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Prospective assessment of patient-reported outcomes in gynecologic cancer patients before and after pelvic exenteration

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HIGHLIGHTS

- One year post exenteration, most women would have an exenteration again.
- Post-exenteration, most women were satisfied with their decision for exenteration.
- Physical function worsened from baseline to 1 year post surgery.
- Sexual pleasure and body image declined from baseline to 1 year post surgery.

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ABSTRACT

Objective. Pelvic exenteration (PE) is a surgical procedure associated with significant morbidity offered to select women with locally advanced or recurrent gynecologic cancers. This ongoing study examines an array of patient-reported outcomes and satisfaction with PE.

Methods. Since February 2009, prospectively enrolled participants completed questionnaires evaluating body image (BIS), depression (CESD), social support (DUFSS), symptoms (MDASI), sexual function (SAQ), functional status (SF-12), quality of life (The Stoma-QOL), satisfaction with decision (SWD) and an investigator-designed survey at baseline, 6, and 12 months after PE. Mann-Whitney and Wilcoxon signed-rank tests were used to evaluate the data.

Results. Fifty-four women enrolled. Median age was 56 years (31, 85). Median BMI was 30.7 kg/m^2 (16.8, 54.4). The majority of patients (78%) were white. Cancer diagnoses included 41% cervix, 22% uterus, 19% vagina, 17% vulva and 2% ovary. Most surgeries were total PEs (76%).

Patients were satisfied with their decision to undergo PE at 6 and 12 months. One year after exenteration, 79% of women stated they would have a PE again. Sexual pleasure decreased from baseline to 12 months after PE ($p = 0.02$), while sexual discomfort remained unchanged ($p = 0.42$). Body image worsened over time ($p = 0.003$). Physical functioning (SF-12) declined ($p = 0.001$), while mental functioning remained stable ($p = 0.46$). There were no significant changes in stoma-related QOL, social support, or depression scores.

Conclusions. Despite a decrease in physical functioning, persistent low body image and sexual pleasure, most women were satisfied with their decision and would undergo pelvic exenteration again. This study identifies survivorship issues that should be addressed after PE.

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1. Introduction

Pelvic exenteration (PE) was first described in 1948 as the removal of the pelvic viscera en bloc for persistent or recurrent gynecologic cancer [1]. The procedure is currently used for advanced primary or locally recurrent cancers to provide curative care for women with isolated central disease [2–4]. PEs are classified as total or partial (anterior or posterior) based on the level of surgical involvement. All PEs are extensive operations resulting in the removal of the vagina and formation of at least one permanent stoma [5].

Due to the extensive nature of the surgery, physical and mental complications are common [6]. Major surgical complications, such as anastomotic leaks, fistulas, infections, and small bowel or ureteral obstructions occur in 40–50% of procedures while minor complications occur in 80–94% of cases [4,7]. The 5-year overall survival following a PE

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is 40–63% [7–9]. Given the well-documented morbidity associated with the procedure, researchers have sought to understand these patients' post-operative quality of life (QOL) [10–12].

PE impacts a wide array of QOL concerns including sexual health, body image, symptoms, communication, social issues, psychological distress, and relationship issues [13]. Patient-reported outcomes (PROs) are one way to assess these issues. PROs in oncology represent how patients feel and function by inquiring about symptoms related to disease or treatment, physical functioning, and QOL factors [14]. A QOL assessment using PROs should include a prospective approach, accounting for baseline differences, and a wide-reaching compilation of questionnaires. Research using this comprehensive evaluation of pelvic exenteration outcomes is limited. The majority of the data have been collected from retrospective studies [13]. Although prospective data exist, limitations exist based on sample size [15,16], lack of comparison pre-operative data [17], or utilization of limited or non-validated questionnaires [18–20]. Furthermore, studies have yet to examine patient perspectives on their decision for surgery and if they would make the same decision again. Therefore, the aim of this prospective longitudinal study was to assess a diverse array of PROs for gynecologic patients during the first year after their PE.

2. Methods

2.1. Study design

This prospective, longitudinal study was approved by the Institutional Review Board at The University of Texas MD Anderson Cancer Center and is ongoing. Patients scheduled for a pelvic exenteration in the Department of Gynecologic Oncology and Reproductive Medicine were identified pre-operatively and approached to participate in this longitudinal study. Patients consented to complete a series of questionnaires from preoperative assessment to ten years post-operation or death. This report represents an interim analysis of PROs collected pre-operatively (baseline) as well as at 6 months and 12 months after pelvic exenteration.

