographic characteristics		
Age Mean (SD)	48.17 (Range: 24-79)	SD=10.24
Residence		
Urban	284	71
Rural	116	29
Marital status		
Celibate	70	17.5
Married	244	61
Divorced	26	6.5
Widowed	60	15
Educational level		
Illiterate	260	65
Primary level	65	16.3
Secondary level	46	11.5
University level	29	7.2
Occupation		
Housewife	345	86.2
Active	44	11
Retired	3	0.8
Student	8	2
Social security		
No	4	1
Yes	396	99
Type of social security (n=396)		
AMO Insurance ¹	53	14.2
RAMED Insurance ²	343	85.8
Clinical characteristics		
Time since diagnostic (months) Mean (SD)	7.3(Range: 1-17)	SD= 3.7
Stage		
I -II	257	46.3
III - IV	143	35.7
Current treatment		
Surgery	133	33.2
Chemotherapy	124	31.0
Radiotherapy	143	35.8
Menopause		
Yes	233	58.2
No	167	41.8
Family history of breast cancer		
Yes	180	45.0
No	220	55.0

¹Social security for employees; ²Social security for poor people

Table 2. Mean score of all items in QLQ-C30 and QLQ-BR23 (N = 400)

Variables	No. of items	Mean	SD	N (%) scoring $\geq 66.7^a$	N (%) scoring 33.3-66.6 ^a	N (%) scoring $< 33.3^a$
QLQ-C30						
Global health status/QoL Functional scales^b	2	53.39	17.71	53 (13.3)	314 (78.5)	33 (8.3)
Physical functioning	5	61.15	20.75	148 (37)	222 (55.5)	30 (7.5)
Role functioning	2	25.54	23.50	0 (0)	220 (55)	180 (45)
Emotional functioning	4	53.83	31.94	139 (34.8)	156 (39)	105 (26.2)
Cognitive functioning	2	64.62	18.52	118 (29.5)	277 (69.3)	5 (1.2)
Social functioning	2	58.33	30.79	128 (32)	212 (53)	60 (15)
Symptom scales^c						
Fatigue	3	60.22	21.76	100 (25)	294 (73.5)	6 (1.5)
Nausea and vomiting	2	19.66	26.02	20 (5)	105 (26.2)	275 (68.8)
Pain	2	36.83	21.21	11 (2.8)	287 (71.8)	102 (25.5)
Dyspnea	1	21.33	19.18	0 (0)	236 (59)	164 (41)
Insomnia	1	53.33	25.52	41 (10.2)	331 (82.8)	28 (7)
Appetite loss	1	47.66	22.01	8 (2)	362 (90.5)	30 (7.5)
Constipation	1	3.50	11.01	0 (0)	39 (9.8)	361 (90.3)
Diarrhea	1	9.58	19.59	0 (0)	87 (21.7)	313 (78.3)
Financial difficulties	1	82.91	22.75	238 (59.5)	162 (40.5)	0 (0)
QLQ-BR23						
Functional scales^b						
Body image	4	38.37	36.05	101 (25.3)	105 (26.3)	194 (48.4)
Sexual functioning	2	4.37	11.05	0 (0)	42 (10.5)	358 (89.5)
Sexual enjoyment	1	20.33	16.39	0 (0)	36 (9)	23(5.8)
Future perspective	1	22.58	29.06	16 (4)	163 (40.8)	221 (55.3)
Symptom scales^c						
Systemic therapy side effect	7	24.46	18.93	10 (2.5)	122 (30.5)	268 (67)
Breast symptoms	4	27.33	18.80	5 (1.2)	175 (43.8)	220 (55)
Arm symptoms	3	26.33	17.21	4 (1)	158 (39.5)	238 (59.5)
Upset by hair loss	1	81.21	28.10	107 (26.8)	55 (13.8)	3 (0.8)

^aFor functional scales, subjects scoring $< 33.3\%$ have problems; those scoring between 33.3-66.6 have average scores and those scoring $\geq 66.7\%$ have good functioning. For symptom scales/symptoms, subjects scoring $< 33.3\%$ have good functioning; those scoring between 33.3-66.6 have average scores and those scoring = 66.7% have problems.

^bFor functional scales, higher scores indicate better functioning.

