Evaluation of quality of life and emotional distress in endometrial cancer patients: A 2-year prospective, longitudinal study

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HIGHLIGHTS
• Menopausal symptoms represents the most heavily affected QoL area in endometrial cancer (EC) patients.
• Sexual activity scores as well as anxiety scores progressively improve over time.
• Multivariate analysis underlines the relevance of socio-demographic factors in influencing EC patient capability to rescue QoL over time.

ABSTRACT

Objectives. The aim of the study was to prospectively, and longitudinally assess Quality of Life (QoL) and emotional distress in a large series of endometrial cancer (EC) patients.

Methods. Global Health Status of the EORTC QLQ-C30 (GHS), the EORTC QLQ-CX24 (CX24), and the Hospital Anxiety and Depression Scale (HADS) questionnaires were administered at diagnosis, and after 3, 6, 12, and 24 months since surgery. The Generalized Linear Model and the Between Subject test were used to analyze QoL changes over time, and the association between factors and patient QoL.

Results. GHS scores improved over time, although the statistical significance was not reached. Worse lymphedema scores were documented worsened over time with a trend to recover at the 12- and 24 month evaluation (p-value = 0.028). Scores for Menopausal Symptoms (MS) dramatically worsened over time reaching a 38.5 difference of mean ± SE compared to baseline (p-value = 0.011). Sexual Activity (SxA) scores improved until the 12-month evaluation (p-value = 0.048), and showed a return to baseline levels at the last assessment (p-value = 0.025). A significant improvement of anxiety scores was documented at the 3-month evaluation, and persisted over time. In multivariate analysis, unmarried status was associated with poor scores for sexual activity, while living with someone was associated with worse MS scores.

Conclusions. Menopausal and lymphedema symptoms heavily affect QoL in EC patients. Since socio-demographic features play a major role in deteriorating SxA and MS, psycho-social intervention and patient education should be considered as an integral part of EC patient treatment.

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treatments on body image, sexual function and hormone function for premenopausal women have not to be underestimated in gynecologic cancer survivors [7–10].

In the context of the efforts attempted to possibly reduce the unfavorable effects of surgery on QoL of endometrial cancer patients, minimally invasive approaches have been shown to be associated with an improvement of QoL, although duration and extent of this benefit remain to be established [11,12].

On the other hand, a significant worsening of global QoL scores has been consistently reported in EC patients administered radiation treatment [13–17]; in particular, the most frequent symptoms involved in QoL impairment are urinary and bowel dysfunctions which can persist even after years since treatment [17].

Although the long term evaluation of QoL in EC patients has been prospectively investigated in EC patients [17], some issues still remain to be addressed, such as the impact of socio-demographic features, comorbidities and obesity on QoL, as well as emotional distress.

Our study was aimed at prospectively, and longitudinally assessing QoL and emotional distress in a large series of EC patients; assessment of unmet needs, as well as clinico-pathological and socio-demographic features associated with fluctuations of QoL scores over time, was performed.

Patients and methods

Study design, recruitment and treatment details

This is a prospective, longitudinal study collecting specific measures of QoL and emotional distress in EC patients. Eligibility criteria include: histological diagnosis of endometrial carcinoma, age ≥ 18 years, ability to read and understand Italian, and the absence of any evident cognitive impairment. Exclusion criteria were: inability to understand Italian language and inability to undergo planned follow up procedures. The study was approved by the Institutional Review Board and by the Ethical Committee.

All patients were treated with total hysterectomy and bilateral salpingo-oophorectomy; pelvic lymphadenectomy was performed in the presence of risk factors at the frozen section. Patients showing metastatic involvement of pelvic lymph nodes also underwent para-aortic lymph node dissection.

Debulking surgery was performed in advanced stage disease in order to obtain complete cytoreduction.

Route of surgery was established evaluating, case by case, patient medical history (i.e. parity, comorbidities, body mass index—BMI, etc.), disease extension and uterus dimensions.

