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ORIGINAL ARTICLE

Perioperative adverse events in women undergoing concurrent urogynecologic and gynecologic oncology surgeries for suspected malignancy

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Abstract

Introduction and hypothesis This study's objectives were to compare the incidence of adverse events after concurrent urogynecologic and gynecologic oncology surgery to gynecologic oncology surgery alone and to describe the frequency of modification in planned urogynecologic procedures. The authors hypothesized there would be no difference in major complications.

Methods This was a retrospective matched cohort study of women who underwent concurrent surgery at a large tertiary care center between January 2004 and June 2017. Cohorts were matched by surgeon, surgery route, date, and final pathologic diagnosis. Perioperative data and postoperative adverse events classified by Clavien-Dindo grade were compared.

Results One hundred and eight patients underwent concurrent surgeries, with 216 matched cohorts. Concurrent-case patients were more likely to be older, postmenopausal, have greater vaginal parity, have had preoperative chemotherapy, and have preoperative cardiac or pulmonary disease. There were no differences in intraoperative complications or Dindo grade ≥ 3 adverse events between groups, but there were more grade 2 adverse events in the concurrent cohort (44 vs 19%, $p < 0.0001$) including postoperative urinary tract infection (UTI) (26 vs 7%, $p < 0.0001$). Concurrent surgery remained associated with a higher incidence of grade ≥ 2 events on multivariate analysis [odds ratio (OR) 2.5, 95% confidence interval (CI) 1.5–4.2, $p = 0.0004$). Discharge with a urinary catheter was more frequent after concurrent cases (35 vs 2%, $p < 0.0001$). Planned urogynecologic procedures were modified in 10% ($n = 11$) of cases.

Conclusions Concurrent surgeries have an increased incidence of minor but not serious perioperative adverse events. One in ten planned urogynecologic procedures is either modified or abandoned during combined surgeries.

Keywords Pelvic floor disorder · Pelvic organ prolapse · Quality of life · Survivorship · Urinary incontinence · Gynecologic oncology

Introduction

One in four adult women in the United States has at least one pelvic floor disorder [1], and recent prevalence studies have reported potentially higher rates of pelvic floor disorders in women with a presumed gynecologic malignancy compared with those with benign gynecologic conditions [2, 3]. This is likely a result of the risk factors that gynecologic malignancies and pelvic floor disorders share, including older age and obesity [2]. For most women with suspected or confirmed pelvic organ cancer, the priority is achieving a disease-free state. However, studies have demonstrated the importance of quality of life (QoL) during the survivorship phase [4–6]. Since most gynecologic malignancies will be treated surgically, and approximately half of women with pelvic floor disorders opt for surgical treatment [7], it is reasonable to consider combining these surgeries to improve patient overall QoL. Many tertiary care centers have fellowship-trained urogynecologists and gynecologic oncologists, and concurrent surgeries are performed on a regular basis.

Major adverse events (AEs) after urogynecologic surgery are rare, and most complications are minor, including urinary tract infection (UTI) and temporary postoperative voiding

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dysfunction [8, 9]. However, a MEDLINE search using the terms urogynecology and oncology of studies published through 2017 revealed no studies addressing the risk of AEs associated with combined surgeries. Therefore, the primary objective of this study was to report the incidence of perioperative AEs in women undergoing concurrent urogynecologic and gynecologic oncology surgery and to compare the incidence of these events with those in patients who undergo gynecologic oncology surgery alone. Our hypothesis was that there would be no difference in significant AEs between groups. The secondary objective of the study was to describe the frequency of abandonment or modification of the planned urogynecologic procedure during these concurrent cases; authors predicted a low incidence of modification.

Materials and methods

This was a retrospective matched cohort study of women undergoing combined urogynecologic and gynecologic oncology surgery and gynecologic oncology surgery alone at a large tertiary referral center between January 2004 and June 2017. Institutional Review Board approval for this study was obtained. The experimental cohort was defined as patients who underwent a planned concurrent urogynecologic and gynecologic oncology surgery. These patients were then compared with a cohort of patients who underwent a gynecologic oncology surgery alone. Patients were matched using the following criteria: primary surgeon, surgery date, surgery route, and final pathologic diagnosis. While AEs vary based on route and type of surgery, an AE rate for the oncology-only cohort was assumed to be 15% based on reports after laparoscopic staging for uterine cancer; this surgery was predicted to be the most frequent type for our study population [10]. In order to detect a 15% absolute difference in incidence of AEs between groups, a 2:1 matching ratio was determined a priori to have 80% power to detect this difference, given the available number of concurrent cases at our institution.

