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The Health-Related Quality of Life Journey of Gynecologic Oncology Surgical Patients: Implications for the incorporation of patient-reported outcomes into surgical quality metrics

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Abstract

Objective—To report the changes in patient-reported quality of life for women undergoing gynecologic oncology surgeries.

Methods—In a prospective cohort study from 10/2013-10/2014, women were enrolled pre-operatively and completed comprehensive interviews at baseline, 1, 3, and 6 months post-operatively. Measures included the disease-specific Functional Assessment of Cancer Therapy-General (FACT-GP), general Patient Reported Outcome Measure Information System (PROMIS) global health and validated measures of anxiety and depression. Bivariate statistics were used to analyze demographic groups and changes in mean scores over time.

Results—Of 231 patients completing baseline interviews, 185 (80%) completed 1-month, 170 (74%) 3-month, and 174 (75%) 6-month interviews. Minimally invasive (n=115, 63%) and laparotomy (n=60, 32%) procedures were performed. Functional wellbeing (20 -> 17.6, p<.0001) decreased at 1-month, and recovered by 3 and 6 months. Emotional wellbeing increased (16.3 -> 20.1, p<.0001) and anxiety decreased (54.2 -> 49.0, p<.0001) at 1-month, and were stable at 3 and 6 months. Physical wellbeing scales were not sensitive to surgery. These patterns were consistent across procedure type, cancer diagnosis, and adjuvant therapy administration. In an exploratory analysis of the interaction of QOL and quality, patients with increased postoperative healthcare resource use were noted to have higher baseline levels of anxiety.

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Conclusions—For women undergoing gynecologic oncology procedures, temporary declines in functional wellbeing are balanced by improvements in emotional wellbeing and decreased anxiety symptoms after surgery. Not all commonly used QOL surveys are sensitive to changes during the perioperative period and may not be suitable for use in surgical quality metrics.

Introduction

Patient-reported outcome (PRO) measures, such as health related quality-of-life (HRQOL), are being increasingly incorporated into cancer care.[1] Symptom monitoring with patient-reported assessments decrease emergency room visits and hospitalizations, and are associated with improved health related quality-of-life in cancer patients.[2] The National Quality Forum has begun to incorporate PROs into quality metrics.[3] As this migration happens, serial PRO assessments, accounting for baseline, pre-treatment scores, will become increasingly important in research and clinical care.[3]

Surgery is a critical component of cancer care. In gynecologic oncology, it is often the first, if not only, part of cancer treatment. Serial assessment of health-related quality of life among gynecologic oncology patients is largely limited to populations participating in clinical trials.[4–6] Often these assessments start after surgery, assigning ‘baseline’ quality of life to recently postoperative patients. In 2006, von Gruenigen *et al* reported on 42 women undergoing gynecologic oncology procedures with pre- and HRQOL post-operative data.[7] The pre and post-operative HRQOL scores came from different groups of patients however, which did not allow for continuous trend analysis from before to after surgery in the same patient.

In an environment focused on measuring quality of care through patient-reported quality of life, there is limited normative data on the quality of life journey of gynecologic oncology patients using validated survey instruments. The quality of life changes over the course of surgical treatment of non-clinical trial patients is unknown. The goal of this study was to document serial assessment of patient-reported health-related quality of life from before surgery to 6 months after surgery, for women undergoing gynecologic oncology procedures in a non-clinical trial setting. In addition, we present an example of anxiety and healthcare resource use to illustrate the potential interaction of patient-reported quality of life and a surgical quality metric.

Methods

Study Design, Enrollment, and Data Collection

We conducted a prospective longitudinal hospital-based cohort study of women enrolled in The Health Registry/Cancer Survivorship Cohort (HR/CSC) at the University of North Carolina. This was an Institutional Review Board approved study (#13-2367), for which all patients provided informed consent. For the HR/CSC, patients are identified and recruited through the UNC Health Care oncology outpatient clinics with the following eligibility criteria: age 18 years or older; North Carolina mailing address; and speak English or Spanish. Patients who are unable to provide informed consent or participate in interview questionnaires are excluded. For this study, eligibility was further restricted to HR/CSC

patients recruited through the gynecologic oncology clinics, with newly diagnosed gynecologic cancer and planned surgical management. Initial exclusion criteria included primary surgery completed or to be completed at an outside institution, previous chemotherapy or radiation therapy, and pregnancy. After the first 10 weeks of enrollment, the exclusion criteria was modified to allow for retention of patients with final benign pathology and those with prior, but not active, chemotherapy or radiation treatment. This was done to allow inclusion of women undergoing surgery for suspicious pelvic masses/ suspected ovarian cancer and patients with new recurrences.

