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Improvement in Quality of Life after Robotic Surgery Results in Patient Satisfaction

Richard G. Arms III, MD[1], **Charlotte C. Sun, Dr PH**[2], **Jennifer K. Burzawa, MD**[2], **Nicole D. Fleming, MD**[2], **Alpa M. Nick, MD**[2], **Vijayashri Rallapalli**[2], **Shannon N. Westin, MD, MPH**[2], **Larissa A. Meyer, MD, MPH**[2], **Pedro T. Ramirez, MD**[2], and **Pamela T. Soliman, MD, MPH**[2,*]

[1]Department of Obstetrics and Gynecology, Creighton University Medical Center, Omaha, Nebraska 68131

[2]Department of Gynecologic Oncology and Reproductive Medicine, University of Texas MD Anderson Cancer Center, Houston, Texas 77030

Abstract

Background—There are well-described benefits to minimally invasive surgery including decreased blood loss, shorter hospital-stay, and faster recovery. The role of robotic surgery in gynecologic oncology has become increasingly prominent; however limited data are available on quality of life (QOL) after robotic surgery.

Methods—In this prospective, IRB-approved study, women scheduled for robotic surgery for a gynecologic indication between May 2008 and February 2012 completed validated QOL measures at baseline, 6 weeks (6wk), and 4 months postoperative (4mo). Functional status (SF-12), symptom severity and interference (MDASI), sexual function (FSFI), and satisfaction with decision (SWD) were assessed at relevant time points. Differences between groups were evaluated using the Mann-Whitney test.

Results—Among 408 women who underwent robotic surgery 278 (68%) completed the QOL measures. Median age was 55.6 years (range 25.7–85.1). Median BMI was 31.3 kg/m^2. The majority of patients were white (75%). The most common indication for surgery was endometrial cancer/hyperplasia (59.7%). While physical functioning declined from baseline to 6wk (51.4 to 41.6, $p<0.001$), it improved by 4mo (53.5). Mental functioning improved over time (baseline 48.6, 6wk 52.8, and 4mo 55.6, $p<0.001$). Symptom severity decreased over time ($p<0.001$) as did symptom interference ($p<0.001$). Sexual function improved significantly from baseline (8.6) to 4mo (20.2, $p<0.001$). Patients were satisfied with their decision making (SWD=30).

Conclusion—In this prospective study, general health, symptom burden and sexual function returned to or improved beyond baseline levels within 6 weeks of surgery. Overall, women were satisfied with their decision to undergo robotic surgery.

[*]To whom correspondence and reprint requests should be addressed at Department of Gynecologic Oncology and Reproductive Medicine, CPB6.3244, Unit 1362, The University of Texas MD Anderson Cancer Center, 1155 Herman Pressler, TX 77030. Phone: (713) 745-2352. Fax: (713) 792-7586. psoliman@mdanderson.org.

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Introduction

Since its clearance by the FDA in 2005, robot-assisted laparoscopic surgery has become increasingly common in gynecology. It is estimated that in 2007 only 0.5% of all hysterectomies for benign indications were performed robotically. By 2010, this figure had increased to 9.5% while rates of laparoscopic, vaginal, and abdominal hysterectomy all decreased in hospitals where robot-assisted laparoscopic hysterectomy was performed (1). Despite concerns regarding economic costs and burden on the healthcare system, robotic surgery continues to gain popularity (2).

Several reasons account for the rapid adoption of robotic surgery in gynecology. Like laparoscopy, robotic surgery offers the advantages of less blood loss, decreased pain, shorter hospital stay, and faster recovery than can be achieved with open surgery (3, 4). Compared to conventional laparoscopy, robot-assisted surgery offers advantages of three dimensional vision, improved ergonomics, articulated instruments, and elimination of hand tremor (5). These attributes are thought to make robotic surgery more accessible, offering a shorter learning curve than conventional laparoscopy, and thereby enabling surgeons who would otherwise depend on an open approach to offer their patients minimally invasive surgery (1, 5). Disadvantages of robotic surgery included increased cost and, often increased operating room time when compared to either conventional laparoscopy or laparotomy (1, 2).

