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Electronic patient-reported outcomes from home in patients recovering from major gynecologic cancer surgery: A prospective study measuring symptoms and health-related quality of life☆,☆☆

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HIGHLIGHTS

- A Web-based model for assessing patient reported outcomes is feasible in the immediate post-operative period.
- Many patients feel empowered by documenting and reporting PROs during the post-operative recovery period.
- A Web-based system for capturing PROs may require additional resources for clinically useful application.

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ABSTRACT

Purpose. We previously reported on the feasibility of a Web-based system to capture patient-reported outcomes (PROs) in the immediate postoperative period. The purpose of this study was to update the experience of these patients and assess patient and provider satisfaction and feedback regarding the system.

Methods. This is a prospective cohort study of patients scheduled to undergo laparotomy for presumed gynecologic malignancy. Patients completed a Web-based Symptom Tracking and Reporting (STAR) questionnaire preoperatively and weekly during a 6-week postoperative period. Email alerts were sent to study nurses when concerning patient responses were entered. The patient and the nurse assessments of STAR's usefulness were measured via an exit survey.

Results. The study enrolled 96 eligible patients. Of these, 71 patients (74%) completed at least four of seven total sessions. Of the patients who completed the exit satisfaction survey, 98% found STAR easy to use; 84% found it useful; and 82% would recommend it to other patients. Despite positive feedback from patients, clinical personnel found that the STAR system increased their current workload without enhancing patient care.

Conclusions. Application of an electronic program for PROs in those recovering from major gynecologic cancer surgery is feasible, and acceptable to most patients. While most clinicians did not find STAR clinically helpful, the majority of patients reported a positive experience with the system and would recommend its use. The program helped many patients feel more empowered in their postoperative recovery.

1. Introduction

The NIH, NCI, FDA and numerous other stakeholders have asserted that the impact of medical interventions and surgery are best evaluated by patients directly, without filtering by clinicians, in the form of patient-reported outcome (PRO) measures [1]. As a result, there has been increasing emphasis on the incorporation of PROs into clinical

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trials and routine clinical practice [2,3]. This is also relevant because the Affordable Care Act (ACA) allows for a financial reward, in the form of small bonuses, for providers who provide quality care. The ACA also allows for financial penalties for providers who fail to provide quality care. Assessment of reward or penalty is based on outcome or performance as measured by a quality indicator [4]. Because stakeholders in cancer care agree that the current quality metrics are insufficient, some have proposed new models. Many of these, such as the National Quality Forum (NQF) model, include PRO measures [5].

Most PRO surveys in cancer patients have been administered at baseline and 3 months post-treatment [2,6]. There is limited data regarding PROs in gynecologic cancer patients in the immediate 6 weeks following surgery. Collecting PROs during this time period can enrich preoperative teaching, help identify complications earlier, and improve symptom control [2]. Currently, however, there is not enough data available to determine if patients are able or willing to self-report symptoms during this critical period, or if providers find this information constructive.

Our previously published pilot study suggested that the use of a Web-based system to capture PROs is feasible and highly acceptable by patients in the acute postoperative period after major gynecologic surgery [7]. The objectives of this study were to update the experience of these patients, and to assess patient and provider satisfaction and feedback regarding the system.

2. Methods

This study was approved by the Institutional Review Board (IRB) at Memorial Sloan Kettering Cancer Center. The patients, study design, and online platform were previously described in a pilot report on the feasibility and acceptability of this Web-based system [7]. English-speaking patients 18 years of age and older, who were scheduled to undergo laparotomy for presumed or known gynecologic malignancy, were recruited to participate. All patients were required to have access to a home computer and a personal email account.

