Published in final edited form as:

Gynecol Oncol. 2016 December ; 143(3): 596–603. doi:10.1016/j.ygyno.2016.10.012.

Quality of Life after Radical Trachelectomy for Early-Stage Cervical Cancer: A 5-year Prospective Evaluation

ND Fleming¹, PT Ramirez¹, PT Soliman¹, KM Schmeler¹, GB Chisholm¹, AM Nick¹, SN Westin¹, and M Frumovitz¹

¹Department of Gynecologic Oncology and Reproductive Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX 77030

Abstract

Objectives—To longitudinally assess quality of life (QOL) in women undergoing radical trachelectomy for early-stage cervical cancer.

Methods—We prospectively enrolled patients with stage IA1-IB1 cervical cancer prior to undergoing radical trachelectomy to complete validated QOL instruments. These instruments included the General Health-Related QOL (SF-12), Functional Assessment of Cancer Therapy-Cervix (FACT-Cx), MD Anderson Symptom Inventory (MDASI), Female Sexual Functioning Index (FSFI), and Satisfaction with Decision scale (SWD). Instruments were filled out at baseline, postoperatively at 6 weeks, 6 months, 1 year, and annually thereafter for 4 years.

Results—Thirty-nine patients enrolled in the study, and 32 patients were evaluable. The scores for FSFI-arousal ($p=0.0002$), lubrication ($p<0.0001$), orgasm ($p=0.006$), pain ($p=0.01$), satisfaction ($p=0.03$) and total score ($p=0.004$) showed a significant decline at 6 weeks then returned to baseline levels by 6 months. The scores for FACT-Cx functional well-being ($p=0.02$) and physical well-being ($p<0.0001$), SF-12 bodily pain ($p<0.0001$), physical functioning ($p<0.0001$), role physical ($p<0.0001$), role emotional ($p=0.03$), social functioning ($p=0.002$), and MDASI total ($p=0.04$) showed significantly worsened symptoms at 6 weeks then returned to baseline by 6 months. The scores for FACT-Cx emotional well-being showed significant worsening of symptoms that persisted at 6-weeks ($p=0.004$), 6 months ($p=0.007$), 1 year ($p=0.001$), 2 year ($p=0.002$), and 4 year ($p=0.03$). There was no difference in SWD.

Conclusions—Several quality of life assessments decline immediately postoperatively after radical trachelectomy, however, return to baseline thereafter. The long-term emotional impact of this surgery highlights a need for perioperative counseling in these patients.

Please send correspondence to: Nicole D. Fleming, MD, 1155 Pressler Drive, Unit 1362, Houston, TX 77030, Phone: (713) 563-1792, Fax: (713) 745-1541, nfleming@mdanderson.org.

*This was presented as an oral presentation at the 2016 Society of Gynecologic Oncology Annual Meeting on Women's Cancer

Conflict of Interest Statement: The authors declare that there are no conflicts of interest.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Background

Although the incidence of cervical cancer in the United States continues to decline, it continues to affect young women who desire future childbearing. Forty-six percent of cervical cancers are diagnosed in women under the age of 45 [1], thus, fertility preserving surgical options for treatment are important to discuss with appropriate patients with newly diagnosed early-stage cervical cancer. Radical trachelectomy is considered to be a safe oncologic alternative to radical hysterectomy and has been recognized by the National Comprehensive Cancer Network (NCCN) as a fertility-sparing treatment option for patients with stage IA1 with lymphovascular space invasion, stage IA2, and stage IB1 cervical cancers. [2]

Several studies have reported on quality of life (QOL) and sexual dysfunction in patients after radical hysterectomy [3-6], however, limited data is available on these measures in patients undergoing radical trachelectomy. The few prospective studies available to date have assessed short-term QOL and sexual function in radical trachelectomy patients undergoing vaginal or abdominal radical trachelectomy and comparing these to patients undergoing radical abdominal hysterectomy or healthy controls. These studies have shown a decrease in QOL measures in patients undergoing radical trachelectomy, which may reflect a new level of functioning in cervical cancer survivorship. [7-9] We sought to prospectively assess quality of life, sexual functioning, symptoms, and satisfaction with healthcare decisions in women undergoing radical trachelectomy for early-stage cervical cancer.

Methods

MD Anderson Institutional Review Board approval was obtained for this prospective study. Informed consent was obtained from eligible patients pre-operatively following surgical consent.

Patient eligibility

Women age 18-40 years diagnosed with histologically confirmed early-stage (stage IA1 with lymphovascular space invasion, stage IA2, and stage IB1) primary adenocarcinoma, squamous cell carcinoma, or adenosquamous carcinoma of the cervix who were eligible for radical trachelectomy were approached for study participation. Patients had to be suitable candidates for surgery, able to read and write in English or Spanish, and signed approved Informed Consent. Patients were excluded if they had stage IB2 or higher disease, history of a second primary malignancy within 3 years, history of pelvic or abdominal radiotherapy, pregnancy, evidence of metastatic disease by imaging, or any contraindications to surgery. Additional patients were excluded from the final analysis post-operatively if the procedure was converted to radical hysterectomy or had limited study participation for baseline or postoperative questionnaire completion.

