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Perioperative trajectory of patient reported symptoms: A pilot study in gynecologic oncology patients

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HIGHLIGHTS

- It is feasible to collect patient-reported symptoms in the postoperative setting.
- We demonstrate an example of the clinical sensitivity of the MDASI tool.
- Prolonged hospital stay correlates with increased symptom burden postoperatively.

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ABSTRACT

Objective. With the growing focus on patient-centered care, patient reported outcomes (PROs) are becoming an important component to clinical trials and quality metrics. The objective of this study was to pilot the collection of patient reported symptom burden in women undergoing surgery in a gynecologic oncology practice.

Methods. Perioperative patient reported symptom burden was measured for women undergoing laparotomy on the gynecologic oncology service at the University of Texas MD Anderson Cancer Center. Symptoms were assessed using the M.D. Anderson Symptom Inventory (MDASI-OC), a 27 item tool validated for use in patients with ovarian cancer. The MDASI-OC was administered as a preoperative baseline, daily while admitted to the hospital after surgery, twice a week on the first week after discharge and then weekly until 8 weeks postoperatively.

Results. 29 patients were evaluable. Seventy-five percent of patients had a diagnosis of ovarian cancer. Of those patients, half underwent a primary debulking surgery and the other half had neoadjuvant chemotherapy prior to interval cytoreductive surgery. In the postoperative inpatient setting, the five symptoms with the highest overall burden were fatigue, pain, abdominal pain, dry mouth and drowsiness. Longitudinal change of the top 5 symptoms during hospitalization did not show any significant difference between those who had neoadjuvant chemotherapy and those who did not.

Conclusion. The collection of longitudinal PROs to assess symptom burden is feasible in patients undergoing gynecologic oncology surgery. Patient reported outcomes are a crucial component of patient-centered research and the longitudinal collection and analysis of symptom burden can allow for more meaningful comparisons of surgical technique and perioperative care.

Introduction

Traditional metrics to assess surgical quality include hospital length of stay, readmission rates, and surgical site infection among other measures of event-related or clinician judgment of morbidity. However, patient-reported outcomes (PROs) which currently represent the gold standard in the related research areas of assessment of symptom burden, health-related quality of life, treatment preferences, and patient satisfaction, have also become an area of increasing focus in comparative effectiveness research, health care quality assessments, as well as endpoints in clinical trials [1,2]. Additionally, there is a burgeoning interest in incorporating PROs into routine surgical clinical care and as a tool to measure providers' performance [3]. The Center for Medical Technology Policy (CMTP) recommends that prospective clinical comparative effectiveness research (CER) captures the subjective patient experience [4].

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Historically, the majority of trials that incorporated PROs were solid tumor treatment trials. The use of PROs in surgical trials has lagged behind. There have been relatively few trials in gynecologic oncology with patient reported outcomes as a primary outcome measure [5]. Two notable trials utilizing PROs as a secondary outcome in gynecologic oncology include the EORTC trial comparison of quality of life in advanced ovarian cancer patients who were randomized to neoadjuvant chemotherapy or primary debulking surgery [6] and the Gynecologic Oncology Group LAP2 trial in which the quality of life was compared between women with endometrial cancer undergoing open or laparoscopic surgery [7]. Despite the inclusion of quality of life in these landmark trials, there continues to be a lack of consensus on the optimal methodology to collect PROs in a surgical population and which outcome measures are most relevant to the patient [3]. Additionally, a more thorough understanding of the clinical sensitivity of specific PRO tools can help establish the role of patient reported outcomes in routine clinical care.

While patient satisfaction with perioperative care and quality of life (QOL) assessments have been previously reported, patient reported symptom burden has not previously been systematically evaluated perioperatively in women undergoing surgery for gynecologic oncology indications. A high proportion of patients undergoing laparotomy for gynecologic oncology indications will also receive chemotherapy, either in a neoadjuvant or adjuvant setting. Moreover, many patients, especially those with ovarian cancer, carry a significant disease-specific preoperative symptom burden. For these reasons, we elected to use an instrument that was tailored to the symptom burden in this oncology population. The M.D. Anderson Symptom Inventory (MDASI) is a validated tool comprised of a core of 13 questions that aims to capture common symptoms experienced by the patient from the patient's own point of view over the previous 24 h [8,9]. The MDASI is a recognized, widely validated and recommended tool for measuring patient reported outcomes (PROs) and symptom burden in cancer patients [4]. The sensitivity of the MDASI has previously been established on the basis of previous data comparing symptoms in patients with different stages of disease, before, during and after aggressive cancer treatment as well as unaffected populations [8,10,11]. Although the disease specific module of MDASI in ovarian cancer (MDASI-OC) [10,12] was developed and validated, there is still a lack of clinical data of how a patient's perspective of their symptom burden corresponds with clinical outcomes in an accurate and timely fashion. The objective of our study was to pilot the collection of patient-reported symptoms in the perioperative setting and to quantify symptom burden of women undergoing open surgical procedures for a known or presumed gynecologic malignancy.