^cFor symptom scales, higher scores indicate worse functioning

Nonetheless, we must be cautious in comparing the data of these studies. The population base vary in terms of time since diagnosis, stage of disease, treatment received and patient recruitment methods. Furthermore, the patients in our study were undergoing treatment during the interview and a majority had been diagnosed for less than a year.

Within the functional scales of the QLQ-C30 the role and emotional functioning had the lowest mean scores (25.5, 53.8 consecutively). Worse emotional and role functioning were reported consecutively by 34.8% and 45% of participants. One of reasons why our study population had a lower score than reported in other studies [27,28]

may be that participants were undergoing treatment during the interview and a majority of them had been diagnosed for less than a year, which had a significant impact on their role and emotional functioning.

Consistent with the studies conducted among Arabic patients [23,27-29], our finding showed that 85% of Moroccan patients had average to good scores on social functioning. This could be referred to religious values and social support they receive. Many studies supported these findings; Hebert et al. indicated that positive religious coping methods predict better mental health and life satisfaction in women with breast cancer [30].

Table 3. Results of multiple linear regression between global health status/ QOLand socio demographic and clinical factors (n =400)

Characteristics	Global QOL					
	Full model			Final model		
	Univariate analysis			Multyariate analysis		
	β	P-value	95% CI	β	P-value	IC
Age (≤50 years)						
No						
Yes	4.57	0.01	[1.14; 8.26]	4.17	0.002	[1.54;6.80]
Education						
No						
Yes	1.11	0.56	[-2.67; 4.89]			
Celibate						
No						
Yes	7.28	0.00	[2.75 ; 11.81]	4.83	0.005	[1.45 ; 8.21]
Time since diagnosis ≤ 3 months						
No						
Yes	0.22	0.91	[-4.05 ; 4.50]			
Advanced stage						
No						
Yes	-3.24	0.07	[-6.86 ; 0.38]	-2.61	0.06	[-4.36 ; 0.04]
Surgery						
No						
Yes	-2.89	0.12	[-6.58; 0.79]	-12.19	0.000	[-15.35 ; -9.02]
Chemotherapy						
No						
Yes	-22.33	0.00	[-25.23; -19.44]	-16.40	0.000	[-19.44;-13.36]
Radiotherapy						
No						
Yes	20.986	0.00	[17.83; 24.13]	12.31	0.000	[9.14;15.48]
Menopause						
No						
Yes	-9.933	0.00	[-13.32; -6.53]	-0.17	0.92	[-3.63;3.29]
Family history of breast cancer						
No						
Yes	1.90	0.28	[-1.59; 5.40]			

Comparing to a former study by Alawadi and Ohaeri [29], the mean score of financial difficulties was well above 50. In our study, more than half of patients (59.5%) had financial problems that they considered due to the disease and his treatment. Even though, 99% of our study population had social security, the high percentage of patients with financial difficulties can be explained by the fact that 85.8% of them were covered by “RAMED insurance” which is for people with low economic status. Despite that the policy of cancer management in Morocco prioritize the financial support of cancer patients and offering health insurance, however patients, especially those with low economic status, still experiencing financial problems due mainly to the costs of transport, feeding and the expense

of biological or radiological investigations that is not always available at the hospital.

In accordance with other studies conducted in Arab and western countries [27,28,31], the worst scores among the QLQ-C30 symptoms in our study were for fatigue (Mean 60.2, SD 21.8). This may be explained by the consequences of the therapeutic process.

Regarding the specific tool QLQ-BR23, in supporting the findings of our study, the studies conducted by Jassim et al. and Fobair et al. [27,32] showed that patients had poor functioning for sexual functioning and enjoyment. This may be related with the sociocultural structure of Moroccan society, which is clearly presented in

study conducted by Sbitti et al. [33] that described sexual impact in breast cancer as a taboo in the clinical setting in Morocco and reported worse sexual functioning, characterized by greater lack of sexual interest. In addition, patients in our study had lower scores in all body image subscales, which is in accordance with finding of Bakwell and Volker in showing that all types of treatment for breast cancer had a significant impact on body image and sexual functioning [34]. Furthermore, most unmarried patients of our study population did not respond to the question on sexual functioning.

In accordance with our results, one of main stress that many patients may experience during the active phases of breast cancer treatment is the fear of cancer recurrence [35]. Results of study in Germany showed that the fear about family and especially about the future of children is one of the most important worries of cancer patients [36].

