Contents lists available at ScienceDirect

Gynecologic Oncology Reports

Endometrial cancer recurrence after the use of a uterine manipulator during laparoscopic surgery

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ARTICLE INFO

ABSTRACT

Objective: Minimally invasive surgery (MIS) is the standard approach for the staging and treatment of early-stage endometrial cancer (EC) and often includes use of a uterine manipulator. Uterine perforation is a known risk in this setting, and the impact of perforation and tumor spillage on cancer recurrence is largely unknown. The aim of this study was to assess the association between uterine perforation and/or tumor spillage at the time of MIS for low-grade, early-stage EC on disease recurrence.
Methods: A retrospective single-center cohort study was conducted including patients who underwent MIS for management of low-grade and early-stage EC with use of a uterine manipulator. Rates of disease recurrence were compared between patients with and without documented uterine perforation and/or tumor spillage at the time of surgery. Statistical significance was defined as $p < 0.05$.
Results: 408 patients with low-grade and early-stage EC were identified from the tumor registry and included in the study. Uterine perforation and/or tumor spillage was documented in 5.9 % (24/408) of cases. Recurrent disease was noted in 8.1 % (33/408) of the entire cohort. Most patients had isolated local recurrence (23/33; 69.7 %), while 9.1 % (3/33) had distant recurrence and 21.2 % (7/33) had both local and distant recurrence. There was no association between uterine perforation and/or tumor spillage and recurrence rates ($p = 0.67$). The trend in disease free survival was shorter among patients with these complications.
Conclusions: Our analysis did not demonstrate a statistically significant difference in disease recurrence rates among patients with early-stage, low-grade EC based on uterine perforation and/or tumor spillage at the time of surgery.

1. Introduction

Endometrial cancer (EC) is the most common gynecologic malignancy in the United States with nearly 67,000 new cases each year (Siegel et al., 2024). The majority of patients have early-stage disease with associated five-year overall survival rates greater than 90 % (Lu and Broaddus, 2020). Minimally invasive surgery (MIS), particularly laparoscopic or robotic surgery, is the standard of care for staging and treating early-stage, low-grade EC and has significant advantages including lower levels of postoperative pain and decreased length of hospital stay without detriment to cancer-related outcomes (Lu and Broaddus, 2020, Walker et al., 2009, Janda et al., 2010; Marcos-San Martín et al., 2016).

During a minimally invasive hysterectomy, a uterine manipulator is often used to enhance exposure to the surgical field and provide a landmark for colpotomy (Padilla-Iserte et al., 2021; Iavazzo and Gkegkes, 2013). Prior studies have found rates of uterine manipulator use between 42–90 % during MIS for EC (Sallee et al., 2022; Chang et al., 2021). Of surgeons utilizing uterine manipulators, up to 87 % reported experiencing a uterine perforation during their careers (Chang et al., 2021), and one study found perforation occurred in up to 11 % of cases (Sallee et al., 2023). A recent study identified the risk of uterine perforation and/or tumor spillage as the primary concern among providers electing against routine use of a uterine manipulator (Sallee et al.,

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2022).

Currently, existing data demonstrates conflicting results regarding intraoperative tumor spillage and EC outcomes. While some studies have found manipulator use to be associated with increased EC recurrence, lower recurrence-free survival, and lower overall survival (Saini et al., 2023, Padilla-Iserte et al., 2021), others have failed to find these relationships (Lee et al. 2013; Uccella et al., 2017; Tinelli et al., 2016; Marcos-San Martín et al., 2016; Iavazzo and Gkegkes, 2013). One study comparing surgical cases with and without uterine manipulator failed to identify differences in recurrence rates and survival outcomes (Lee et al., 2013). Still, the relationship between manipulator-related uterine perforation, tumor spillage, and EC recurrence remains unclear.

The primary aim of this study was to evaluate differences in recurrence rates between patients with low-grade, early-stage EC who experienced uterine perforation and/or tumor spillage during MIS and those who did not. The secondary aim was to evaluate differences in the location of EC recurrence.