Since February 1, 2009, patients scheduled for pelvic exenteration have been identified through the Gynecologic Center database and by physician referral. Inclusion criteria required a history of gynecologic malignancy and associated plan for PE, age > 18 years, English or Spanish proficiency, and a willingness to complete self-administered PRO questionnaires. Eligible patients were offered enrollment at their pre-operative clinic appointment by the research team. Patients enrolled on the study provided written informed consent. Preoperative demographic and clinical data were abstracted from the medical record. Patients were asked to complete PRO instruments prior to undergoing PE. Patients whose PE was aborted due to the discovery of distant metastasis or unresectable disease at the time of surgery were removed from the study. Patients were considered eligible for questionnaire participation until their consent was withdrawn or death.

At baseline, six months and 12 months after PE, patients were approached at their regular clinic visits to complete all PRO surveys except for sexual function which was measured at baseline and 12 months. PRO surveys were completed in person during regular clinic visits or were mailed to patients in a prepaid envelope with return mailing materials. If surveys were not returned within one month of mailing, a study staff member called patients and offered the opportunity to provide responses via the telephone.

2.2. PRO measures

The issues affecting gynecologic oncology patients who undergo exenteration patients are multi-faceted and complicated. Since a comprehensive, validated PRO instrument has not yet been developed for this patient population, we included several validated measures to address a wide array of patient issues:

- Patient satisfaction surrounding decision for exenteration was determined using the Satisfaction with Decision Scale (SWD), with a score of 6 indicating poor satisfaction and 30 representing complete satisfaction [21].
- An investigator-developed questionnaire was designed to assess patients' perspectives on their decisions for undergoing PE. For example, “If given the opportunity, would you choose an exenteration again?”, (possible answers include “I would choose an exenteration again”, “I would not choose an exenteration again”, or “I am unsure about undergoing an exenteration again”).
- Stoma-related QOL was assessed using The Stoma-QOL, a 20-item validated scale developed to assess quality of life with regards to bowel reconstruction stoma and bladder reconstruction stoma. Higher scores indicate better QOL; the max score is 80 [22].
- The Sexual Activity Questionnaire (SAQ) is composed of three components, pleasure, discomfort and habit. Pleasure scores range from 0 (no desire, enjoyment) to 18 (very enjoyable, more desire), while discomfort scores range from 0 (no discomfort) to 6 (severe discomfort). Finally, a habit scores of 0 indicates “less than normal” amount of sexual activity and 3 indicates “much more” than usual sexual activity [23].
- The Body Image Scale (BIS) assesses body image changes with scores ranging from 0 to 30, where 0 indicates no distress and 30 specifies a high-degree of symptoms or stress. Scores of 8 or below suggest poor body image [24].
- Social support was determined using Duke-UNC Functional Social Support Scale (DUFSS), with a score of 0 signifying poor social support and 5 designating high social support [25].
- Depression was assessed using the Center for Epidemiologic Studies-Depression Scale (CES-D), with scores ranging from 0 to 60. Higher scores suggest more severe depression and a score of 16 or greater identifies possible depression [26]. The principle investigator and primary attending physician were notified within 24 h of receiving a questionnaire with a score of higher than a 16. The primary attending made an assessment of suicide risk and made recommendations according to the severity of the situation.
- Functional status was evaluated using the 12-Item Short Form Survey (SF-12), which includes a physical component score (PCS) and a mental component score (MCS). Scores span 0 to 100, with 0 indicating the lowest level of health and 100 representing the highest health level [27].
- The MD Anderson Symptom Inventory (MDASI) was used to determine how the patient's symptoms interfered with her well-being. The MDASI consists of 13 core symptom items (pain, fatigue, nausea, sleep disturbance, distress/upset, shortness of breath, memory, appetite, sleepiness, dry mouth, sadness, vomiting, and numbness/tingling) and 6 interference items (work, general activities, walking ability, relations with others, enjoyment of life, and mood). MDASI interference scores are comprised of physical and emotional interference subscale scores. Items are rated from 0 to 10, with 0 representing no symptom burden and 10 indicating maximal symptom burden [28].

2.3. Statistical analysis

Descriptive statistics were used to characterize clinical, demographic, and treatment information. Mann-Whitney, Wilcoxon signed-rank, and Kruskal-Wallis tests were used to compare data at individual time points. *P*-values were two-sided and considered significant if the *p*-value was <0.05. Statistics were performed using IBM SPSS Statistics, version 23 (Armonk, NY: IBM Corp.). Data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at MD Anderson [29]. REDCap is a secure, web-based application designed to support data capture for research studies,

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