Adjuvant treatment was administered according to NCCN guidelines: in particular, patients with FIGO stage IA2–IC2, were triaged to utero-vaginal brachytherapy plus/minus external beam radiation (EBRT) based on the adequacy of surgery; high risk patients (stage IB, G3-IIIC), received platinum based chemotherapy plus radiotherapy.

Women refusing radiation or affected by severe comorbidities contraindicating radiation therapy received chemotherapy as adjuvant treatment.

Study procedures

Investigators had to provide potential participants with oral and written information about the aim and procedures of the study at their first admission. Eligible patients who accepted to participate had to give written informed consent to the study procedures. Baseline questionnaires had to be administered within a week from communication of diagnosis and before any counseling about treatment. Patients also had to complete the questionnaires after 3, 6, 12 and 24 months after surgery (Fig. 1). QoL evaluations were discontinued in patients experiencing recurrence/progression of disease. All questionnaires were administered by psycho-oncologists from our hospital service.

Fig. 1. Time line of questionnaire administration, and flow chart of our patient population.

Measures

The Global Health Status scale of EORTC QLQ-C30 (version 3.0) (GHS) has been used [18]. The EORTC QLQ-CX24 (CX24) questionnaire, which is specific for assessment of QoL in cervical cancer patients, was used [19], since the specific questionnaire for assessment of QoL in EC patients (EORTC QLQ-EN24) was not available when the study was planned.

Indeed, both questionnaires cover the same QoL areas (i.e. sexual functioning, body image, gastrointestinal and urologic symptoms, as well as vaginal symptoms and lower limb lymphedema). Moreover, about 70% of questions of each questionnaire are formulated the same way. Finally, the only differences between the two questionnaires are the presence of specific items relative to menopausal symptoms and vaginal discharge in the EORTC-QLQ-CX24, and the presence of specific questions on alopecia and taste modifications in the EORTC-QLQ-EN24. In this context, we think that the use of the EORTC-QLQ-CX24 instead of the EORTC-QLQ-EN24 questionnaire should not have limited the results of our study.

Both the GHS and the CX24 questionnaires were linearly transformed and analyzed according to the procedures of the EORTC Qol Group [18,19].

Higher scores on the GHS and sexual activity subscales indicate a higher level of functioning and a better QoL, while higher scores correspond to worse or more symptoms for the remaining subscales.

Symptoms of anxiety and depression were evaluated with the Italian validated version of the Hospital Anxiety and Depression Scale (HADS) questionnaire [20,21]. Responses were provided on verbal scales coded
0–3, and were grouped as follows: 0–7 = normal, 8–10 = borderline, and 11–21 = abnormal.

To the purpose of the study, a difference of mean score values larger than 5% compared to baseline was considered of clinical interest [22].

**Statistical analysis**

Non-parametric Wilcoxon rank sum non-parametric test was used to analyze the baseline difference of QoL scores according to clinico-pathological and socio-demographic features. ANOVA for repeated measures with post-hoc tests based on the Bonferroni correction was used to analyze the modifications of QoL measures over time. The Generalized Linear Model (GLM) for repeated measure ANOVA test was used: a p value < 0.05 was taken as statistically significant. The Between Subject test was used in order to investigate the association between factors and patient QoL scales/items. The SPSS Software 18 (SPSS Inc., Chicago, IL) was used.

**Results**

Between February 2007 and July 2010, 132 EC patients were enrolled in the study. Clinico-pathological characteristics and treatment details of our study population have been summarized in Table 1.

As expected, most patients (N = 105, 79.5%) were postmenopausal; 32.4% and 39.2% of the patients were overweight and obese, respectively. Almost half of the patients presented with co-morbid conditions. About 80% of our population had stage I disease and showed endometrioid histology, respectively. Laparotomy was the most frequent (72%) surgical approach; pelvic lymphadenectomy was performed in 74.2% of cases, while aortic lymphadenectomy was necessary in 12.8% of cases. Adjuvant treatment was administered to 56.1% of patients and was more frequently represented by radiotherapy. A shown in Supplementary Table 1, around 72% of the patients were married and 79.5% lived with someone. The vast majority of patients had children (76.5%), a high education level (78.0%), and a stable job (68.2%).