In the current literature, robotic surgery has been compared to both open surgery and conventional laparoscopy focusing on common outcome measures such as operative time, total blood loss, pain, conversion to laparotomy, complication rates, and rates of hospital readmission (3, 4, 6). While quality of life (QOL) has been shown to be significantly better for up to 6 months after total laparoscopic hysterectomy when compared to total abdominal hysterectomy (7), there is little published data on patient satisfaction and QOL measures after robotic surgery. The purpose of this study was to use validated QOL of measures to evaluate patient reported outcomes and QOL at baseline and then after robotic surgery. Based on clinical experience and data in laparoscopy, we hypothesized that patient reported outcomes would return to baseline within the 6 week postoperative recovery period.

Materials and Methods

This prospective QOL study was approved by the Institutional Review Board at MD Anderson Cancer Center and St. Luke's Episcopal Hospital in 2008. Patients scheduled for robotic surgical procedures were prospectively identified and approached at their preoperative clinic visit. All English or Spanish speaking women, 18 years or older scheduled to undergo a robot-assisted gynecologic procedure were eligible. Written informed consent was obtained by the primary surgeon or a member of the research team.

Demographic data including age, body mass index, indication for surgery, and complications from surgery were collected from the medical record and maintained in a prospective database. Patients who agreed to participate were assessed over four domains including: overall functional status, symptom severity and symptom impact on daily activity, sexual functioning, and satisfaction with the decision to have robotic surgery. If the patient's

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procedure was converted to a laparotomy or the procedure was done by laparoscopy due to scheduling, the patient was no longer eligible for the study.

Overall functional status was assessed using the SF-12 which addresses general measures of health and well-being, and includes both physical and mental components. Scores range from 0 to 100 where 0 indicates the lowest level of health and 100 measures the highest level of health (8). The MD Anderson Symptom Inventory (MDASI) was used to evaluate symptom severity over the preceding 24 hours and gauge symptom interference upon six daily activities including general activity, mood, work, relations with others, walking, and enjoyment of life. Items on this scale are rated from 0 to 10 where 0 represents no symptom burden and 10 represents the greatest symptom burden. Component symptom severity and symptom interference scores are computed by taking the average of each item rated. Higher scores reflect worse symptoms (9).

The Female Sexual Function Index (FSFI) was used to assess sexual function in study subjects. The FSFI assesses six domains of sexual functioning including desire, arousal, lubrication, orgasm satisfaction, and pain. The FSFI total score is the sum of all scores obtained in each domain. The total scale score ranges from 2 to 36. Higher scores indicate better functioning. Patient satisfaction with the decision to have robotic surgery was evaluated with the 6 question Satisfaction with Decision Scale (SWD). Questions are answered on a 1–5 scale, with 1= strongly disagree and 5 = strongly agree. Scores range from 6 – 30; with higher scores reflecting higher satisfaction with decision (10, 11).

Patients were assessed at three time-points as shown in Table 1. While overall function, general health, and symptom burden were assessed at baseline, 6 weeks, and 4 months postoperative, sexual function was measured only at baseline and 4 months because patients were expected to abstain from intercourse during the first six weeks after surgery. Upon completion of the final battery of questionnaires a subject’s participation was complete. Data were collected at scheduled clinic visits and entered into a password-protected database to which only the investigators had access. If patients failed to complete questionnaires during scheduled appointments the research study coordinator contacted them and study instruments were mailed to them with a self-addressed envelope. Alternatively, patients could provide answers to the questionnaires over the phone. Data were analyzed using SPSS 19. The Mann-Whitney test was used to evaluate differences between each post-op assessment and baseline QOL. P-values < .05 were considered statistically significant.