Regarding symptoms scales of the QLQBR23, "upset by hair loss" had the highest mean score (Mean 81.21, SD 28.10) indicating worse functioning. This score is higher than those reported in Jordan (Mean 69, SD43.02) [28], Germany (mean=59.3±37.5SD) [33] and Nepal (Mean 40.3, SD 43.2) [24].

3.2.2 Factors associated with QOL

In this study, insurance and occupation were not included as independent variables for QOL because the majority of participants had insurance (99%) and almost all were housewives (86.3%). Therefore, predictive ability of these characteristics of outcomes would be less due to low prevalence of those without insurance or not housewives.

The notable associations with GHS-QOL in this study were age, marital status, chemotherapy, surgery and radiotherapy.

The association between age and QOL as often opposed [37,38], the analysis of our results showed a significant association. The younger patients tended to have a better GHS-QOL. This can be explained by the ability of young women to tolerate better the side effects of treatment.

The correlation of marital status with GHS-QOL was in line with the international data in showing that celibate women with cancer tend to have better global quality of life [39]. This may be

related to the fact that single women are under less pressure to worry about their families' needs and their partner's opinion.

One of other considerable findings was the presence of a significant correlation between QOL and chemotherapy, surgery and radiotherapy. In consistent with our results, Bayram, et al. reported that chemotherapy was associated with more negative impact on QOL during the treatment period [40]. This is reinforced by Schou et al. who reported a negative correlation between chemotherapy and QOL [41].

The logistic regression indicated that surgical intervention was a determinant for poorer QOL. This is consistent with a previous studies conducted by Alferi et al. [42] who reported that surgical procedures following the diagnosis of breast cancer was considered as an emotional and distressing experience and had a significant impact on women's QOL.

Another finding that the present study supported was reported by Al Naggat et al. [43] who stated that a positive association was detected in GHS-QOL depending on the received radiation. This may be related to the patient's appreciation of an improved global health in radiotherapy period compared to the chemotherapy.

Analysis of the effect of disease duration on the patients' QOL showed that results of the published studies were contradictory. Bottomley et al. stated that the subjects' quality of life worsened with increasing time from the diagnosis to the study [44] while according to Waldman et al. and our findings, this factor had no statistically significant effect [31].

Our outcomes are similar to those reported by Chie et al. in showing that no statistically significant differences between different clinical stages of breast cancer and QOL[45]. It has been suggested that the diagnosis of breast cancer is so stressful that it may result in a pattern of psychological morbidity for women in early stages that is similar to that experienced by women with more advanced disease [9].

Of other factors investigated, no differences were observed across categories of educational level, menopause and family history of breast cancer. Studies from Bahrain, Jordan and Yemen offer much evidence and showed that no significant relationships between GHS-QOL and

educational level [28,43], menopause [27] and family history of breast cancer [43].

Given the study design was cross-sectional; these findings should be interpreted with caution. On the other hand, it should be noted that a considerable number of patients in the present study were illiterate or low educated; Therefore, data collection in all patients was done as the researcher read the questions and completed the questionnaire. Therefore, it is likely that intimates questions, are not precisely and honestly answered and it was one of the limitations of the study.

4. CONCLUSIONS

Results of our research indicate that Moroccan breast cancer patients undergoing treatment reported an average global health status and experience problems in multiple QOL domains. There were important effects of age, marital status, chemotherapy, surgery and radiotherapy on GHS-QOL. A holistic and integrated care with psychological and financial support will improve QOL of patients. More attention should be targeted toward older women, those married and those under surgery and chemotherapy. Improving QOL is a pivotal concern for these patients and healthcare professionals must take into consideration the importance of well being besides medical treatment. This study should help to fill gaps of limited knowledge and identify areas in which the patients need extra support. However, his findings should be the reason for further research to investigate other dimensions of QOL and evaluate the influence of other factors on QOL.

CONSENT

All authors declare that written informed consent was obtained from the patient for publication of this article.

ETHICAL APPROVAL

The ethical committee of Medical and pharmacy school of Rabat approved the study protocol. Before the interview survey, the interviewer explained the purpose of the questions to all eligible women and requested their participation. All participants signed an informed consent form prior to being interviewed. All assessments were based on private interviews conducted all by researcher.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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