Procedure

MD Anderson faculty trained in radical trachelectomy surgical techniques performed the procedure via abdominal, laparoscopic, or robotic method as previously described. [10-12] Pelvic lymphadenectomy with or without sentinel lymph node mapping and biopsies was

performed. Method of vaginal closure, cerclage placement, and insertion of device to prevent cervical stenosis was left to the discretion of the primary surgeon. Intraoperative frozen section pathology analysis of the endocervical margin and any suspicious lymph nodes was routinely performed. If frozen section pathology revealed a positive margin <10mm from the endocervical resection of the specimen, either an additional margin was taken if possible, or the procedure was converted to a radical hysterectomy. If frozen section pathology revealed a positive lymph node, then the procedure in its entirety was aborted and the patient was referred for combined chemotherapy and pelvic radiation.

Study survey and data collection

After providing written consent, pre-operative demographic data and surgical outcomes were collected from the patient's electronic medical record. Patients were asked to complete 5 self-administered questionnaires pre-operative (within 2 weeks of scheduled surgery), and approximately 4-6 weeks postoperatively, 6 months after surgery, 1 year after surgery, and annually thereafter for 4 years to complete 5 years after initial surgery. For women not receiving their follow-up at MD Anderson, questionnaires were mailed to the patients at the above time points with a pre-paid return envelope marked confidential and addressed directly to the principal investigator. The 5 self-administered questionnaires included:

1. The *General Health-Related Quality of Life (SF-12)* instrument is a 12-item questionnaire estimating 8 health domains including physical functioning, role-physical, role-emotional, mental health, bodily pain, vitality, social functioning, and general health. Scores are given in each domain and summary scores for overall physical and mental status. [13]
2. The *Functional Assessment of Cancer Therapy (FACT-Cx)* is the FACT-G plus cervix subscale. The FACT-G is the generic core to measure quality of life for patients with cancer. This instrument contains 27 questions from 4 domains: physical well-being, social/family well-being, emotional well-being, and functional well-being. The cervix subscale consists of 15 questions pertaining to patients with cervix cancer. [14] Scores range from 0 to 108 for the FACT-G, and 0 to 60 on the cervix subscale. [15]
3. The *MD Anderson Symptom Inventory (MDASI)* is a 19-item questionnaire assessing symptoms including pain, fatigue, nausea/vomiting, anorexia, sleep disturbances, and distress. This also includes an assessment on how those symptoms have interfered with the patient's general well-being, including their general activity, mood, ability to walk and perform normal work functions, relationships with others, and enjoyment of life. The validity and reliability of the MDASI has been well-established. [16]
4. The *Female Sexual Functioning Index (FSFI)* is a 19-item multidimensional survey measuring 5 domains including sexual desire, arousal (both subjective and physiological), lubrication, orgasm, satisfaction, and pain. Higher scores indicate better sexual functioning. [17] The full scale score for women with sexual dysfunction was a mean of 19.2, compared with a mean of 30.5 for controls. [18]

5. The *Satisfaction with Decision (SWD)* scale is a 6-item survey that measures the patient's satisfaction with health care decisions. The instrument has excellent reliability (Cronbach's alpha=0.86) and good validity. [19]

Statistics

We used descriptive statistics to summarize demographic and clinical characteristics of the patients in this study. Demographic characteristics included age, race, weight, and body mass index (BMI). Clinical characteristics included diagnosis, comorbidities, and surgical history. We used descriptive statistics to summarize the scores for the SF-12, FACT-Cx, MDASI, and FSFI instruments at baseline and at each follow-up visit (4-6 weeks -all except FSFI, 6 months, 1 year, and annually for 4 years). We estimated the mean score for each instrument at each time point with a 95% confidence interval. We illustrated the distribution of the instrument scores over time with boxplots. We summarized and analyzed the change from baseline to each follow-up visit for the SF-12, FACT-Cx, MDASI, and FSFI instruments. We used mixed effects regression to model the change from baseline in scores for the SF-12, FACT-CX, MDASI, and FSFI instruments as a function of time. As a sensitivity analysis we conducted the analysis of change scores described above with the last available instrument score replacing missing instrument scores for those patients who drop out of the study or become ineligible due to recurrence.

Results

Surgical outcomes

Thirty-nine patients enrolled to the study, and 32 patients were evaluable for QOL analysis after undergoing radical trachelectomy. Seven patients were excluded from final QOL analysis due to conversion to radical hysterectomy intra-operatively (n=3) or limited study participation due to no baseline or postoperative questionnaires completed (n=4). Clinical and demographic data is listed in Table 1. Median age was 30.7 years (range 21.4-38.7). Median BMI was 25.3 kg/m² (range 16.1-44.4). Majority of patients had stage IB1 disease (n=16, 50%), grade 2 (n=14, 44%) or grade 3 (n=13, 40%), and adenocarcinoma (n=15, 47%) or squamous (n=14, 44%) histology. Most patients underwent a robotic surgical approach (n=21, 66%) for the radical trachelectomy compared to open (n=9, 28%) or laparoscopic (n=2, 6%).