2. Methods

2.1. Patient population

A retrospective cohort study was performed including patients treated at Atrium Health Wake Forest Baptist Medical Center from January 1, 2013, to December 31, 2021. Atrium Health Wake Forest Baptist Health Institutional Review Board approval was obtained (IRB #: IRB00086531). Patients were identified from the institution's Tumor Registry based on diagnosis with low-grade, early-stage EC (defined as FIGO 2018 Stage 1A, 1B, or II and histological grade 1 or 2). Individual patient charts were screened, and surgical pathology results were reviewed to determine final study eligibility. Additional inclusion criteria were patients 18 years of age or greater at the time of diagnosis, surgical management of EC with MIS (inclusive of laparoscopy and robotic-assisted laparoscopic surgery), and patients whose surgeries involved the use of a uterine manipulator. Patients with advanced-stage (FIGO 2018 stage III or IV) or high-grade disease (grade 3, papillary serous uterine carcinoma) EC were excluded.

2.2. Patient outcomes

Chart review was performed for all patients meeting inclusion criteria. Patient characteristics and demographic data were collected including: age at diagnosis, race, ethnicity, body mass index (BMI), history of prior abdominal surgery, length of surgery, documentation of uterine perforation, documentation of tumor spillage (defined as an intra-operative exposure of the peritoneal cavity to tumor cells during surgery), histologic tumor grade, FIGO stage, presence of lymphovascular space invasion (LVSI), perioperative complications, EC recurrence, and overall survival (OS). Additionally, rates of adjuvant radiation therapy, including vaginal brachytherapy (VBT) and/or whole pelvic radiotherapy, were collected. In cases of EC recurrence, data on the location of recurrence (local vs. distant) and methods of treatment were collected. Analysis of adjuvant radiotherapy treatments and treatment methods for recurrent disease were considered exploratory.

2.3. Statistics

Descriptive statistics were used to describe the demographic and clinical characteristics of the study population. Uterine perforation and tumor spillage were combined to create one variable, termed "UteSpill" for all analyses. Disease-free survival and overall survival were evaluated by using Kaplan-Meier survival estimates and Cox regression models. Disease-free survival was measured from the date of surgery to the date of first recurrence, progression, or date of death, whichever event occurred first. Overall survival was measured from the date of surgery to the date of death, when available, or the date of last contact.

Fisher's exact and Chi square tests were used for statistical analysis and statistical significance was defined as $p < 0.05$. All analyses were performed using R software (R Core Team 2021).

3. Results

A total of 408 patients with early-stage, low-grade EC managed with MIS hysterectomy were included in the analysis. Patient characteristics were similar between patients with and without EC recurrence (Table 1). The median age at diagnosis for the entire cohort was 62 years (interquartile range 14). Most patients had stage IA disease (77.6 %). There were 24 documented cases of uterine perforation and/or tumor spillage (5.9 %). Of these cases, 18 (4.41 %) had documented uterine perforation at the time of surgery, 4 (0.98 %) had documented tumor spillage, and 2 (0.49 %) had documentation of both perforation and tumor spillage at the time of surgery (Fig. 1).

Overall, 33 patients (8.1 %) experienced recurrence, including 3 in the uterine perforation/tumor spillage group (Table 2). Most recurrences were limited to the pelvis (23/33; 69.7 %), while 3/33 (9.1 %) experienced distant recurrence and 7/33 (21.2 %) were noted to have both local and distant recurrence. Among those with local recurrence, 25/30 (83.3 %) patients had recurrent disease involving the vagina, of which two had experienced uterine perforation/tumor spillage at the time of surgery. Fifteen patients had recurrent disease in the pelvis, of which one had experienced uterine perforation/tumor spillage at the time of surgery. For patients with distant recurrence, none had experienced uterine perforation/tumor spillage at the time of surgery (Fig. 2).