Methods

Subjects

Women age 18 and older undergoing exploratory laparotomy at the University of Texas MD Anderson Cancer Center with known or suspected gynecologic cancer were enrolled prospectively. All patients signed consent to participate in this institutional review board approved study. Exclusion criteria included non-English speaking patients, and patients who did not undergo an open abdominal surgical procedure.

Assessment measures

Symptoms were assessed using the M.D. Anderson Symptom Inventory (MDASI-OC), a 27 item tool previously validated for use in patients with ovarian cancer (MDASI-OC) [10] Two additional questions to address diarrhea and gastrointestinal reflux were added based on clinician impression of their prevalence in the post-operative period. Each symptom was rated on an 11-point scale, with 0 being “not present” and 10 being “as bad as you can imagine” with the rating to reflect the symptom at its most severe in the preceding 24 h. Patients also rated the degree to which their symptoms interfered in the previous 24 h with six common functional domains, including walking, work (including work around the house), general activity, mood, enjoyment of life, and relations with others. Relevant demographic and clinical information was abstracted from the medical record.

The MDASI-OC was administered at the following time points: preoperatively, daily while in the hospital, twice a week on the first week after discharge and then weekly until 8 weeks postoperatively. For the subset of patients undergoing chemotherapy, the MDASI-OC was administered every 2 weeks while receiving chemotherapy after the completion of the 8 week perioperative period.

The preoperative and inpatient MDASI-OC was administered via a paper form. After hospital discharge, the MDASI-OC was administered using a telephone based, interactive voice response (IVR) system. Study staff attempted to contact the patients by phone to administer the MDASI-OC when the IVR system failed to record a scheduled time point. Clinical and demographic information was abstracted from the medical record.

Statistical analysis

The top 5 symptoms were defined as the most severe symptoms during hospitalization after surgery. A composite top 5 symptom score was obtained by averaging severity levels of those 5 symptoms. Major clinical and demographic factors were demonstrated as percent (for categorical variables) and mean (for continuous variables). For patients with ovarian cancer, we compared baseline levels of the top 5 symptoms between those who underwent a primary debulking surgery and those who underwent an interval cytoreduction after neoadjuvant chemotherapy (NACT) using the Wilcoxon rank test. Linear mixed models were used to examine whether symptoms developed differently between those who did not and who did receive NACT during hospitalization. SAS version 9.2 statistical software (SAS Institute, Cary, NC) was used to perform all analyses. All statistical tests were 2-sided, and P values $< .05$ were considered statistically significant.

Results

29 women were enrolled and included in this analysis. Demographic and clinical variables are illustrated in Table 1. The median age was 57 years (range 38–77 years). The median surgical time was 221 min (range 98–523) and median length of stay was 4 days (range 2–27). Seventy-five percent of patients had ovarian cancer. Of the ovarian cancer patients, eleven patients (50%) were undergoing an interval cytoreductive surgery after neoadjuvant chemotherapy.

There was 100% compliance with preoperative evaluation and 68% compliance with completion of the MDASI-GYN during hospitalization (108/159 instruments returned). Reasons for not completing the MDASI-OC during hospitalization included patient factors such as intubation and altered mental status as well as system issues such as failure to administer on the weekend. During the first week post discharge, only 50% compliance was achieved using the IVR system.

The five symptoms with the highest overall burden post-operatively in the hospital were pain (mean score 5.75, SD 3.68), abdominal pain (mean score 5.58, SD 3.63), fatigue (mean score 5.52, SD 3.10), dry mouth (mean score 5.50, SD 3.85), and drowsiness (mean score 5.05, SD 3.18). The mean composite score from 119 observations was 5.48 with a standard deviation of 2.74. The daily trend of the top five symptoms demonstrates a double peak, with the highest symptom burden on post-operative day 1 and for those who remained hospitalized, on post-operative day 6 (Fig. 1). Fig. 2 compares the symptom burden in patients who were discharged before and after the mean hospital stay of five days. The individual symptoms (fatigue, pain, abdominal pain, drowsiness and dry mouth) as well as the composite mean of the top 5 rated symptoms are compared. The secondary rise in symptoms in patients with prolonged hospital stay is most notable for the symptoms of fatigue, pain, abdominal pain, and dry mouth.