Baseline interviews were conducted within 2 weeks of enrollment, prior to surgery, by trained staff using a computer-assisted telephone interview (CATI) software tool specifically developed for the HR/CSC. Follow-up interviews were conducted at 1, 3, and 6 months after surgery. Patients were included who completed follow-up interviews within a 3 week interval around each targeted time point (1 week prior or up to 2 weeks after the target date [e.g. 1, 3 or 6 months post-surgery]). Participants received gift cards as compensation after completion of each interview. Interview questionnaire topics included medical and social histories, and general and cancer-specific HRQOL assessments.

The following structured and validated questionnaires were included in this analysis: Functional Assessment of Cancer Therapy - General Population (FACT-GP),[8] National Institute of Health Patient Reported Outcomes Measurement Information System (PROMIS©) global mental and physical health,[9] PROMIS Anxiety,[10] and PROMIS Depression.[10] The FACT-GP version 4 is a 21-item scale that measures HRQOL using four subscales: physical, functional, emotional, and social wellbeing. The minimally important difference (MID) for the FACT-G is 5–7 points, and 2–3 points for each subscale. The PROMIS© v1.0 global is a 10-item scale that measures the domains of fatigue, physical function, pain, emotional distress, and social health. The PROMIS anxiety and depression measures[11] are 4-item short form scales for each domain. PROMIS scales are scored using T scores, which are standardized to the U.S. general population and have a mean of 50 and a standard deviation of 10, and MIDs fall between 4 to 7 points. Scores above or below 50 are above or below the population average in the U.S., respectively.

Patient age, self-reported race/ethnicity, marital status, and employment status were abstracted from the HR/CSC baseline interview. The electronic medical record was reviewed to abstract clinical data at the time of new patient visit (BMI, co-morbid conditions, cancer site) and during the 30-day postoperative follow up window (surgical procedure, postoperative complications, and adjuvant treatment plan).

A composite variable of major medical comorbidity was created using the Charlson Comorbidity Index.[12] Insurance status, at the time of new patient visit, was also abstracted from the medical record. The medical record information was then merged with the HR/CSC demographic and interview data.

Health care resource use (HCR) was defined as an unplanned clinic or emergency room (ER) encounter within 30 days after surgery. This definition excluded the standard post-operative visit that is a part of every patient’s care, as well as any additional follow up that

was planned and noted at the time of hospital discharge. In an attempt to isolate those who sought additional care without an identifiable deviation from a normal postoperative course, we excluded patients who were subsequently diagnosed with a complication from one of these unplanned encounters.

Statistical Analysis

Summary statistics were generated using simple frequencies and percentages for categorical variables and mean with standard deviation for continuous variables. Mean scores of the FACT-GP and subscales, PROMIS global health measures, and PROMIS anxiety and depression measures were plotted. We used the paired t-test to compare change in mean scores over time (at 1, 3, and 6 months), as compared to baseline values. Although FACT score means have been commonly used to compare gynecologic oncology populations in observational and clinical trial studies[4,7,13,14], as a sensitivity analysis, we also compared median scores using the Wilcoxon signed-rank test, with similar results. Graphs of mean score over time, stratified by different clinical groups, were constructed. Exploratory analysis of comparator groups of healthcare resource use was performed using student's t-tests accounting for unequal variance.

Results

Study Population

Of the 281 women who consented for the study, 231 completed baseline interviews, 187 completed 1-month interviews, and 185 (80%) had completed medical record abstraction and are described in Table 1. A total of 170 (74%) completed the 3-month and 174 (75%) completed 6-month interviews (Supplemental Figure 1). Interview responders and non-responders were assessed for differences in baseline characteristics. There was a greater proportion of ovarian cancer (39% vs 12%) and debulking procedures (26% vs 10%) in non-responders. These differences were expected as ovarian cancer patients have the highest rate of complications and readmissions among gynecologic cancers, and thus may be the most difficult to follow for serial interview assessments. Responders and non-responders were balanced on all other characteristics (Supplemental Table A.1).

The baseline characteristics of the final analytic cohort are presented in Table 1. For the overall cohort, age at time of consent ranged from 22 to 93 years, with a median of 58 and interquartile range of 46 – 81. Due to small numbers, non-White and non-Black races were collapsed into an "Other" category, which included Asian (n=2, 1%), Native American (n=3, 1.6%), and Other (n=5, 2.7%) respondents. There were 8 Hispanic women, 1 who identified as White, 1 as Black, and 5 as Other. There were 54 women with suspected malignancy who had benign disease on final pathology (49 with benign ovarian disease and 5 with vulvar dysplasia). BMI ranged from 17 to 58, with a median of 31.