Adjuvant radiotherapy was prescribed in 88/408 (21.6 %) patients. Most patients received VBT (71/88; 80.7 %) and 19.3 % (17/88) received whole pelvic radiation. In total, 5/88 (5.7 %) patients receiving adjuvant radiation therapy had experienced uterine perforation/tumor spillage at the time of surgery (Table 3). There was no significant difference in radiotherapy usage based on the presence or absence of uterine perforation/tumor spillage (32 % vs. 22 %; p = 0.30). In total, 7 % of patients who received VBT experienced EC recurrence (5/71), and

Table 1

Demographics and patient characteristics for patients with low-grade, early-stage endometrial cancer treated from 2013 to 2021. Abbreviations: LVSI=lymphovascular space invasion.

| Patient Characteristics			
	No Recurrence (n = 375)	Recurrence (n = 33)	p-value
Age at Diagnosis			0.29
Mean (range)	61.0 (28–88)	63.1 (41–81)	
BMI (kg/m^2)			0.24
Mean (range)	37.2 (17.2–74.4)	35.0 (21.7–58.6)	
Race			0.26
Asian	4	0	
Native American	1	0	
Black/African American	31	6	
American	329	26	
White	7	1	
Unknown/Not reported			
Grade, no. (%)			0.25
1	231 (61.8)	17 (51.5)	
2	143 (38.2)	16 (48.5)	
Indeterminate	1 (0.3)	0 (0)	
Stage, no. (%)			0.20
IA	291 (77.6)	26 (78.8)	
IB	71 (18.9)	4 (12.1)	
II	13 (3.5)	3 (9.1)	
LVSI, no. (%)			0.14
Yes	23 (6.1)	5 (15.1)	
No	351 (93.6)	28 (84.9)	
Length of Surgery (min)			0.35
Mean (range)	206.6 (75–550)	216.7 (87–328)	
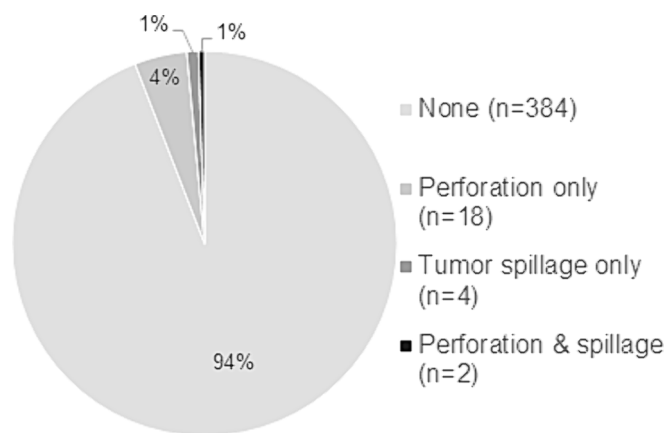
Fig. 1. Rates of intraoperative uterine perforation and/or tumor spillage.

Table 2

EC recurrence rates based on uterine perforation and/or tumor spillage (uterine perforation/tumor spillage). *UteSpill is defined as the combination of uterine perforation and/or tumor spillage.

Recurrence by Uterine Perforation and/or Tumor Spillage

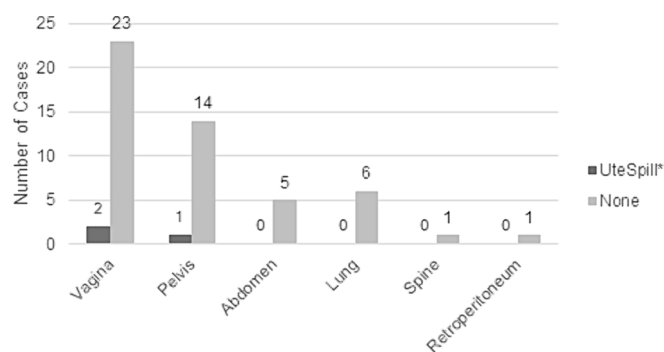|	No UteSpill*	UteSpill	Total	p-value
No Recurrence	344	31	**375**	0.67
Recurrence	30	3	**33**	
Total	**374**	**34**	**408**	

Fig. 2. Location of EC recurrence based on uterine perforation and/or tumor spillage. *UteSpill = the combination of uterine perforation and/or tumor spillage.