At the time of enrollment, patients were trained in the use of the Symptom Tracking and Reporting (STAR) system. They were asked to complete a baseline information questionnaire and seven STAR surveys. This paper questionnaire was administered by the consenting professional immediately after consent was obtained. It measures variables that we expected to be predictors of STAR utilization, including age, education level, employment status, and prior internet experience. Demographic data was gathered from the electronic medical records. The surveys consisted of the patient adaptation of the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 3.0 and the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 version 3.0 [8,9]. Both of these are validated instruments that have undergone extensive psychometric testing, and meet established standards for validity and reliability as detailed in the FDA Draft guidance for PROs [1,10]. Patients completed the surveys preoperatively, and weekly during a 6-week postoperative period. Reminders to complete the reports were sent to participants via email.

Email alerts were also sent to the study nurses when concerning patient responses were entered. Alerts were considered concerning according to pre-specified limits set by the Gynecologic Oncology Service. This is the same system presently used to triage patient phone calls. Any actions taken by the nurses in response to these alerts were recorded. However, specific responses were not required. Patients were encouraged to call their physician's office if medical attention was needed, as there was no regularly scheduled monitoring of information entered into the STAR system.

Patient and nurse assessments of STAR's usefulness were measured via an exit survey. A "responder" was defined as a patient who logged in and completed at least half of the questionnaire, and participated in at least four of the seven potential login times.

3. Results

3.1. Demographics

The study accrued 120 consecutive patients between July 2009 and January 2015. All participants were scheduled to undergo laparotomy for suspected or confirmed gynecologic malignancy. Twenty-four patients were eventually removed from the study, leaving 96 eligible, evaluable patients (Fig. 1). The median age was 55.5 (range 18–74). Table 1 reports the demographic and clinical characteristics of the included patients.

3.2. Intervention

Seventy-one patients (74%) completed at least four of seven surveys, and were therefore considered responders. Sixty-nine (63%) patients completed the preoperative session in STAR. The remaining patients did not complete the preoperative session, but did complete subsequent surveys. Nine (9%) patients completed only one survey. Similar to the pilot study, patient compliance gradually decreased as the postoperative period elapsed (Fig. 2). There was no statistically significant difference in the demographic or clinical characteristics of responders versus non-responders.

3.3. Alerts

One hundred and twelve patient-reported symptoms generated an alert, resulting in 28 contacts and two Emergency Department referrals. Overall, the CTC generated 81 individual episode alerts and the EORTC generated 31 episode alerts of 84 different symptoms. The most common CTC symptoms were poor performance status, nausea, and fatigue. The most common EORTC symptoms were difficulty with strenuous activity, constipation, and pain. Tables 2 and 3 show the distribution of all symptoms. Most alerts were read by a nurse within one day (mean 1, median 0 days). Ten alerts (12%) had already been addressed by a recent patient phone call or clinic visit. Three (4%) patients had already been scheduled for a clinic visit, during which the issue could be addressed. One (1%) patient was admitted while completing her survey, and her symptoms were addressed by the inpatient care team.

3.4. Patient satisfaction

Fifty-one patients (46%) completed the exit satisfaction survey. Table 4 shows the patient satisfaction survey (excluding 7 patients who did not use the STAR system to record their symptoms). Ninety-eight percent found STAR easy to use, 84% found it useful, and 82% would recommend it to other patients. One patient reported,

> "*During acute phase of rehab, looked forward to reporting symptoms (in control of something that is otherwise not controllable) Questions prompted the patient to consider contacting office regarding symptoms.*

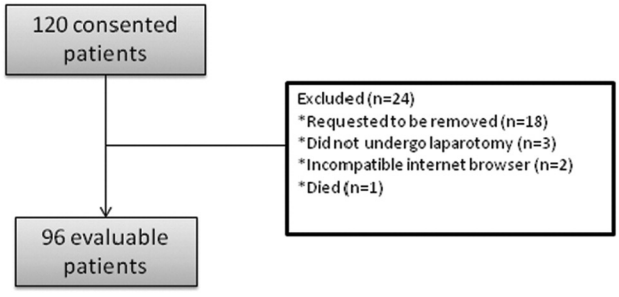

Fig. 1. Consort diagram. Diagram demonstrates study accrual between July 2009 and January 2015, exclusion, and participation. All participants were scheduled to undergo laparotomy for suspected or confirmed gynecologic malignancy.

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