Of 132 cases, 23 (17.4%) showed recurrence of disease, thus leaving 109 patients available for analysis; of these, 94 women completed the questionnaire, leading to a compliance rate of 86.2%.

No statistically significant difference was detected in the distribution of clinico-pathological and socio-demographic features between patients completing all the questionnaires or excluded from the analysis due to refusal or recurrence of disease (data not shown).

**Baseline evaluation of QoL scores**

Table 2 summarizes the GHS and CX24 scores as mean ± Standard Error (SE) at baseline in the whole series and according to clinico-pathological and sociodemographic factors.

Baseline mean ± SE scores for the GHS were 77.1 ± 3.2, and did not vary according to different characteristics with the exception of the status “living alone” which appeared associated with worse GHS scores compared to baseline (13.8% difference in mean scores, p-value = 0.001); A trend to better GHS scores was also observed in married versus unmarried patients (6.2% difference in mean score, p-value = 0.052). Scores for Symptom Experience (SyE) were 85 ± 1.3 at baseline in the whole series, and appeared slightly better in patients still employed at time of evaluation (p-value = 0.049).

Baseline mean ± SE scores for Body Image (BI) were 9.2 ± 2.5, and were better in cases with BMI ≤ 30 compared to obese patients (5.0% difference in mean scores, p-value = 0.040).

Mean ± SE scores for lymphedema (LY) were 13.1 ± 1.9 at baseline: worse scores were documented in older (11.6% difference in mean scores than baseline, p-value = 0.002), postmenopausal (9.3% difference in mean scores than baseline, p-value = 0.004), as well as in less educated (8.7% difference in mean scores than baseline, p-value = 0.010), and unemployed patients (11.7% difference in mean scores than baseline, p-value = 0.002).

Scores for Menopausal Status (MS) at baseline were 116 ± 2.1, and were worse in patients ≤ 60 years (7.5% difference in mean scores than baseline, p-value = 0.023), and in patients with early stage disease (11.1% difference in mean scores than baseline, p-value = 0.018).

Finally, mean ± SE scores for Sexual Activity (SxA) were 10.2 ± 3.1 at baseline evaluation, and resulted better in ≤ 60 years old patients (12.1% difference in mean scores than baseline, p-value = 0.001), and premenopausal women (10.9% difference in mean scores than baseline, p-value = 0.002). SxA was also reported to achieve better scores in married patients (11.1% difference in mean scores than baseline, p-value = 0.001), and in patients still employed at time of evaluation (11.0% difference in mean scores than baseline, p-value = 0.008). Scores relative to Sexual Vaginal functioning (SxV) and Sexual Enjoyment (SxE) were calculated on patients reporting to be sexually active (N = 32): mean ± SE levels were 10.1 ± 2.4 for SxV and did not show significant variations, while mean ± SE values for SxE were 44.4 ± 2.8 and appear worse in patients presenting with more advanced stage (p-value = 0.007), as well as in unmarried women (p-value = 0.033), without children (p-value = 0.048).

**Longitudinal evaluation of CX24 scores**

As shown in Fig. 2 (and Supplementary Table 2), GHS scores slightly improved over time (4.1% difference in mean scores at the 3-month evaluation compared to baseline), although the statistical significance was not reached. There was no difference in mean scores of SyE and BI over time compared to the corresponding baseline values.
As expected, LY scores worsened over time with the highest difference of the mean values at 6 months, and a trend to recover from lymphedema-related QoL impairment at the 12- and 24-month evaluation (p-value = 0.028). Mean ± SE scores for Peripheral Neuropathy (PN) worsened over time with a difference of 4.6% between the score at the 24-month assessment compared to baseline score (p-value = 0.038). Similarly, scores for Menopausal Symptoms (MS) quickly and dramatically worsened over time reaching a 38.5 difference of mean ± SE compared to baseline score (p-value = 0.011). SxW scores showed a slow but progressive deterioration over time (p-value = 0.052), while SxA scores improved (p-value = 0.048) until the 12-month evaluation, and showed a return to baseline levels at the last assessment (p-value = 0.025).