5.9 % of patients who received whole pelvic radiation experienced EC recurrence (1/17) (Suppl. Table 1). Treatment strategies in cases of EC recurrence included whole pelvic radiation therapy for 54.5 % (n = 18) of patients, systemic chemotherapy for 42.4 % (n = 14) of patients, and VBT for 36.4 % (n = 12) of patients. Surgery was performed for only 9.1 % (n = 3) of patients with recurrent disease.

The mean disease-free interval (DFI) for the entire cohort was 29.1 months (range 3.9–100.6, SD 23.9, hazard ratio 1.66, p = 0.40) (Fig. 3). For patients who experienced uterine perforation/tumor spillage, the mean DFI was 8.1 months (standard deviation/SD 3.4) compared to 31.2 months (SD 24.0) for patients without uterine perforation/tumor spillage at the time of surgery (p = 0.07) (Suppl. Table 2). The mean overall survival was 39.5 months (SD 25.7, hazard ratio 1.36, p = 0.67) (Fig. 3). The mean time of follow-up was 38.02 months (SD 25.67).

4. Discussion

Overall, the rate of uterine perforation/tumor spillage in our study was 5.9 %. This is lower than that of other studies investigating similar outcomes of interest (Sallee et al., 2023; Saini et al., 2023). Rates of EC recurrence were consistent with historical data, and we did not identify a significant association between uterine perforation and/or tumor spillage at time of MIS staging and risk of EC recurrence. This contrasts with the findings presented by Saini et al., which demonstrated 5.6 times increased odds of recurrence for patients with intraoperative tumor spillage (Saini et al., 2023). However, this is in line with the findings of a *meta*-analysis that found no effect of uterine manipulator use on disease recurrence (Meng et al., 2020). The majority of EC recurrences in our study were in the vagina and pelvis, which is consistent with recurrence location data from prior studies (Iavazzo and Gkegkes, 2013). Data on the collection of pelvic washings and/or cytology specimens at the time of surgery was not explored, as this has been removed from contemporary staging guidelines and is no longer standard practice at our institution.

As anticipated, based on standard practices, the use of adjuvant radiotherapy differed considerably based on stage and grade of EC (Suppl. Table 3). After controlling for patient factors including stage and grade, the use of adjuvant therapy did not differ based on the presence or absence of uterine perforation/tumor spillage at the time of surgery (Table 3). This contrasts with some existing studies (Chang et al., 2021; Sallee et al., 2023), which noted increased rates of adjuvant radiotherapy in cases of uterine perforation or tumor spillage, respectively. Given the absence of known clinical implications of uterine perforation/tumor spillage in early-stage low-risk EC patients, clinicians should avoid altering adjuvant therapy recommendations due to uterine perforation/tumor spillage alone.

Interestingly, while the difference in disease-free survival in our study did not meet statistical significance, survival was numerically lower in the cohort of patients who experienced perforation/tumor spillage (Suppl. Table 2). This finding was consistent regardless of stage and grade of EC for patients in our study (Suppl. Table 4). These findings may suggest that while uterine perforation/tumor spillage does not directly increase the risk for disease recurrence, these events may hasten the time to disease recurrence. Unfortunately, this study was underpowered to detect a statistically significant difference in EC recurrence rates. This was largely due to the low recurrence rate overall, the small difference between recurrence rates in the UteSpill and no UteSpill groups, and the limited number of patients included in the analysis. Assuming a significance level of 0.05 and utilizing a two-sided test, this

Table 3

Rates of adjuvant therapy usage based on uterine perforation and/or tumor spillage. *UteSpill is defined as the combination of uterine perforation and/or tumor spillage.