The system-wide electronic medical record was queried to identify patients who had concurrent surgery by finding patients who had a surgery performed by urogynecology and gynecologic oncology staff surgeons on the same date. Patients were excluded if involvement of either surgical team was unplanned (i.e., an intraoperative consultation). A separate cohort of patients who underwent gynecologic oncology surgery alone was identified using the previously described matching criteria. The medical record was queried for peri- and postoperative data.

Adverse events were defined a priori and included those occurring intraoperatively, within 30 days of surgery, and death within 1 year of surgery. While UTI has previously been excluded in descriptions of urogynecology postoperative AEs [11], this was included, as it could impact postoperative oncologic care, including chemotherapy planning. The Clavien-Dindo scoring system was used to grade all peri- and postoperative AEs [12]. Significant events were defined as grade ≥2 A grade 2 complication includes need for total parenteral nutrition, transfusion, or pharmacologic treatment beyond what meets criteria for grade 1 (antiemetics, analgesics, antipyretics, electrolytes, diuretics). A grade 3 complication requires surgical, endoscopic, or radiologic intervention. A grade 4 complication is considered life threatening, and grade 5 is a patient mortality. To report the frequency of significantly changed urogynecologic procedures, the operative note was compared with the preoperative urogynecology consultation note and consent form. Significant changes included patients who did not receive any planned urogynecologic procedure and those who underwent a different procedure than planned, excluding changes due to surgical decision making (i.e., not performing a colporrhaphy after apical suspension corrected the defect). The reasons for modifying the procedure were categorized into three themes: surgical complications, technical difficulties, or oncologic planning.

The primary analysis of AEs was comparative between cohorts. Statistics were reported for all groups as % (n) for categorical variables and as mean [± standard deviation (SD) or median (range)] for continuous variables. Comparisons between cohorts were performed using the Student t test for parametric continuous outcomes, the Mann-Whitney U test for nonparametric outcomes, and a χ^2 test for all categorical outcomes; associations between outcomes were measured using Pearson correlation. All tests were two sided and considered significant at 0.05. Multivariate analysis to predict the incidence of Dindo grade ≥ 2 AEs was also performed using all statistically significant variables found on univariate analysis and reported as adjusted odds ratios (OR) with 95% confidence intervals (CI). All statistical analyses were performed using JMP® software (version 14.0) [13].

Results

Figure 1 shows the result of screening of eligible participants in accordance with Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. We identified 324 patients: 108 were scheduled for concurrent urogynecologic and gynecologic oncology cases and 216 were matched controls. Table 1 summarizes the planned urogynecologic procedures. Most planned procedures were for concurrent pelvic organ prolapse (POP) and stress urinary incontinence (SUI) (47%, $n = 50$). The most common anti-incontinence procedure planned was a transobturator midurethral sling, and the most frequently planned prolapse repair was a transvaginal native tissue colpopexy including uterosacral vaginal vault suspension ($n = 40$) and sacrospinous ligament fixation ($n = 1$). Table 2 summarizes gynecologic oncology cases and associated pathologic diagnoses. The most