Pre and Postoperative Trends in Health-Related Quality of Life

Different domains of health-related quality of life were affected differently by surgery. Overall mean FACT-GP score differed minimally at each time point assessment. There was a 1 point change between baseline and 1-month mean scores. Final 6-month mean FACT-GP

scores were 3 points above baseline (Table 2). This lack of variation masks the actual changes that occurred within the FACT-GP subscales of functional and emotional wellbeing. Mean functional wellbeing scores decreased from 20.1 to 17.6 ($p<.001$) and mean emotional wellbeing scores increased from 16.3 to 20.3 ($p<.0001$) from baseline to 1 month post-operatively. After 1 month, the functional and emotional well-being subscales remained nearly unchanged at the 3 and 6 month time points. For the social and physical wellbeing subscales, there were no significant differences at 1, 3, or 6 months (Figure 1).

The non-cancer specific, global quality of life scores of the PROMIS physical and mental health domains demonstrated minimal change over the 1, 3, and 6 month assessment points (Table 2, Supplemental Figure 2). The physical health scores were all slightly below population mean (50), which did not represent a clinical difference.

With regard to anxiety, overall, the cohort had a notably high baseline mean score on PROMIS Anxiety (54.1), which represented a clinically meaningful difference one-half standard deviation above population norms. This mean anxiety score decreased significantly 1-month after surgery, from 54.1 preoperatively to 49.0 postoperatively ($p<.001$) (Table 2). Anxiety scores then remained near normal levels at 3 and 6 months. With regard to depression, although the PROMIS Depression scores were stable over 1, 3, and 6 month assessment points, they were nearly half a standard deviation higher than population norms. There were 41 women with PROMIS Depression scores over 60, representing a full standard deviation above population mean. Of note, only 1 of these women was noted to have a diagnosis of depression recorded in the medical record (Figure 2).

The cohort included different procedure types, women with final benign pathology, and those who did and did not require adjuvant therapy in the form of radiation or chemotherapy. We stratified the cohort by these groups to assess if the HRQOL trends differed by these factors. Although the baseline scores and the magnitude of change varied between groups, the overall trend of temporary functional wellbeing decline, alongside improvement of emotional wellbeing and decreased anxiety was consistent across all groups (Figure 3).

Exploratory Analysis: Anxiety and Healthcare Resource Use

This goal of this analysis was to explore a potential relationship between excess use of the healthcare system and a baseline patient-reported symptom, like anxiety. As stated in the methods, the healthcare resource use (HCR) variable was limited to patients with additional clinical encounters through the clinic or emergency room, which were unplanned, and did not result in any diagnosis of a complication. Patients were divided into HCR+ (n=14, 8%) and HCR- (n=171, 92%) users and mean anxiety scores compared over time. The HCR(+) group had higher baseline, pre-operative PROMIS Anxiety scores compared to HCR non-users (58.3 vs 53.8, $p=0.06$), which quickly resumed to general population norms by 1 month after surgery (Figure 4).

Discussion

The normal health-related quality of life journey for women undergoing gynecologic oncology procedures is nuanced. At the traditional time of post-operative assessment, 30

days or 1 month after surgery, decreases in functional wellbeing scores are balanced by increases in emotional wellbeing and decreases in anxiety. By 3 months, functional wellbeing returns to baseline levels, and emotional/anxiety improvements are maintained. The National Quality Forum has endorsed surgical PRO measures such as patient satisfaction and patient-reported trends in functional status after surgery for other surgical populations.[15] The trends that we report from this study are important to the task of incorporating patient-reported outcome measures in the gynecologic oncology population, as the choice of scale or subscale, and the timing of assessment, will influence interpretation.

