



## Preoperative quality of life and surgical outcomes in gynecologic oncology patients: A new predictor of operative risk?



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### HIGHLIGHTS

- Patient-reported pre-operative QoL measures are associated with post-operative outcomes in gynecologic oncology patients.
- Measures of lower functional and physical ability are most strongly correlated with risk of post-operative morbidity and hospital readmissions.
- Identifying QoL deficits pre-operatively can improve patient selection and counseling, and targeting of high-risk patients for pre- and post-operative intervention.

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### ABSTRACT

**Objective.** Quality of life (QoL) for women with gynecologic malignancies is predictive of chemotherapy related toxicity and overall survival but has not been studied in relation to surgical outcomes and hospital readmissions. Our goal was to evaluate the association between baseline, pre-operative QoL measures and 30-day post-operative morbidity and health resource utilization by gynecologic oncology patients.

**Methods.** We analyzed prospectively collected survey data from an institution-wide cohort study. Patients were enrolled from 8/2012 to 6/2013 and medical record data was abstracted (demographics, comorbid conditions, and operative outcomes). Responses from several validated health-related QoL instruments were collected. Bivariate tests and multivariable linear and logistic regression models were used to evaluate factors associated with QoL scores.

**Results.** Of 182 women with suspected gynecologic malignancies, 152 (84%) were surveyed pre-operatively and 148 (81%) underwent surgery. Uterine (94; 63.5%), ovarian (26; 17.5%), cervical (15; 10%), vulvar/vaginal (8; 5.4%), and other (5; 3.4%) cancers were represented. There were 37 (25%) cases of postoperative morbidity (PM), 18 (12%) unplanned ER visits, 9(6%) unplanned clinic visits, and 17 (11.5%) hospital readmissions (HR) within 30 days of surgery. On adjusted analysis, lower functional well-being scores resulted in increased odds of PM (OR 1.07, 95%CI 1.01–1.21) and HR (OR 1.11, 95%CI 1.03–1.19). A subjective global assessment score was also strongly associated with HR (OR 1.89, 95%CI 1.14, 3.16).

**Conclusion.** Lower pre-operative QoL scores are significantly associated with post-operative morbidity and hospital readmission in gynecologic cancer patients. This relationship may be a novel indicator of operative risk.

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### Introduction

The primary treatment modality for many gynecologic malignancies is surgery, often followed by adjuvant chemotherapy and/or radiation.

Surgery is often radical, with perioperative complication rates of up to 50% depending on cancer site [1–4]. In addition, gynecologic oncology patients are frequently surgically and medically complex, which compounds surgical risk. This contributes to rates of post-operative morbidity between 20 and 30% and rates of hospital readmission of 10–15% after primary surgical management [5,6].

Both postoperative morbidity and hospital readmission in cancer patients prolong surgical recovery, delay vital adjuvant treatment, increase overall health care costs and can have a negative psychosocial

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impact on the patient and her family [7,8]. The factors that contribute to surgical outcomes are multifactorial. Efforts to identify discrete predictive factors, including frailty measures, have largely focused on medical comorbidity and patient characteristics as assessed and interpreted by health care providers [9–11]. Data on the relationship between patient-reported outcomes – information provided directly from the patient, without interpretation or modification – and surgical outcomes is limited.

Quality of life (QoL) assessments are a form of patient-reported outcomes, and have been validated in assessing disease burden, treatment, and prognosis across a spectrum of cancer sites [12–14]. These scores are derived from QoL surveys, which are designed to measure physical, functional, social and/or emotional well-being domains. Within gynecologic oncology, specifically in women with ovarian cancer, QoL scores are predictive of disease status, chemotherapy toxicity, and overall survival [12,13,15]. The strongest associations have been found within physical and functional domains. In two large Gynecologic Oncology Group (GOG) chemotherapy trials, women in the lowest quartile of physical wellbeing scores had decreased overall survival [12,15]. In colon cancer patients undergoing surgery, preoperative patient-reported measures of poor functional status have been associated with postoperative morbidity and mortality, with lower scores being associated with increased risk [16–18]. Such baseline factors that are found to predict poor surgical outcomes would represent new targets for intervention to improve the quality of surgical recovery, avoid delays in adjuvant therapy, and decrease cancer care costs.

Our primary study objective was to explore the association between preoperative, baseline QoL domain scores and postoperative morbidity and hospital readmission in gynecologic oncology patients. We hypothesized that worse QoL scores would be associated with poor surgical outcomes and this relationship would be strongest within the functional and physical wellbeing domains.