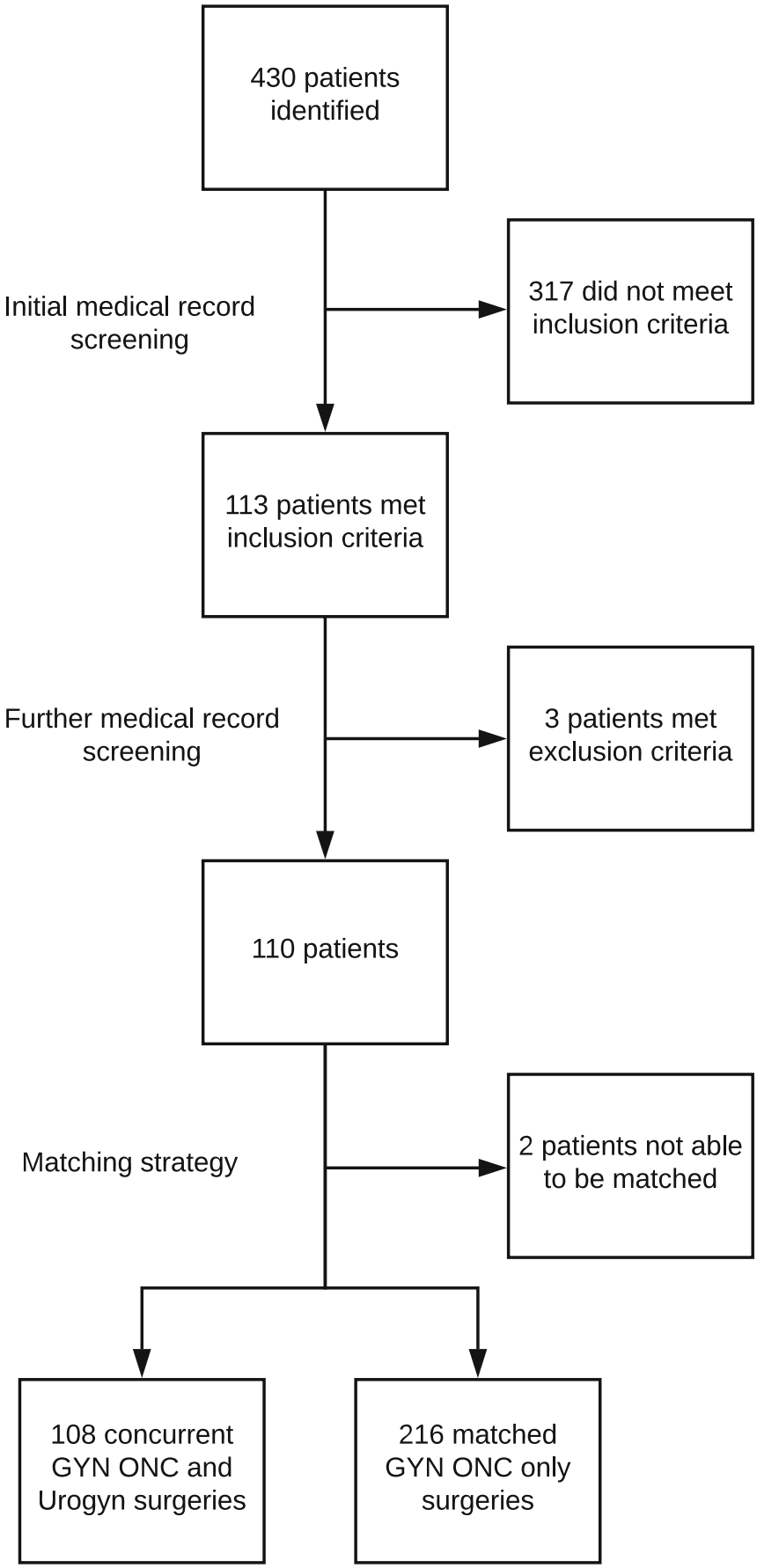

Fig. 1 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline flow diagram for patient inclusion

Table 1 Preoperative urogynecologic diagnoses and planned procedures

	Percent (*n*)
Pelvic floor disorder	
Stress urinary incontinence	76.9 (83)
Pelvic organ prolapse	79.4 (85)
Stage 1	5.9 (5)
Stage 2	42.4 (36)
Stage 3/4	51.8 (44)
Planned urogynecology procedures	
Prolapse repair	71.3 (77)
Sacrocolpopexy	23.4 (18)
Native tissue transvaginal colpopexy	53.2 (41)
Only colporrhaphy	23.4 (18)
Anti-incontinence surgery	75.0 (81)

common case type was a minimally invasive abdominal hysterectomy, and most cases resulted in benign pathology, which included endometrial hyperplasia and endometrial intraepithelial neoplasia. The most frequent oncologic diagnosis was endometrial carcinoma.

Table 3 shows characteristics for patients who did and did not undergo concurrent surgery. Patients who underwent a concurrent surgery were older (64 vs 57 years, $p = 0.004$), had higher vaginal parity (3 vs 2, $p = 0.0001$), were more likely to have had preoperative chemotherapy (9 vs 2%, $p = 0.002$), and were more likely to have had known preoperative pulmonary and cardiac comorbidities (24 vs 11%, $p = 0.002$ and 22 vs 13%, $p = 0.02$, respectively).