We found that disease-specific (FACT-GP) and general population (PROMIS global health) instruments perform differently in the perioperative period. The FACT scales are among the most commonly used disease-specific health related quality of life instruments in gynecologic oncology.[3–5,13,16,17] The physical wellbeing scale of the FACT-GP did not register any change at the 1-month postoperative time point. This is due, in part, to the timing of our assessment. Abitbol *et al* reported on the FACT-G scores of 121 gynecologic oncology patients who underwent robotic procedures.[13] This study included assessments at 1 week and 3 weeks after surgery, and did find decrements in the physical wellbeing scale (−5.0 points) at the 1 week mark, that normalized by 3 weeks. This study was limited by high attrition rate, with 37% non-response at 1 week and 52% non-response by 3 weeks. In contrast to our work, the study by Abitbol *et al* did demonstrate some change in the physical wellbeing scale at 1 week. One week after surgery is far sooner than the average 4–6 week recovery time expected for most major gynecologic oncology procedures. Although valuable information can be gained from immediate post-operative PRO data, we propose that national level quality measures would most meaningfully be assessed at a time point when the majority of patients are expected to have recovered. This allows for identification of true outliers. For example, substantial differences in patient-reported quality of life at 1 month after surgery between surgeons, procedure types, or hospital systems, would be more likely to highlight systematic underlying quality differences that warrant process reviews and potential penalties. In that context, the physical wellbeing subscale, a seemingly appropriate ‘physical’ indicator of quality of life, may not best provide information as to different patient experiences based on surgical quality. In contrast, more immediate (e.g. 1 week) PRO measures may be more appropriate on a small scale, like an in-hospital quality improvement initiative, to fine tune perioperative processes.

In contrast, the functional wellbeing subscale was reactive to surgery, with a clinically meaningful decrease at 1 month post-operatively with resumption to baseline by 3 months. This could be used as a patient-centered benchmark of routine surgical recovery: the resumption of baseline patient-reported functional status by 30 to 60 days post-operatively, for example.

Another aspect to consider when choosing a PRO instrument, is that just having a score change does not make a PRO suitable as a quality measure. Our findings of increased emotional wellbeing and decreased anxiety are examples. These “improvements” likely reflect the abnormally heightened fear and anxiety preoperative patients can feel when facing the unknown experience of major surgery and unclear diagnosis. The improvement in emotional quality of life and anxiety likely reflect resolution of the feared unknown. This is

supported by the fact that the baseline values for these two domains were worse (higher anxiety, lower emotional wellbeing) than the general population and the changes seen represent a recovery back to normal. Using either of these measures as a surrogate patient-reported assessment of quality, may falsely assign value to a normal change based only on having had a procedure.

Another lens into the use of patient-reported outcomes for surgical quality measures is in risk-adjustment. Our exploratory analysis of anxiety and health care resource is use is very limited and not meant to be conclusive. It is however an interesting example of how patient factors that currently go unmeasured, like preoperative anxiety, may very well have effects on quality measures, like unplanned emergency room encounters without a diagnosis of complication. Anxiety is known to affect medical decision making[18] in other areas of cancer care. It is reasonable to consider that heightened anxiety may lead to the need for clinical reassurance in a patient having a routine recovery. Just as we risk-adjust our complication rates, to account for obesity, diabetes, and other major contributors to increased complication, baseline patient-reported outcomes can expand our ability to adjust for previously ‘intangible’ patient factors that lead to increased resource use.

Finally, although the point has been well made in other publications,[19–21] we want to emphasize the discrepancy between patient-reported anxiety and depression levels, and the limited notation of such in the medical record. Patient reported outcomes have the power, right now, to better inform us of the physical and mental wellbeing of our patients. They can be currently embraced as a way to improve all aspects of care for each and every patient in gynecologic oncology.

Our study has important limitations to note. It is a single-institution study and therefore the results may not be generalizable on a broader scale. Unlike clinical trials, the proportion of Black women (17%) in our study was actually representative of the larger state population (22%),[22] however, we had under-representation of Hispanic women (3.4%) compared to the state (8%).[22] This may in part be due to the relatively young median age of Hispanics in the state (33 years)[23] compared to the median age of gynecologic oncology patients (49 – 68 years).[24] We also had an over-representation of patients with private insurance (84%) compared to the state population of women > 18 years (68%).[22] Our first postoperative assessment was at 1-month and each interview asked the patient to recall experiences over the past 7 days. This schedule may have missed early 1–3 week experiences in surgical recovery, although as noted above, this 1 month time point may be more appropriate when considering surgical quality metrics. In addition, we included multiple different procedure types that may inherently affect quality of life differently. We did, however, use the same scales used in surgical randomized trials, where these scores were not found to differ by procedure type such as laparoscopy versus laparotomy or sphincter-sparing surgery versus abdominoperineal repair.[4,25] Within the cancer patients, trends in HRQOL may have varied by confirmed versus suspected cancer diagnoses prior to surgery. For those patients without a definitive pre-operative cancer diagnosis, we did not have preoperative information regarding perceived risk of cancer by the patient and/or provider to address this question.

