

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



Gabriella Ferrandina<sup>a,\*</sup>, Marco Petrillo<sup>a</sup>, Giovanna Mantegna<sup>b</sup>, Gilda Fuoco<sup>a</sup>, Serena Terzano<sup>b</sup>, Laura Venditti<sup>b</sup>, Andrea Marcellusi<sup>c</sup>, Rosa De Vincenzo<sup>a</sup>, Giovanni Scambia<sup>a</sup>

<sup>a</sup> Gynecologic Oncology Unit, Department of Obstetrics and Gynecology, Catholic University, Rome, Italy

<sup>b</sup> Psycho-Oncology Service, Fondazione "Giovanni Paolo II", Campobasso, Italy

<sup>c</sup> CEIS, Sanità (CHEM—Centre for Health Economics and Management), University of Tor Vergata, Rome, Italy

### 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.

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### 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  $\pm$  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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### Introduction

Progressive aging of the female population and the dramatic increase of obesity rates [1] have led in the last decades to a relevant rise of incidence of endometrial cancer (EC) in industrialized countries [2].

Given the relatively early onset of the most frequent symptom (i.e. vaginal bleeding), the vast majority of cases are diagnosed as stage I disease [2]; in these patients, surgery followed by radiotherapy on the basis of pathologically assessed risk factors provides 5-year overall survival rates around 80% [3,4], thus resulting in a high number of long-term survivors and emergence of Quality of Life (QoL) issues.

On the other hand, in patients with high risk stage I or more advanced stage disease, multimodal therapeutic approaches including adjuvant radiotherapy plus sequential or concomitant chemotherapy are employed [5,6], thus fuelling concerns about the negative impact of treatment-related toxic effects on patient QoL. Indeed, the psychological implications of cancer diagnosis by itself, as well as the impact of

\* Corresponding author at: Gynecologic Oncology Unit, Catholic University Rome, L.go A. Gemelli, 8, 00168 Rome, Italy.

E-mail address: [gabriella.ferrandina@libero.it](mailto:gabriella.ferrandina@libero.it) (G. Ferrandina).

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  $\geq 18$  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 IAG3-IBG1,2 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.

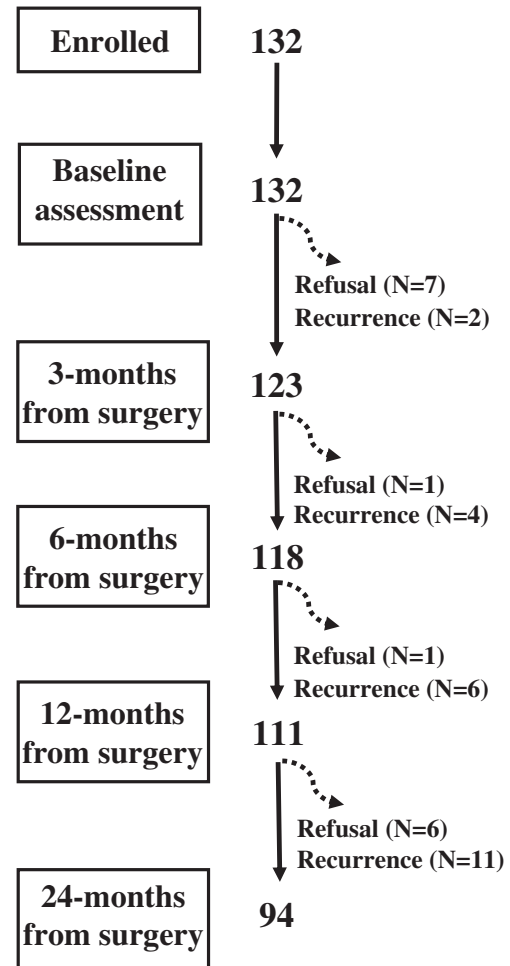


Fig. 1. Time line of questionnaire administration, and flow chart of our patient population.

### 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

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