Table 4 shows perioperative data and primary outcome of AEs for patients who underwent concurrent surgery and for the oncology-only cohort. Median operating time for the concurrent cases was longer than for the oncology-only cases (187 vs 110 min, $p = 0.0002$). There were no differences in intraoperative complications between groups. Estimated blood loss for concurrent cases was higher although not clinically relevant (150 vs 67.5 ml, $p < 0.0001$), but patients who underwent concurrent surgery were more likely to receive a blood transfusion in the postoperative period than those who underwent gynecologic oncology surgery alone (9 vs 3%, $p = 0.02$). Concurrent cases were more likely to experience renal failure (3 vs 0%, $p = 0.01$) and postoperative pulmonary complications, such as pneumonia, pulmonary hypertension, and pulmonary edema (7 vs 2%, $p = 0.03$). However, when we controlled for baseline differences in preoperative pulmonary and cardiac comorbidities between cohorts, these findings were no longer statistically significant. Concurrent cases were also more likely to experience a postoperative ileus (6 vs 1%, $p = 0.03$), but this was no longer statistically significant when we controlled for operative time. Patients who underwent a concurrent case did not have a longer postoperative admission (2.4 vs 2.5 days, $p = 0.12$), but they were more likely to be discharged home with a transurethral Foley catheter (35 vs 2%, $p < 0.0001$). Postoperative UTI was also more common in concurrent cases (26 vs 7%, $p < 0.0001$).

Table 2 Concurrent surgery route and resultant pathology

	Percent (*n*)
Route of surgery	
Laparotomy	32.4 (35)
Minimally invasive abdominal hysterectomy	54.6 (59)
Laparoscopic surgery, no hysterectomy	5.6 (6)
Vaginal hysterectomy	0.9 (1)
Minor vaginal surgery	6.5 (7)
Final pathologic diagnosis	
Benign pathology	50.9 (55)
Uterine cancer	36.1 (39)
Ovarian cancer	12.0 (13)
Vulvar cancer	0.9 (1)

Table 5 shows the incidence of AEs graded using the Dindo classification for the concurrent and oncology-only cohorts. Dindo grade 2 complications were more common in the concurrent case cohort, and this was ascribed to the greater incidence of postoperative UTIs requiring antibiotic treatment. There was no difference in Dindo grade ≥ 3 complications between groups. After controlling for age, menopausal status, preoperative cardiac and pulmonary comorbidities, and preoperative chemotherapy, concurrent surgery cases remained associated with Dindo grade ≥ 2 events (adjusted OR 2.5, 95% CI 1.5–4.2). As >50% of patients in this cohort had benign disease, a sensitivity analysis was performed based on presence of malignancy. In confirmed cancer cases, the increased incidence of grade ≥ 2 Dindo complications in concurrent cases remained statistically significant (60 vs 23%, $p < 0.0001$) although not significant in benign cases. A sensitivity analysis was also performed on women with minimally invasive hysterectomy only and endometrial cancer only (the most frequently performed procedure and cancer type), and there remained a significantly increased risk of grade ≥ 2 Dindo AEs in the combined cases (48 vs 26%, $p = 0.003$ and 56 vs 21%, $p < 0.001$, respectively).

In 10% ($n = 11$) of concurrent cases, the planned urogynecologic surgical procedure was significantly changed intraoperatively. In five cases, this was due to an intraoperative complication. In three cases, technical difficulties resulted the change. In the remaining three cases, the urogynecologic procedure was altered or aborted as a result of a change in the oncologic care plan, including the need for postoperative radiation precluding a sling procedure. Patients whose procedure was modified were analyzed separately. These patients were more obese than those who had no change in procedure, but this was not statistically significant [body mass index

Table 3 Patient characteristics

Characteristics	All cases $N = 324$	Combined surgery cohort $N = 108$	Oncology-only cohort $N = 216$	P value
Age, median (range)	58.5 (28–93)	64 (36–93)	57 (28–90)	0.004
Body mass index, mean (±SD)	32.2 (±0.2)	31.7 (±8.12)	32.4 (±9.7)	0.84
Current tobacco use % (*n*)	9.5 (30)	10.6 (11)	8.92 (19)	0.64
Postmenopausal status % (*n*)	71.9 (233)	80.6 (87)	67.6 (146)	0.01
Vaginal parity, median (range)	2 (0–8)	3 (0–8)	2 (0–7)	0.0001
Preoperative chemotherapy % (*n*)	4.3 (14)	9.3 (10)	1.9 (4)	0.002
Preoperative radiation therapy % (*n*)	1.9 (6)	2.8 (3)	1.4 (3)	0.38
Preoperative comorbidities % (*n*)				
Cardiovascular disease	15.4 (50)	24.1 (26)	11.1 (24)	0.002
Pulmonary disease	15.7 (51)	22.2 (24)	12.5 (27)	0.02
Diabetes	17.6 (57)	20.4 (22)	16.2 (35)	0.35
Chronic kidney disease	2.8 (9)	2.8 (3)	2.8 (6)	1

SD standard deviation

(BMI) 38.2 vs 32.0 kg/m^2, $p = 0.16$). An intraoperative complication occurred in half of these changed procedures, and mean blood loss was greater than in surgeries that were not modified, but this also did not reach statistical significance (587 vs 196 ml, $p = 0.06$).