Our study has many unique strengths. We had a high response rate (>80%) at each assessment interval through the 6-month interviews, adding robustness to the follow up data. The interviews were performed by independent, trained administrators in person or over the phone, limiting bias with literacy skills. Additionally, assessments included multiple aspects of health-related quality of life including depression and anxiety. This analysis highlights the need for more longitudinal studies of different, and potentially newly developed, HRQOL instruments to ensure we have the most informed and valuable patient-reported outcome measures for gynecologic oncology patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Temporary declines in functional wellbeing are balanced by improvements in emotional wellbeing and anxiety at 1 month post-operatively.
- Current commonly used health-related quality of life instruments may not best reflect the perioperative surgical experience.
- Increased patient-reported baseline anxiety may be associated with increased post-operative healthcare resource use.

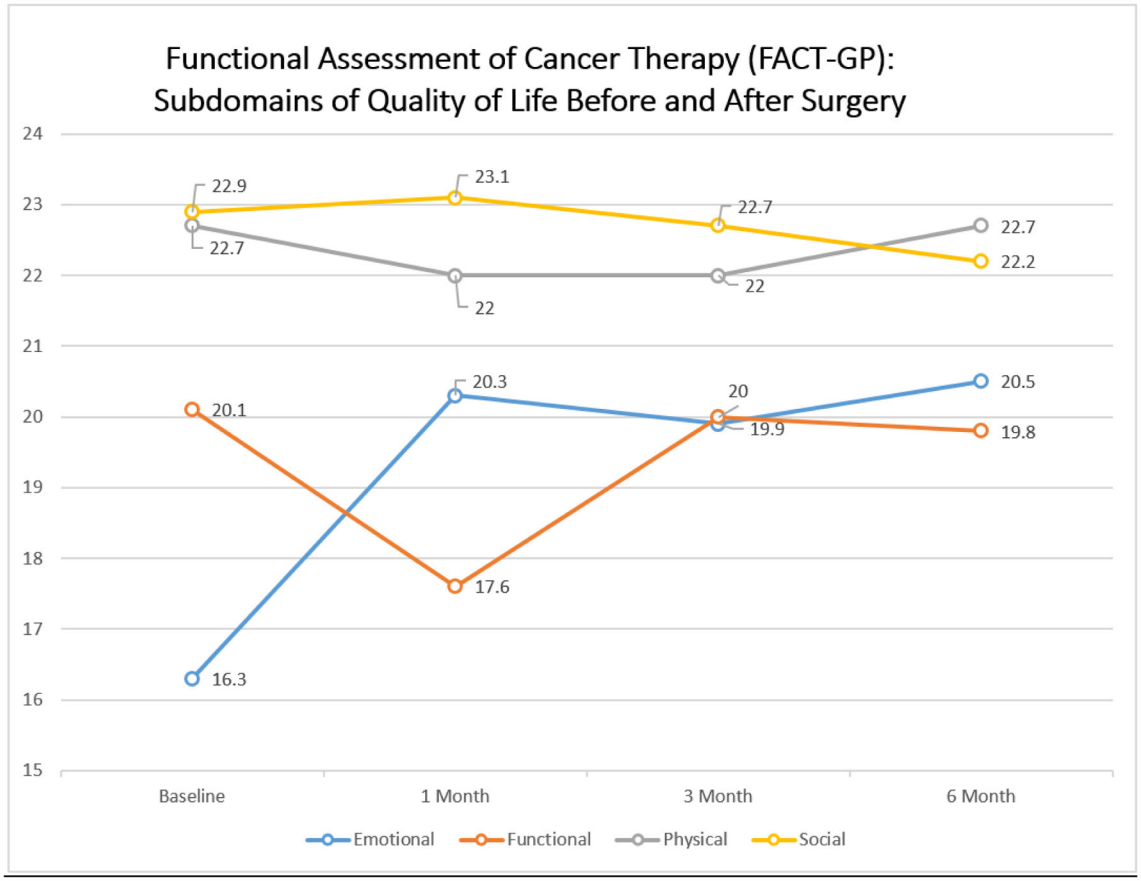

Figure 1.

The subdomains of the Functional Assessment of Cancer Therapy-General for all women undergoing gynecologic oncology procedures. Physical and Social domains were minimally responsive to surgery. Functional wellbeing declined at 1 month and recovered. Emotional wellbeing began at low levels and increased to normal levels after surgery. The changes in functional and emotional wellbeing represent changes larger than the minimally important differences (MID) for each scale.