When undergoing radical trachelectomy (n=32), majority had a cerclage placed (n=31, 97%) and a device inserted to prevent cervical stenosis (n=31, 97%). The most common suture used for cerclage placement was Ethibond (n=30, 94%) and the most common device used to prevent cervical stenosis was a Smit sleeve (Nucletron, Inc.) (n=25, 78%). The most common suture used to close the utero-vaginal anastomosis was the V-loc™ (Covidien, Inc.) barbed running suture (n=17, 53%), followed by interrupted Vicryl suture (n=12, 38%). Median surgical time was 324 minutes (range 234-444 minutes) in the entire cohort and was not significantly different between open versus minimally invasive surgical approach (318 vs. 348 minutes, p=0.09, Table 2a). Median estimated blood loss (EBL) was higher in open compared to minimally invasive surgical approach (200 vs. 50 mL, p=0.002). Median length of hospitalization was also longer in open compared to minimally invasive surgical approach

(4 vs. 1 day, $p=0.002$). Median number of pelvic lymph nodes removed was 7 nodes in the left (range 1-20) and 10 nodes in the right pelvis (range 3-25), and did not differ between surgical methods. There were 2 patients (6%) in the entire cohort who required readmission within 30 days of surgery (postoperative pelvic abscess ($n=1$) and ureteral fistula ($n=1$), and this did not differ between the open compared to minimally invasive surgical approach. Surgical complication rates in the cohort are listed in Table 2b. There was no bowel-related intraoperative complications, however, there was one (3%) ureteral complication from thermal injury presenting as a postoperative fistula. There was one (3%) intraoperative vascular injury of the left external iliac vein from thermal injury that was repaired intraoperatively. Median time to removal of Foley catheter was 9 days (range 6-28 days).

Infectious complications within 30 days of surgery included febrile morbidity ($n=4$, 11%), pneumonia ($n=1$, 3%), urinary tract infection ($n=2$, 6%), vaginal cuff cellulitis ($n=1$, 3%), pelvic abscess ($n=3$, 9%), and pelvic hematoma ($n=2$, 6%). Non-infectious complications within 30 days included lymphocyst formation ($n=1$, 3%), ureteral fistula ($n=1$, 3%), cerclage erosion ($n=2$, 6%), uterine necrosis ($n=1$, 3%), and grade 3 anemia requiring blood transfusion ($n=3$, 9%). Non-infectious complications greater than 30 days from surgery included cervical stenosis ($n=5$, 14%), premature ovarian failure ($n=1$, 3%), poor healing of the utero-vaginal anastomosis ($n=2$, 6%), and cerclage erosion ($n=7$, 22%). Three patients underwent hysterectomy 6 months from the time of radical trachelectomy. One patient was diagnosed with recurrent adenocarcinoma of the cervix at 6 months and underwent hysterectomy followed by adjuvant therapy. Two patients underwent hysterectomy 24 and 36 months after radical trachelectomy due to recurrent cervical stenosis and severe pelvic pain.

Based on final pathologic evaluation after radical trachelectomy, 12 patients (37%) had residual disease in the trachelectomy specimen, and 20 patients (63%) had no residual disease. One (3%) patient undergoing radical trachelectomy required postoperative adjuvant chemoradiation due to positive pelvic lymph nodes and a positive vaginal margin. This patient had a negative endocervical margin both on intra-operative frozen section and final pathology.

Survey results

The median follow-up of our study was 39 months (range 23.0-52.2 months). The median completion rate of the QOL instruments by patients enrolled to the study was 94% at baseline, 78% at 6 week postoperative visit, 56% at 6 months, 46% at 12 months, 46% at 24 months, 24% at 36 months, 36% at 48 months, and 50% at 60 months.

The scores for FSFI-arousal ($p=0.0002$), FSFI-lubrication ($p<0.0001$), FSFI-orgasm ($p=0.006$), FSFI-pain ($p=0.01$), FSFI-satisfaction ($p=0.03$) and FSFI-total ($p=0.004$) showed a significant decline at the 6-week postoperative visit then returned to baseline levels by 6 months (Table 3). The assessment for FSFI-desire showed no significant change in score from baseline throughout the follow-up period. The scores for FACT-Cx functional well-being ($p=0.02$) and FACT-Cx physical well-being ($p<0.0001$) showed a similar decline at the 6-week postoperative visit then returned to baseline by 6 months. The scores for FACT-Cx emotional well-being showed significant worsening of symptoms that persisted at the 6-week ($p=0.004$), 6 month ($p=0.007$), 1 year ($p=0.001$), 2 year ($p=0.002$), and 4 year ($p=0.03$)

time points. There was no difference at the 3 year and 5 year time points, however this could be due to the limited number of patients on study at these time points. The scores for the FACT-Cx social and family well being and the total scores showed no significant differences throughout the follow-up period. The MDASI symptom distress total score ($p=0.04$) also showed a significant decline at the 6-week postoperative visit but returned to baseline by 6 months. However, the MDASI symptom severity total score did not differ throughout the follow-up period from baseline. The scores for the SF-12 bodily pain ($p<0.0001$), SF-12 physical functioning ($p<0.0001$), SF-12 role physical ($p<0.0001$), SF-12 role emotional ($p=0.03$), and SF-12 social functioning ($p=0.002$) showed significantly worsened symptoms at the 6-week postoperative visit then returned to baseline by 6 months. The scores for the SF-12 general health, mental health, and vitality showed no significant differences throughout the follow-up period. There was no significant difference in the SWD scores over the follow-up period from baseline.

In a subset analysis, all QOL scores were compared by surgical technique for differences. There were no differences in QOL scores based on an open versus minimally invasive surgical approach.