Results

Between May 2008 and February 2012, 408 women were scheduled for robotic surgery. The QOL study was offered to 324 women and 286/324 women (88.3%) provided written informed consent to participate in the study. We were unable to capture all patients if the OR schedule changed or if the data coordinator was not informed about the patient coming for preoperative assessment. Of the 286 women who provided consent to participate, 8 were excluded (1 had an open procedure, 1 patient had an IUD placed and did not undergo robotic surgery, 5 patients had laparoscopy only, and 1 patient had surgery at a different hospital). Demographic characteristics for the 278 participants in the final analysis group are listed in

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Table 2. The median age of all study participants was 55.6 years. Median BMI was 31.3 kg/m^2. The majority of study participants were white (74.7%). The most common medical comorbidity was hypertension (43.3%), followed by smoking (26.0%) and diabetes (18.8%). The most common indication for surgery was endometrial cancer/hyperplasia (59.7%).

The surgical procedures performed and related data are presented in Table 3. Hysterectomy with or without bilateral salpingoophorectomy was the procedure most commonly performed. For all procedures, median operative time was 193 minutes (mean 214 minutes, range 97–453 minutes) and median console time was 120 minutes (mean 136 minutes, range 29–670 minutes). Median estimated blood loss was 75 mL (mean 108 mL, range 5–1,000 mL). Fifteen cases were converted from a robotic to an open approach, for a total conversion rate of 5.4%. These patients were therefore excluded in the analysis.

Two hundred and thirteen women completed some or all baseline QOL assessment and were included in the statistical analysis. QOL measures were obtained from 212 study participants at 6 week post-operative follow-up and from 196 study participants at 4 month follow-up. Median QOL data are presented in Table 4. Overall results from the Functional status (SF-12) demonstrated improvement in both physical and mental function between baseline and 4 month follow up. Physical functioning declined initially from baseline to 6 weeks (51.4 to 41.6, p<.001), but improved at 4 months (53.5), although the magnitude of this improvement did not reach statistical significance (p=0.81). Mental functioning improved significantly over time: baseline (48.6), 6 weeks (52.8), and 4 months (55.6, p<.001). As shown by the MD Anderson Symptom Severity and Interference scale (MDASI), symptom severity decreased over time. The median baseline score decreased from 1.04 to 0.85 at 6 weeks (p=.04), and to 0.62 four months after surgery (p<.001). The same general trend was observed for symptom interference. The median baseline score decreased from 1.0 to 0.83 at 6 weeks (p=.32), and to 0.17 four months after surgery (p<.001). At 4 months, pain, nausea, sleep disturbance, sadness, distress, and drowsiness had completely resolved (scores = 0) with the exception of fatigue, which had decreased significantly from baseline levels (score = 1, p<.001).

Sexual function as measured by the Female Sexual Function Index (FSFI) improved significantly at 4 months (20.2) compared to baseline (8.6, p<.001). Significant improvement was noted in all six measured domains (p<.001 to p=.005). Satisfaction with the decision to undergo robotic surgery was measured at 6 weeks and 4 months. Patients were satisfied with their decision to have robotic surgery at both 6 weeks (30) and at 4 months (30). These findings remained consistent by age and other demographic factors.

Discussion

In our study, women who underwent robotic gynecologic surgery had a quick return to baseline quality of life after a short period of time and were satisfied with their decision to undergo robotic gynecologic surgery. This study is one of the first to directly address QOL prospectively after robot-assisted surgery for gynecologic indications. We used validated metrics to measure overall functioning, symptom burden, sexual function, and satisfaction with the decision to pursue robotic surgery at both 6 weeks and 4 months postoperatively.

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Women in this study reported return to baseline or improvement beyond baseline in all parameters and expressed a high degree of satisfaction with the decision to pursue robotic surgery.

Studies comparing quality of life after conventional laparoscopy and laparotomy performed for gynecologic indications show that patients report better outcomes after minimally invasive surgery (7, 12, 13). As a form of minimally invasive surgery, robot-assisted laparoscopy might be expected to offer similar advantages to conventional laparoscopy where QOL is concerned. Studies assessing short-term perioperative parameters have shown that robot-assisted laparoscopy does not increase postoperative pain or narcotic use compared to conventional laparoscopy (6, 14). However, few investigators have looked broadly at QOL after robotic surgery or followed patients beyond the immediate perioperative period. Little has been published regarding QOL after robotic surgery (15).