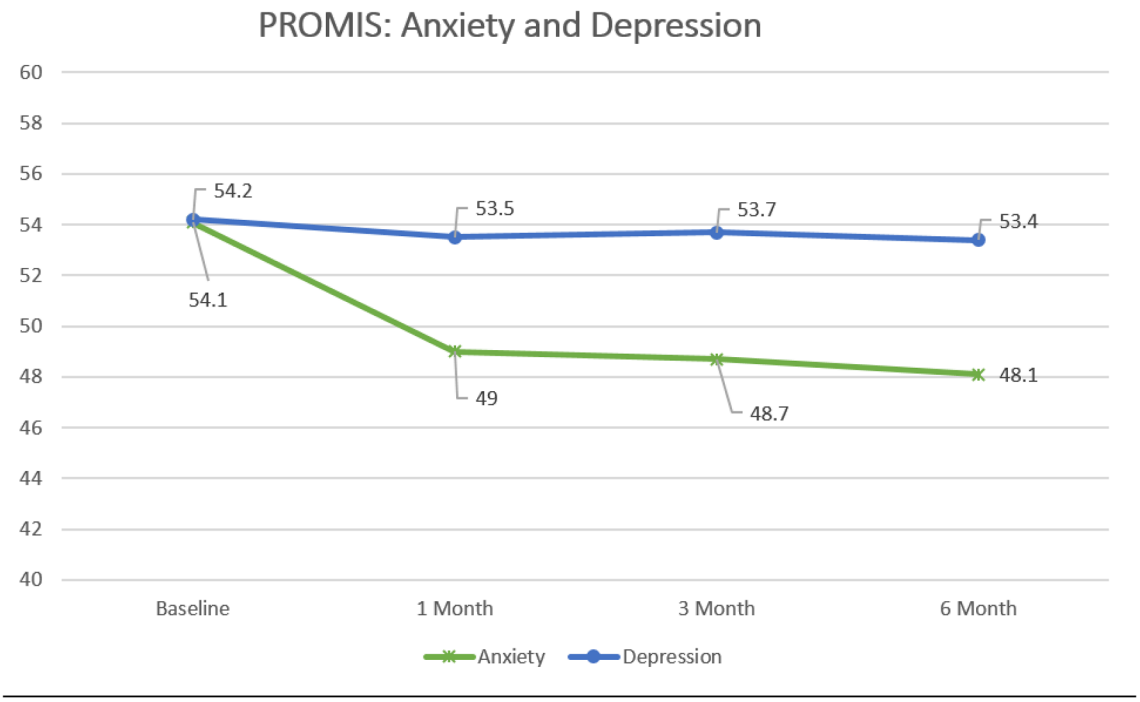

Figure 2.

Mean scores on PROMIS Anxiety 4-s and PROMIS Depression 4-s surveys, from baseline to 6 months post-operatively for women undergoing gynecologic oncology procedures. A score of 50 represents mean normal value of the general population.