Discussion

Our prospective study showed that several quality of life, sexual, and functional assessments decline immediately postoperatively after radical trachelectomy, however, most return to baseline measures by 6 months postoperatively. A persistent decline in emotional well-being was seen up to 4 years after the radical trachelectomy procedure. While a decline in sexual functioning would be expected immediately postoperative given restrictions on intercourse, our study also highlighted overall low baseline and follow-up scores on the FSFI suggesting overall sexual dysfunction. Majority of the scores, however, did return to baseline levels and persisted at these levels throughout the follow-up period. In addition, there was no difference in scores on the SWD scale from baseline throughout the follow-up period, suggesting long-term satisfaction with their procedural outcomes.

Our study contributes to the small amount of literature to date, on the quality of life of young cervical cancer patients undergoing fertility-sparing treatment for an early cervical cancer. In a study by Carter et al., 33 radical abdominal or vaginal trachelectomy and 19 radical hysterectomy patients were evaluated in a prospective 2-year trial. Both groups had a decline in quality of life and sexual dysfunction, as measured by the FACT-Cx, Center for Epidemiological Studies Depression Scale (CES-D), Impact of Event Scale (IES), and FSFI, postoperatively compared to preoperative baseline measures. However, both groups demonstrated adaptive processes over the next 2 years with improvement in scores from the initial postoperative decline. [7] Another study by Froeding et al. assessed QOL in 18 patients undergoing radical vaginal trachelectomy compared to 32 radical hysterectomy and 30 healthy control patients over a 1-year follow-up period. These authors used several validated questionnaires including the FSFI, Female Sexual Distress Scale (FSDS), the Sexual function-vaginal changes Questionnaire (SVQ), and the EORTC cervical cancer module. This study demonstrated that patients undergoing radical vaginal trachelectomy had a significant decline in sexual dysfunction and global health status during the 12 months

post-treatment. However, despite sexual activity increasing over the follow-up period, the scores never reached those of healthy controls. [8] Our data showed a decline in sexual function and QOL scores in the initial 6 week postoperative period, but an improvement to baseline scores was seen by 1 year postoperative in most instrument scores.

Our study did reveal a persistent decline in emotional well-being through the FACT-Cx that persisted up to 4 years postoperative. This may represent an opportunity for peri-operative and long-term counseling on the effects of surgical treatment on social, emotional, and sexual functioning in these young women diagnosed with early-stage cervical cancers. Also, consideration could be taken to additional psychological interventions both peri-operatively and long-term to improve the negative emotional impact our study suggests. This may serve as a hypothesis for future prospective trials in this patient population.

Our study also highlighted several postoperative and long-term complications that can occur in patients undergoing radical trachelectomy that can affect quality of life. Our data set also included the largest cohort of prospective quality of life outcomes reported to date on patients undergoing radical trachelectomy via a minimally invasive surgical method. The feasibility of radical trachelectomy via a vaginal, abdominal, laparoscopic or robotic method has been well described in the literature [20-25] with apparent equivalent oncologic outcomes to radical hysterectomy. [26] Given the acceptance of radical trachelectomy as a safe oncologic alternative to radical hysterectomy, it is important to understand the physical impact and complications that can occur with this procedure. Our data reported a 14% rate of cervical stenosis, 28% rate of cerclage erosion, and 6% rate of poor healing of the utero-vaginal anastomosis. While our rates are similar to those previously reported in the literature [27-28], it does represent important areas to consider with quality of life and sexual functioning outcomes in these patients. These complications and overall physical adjustment may play a role in the initial postoperative decline from baseline in the quality of life instrument scores in our study. It would be important to consider future studies comparing surgical complication rates amongst different surgical techniques and suture choices when performing radical trachelectomy procedures.

Our study adds to the current body of literature on the quality of life and sexual function of patients undergoing radical trachelectomy. Our study is the largest to date to report these outcomes prospectively in patients undergoing this procedure via minimally invasive surgery. The weakness of the study is the overall low patient numbers and the lack of a comparison group of either healthy controls, radical hysterectomy, or pelvic radiation patients. Previous studies reported from our group [29] did show a difference in QOL and particularly sexual functioning in patients receiving pelvic radiation versus radical hysterectomy when compared healthy controls. Thus, the QOL differences seen in patients with early-stage cervical cancer is likely treatment related. Another limitation of the study is the possible introduction of bias by excluding patients that were converted to radical hysterectomy at the time of their radical trachelectomy procedure. The purpose of this exclusion was to focus the analysis solely on patients that underwent radical trachelectomy procedure to observe QOL and sexual functioning specifically related to this procedure. One patient in our analysis did require postoperative adjuvant chemo-radiation and was included in the analysis. However, excluding those patients converted to radical hysterectomy may

have biased results given that these patients had more aggressive tumor characteristics. Overall, our data is in agreement with the other small series in the literature recognizing the changes in emotional, social, and sexual functioning in young women undergoing radical trachelectomy for early-stage cervical cancer.

Given that 63% of patients in our cohort had no residual cancer in the trachelectomy specimen, this may represent a group in which radical treatment for early-stage cervical cancer could be avoided and consideration can be taken for more conservative surgery options. Along with our own institutional trial (ConCerv), there are several prospective trials evaluating the safety and feasibility of less radical surgery for early-stage cervical cancer with either conization or simple hysterectomy and pelvic lymphadenectomy for stage IA2 or IB1 disease. [30–32] If the safety of less-radical surgery is determined, then this may represent a method to improve quality of life and sexual functioning in patients undergoing treatment for early-stage cervical cancer.