Longitudinal scores of SxV and SxE did not show any clinically or statistically significant fluctuations.

HADS-assessed emotional distress and fluctuations over time

As shown in Fig. 3, mean ± SE anxiety levels at baseline were 7.1 ± 1.1, while baseline depression levels were 3.5 ± 0.7. There was no difference in basal anxiety or depression levels according to clinico-pathological or socio-demographic features (data not shown).

A statistically significant improvement of anxiety scores was already documented at the 3-month evaluation and persisted over time (Fig. 3A); indeed, at baseline, the rate of patients exhibiting pathological anxiety (score ≥ 11) was 19.5%, and this figure dropped to 12.3% at the 3-month evaluation and to 6.2% at the last evaluation (Fig. 3B). On the other hand, there was no difference in the longitudinally assessed mean ± SE depression scores or distribution of cases with pathological depression (Fig. 3C, D).

Univariate and multivariate analyses of factors associated with QoL scales and emotional distress

Table 3 summarizes the results of univariate and multivariate analyses relative to the association between patient features and QoL scales or HADS scales, when at least 1 statistically significant association was documented. In univariate analysis, older age was associated with worse scores for LY and SxA, while postmenopausal status negatively affected only SxA scores. Lymphadenectomy was associated with worse perception of SyE, LY and SxA scores, and adjuvant therapy also had a statistically significant association with SxA scores.
negatively affects SxA scores. As far as socio-demographic features are concerned, married patients presented worse menopausal symptoms but better scores for SxA.

While living with someone was associated with worse MS, patients with low education level more frequently presented impaired LY scores. Finally, being unemployed played a detrimental effect on SyE, LY and anxiety scores.

In multivariate analysis, only lymphadenectomy still retained a borderline association with poor scores for SyE; among socio-demographic characteristics, unmarried status remained associated with poor scores.

Fig. 2. Plots of QoL scales/items variations over time. P-values have been calculated by the Generalized Linear Model.
for sexual activity, while living with someone was still associated with worse MS scores.

**Discussion**

To our knowledge, this is the largest, prospective, longitudinal study, providing a comprehensive assessment of QoL issues and emotional distress in a large series of EC patients.

During the whole study period, more than five hundred questionnaires have been successfully administered with a compliance rate of 86.2%, a figure in line with previously reported results [17]. This high compliance may be partially due to direct administration of questionnaires by a specialized team of psycho-oncologists who provided patients with a precious opportunity to process their own feelings about disease experience.

In our series mean GHS scores at the baseline evaluation appeared slightly higher compared to those reported in other EC samples, despite the limits inherent in a direct comparison of heterogeneous populations [7,17]. However, it is worth noting that besides patient and disease features (i.e., age, menopause, BMI, stage of disease), socio-demographic characteristics were also shown to impact on QoL domains, as previously reported for patients affected by other gynecological malignancies [7, 23,24]: for instance, poor GHS levels were documented in patients living alone; moreover, unemployed patients experienced worse perception of symptom experience and lymphedema. In this context, psychosocial intervention is likely to play a role in ameliorating treatment-related decline of QoL of long term EC survivors [25].