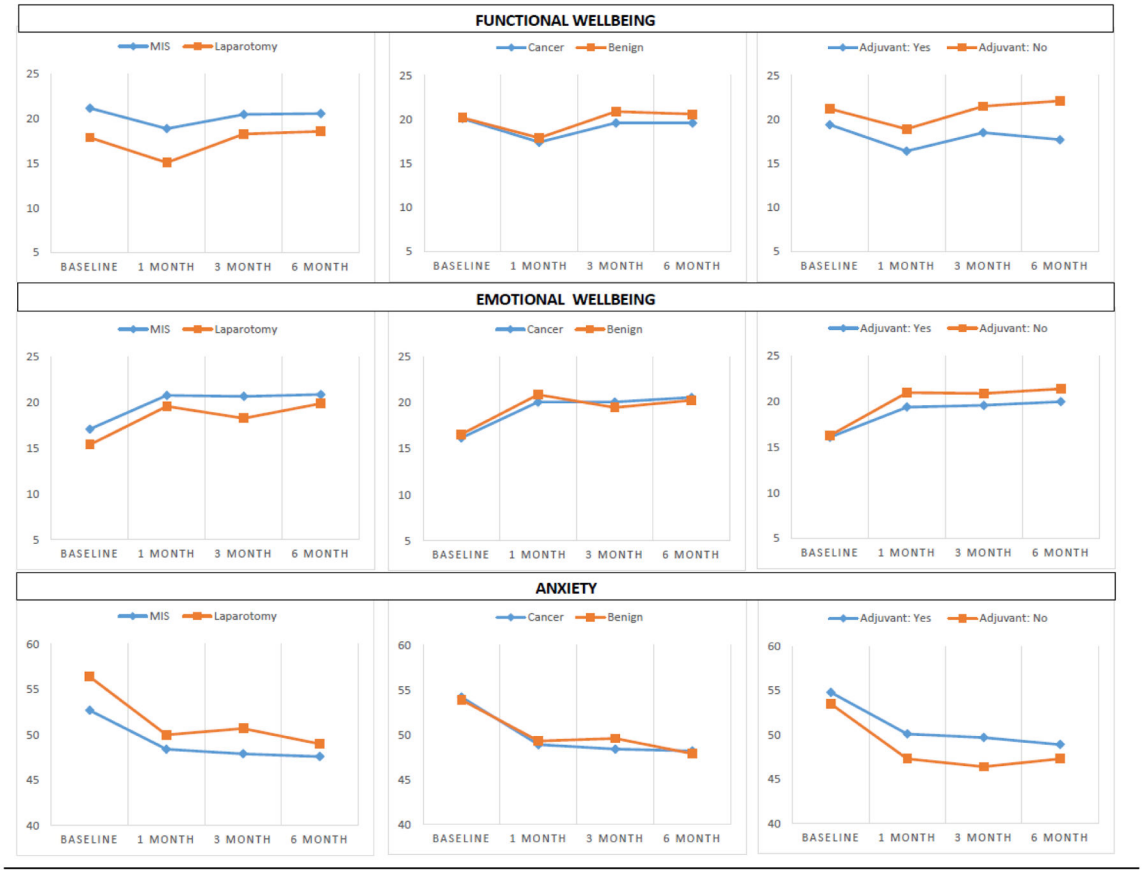

Figure 3.

The main trends of functional wellbeing, emotional wellbeing, and anxiety were stratified by major clinical characteristics: procedure type (MIS [n=115] vs. Laparotomy [n=60]), final pathology (Cancer [n=131] vs. Benign [n=54]), and the need for adjuvant therapy within the cancer group (Yes [n=77] vs. No [n=54]). Although baseline values and magnitude of changes differed, the trend directions were the same.