References

1. SEER statistics
2. NCCN Cervical Cancer Guidelines. 2015
3. Bjelic-Radisic V, Jensen PT, Vlasic KK, et al. Quality of life characteristics in patients with cervical cancer. *Eur J Cancer*. 2012; 48:3009–18. [PubMed: 22683166]
4. Frumovitz M, Sun CC, Schover LR, et al. Quality of life and sexual functioning in cervical cancer survivors. *J Clin Oncol*. 2005; 23:7428–36. [PubMed: 16234510]
5. Jensen PT, Groenvold M, Klee MC, Thranov I, Petersen MA, Machin D. Early-stage cervical carcinoma, radical hysterectomy, and sexual function. A longitudinal study *Cancer*. 2004; 100:97–106. [PubMed: 14692029]
6. Korfage IJ, Essink-Bot ML, Mols F, Poll-Franse L, Kruitwagen R, van Ballegooijen M. Health-related quality of life in cervical cancer survivors: A population-based survey. *Int J Radiat Oncol Biol Phys*. 2009; 73:1501–9. [PubMed: 18823716]
7. Carter J, Sonoda Y, Baser RE, et al. A 2-year prospective study assessing the emotional, sexual, and quality of life concerns of women undergoing radical trachelectomy versus radical hysterectomy for treatment of early-stage cervical cancer. *Gynecol Oncol*. 2010; 119:358–365. [PubMed: 20817227]
8. Froeding LP, Ottosen C, Rung-Hansen H, Svane D, Mosgaard BJ, Jensen PT. Sexual functioning and vaginal changes after radical vaginal trachelectomy in early stage cervical cancer patients: a longitudinal study. *J Sex Med*. 2014; 11:595–604. [PubMed: 24286464]
9. Froeding LP, Ottosen C, Mosgaard BJ, Jensen PT. Quality of life, urogynecological morbidity, and lymphedema after radical vaginal trachelectomy for early-stage cervical cancer. *Int J Gyn Cancer*. 2015; 25:699–706.
10. Smith JR, Boyle DJ, Corless L, et al. Abdominal radical trachelectomy: a new surgical technique for the conservative management of cervical carcinoma. *Br J Obstet Gynecol*. 1997; 104:1196–1200.
11. Lee CL, Huang KG, Wang CJ, Yen CF, Lai CH. Laparoscopic radical trachelectomy for stage Ib1 cervical cancer. *J Am Assoc Gynecol Laparosc*. 2003; 10:111–115. [PubMed: 12555004]
12. Persson J, Kannisto P, Bossmar T. Robotic-assisted abdominal laparoscopic radical trachelectomy. *Gynecol Oncol*. 2008:564–67. [PubMed: 18620742]
13. Ware J Jr, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996; 34:220–233. [PubMed: 8628042]
14. Cella DF, Tulsky DS, Gray G, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol*. 1993; 11:570–9. [PubMed: 8445433]

15. Monk BJ, Huang HQ, Cella IID. Quality of life outcomes from a randomized phase III trial of cisplatin with or without topotecan in advanced carcinoma of the cervix: a Gynecologic Oncology Group study. *J Clin Oncol*. 2005; 23:4617–25. [PubMed: 15911864]
16. Cleeland CS, Mendoza TR, Wang XS, et al. Assessing symptom distress in cancer patients: the MD Anderson Symptom Inventory. *Cancer*. 2000; 89:1634–46. [PubMed: 11013380]
17. Basson R, Berman J, Burnett A, et al. Report of the international consensus development conference on female sexual dysfunction: definitions and classifications. *J Urol*. 2000; 163:888–93. [PubMed: 10688001]
18. Rosen R, Brown C, Heiman J, et al. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. *J Sex Marital Ther*. 2000; 26:191–208. [PubMed: 10782451]
19. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions: the satisfaction with decision scale. *Med Decis Making*. 1996; 16:58–64. [PubMed: 8717600]
20. Johansen G, Lonnerfors C, Falconer H, Persson J. Reproductive and oncologic outcome following robot-assisted laparoscopic radical trachelectomy for early-stage cervical cancer. *Gynecol Oncol*. 2016; 141:160–5. [PubMed: 26845228]
21. Api M, Boza A, Ceyhan M. Robotic versus laparoscopic radical trachelectomy for early stage cervical cancer: a case report and review of literature. *J Minim Invasive Gynecol*. 2015 Epub ahead of print.
22. Vieira MA, Rendon GJ, Munsell M, et al. Radical trachelectomy in early-stage cervical cancer: a comparison of laparotomy and minimally invasive surgery. *Gynecol Oncol*. 2015; 138:585–89. [PubMed: 26095894]
23. Park JY, Joo WD, Chang SJ, et al. Long-term outcomes after fertility-sparing laparoscopic radical trachelectomy in young women with early-stage cervical cancer: an Asan Gynecologic Cancer Group (AGCG) study. *J Surg Oncol*. 2014; 110:252–7. [PubMed: 24863069]
24. Pareja R, Rendon GJ, Sanz-Lomana CM, Monzon O, Ramirez PT. Surgical, oncological, and obstetrical outcomes after abdominal radical trachelectomy-a systematic literature review. *Gynecol Oncol*. 2013; 131:77–82. [PubMed: 23769758]
25. Nick AM, Frumovitz MM, Soliman PT, Schmeler KM, Ramirez PT. Fertility sparing surgery for treatment of early-stage cervical cancer: open vs. robotic radical trachelectomy. *Gynecol Oncol*. 2012; 124:276–80. [PubMed: 22035808]
26. Diaz JP, Sonoda Y, Leitao MM, et al. Oncologic outcome of fertility-sparing radical trachelectomy versus radical hysterectomy for stage IB1 cervical carcinoma. *Gynecol Oncol*. 2008; 111:255–60. [PubMed: 18755500]
27. Carter J, Sonoda Y, Chi DS, Raviv L, Abu-Rustum NR. Radical trachelectomy for cervical cancer: postoperative physical and emotional adjustment concerns. *Gynecol Oncol*. 2008; 111:151–7. [PubMed: 18662827]
28. Li X, Li J, Wu X. Incidence, risk factors and treatment of cervical stenosis after radical trachelectomy: a systematic review. *Eur J Cancer*. 2015; 51:1751–9. [PubMed: 26049687]
29. Frumovitz M, Sun CC, Schover LR, et al. Quality of life and sexual functioning in cervical cancer survivors. *J Clin Oncol*. 2005; 23:7428–36. [PubMed: 16234510]
30. Ramirez PT, Pareja R, Rendon GJ, Millan C, Frumovitz M, Schmeler KM. Management of low-risk early-stage cervical cancer: should conization, simple trachelectomy, or simple hysterectomy replace radical surgery as the new standard of care? *Gynecol Oncol*. 2014; 132:254–59. [PubMed: 24041877]
31. Plante, M. The SHAPE trial. https://gciggroup.com/system/files/2012_june_shape_trial.pdf
32. Covens, A. GOG Protocol 278. https://gciggroup.com/system/files/2012_june_cervix_cancer_committee.pdf