Generally, results of this study are consistent with what has been published on the topic. Two recent trials from general gynecology comparing robot-assisted surgery with conventional laparoscopy suggest patients experience comparable QOL outcomes. A study by Sarlos *et al* evaluated mobility, self-care, usual activities, pain, discomfort, anxiety and depression and found that patients who underwent robotic surgery reported significantly greater improvement in QOL measures compared to those who underwent conventional laparoscopy (16). Paraiso *et al* followed patients for 6 months after robotic and conventional laparoscopic surgery and found no differences in QOL measures between groups at 6 months, although certain measures had improved for both groups compared to baseline (2). Neither study was powered to detect differences in QOL between study arms, making the significance of their conclusions unclear.

In our study, patients experienced a rapid return to preoperative QOL in most domains. SF-12 mental component and MDASI scores reached or exceeded baseline levels 6 weeks after surgery; while the SF-12 physical component score remained depressed at 6 weeks, it returned baseline by 4 months postoperative. It is unclear why QOL would improve over baseline in some patients but it could be related to indications for surgery. When undergoing surgery for a newly diagnosed cancer, patients may experience a degree of emotional relief from having their disease treated. This could affect how they perceive symptom burden and rate functional status postoperatively. Results published elsewhere support these findings. Abitbol *et al.* followed 211 patients with gynecologic cancer for one year after robot-assisted laparoscopy. Their group used the FACT-G to evaluate QOL at baseline, 1 and 3 weeks, and 6, 9, and 12 months after surgery. Overall FACT-G scores fell initially but returned to baseline at 3 weeks and remained at that level before climbing again at 12 months (15). Use of different metrics and time-points limits direct comparison with our results; however, their findings support the idea that patients undergoing robot-assisted laparoscopic surgery for gynecologic cancer experience a rapid return to preoperative QOL.

There are several strengths to the current study. First, data was collected prospectively, avoiding recall bias. In addition, use of validated QOL metrics allowed data to be quantified objectively while use of multiple QOL metrics permitted a broad assessment of QOL to include general functioning, symptom burden, sexual function, and overall satisfaction.

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Evaluation of sexual functioning after therapy is especially relevant in gynecology. The current study is one of the first to do so after robot-assisted laparoscopic surgery. Although this study was conducted by a single academic practice, the surgery was performed by ten attending physicians and several fellows at two hospitals making the results somewhat easier to generalize.

Limitations of this study include the fact that study participants had varying types of surgical procedures. We attempted to determine if demographic factors, cancer diagnosis or surgical procedure had an impact on QOL measures but we were unable to determine differences due to small numbers within each group. In addition, participants were offered robot-assisted surgery at the discretion of their surgeon and were not blinded to their surgical approach. As others have noted, robotic surgery is widely promoted by health systems and the general media. The degree to which this might have influenced a patient's perception is not known. Finally, the main limitation of this study was lack of a control group. Our data demonstrated that patients experienced improvement in quality of life measures postoperatively and that in some cases outcomes exceeded baseline; however, it is uncertain to what degree this resulted from simply having undergone surgery as opposed to benefits unique to the surgical approach. When this study was initially proposed there were very limited data on QOL after robotic surgery. Therefore, this was planned to be a feasibility and hypothesis generating study.

In this prospective study on QOL after robotic surgery in gynecology, general health, symptom burden, and sexual function returned to or improved beyond baseline levels within 6 weeks of surgery. This information adds to the existing data that minimally invasive surgery results in a faster recovery when compared to other surgical approaches. Prospective, randomized trials are needed to determine if this benefit on physical, emotional, and sexual function is unique to robotic surgery or a benefit found with all minimally invasive surgical techniques.