Rate of Adjuvant Therapy by Uterine Perforation and/or Tumor Spillage

UteSpill*	Adjuvant Therapy				Total	p-value
	None	Vaginal Brachytherapy	Whole Pelvic Radiation	Unknown		
No	281 (73.2 %)	65 (16.9 %)	15 (3.9 %)	23 (6.0 %)	**384**	0.44
Yes	15 (62.5 %)	5 (20.8 %)	2 (8.3 %)	2 (8.3 %)	**24**	
Total	**296**	**70**	**17**	**25**	**408**	

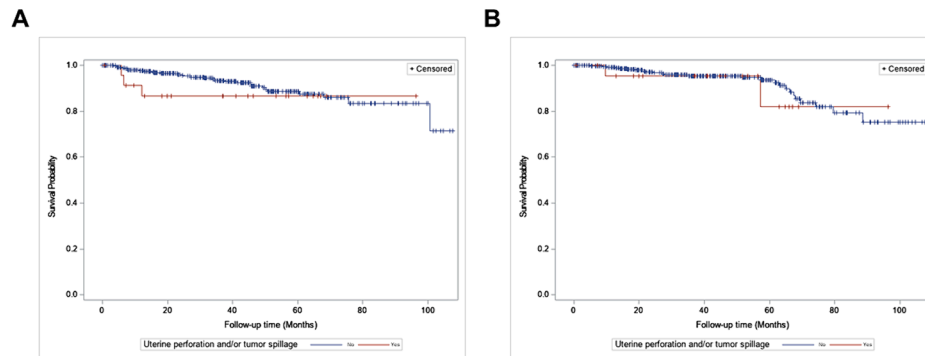A   B

Fig. 3. Kaplan-Meier survival curves based on disease free interval (A) and overall survival (B).

study would have required 79,000 patients to reach 80 % power which is not feasible for a single-center study such as ours.

Multiple theories have been proposed cautioning surgeons on uterine manipulator use (Gueli Alletti et al., 2021). These include the potential for uterine manipulators to encourage retrograde tumor dissemination through patent fallopian tubes (Lim et al., 2008) or to result in an increased incidence of LVSI (Zorzato et al., 2023; Machida et al., 2018; Tinelli et al., 2016). An additional concern is seeding the vaginal vault with cancer cells, thereby trapping cancer cells in the vaginal cuff closure (Iavazzo and Gkegkes, 2013). However, a meta-analysis by Zorzato et al. did not identify differences in peritoneal cytology before and after intrauterine manipulator insertion (Zorzato et al, 2023), and one study found uterine manipulator to be associated with positive peritoneal washing cytology in only a small proportion of patients (Lim et al, 2008). Given the low rate of EC recurrence noted in our study, a growing body of evidence exists that supports the overall safety of uterine manipulator use for low-risk EC patients.

One limitation of this study is the small number of uterine perforation/tumor spillage events and the low rate of EC recurrence. This limited the power to detect a significant difference in recurrence and survival outcomes, but our findings are nonetheless hypothesis-generating. Larger-scale retrospective or case-control studies will need to be conducted in the future to have sufficient power. Likewise, an inherent limitation to retrospective chart review is the possibility of missing cases with uterine perforation/tumor spillage that are not well documented in the electronic health record, thereby resulting in fewer events. A strength of the study is the inclusion of both uterine perforation and tumor spillage events, which are likely to share similar physiologic consequences. Another strength of the study is the mean follow-up time of greater than three years, as most recurrences of low-grade, early-stage disease occur within this time frame.

While the overall risk of disease recurrence in early-stage, low-grade EC is as low as 3 % (Padilla-Iserte et al., 2021), it is important to avoid interventions that may increase the chance of recurrence in this low-risk population. Given the disparate findings of studies assessing uterine perforation and tumor spillage on short- and long-term patient outcomes, continued analysis should be performed. Additionally, the impact of uterine perforation/tumor spillage on EC recurrence risk in higher-risk populations including patients with high-grade histology warrants investigation, as these patients are known to have an independently increased risk for disease recurrence. Finally, given our limited data on the location of EC recurrence in patients who experienced uterine perforation or tumor spillage, more inquiries are necessary to examine the impact of these complications on the location of and salvageability of EC recurrence.

CRediT authorship contribution statement

Jessica M. Souza: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing –

review & editing. **Kristen Stearns:** Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Fang-Chi Hsu:** Formal analysis, Software. **Laurel K. Berry:** Writing – review & editing. **Michael G. Kelly:** Writing – review & editing. **Janelle P. Darby:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.gore.2024.101468.

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