Research Highlights

- Several QOL measures decline postoperatively after radical trachelectomy.
- Most QOL scores return to baseline by 6 months after radical trachelectomy.
- A persistent decline in emotional well-being was seen up to 4 years postoperative.

Table 1
Demographics and Clinical Characteristics

	RT patients (n=32)
Age, median (range)	30.7 (21.4-38.7)
Race	
Caucasian	30 (94%)
Black	1 (3%)
Asian	1 (3%)
BMI, median (range)	25.3 (16.1-44.4)
Tobacco use	
Yes	8 (25%)
No	21 (66%)
Unknown	3 (9%)
Stage	
IA1 with LVSI	6 (19%)
IA2	10 (31%)
IB1	16 (50%)
Grade	
1	5 (16%)
2	14 (44%)
3	13 (40%)
Histology	
Adenocarcinoma	15 (47%)
Squamous	14 (44%)
Adenosquamous	1 (3%)
Other	2 (6%)
LVSI present	
Yes	13 (41%)
No	19 (59%)
Cerclage placed	
Yes	31 (97%)
No	1 (3%)
Device to prevent cervical stenosis	
Yes	31 (97%)
No	1 (3%)
Residual tumor in RT specimen	
Yes	12 (37%)
No	20 (63%)

BMI=body mass index, LVSI=lymphovascular space invasion, RT=radical trachelectomy

Table 2a
Surgical data

Surgical Variables	Open Surgical Approach (n=9)	MIS Surgical Approach (n=23)	P-value
Surgical time, median (minutes, range)	318 (234-360)	348 (246-444)	0.09
Estimated blood loss, median (mL, range)	200 (150-1100)	50 (0-400)	0.002
Length of stay, median (days, range)	4 (2-9)	1 (1-9)	0.002
Number of pelvic nodes (range)			
Left	6 (3-13)	7 (1-20)	0.62
Right	12 (11-14)	10 (3-25)	0.12
Readmission within 30 days of surgery			0.45
Yes	0 (0%)	2 (9%)	
No	9 (100%)	21 (91%)	

MIS=minimally invasive surgery

Table 2b
Surgical complication rates

	RT patients (n=32)
Intraoperative complications	
Bowel	0 (0%)
Urinary tract	1 (3%)
Vascular	1 (3%)
Postoperative complications	
Infectious complications 30 days	
Febrile morbidity	4 (11%)
Pneumonia	1 (3%)
Urinary tract infection	2 (6%)
Vaginal cellulitis	1 (3%)
Pelvic abscess	3 (9%)
Pelvic hematoma	2 (6%)
Non-infectious complications 30 days	
Lymphocyst	1 (3%)
Ureteral fistula	1 (3%)
Cerclage erosion	2 (6%)
Uterine necrosis	1 (3%)
Grade 3 anemia	3 (9%)
Non-infectious complications >30 days	
Cervical stenosis	5 (14%)
Premature ovarian failure	1 (3%)
Poor healing utero-vaginal anastomosis	2 (6%)
Cerclage erosion	7 (22%)
Hysterectomy performed	
Cancer recurrence	1 (3%)
Benign indication	2 (6%)