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Table 1

Schedule of QOL Measures

QOL Measure	Baseline	6 weeks postop	4 months postop
SF-12	X	X	X
MDASI	X	X	X
FSFI	X	-	X
SWD	-	X	X

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Table 2

Demographic Characteristics (N=278)

Median Age (Years)	55.6 (25.7–85.1)
Median BMI (kg/m^2)	31.3 (13.9–63.7)
Race/Ethnicity	
White	207 (74.7%)
Black	21 (7.6%)
Asian	8 (2.9%)
Hispanic	41 (14.8%)
Major Comorbidities	
Hypertension	120 (43.3%)
Smoking	72 (26.0%)
Diabetes Mellitus	52 (18.8%)
Depression	23 (8.3%)
Myocardial Infarction	7 (2.5%)
COPD	5 (1.8%)
Asthma	15 (5.1%)
Preoperative Diagnosis	
Cervical Cancer/Dysplasia	47 (17.0%)
Endometrial Cancer/Hyperplasia	166 (59.7%)
Adnexal Mass	50 (18.3%)
Other	15(5.4%)

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Table 3

Operative Data

Procedure	N
Hysterectomy +/− BSO	144
Radical Hysterectomy	17
Hysterectomy/BSO/Staging	41
BSO/Staging	1
USO/BSO	22
Staging	2
Radical Trachelectomy	12
Hybrid Staging	16
Other	8
Conversion	15
Surgical Time (Min)	Median 193 Range 97–453
	Mean 214
Console Time (Min)	Median 120 Range 29–670
	Mean 136
Estimated Blood Loss (mL)	Median 75 Range 0–1000
	Mean 108

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Table 4

Median QOL scores

	Time 1	Time 2	Time 3	Time 1 vs Time 2	Time 1 vs Time 3
	Baseline (range)	**6 Weeks Post-op (range)**	**4 Months Post-op (range)**	**p-value**	**p-value**
SF-12[1]					
PCS	51.4 (12.2, 69.5)	41.6 (14.5, 62.4)	53.5 (17.0, 65.1)	<.001	0.81
MCS	48.6 (12.5, 67.0)	52.8 (13.2, 70.2)	55.6 (7.8, 65.6)	<.001	<.001
MDASI[2]					
Symptom Severity	1.04 (0.0 7.9)	0.85 (0.0, 6.7)	0.62 (0.0, 8.3)	0.04	<.001
Symptom Interference	1.0 (0.0, 8.83)	0.83 (0.0, 9.5)	0.17 (0.0, 10.0)	0.32	<.001
FSFI[3]					
Total	8.6 (0.0, 35.4)	-	20.2 (0.0, 36.0)	-	<.001
Desire	2.4 (1.2, 6.0)	-	3.6 (1.2, 6.0)	-	.001 .005
Arousal	1.2 (0.0, 6.0)	-	3.3 (0.0, 6.0)	-	<.001
Lubrication	0.3 (0.0, 6.0)	-	3.6 (0.0, 6.0)	-	.001
Orgasm	0.0 (0.0, 6.0)	-	3.4 (0.0, 6.0)	-	<.001
Satisfaction	4.0 (0.8, 6.0)	-	4.8 (0.8, 6.0)	-	<.001
Pain	0.0 (0.0, 6.0)	-	4.8 (0.0, 6.0)		
				Time 2 vs Time 3	
SWD[4]	-	30.0 (6.0, 30.0)	30.0 (6.0, 30.0)	.11	

[1]The SF-12 consists of the physical and mental health summary measures: PCS refers to the Physical Component Scale and MCS is the Mental Component Scale. Scores range from 0 to 100. Higher scores reflect better health function.

[2]The MDASI consists of symptom severity and symptom interference component scores. Component scores range from 0 to 10. Higher scores reflect worse symptom burden.

[3]The FSFI consists of six domains which are scored and summed to arrive at a total score which may range from 2.0 to 36.0. The minimum and maximum score for each domain are as follows: Desire (1.2 to 6.0), Arousal, Lubrication, Orgasm, and Pain domains (0.0 to 6.0), and Satisfaction (0.8 to 6.0). Higher scores reflect better functioning.

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The SWD score ranges from 6 – 30, with higher scores reflect higher satisfaction with decision.

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