In the longitudinal evaluation, we could not observe clinically significant changes of GHS scores probably because of the relatively high baseline levels. On the other hand, we documented a significant worsening of lymphedema symptoms up to the 6-month evaluation, with a trend toward a recovery only during the second year of observation. This behavior appears different compared to our previous results with early and locally advanced cervical cancer women in which lymphedema continued to worsen up to 2 years after surgery likely due to the employment of more radical hysterectomy and systematic pelvic lymphadenectomy [24]. However, factors contributing to the lower limb lymphedema (LLL) development, such as older age, obesity and vascular disease [26] are expected to be frequently represented in EC patients, thus emphasizing the need to promptly identify patients at high risk of LLL, and set up an adequate prevention and support in the follow up period [25,27]. Moreover, given the association between some socio-demographic features and worse perception of lymphedema symptoms, high risk patients might also take advantage of social support in order to get an easier, preferential access to specialized physicians and treatments.

Interestingly enough, in our series, menopausal symptoms emerged as the most disabling sequelae with a peak of score deterioration after 1 year from surgery and persistence of symptoms even at the 2-year evaluation. Despite the fact that EC commonly arises in postmenopausal

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**Fig. 3.** HADS assessed anxiety (A) and depression (C) mean scores at each assessment. Longitudinal distribution of patients with normal (HADS scores = 7), borderline (HADS scores 8–10), and pathologic (HADS scores ≥ 11) levels of anxiety (B) and depression (D). P-values have been calculated by the Generalized Linear Model.
Table 3
Univariate and multivariate analysis of the association between patient characteristics and QoL scales.

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>Symptom Experience</th>
<th>Lymphedema</th>
<th>Menopausal Symptoms</th>
<th>Sexual activity</th>
<th>Anxiety</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Association with poor score&lt;sup&gt;a&lt;/sup&gt; (p-value)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Association with poor score&lt;sup&gt;a&lt;/sup&gt; (p-value)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Association with poor score&lt;sup&gt;a&lt;/sup&gt; (p-value)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Association with poor score&lt;sup&gt;a&lt;/sup&gt; (p-value)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Association with poor score&lt;sup&gt;a&lt;/sup&gt; (p-value)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Age ≤60 years</td>
<td>No difference 0.827 /</td>
<td>No difference 0.039 0.894 /</td>
<td>No difference 0.684 /</td>
<td>No difference 0.001 0.093 /</td>
<td>No difference 0.586 /</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>No difference 0.430 /</td>
<td>No difference 0.647 /</td>
<td>No difference 0.829 /</td>
<td>No difference 0.001 0.384 /</td>
<td>No difference 0.288 /</td>
</tr>
<tr>
<td>Menopause</td>
<td>No difference 0.471 /</td>
<td>No difference 0.455 /</td>
<td>No difference 0.352 /</td>
<td>No difference 0.240 /</td>
<td>No difference 0.267 /</td>
</tr>
<tr>
<td>BMI levels ≤30</td>
<td>No difference 0.077 0.251</td>
<td>No difference 0.339 /</td>
<td>No difference 0.200 /</td>
<td>No difference 0.267 /</td>
<td>No difference 0.317 /</td>
</tr>
<tr>
<td>&gt;30</td>
<td>No difference 0.999 /</td>
<td>No difference 0.566 /</td>
<td>No difference 0.992 /</td>
<td>No difference 0.001 0.366 /</td>
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<tr>
<td>Co-morbidities</td>
<td>No difference 0.021 0.056</td>
<td>No difference 0.000 0.099</td>
<td>No difference 0.217 /</td>
<td>No difference 0.011 0.750 /</td>
<td>No difference 0.221 /</td>
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<tr>
<td>Adjuvant therapy</td>
<td>No difference 0.714 /</td>
<td>No difference 0.523 /</td>
<td>No difference 0.169 0.915 /</td>
<td>No difference 0.030 0.965 /</td>
<td>No difference 0.637 /</td>
</tr>
<tr>
<td>FIGO stage I</td>
<td>No difference 0.833 /</td>
<td>No difference 0.532 /</td>
<td>No difference 0.180 /</td>
<td>No difference 0.100 0.001 /</td>
<td>No difference 0.267 /</td>
</tr>
<tr>
<td>II–III</td>
<td>No difference 0.455 /</td>
<td>No difference 0.811 /</td>
<td>No difference 0.008 0.032 /</td>
<td>No difference 0.091 0.809 /</td>
<td>No difference 0.365 /</td>
</tr>
<tr>
<td>Lymphadenectomy</td>
<td>No difference 0.455 /</td>
<td>No difference 0.821 /</td>
<td>No difference 0.270 /</td>
<td>No difference 0.452 /</td>
<td>No difference 0.161 0.496</td>
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<tr>
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<td>No difference 0.113 0.095</td>
<td>No difference 0.025 0.111</td>
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<td>No difference 0.485 /</td>
<td>No difference 0.267 /</td>
</tr>
<tr>
<td>Marital status</td>
<td>Married No difference 0.833 /</td>
<td>No difference 0.532 /</td>
<td>No difference 0.180 /</td>
<td>No difference 0.100 0.001 /</td>
<td>No difference 0.267 /</td>
</tr>
<tr>
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<td>Primary school No difference 0.006 0.644</td>
<td>No difference 0.001 0.165</td>
<td>No difference 0.690 /</td>
<td>No difference 0.072 0.422 /</td>
<td>No difference 0.100 /</td>
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<tr>
<td></td>
<td>High school graduate No difference 0.006 0.644</td>
<td>No difference 0.001 0.165</td>
<td>No difference 0.690 /</td>
<td>No difference 0.072 0.422 /</td>
<td>No difference 0.100 /</td>
</tr>
</tbody>
</table>