RT=radical trachelectomy

Table 3**Instrument results at baseline and follow-up timepoints**

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
FSFI				
Arousal	0	30	5.0 (0.0-6.0)	---
	1	6	0.0 (0.0-3.9)	0.0002
	6	18	4.8 (1.2-6.0)	0.999
	12	13	5.1 (0.0-6.0)	0.900
	24	12	3.8 (0.0-6.0)	0.897
	36	5	3.6 (0.0-6.0)	1.000
	48	4	5.9 (0.0-6.0)	0.975
	60	3	4.5 (2.1-5.1)	0.989
Desire	0	30	3.6 (1.2-6.0)	---
	1	6	2.1 (1.2-3.6)	0.178
	6	18	3.9 (1.8-6.0)	0.902
	12	13	4.2 (2.4-5.4)	0.307
	24	12	2.4 (1.2-6.0)	1.000
	36	5	2.4 (1.8-6.0)	1.000
	48	4	4.2 (3.0-4.8)	0.998
	60	3	2.4 (2.4-4.2)	0.924
Lubrication	0	30	5.7 (0.0-6.0)	---
	1	6	0.0 (0.0-4.2)	<0.0001
	6	18	5.3 (2.1-6.0)	0.568
	12	13	5.4 (0.0-6.0)	0.998
	24	12	5.1 (0.0-6.0)	1.000
	36	5	3.0 (0.0-4.2)	0.549
	48	4	5.0 (0.0-6.0)	1.000
	60	3	4.2 (2.7-5.1)	1.000
Orgasm	0	30	5.6 (0.0-6.0)	---

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
Pain	1	6	0.0 (0.0-4.4)	0.006
	6	18	4.8 (1.2-6.0)	0.868
	12	13	5.6 (0.0-6.0)	0.861
	24	12	4.2 (0.0-5.6)	0.992
	36	5	2.8 (0.0-6.0)	0.999
	48	4	5.0 (0.0-5.6)	0.999
	60	3	4.0 (3.2-5.6)	0.876
	0	30	4.4 (0.0-6.0)	---
	1	5	0.0 (0.0-0.0)	0.010
	6	18	4.8 (0.0-6.0)	0.894
Satisfaction	12	13	4.8 (0.0-6.0)	0.999
	24	12	4.8 (0.0-6.0)	0.987
	36	5	4.0 (0.0-6.0)	1.000
	48	4	5.0 (0.0-6.0)	1.000
	60	3	4.8 (4.8-5.6)	0.754
	0	30	5.2 (0.8-6.0)	---
	1	6	2.8 (0.0-4.0)	0.026
	6	18	4.4 (1.2-6.0)	0.965
	12	13	5.6 (0.8-6.0)	0.823
	24	12	3.4 (0.8-6.0)	0.895
FSFI Total	36	5	4.4 (0.8-6.0)	0.875
	48	4	5.4 (0.8-6.0)	0.732
	60	3	4.4 (1.6-6.0)	0.920
	0	30	27.5 (3.2-36.0)	---
	1	5	5.8 (3.2-19.7)	0.004
	6	18	27.2 (10.9-35.4)	0.855
	12	13	31.1 (3.2-35.0)	0.837
	24	12	21.6 (2.0-34.4)	0.969
	36	5	20.8 (3.2-32.7)	1.000
	48	4	31.0 (3.8-33.2)	1.000

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
FACT-Cx		3	26.1 (17.6-29.0)	0.985
Functional well being	0	30	21.5 (4.0-28.0)	---
	1	25	17.0 (5.0-28.0)	0.019
	6	18	27.0 (11.0-28.0)	0.582
	12	13	27.0 (20.0-28.0)	0.428
	24	12	26.5 (16.0-28.0)	0.295
	36	5	24.0 (20.0-27.0)	0.949
	48	4	24.5 (23.0-28.0)	0.846
	60	3	25.0 (24.0-28.0)	0.762
Physical status	0	30	26.0 (19.0-28.0)	---
	1	25	19.0 (1.0-28.0)	<0.0001
	6	18	26.9 (17.0-28.0)	0.995
	12	13	26.0 (23.0-28.0)	1.000
	24	12	27.0 (18.0-28.0)	1.000
	36	5	24.5 (20.0-27.0)	0.750
	48	4	21.5 (20.0-28.0)	0.573
	60	3	28.0 (25.0-28.0)	1.000
Emotional well being	0	30	16.5 (6.0-23.0)	---
	1	25	20.0 (13.0-24.0)	0.004
	6	18	20.5 (3.0-24.0)	0.007
	12	13	22.0 (17.0-24.0)	0.001
	24	12	21.0 (13.0-24.0)	0.002
	36	5	18.0 (17.0-23.0)	0.349
	48	4	22.5 (18.0-24.0)	0.032
	60	3	21.0 (20.0-21.0)	0.194
Social/family well being	0	30	22.0 (10.0-24.0)	---
	1	25	21.0 (8.0-24.0)	0.999
	6	18	21.5 (12.0-24.0)	1.000

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
FACT-Cx Total	12	13	21.0 (15.0-24.0)	0.967
	24	12	21.0 (16.0-24.0)	0.997
	36	5	20.0 (12.0-24.0)	0.845
	48	4	20.0 (12.0-22.0)	0.572
	60	3	23.0 (15.0-24.0)	1.000
MDASI	0	30	87.0 (46.0-100.0)	---
	1	25	74.0 (41.0-101.0)	0.089
	6	18	92.0 (51.0-104.0)	0.875
	12	13	93.0 (75.0-104.0)	0.641
	24	12	95.0 (63.0-103.0)	0.463
	36	5	82.0 (78.0-101.0)	1.000
	48	4	86.5 (77.0-102.0)	1.000
	60	3	96.0 (85.0-101.0)	0.954
Symptom severity Total	0	30	15.0 (0.0-74.0)	---
	1	26	22.0 (0.0-94.0)	0.800
	6	18	7.5 (0.0-57.0)	0.869
	12	13	6.0 (0.0-26.0)	0.350
	24	12	4.0 (0.0-33.0)	0.412
	36	5	17.0 (3.0-48.0)	1.000
	48	4	15.5 (0.0-22.0)	0.998
	60	3	14.0 (8.0-32.0)	1.000
Symptom distress Total	0	30	4.5 (0.0-45.0)	---
	1	26	9.0 (0.0-60.0)	0.043
	6	18	0.0 (0.0-40.0)	0.945
	12	13	0.0 (0.0-6.0)	0.523
	24	12	0.0 (0.0-22.0)	0.795
	36	5	0.0 (0.0-10.0)	0.975
	48	4	0.0 (0.0-3.0)	0.924