## Methods

### *Study design, enrollment, and data collection*

We conducted an analysis of data prospectively collected for a large hospital-based observational cohort. The Health Registry/Cancer Survivorship Cohort (HR/CSC) is an institutional review board approved University of North Carolina (UNC) Health Care registry of cancer patients that integrates a comprehensive database of clinical, epidemiological, and interview data, with repositories of biologic specimens and tumor tissue. Patients are identified and recruited through UNC Health Care oncology outpatient clinics with the following eligibility criteria: age 18 years or older; North Carolina mailing address; and English or Spanish proficiency. Patients who are unable to provide informed consent or participate in interview questionnaires are excluded. For this analysis, eligibility was further restricted to HR/CSC patients recruited through the gynecologic oncology clinics, who completed the baseline interview prior to any cancer treatments, and had documented 30 day post-operative follow-up.

Interviews were conducted within 2 weeks of enrollment by trained staff using a computer-assisted telephone interview software tool specifically developed for the HR/CSC. Interview questionnaire topics include medical and social histories, and general and cancer-specific health assessments. The following structured and validated questionnaires were included in the analysis: Functional Assessment of Cancer Therapy-General Population (FACT-GP), NIH Patient Reported Outcomes Measurement Information System (PROMIS®) global mental (GMH) and physical health (GPH), a modified Work Ability Index, PG-SGA (Patient Generated-Subjective Global Assessment), and cancer-specific FACTs (Endometrial – En, Ovarian – O, Vaginal/Vulvar – V, Cervical – Cx). The FACT-GP version 4 is a 21-item scale that measures health related QoL using four subscales: physical (PWB), functional (FWB), emotional (EWB), and social (SWB) wellbeing. The cancer-

specific FACT scales include the FACT-GP in addition to multi-item subscales that measure cancer site-specific symptoms [19–22]. The PROMIS® v1.0 global is a 10-item scale that measures the domains of fatigue, physical function, pain, emotional distress, and social health [23]. The modified work ability index includes a subset of questions from the original scale, designed to assess work ability compared to lifetime best, in relation to mental and physical demands, and sick leave [24]. The specific question analyzed for this study was, “Assume that your ability to work at its best has a value of 10 points and 0 means that you cannot currently work at all. How many points would you give your current ability to work?” with a 0–10 scale response. The PG-SGA is a measure of overall functional status on a 5 tier scale, mirroring the Eastern Cooperative Oncology Group (ECOG) performance status ratings [25], but from the patient’s perspective [26].

Patient age, self-reported race/ethnicity, and employment status were abstracted from the HR/CSC baseline interview. The electronic medical record was reviewed (physician, nursing, and case management staff documentation) to abstract clinical data at the time of new patient visit (BMI, co-morbid conditions, mental health history, cancer site) and during the 30 day post-operative follow-up window (surgical approach, intra/post-operative complications, discharge location, unplanned clinic or emergency room visits, readmission, and adjuvant treatment). Insurance status, at the time of new patient visit, was also abstracted from the medical record. All medical record data were limited to encounters at our institution.

The medical record data file was then merged with the HR/CSC demographic and QoL data, using an honest broker model. The HR/CSC subsequently provided a de-identified data set for analysis.

### *Statistical analysis*

Summary statistics were generated using simple frequencies for categorical variables and mean/medians for continuous variables. Composite variables of major medical comorbidity, mental health diagnoses, and post-operative morbidity were created. The major comorbidity variable included notation in the record for at least one of these conditions: diabetes, pulmonary disease (chronic obstructive pulmonary disease, restrictive lung disease, home oxygen requirement), cardiac disease (congestive heart failure, history of MI, coronary artery disease), immunocompromised states (HIV, chronic steroid use), and chronic kidney disease. For the composite mental health variable, we combined any notated diagnosis of anxiety, depression, and chronic pain. Surgical morbidity was divided into intraoperative complications (bladder, ureteral, vascular, nerve, and GI injury) and post-operative complications (thromboembolic events, abscesses, cardiac event, renal insufficiency, pulmonary events, organ injury, wound infection, wound opening, ileus, blood transfusion, urinary tract infection). QoL scores were analyzed continuously and by 5-point increments in relation to two outcomes: post-operative morbidity and hospital readmission (both 30 day post-operative measures). The 5-point increment was chosen due to the minimally important difference in most scale measures of 2–3 points [18–21]. QoL scores were also treated as the outcome and compared between patients who did and did not experience postoperative morbidity and/or hospital readmission (analysis groups). Due to the modification of the work ability index, no summary score could be generated and analyzed, therefore a simple comparison of median responses to the selected question was performed between the analysis groups. Only employed patients had recorded responses for this question. Baseline characteristics between analysis groups were compared using Fisher’s exact tests for categorical variables, and Student’s t-tests for continuous variables. The relationship between the various QoL domains and post-operative outcomes was evaluated using univariable and multivariable linear and logistic regression models.

We included factors in the multivariable analysis if they were identified clinically and known to directly contribute to postoperative outcomes and if they differed substantially between the analysis groups.

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