Bold values highlight statistically significant differences.

<sup>a</sup> Positive (+) values indicate the variables directly associated with poor scores, while negative (−) values indicate the variables inversely associated with poor scores.

<sup>b</sup> P values calculated by the Between Subject test including in multivariate analysis all variables showing a p value ≤0.20 in univariate analysis (Generalized Linear Model).

<sup>c</sup> There was no difference in QoL scores between patients receiving vaginal brachytherapy versus pelvic radiation, although the very small sample series of the latter group (N = 8) could have limited the reliability of results.
age, the unmet needs of premenopausal women affected by endometri- 
al malignancies should not be underestimated, and maximal effort 
should be devoted to take into account the ovarian preservation in se-
lected groups of patients [8].

As far as sexual dysfunction is concerned, we documented an im-
provement of sexual activity over time as also reported in cervical pa-
tients [8]; on the other hand, we showed no significant fluctuation of 
sexual vaginal functioning and enjoyment contrary to what was report-
ed by other authors [30]. This finding could be related to the lower pro-
portion of our patients administered adjuvant treatment, and to the 
relatively low number of cases declaring to still have sexual activity at 
time of study enrollment. Alternatively, it is conceivable that leaving 
behind the troubled period of symptoms, diagnosis and treatment could 
also contribute to the gradual return to a someway normal life, and 
even to the improvement of sexual activity and anxiety. In this context, 
the loss of association of clinico-pathological and treatment related 
variables with QoL scales, as shown in multivariate analysis, underlines the 
individual capability to rescue over time from QoL disruption and con-
firms the relevance of socio-demographic features in affecting women's 
QoL.

Despite some weaknesses of our study, such as a certain degree of 
patient and treatment heterogeneity and lack of a control population 
that have to be taken into account, nonetheless our results seem to provide 
useful information to guide future investigation. Gynecologic oncolo-
gists should have careful balance surgical radicality and avoid unneces-
sary lymphadenectomy and bilateral adnexectomy if possible, in order 
to reduce the burden of treatment sequelae; moreover, since socio-
demographic features play a major role in deteriorating Sx and Sx in 
EC patients, time has also to consider lifestyle modifications, 
psychosocial interventions, and patient education as an integral part of 
treatment [26,27].

Efforts should also be made to keep sensitizing all professional fig-
ures involved in the management of this vulnerable subset of patients to 
the issues of QoL disruption and emotional distress.

Supplementary data to this article can be found online at http://dx.
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Conflict of interest statement
The authors declare that there are no conflicts of interest.

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