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
SF 12	60	3	6.0 (0.0-6.0)	1.000
Bodily pain	0	29	5.0 (2.0-5.0)	---
	1	26	3.0 (1.0-5.0)	<0.0001
	6	18	5.0 (3.0-5.0)	1.000
	12	12	5.0 (3.0-5.0)	1.000
	24	12	5.0 (3.0-5.0)	1.000
	36	4	5.0 (4.0-5.0)	1.000
	48	4	5.0 (5.0-5.0)	0.940
	60	3	5.0 (4.0-5.0)	1.000
General health	0	30	4.4 (1.0-5.0)	---
	1	26	4.4 (2.0-5.0)	0.336
	6	18	4.4 (2.0-5.0)	1.000
	12	11	3.4 (2.0-5.0)	0.779
	24	12	4.4 (3.4-5.0)	1.000
	36	4	4.2 (2.0-5.0)	0.984
	48	4	3.9 (3.4-4.4)	1.000
	60	3	4.4 (3.4-5.0)	1.000
Mental health	0	30	5.5 (3.0-7.0)	---
	1	26	5.0 (3.0-7.0)	0.739
	6	18	5.5 (3.0-6.0)	1.000
	12	13	5.0 (3.0-8.0)	1.000
	24	12	5.0 (3.0-6.0)	1.000
	36	4	6.0 (5.0-8.0)	0.446
	48	4	5.5 (4.0-8.0)	0.779
	60	3	6.0 (5.0-6.0)	0.979
Physical functioning	0	30	6.0 (2.0-6.0)	---
	1	26	3.0 (2.0-6.0)	<0.0001
	6	18	6.0 (4.0-6.0)	1.000

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
Role emotional	12	13	6.0 (3.0-6.0)	0.981
	24	12	6.0 (3.0-6.0)	1.000
	36	4	5.5 (5.0-6.0)	0.966
	48	4	6.0 (5.0-6.0)	1.000
	60	3	6.0 (6.0-6.0)	1.000
	0	30	8.5 (2.0-10.0)	---
	1	26	8.0 (2.0-10.0)	0.030
	6	18	9.0 (4.0-10.0)	0.978
	12	13	9.0 (8.0-10.0)	0.999
	24	12	10.0 (9.0-10.0)	0.734
Role physical	36	4	9.0 (6.0-10.0)	0.983
	48	4	10.0 (6.0-10.0)	1.000
	60	3	9.0 (8.0-10.0)	1.000
	0	30	10.0 (4.0-10.0)	---
	1	26	4.0 (2.0-10.0)	<0.0001
	6	18	10.0 (6.0-10.0)	0.985
	12	13	9.0 (8.0-10.0)	1.000
	24	12	10.0 (8.0-10.0)	1.000
	36	4	9.0 (8.0-10.0)	0.991
	48	4	10.0 (8.0-10.0)	1.000
Social functioning	60	3	10.0 (9.0-10.0)	1.000
	0	30	4.0 (2.0-5.0)	---
	1	26	4.0 (1.0-5.0)	0.002
	6	17	5.0 (4.0-5.0)	0.933
	12	12	5.0 (4.0-5.0)	0.963
	24	12	5.0 (4.0-5.0)	0.584
	36	4	4.5 (4.0-5.0)	1.000
	48	4	4.5 (2.0-5.0)	0.936
	60	3	4.0 (4.0-5.0)	1.000

Survey instrument	Follow-up timepoint (months)	No. of patients	Median Score (range)	P-value
Vitality	0	30	2.0 (1.0-5.0)	---
	1	26	2.0 (1.0-5.0)	0.467
	6	18	4.0 (1.0-5.0)	0.656
	12	13	4.0 (1.0-4.0)	0.940
	24	12	4.0 (2.0-5.0)	0.564
	36	4	3.0 (2.0-4.0)	1.000
	48	4	3.0 (2.0-4.0)	1.000
	60	3	4.0 (4.0-4.0)	0.573
SWD				
	0	28	29.0 (6.0-30.0)	---
	1	24	29.0 (12.0-30.0)	0.915
	6	17	30.0 (21.6-30.0)	0.999
	12	10	29.5 (22.0-30.0)	1.000
	24	12	26.5 (6.0-30.0)	0.909
	36	5	30.0 (10.8-30.0)	0.994
	48	4	29.0 (24.0-30.0)	0.971
	60	3	24.0 (6.0-30.0)	0.185

FSFI=Female Sexual Functioning Index, FACT-Cx=Functional Assessment of Cancer Therapy-Cervix, MDASI=MD Anderson Symptom Inventory, SF-12=General Health-Related Quality of Life, SWD=Satisfaction with Decision scale