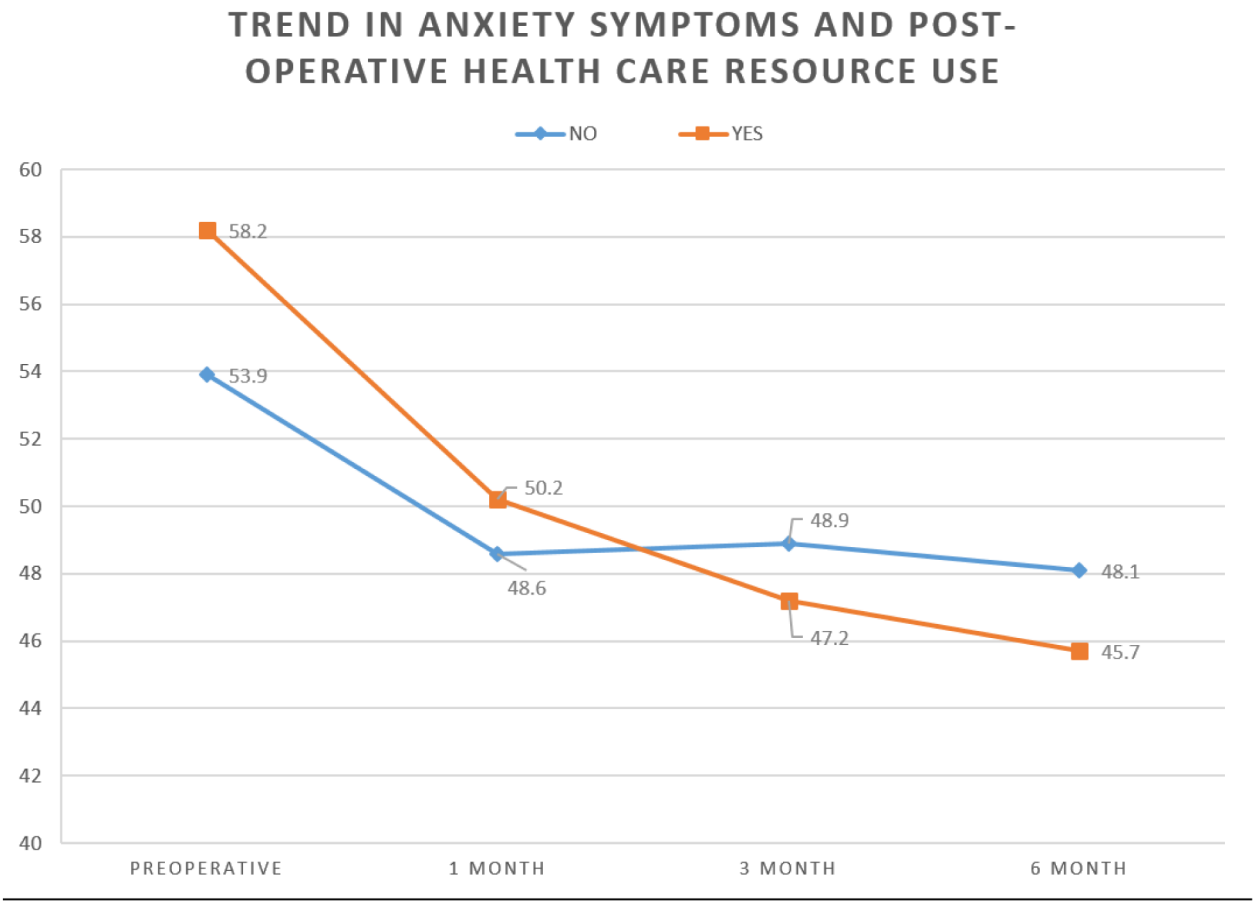

Figure 4.

There were 15 HCR (+) users, 10 clinic visits and 5 ER visits. The HCR(+) group had higher baseline, pre-operative PROMIS Anxiety scores compared to HCR non-users (58.2 vs 53.8, p=0.06).

Table 1

Cohort Characteristics of Women Undergoing Gynecologic Oncology Surgery[a]

Characteristics		Overall N = 185
Age, mean (SD)		56.5 (13)
Race	White	143 (77)
	Black	32 (17)
	Other	10 (5)
Cancer Site	Uterine	84 (45)
	Ovary	23 (12)
	Cervix	17 (9)
	Vulva/Vaginal	3 (1.6)
	Other[b]	4 (2)
	Benign	54 (29)
Insurance	None	14 (8)
	Medicare Only	8 (4)
	Medicaid	7 (4)
	Any Private	156 (84)
Marital Status	Partnered	114 (62)
	Single	51 (28)
	Widowed	20 (11)
Employment	No	98 (53)
	Yes	87 (47)
Charlson Comorbidity Index		
	0	117 (63)
	1	48 (26)
	2+	20 (11)
BMI, mean(SD)		32.9 (SD 9)

Characteristics		Overall N = 185
Procedure Type[c]	MIS[d]	116 (63)
	Laparotomy	60 (32)
	Debulking	20 (10)
	Radical Hysterectomy	13 (7)
	Bowel surgery	12 (7)
	Groin Surgery	8 (4)
Adjuvant Therapy[d]	Yes	77 (42)
	No	55 (30)
	NA[e]	54 (29)

[a]All data presented as No. (%) unless otherwise noted.

[b]Other includes: 1 patient with gynecologic malignancy, unknown primary and 3 patients with final pathology of gastro-intestinal origin.

[c]These are non-exclusive categories of procedures performed and therefore do not add up to 100%. MIS: Minimally invasive surgery, including traditional and robotic-assisted laparoscopy.

[d]Including chemotherapy, radiation, or hormonal therapy.

NA: not applicable, refers to benign disease patients.

Table 2

Health-Related Quality of Life Over Time: from Preoperative Baseline to 6-Months After Surgery for Entire Cohort[a]

Survey Instrument	Baseline N=185	1-Month N=185	3-Month n=170	6-Month n=174
FACT-GP	82 (19)	83 (18)	85 (19)	85 (18)
Physical	23 (5)	22 (5)	22 (6)	23 (5)
Functional	20 (7)	18 (7)[b]	20 (7)	20 (7)
Emotional	16 (6)	20 (5)[b]	20 (5)[b]	21 (5)[b]
Social	23 (6)	23 (5)	22 (6)	22 (6)
PROMIS Global Health				
Physical	47 (8)	46 (7)	47 (10)	48 (10)
Mental	50 (8)	51 (8)	51 (9)	51 (10)
PROMIS Anxiety	54 (9)	49 (9)[b]	49 (9)[b]	48 (8)[b]
PROMIS Depression	54 (7)	53 (6)	54 (6)	54 (7)

[a] All scores represented as mean(SD).

[b] Indicates $p < .05$ for paired t-test comparing baseline mean score to follow up score.