Discussion

The aim of this study was to report the incidence of perioperative AEs after concurrent urogynecologic and gynecologic oncology surgery and to compare it with the incidence after gynecologic oncology surgeries alone. We found that patients undergoing combined surgery were not more likely to experience any serious complications. Combined surgery patients, however, were more likely to experience minor AEs, such as UTI and postoperative voiding symptoms. Since completion of this study, two studies using a large national surgical database have described the safety of these combined surgeries [14, 15]. While Bretschneider et al. found more complications in combined prolapse and oncology surgery [15], Bochenska et al. found no difference in AEs [14]. Our work adds to the literature due to its matching study design to better control for confounders and to provide further detail regarding what AEs occur after combined surgeries, and it uniquely captured the frequency of aborted or modified procedures.

It is not unexpected that patients undergoing combined surgery had more postoperative UTIs and voiding symptoms, as these are higher in urogynecologic surgeries. Prior studies describing AEs related to pelvic reconstructive surgery report an incidence of UTI ranging from 9 to 31% [8]. In our study, we found an incidence of 25% in the combined cases, which is consistent with this range reported previously published data from our institution [9]. It is possible that combined surgery patients were more likely to have incidentally diagnosed UTIs compared with the gynecologic oncology-only group due to differing practice patterns for routine urinalyses after catheter use between oncology and urogynecology teams. However, it is also likely that prolonged catheterization itself (more frequent in urogynecologic surgery) was the predisposing factor for the high incidence of postoperative UTI in this cohort. The difference in incidence in urinary retention between groups is likely confounded by different practices between urogynecology and oncology practices at our institution regarding postoperative voiding trials; routine care of urogynecology patients at our institution involves a retrograde-filled voiding trial with a strict cutoff for retention, while gynecologic oncology patients are only required to void after catheter removal. Patients undergoing combined surgery should be counseled about the risk of UTI and urinary retention and should be given precautions about voiding symptoms and, if possible, preoperatively taught how to perform intermittent self-catheterization.

We also found that one in ten surgeries had a modification of the planned urogynecologic procedure. This change in care plan was decided intraoperatively and was dependent on the outcome of or a change in care plan of the primary oncologic surgery. This has important implications for the preoperative discussion. Before a combined surgery is performed, patients should be counseled that they may not receive the planned urogynecologic portion of the surgery and that surgeons will use their clinical judgment at the time of surgery to make this decision. This type of counseling may avert potential patient dissatisfaction associated with not receiving the anticipated reconstructive or anti-incontinence procedure. Based on our findings, this counseling is most relevant for cases performed for a high suspicion of cancer requiring postoperative

Table 4 Perioperative adverse events

Adverse events	All cases $N = 324$	Combined surgery $N = 108$	Oncology only surgery $N = 216$	*P* value
Intraoperative complication % (*n*)	10.4 (33)	12.1 (13)	9.5 (20)	0.46
Cystotomy	2.8 (9)	2.8 (3)	2.8 (6)	1
Ureteral injury	0.3 (1)	0 (0)	0.5 (1)	0.18
Bowel injury	2.2 (7)	3.7 (4)	1.4 (3)	0.18
Vascular injury	0.3 (1)	0.9 (1)	0 (0)	0.16
Estimated blood loss ≥500 ml	8.0 (26)	7.4 (8)	8.3 (18)	0.77
Transfusion	3.4 (11)	3.7 (4)	3.2 (7)	0.83
Operating time, median (range) min	122.5 (4–570)	186.5 (37–474)	110 (4–570)	0.0002
Blood loss, median (range) ml	100 (0–3400)	150 (10–2000)	67.5 (0–3400)	<0.0001*
Length of admission, mean (SD), days	2.5 (3.5)	2.4 (2.2)	2.5 (4.0)	0.12
Discharge with catheter % (*n*)	13.0 (40)	34.6 (37)	1.49 (3)	<0.0001
Postoperative complication % (*n*)	38.3 (124)	55.6 (60)	29.6 (64)	0.46
Death within 1 year	2.8 (9)	1.9 (2)	3.2 (7)	0.47
Reoperation within 30 days	2.5 (8)	0.9 (1)	3.2 (7)	0.21
Readmission within 30 days	5.6 (18)	6.5 (7)	5.1 (11)	0.61
Transfusion	5.3 (17)	9.3 (10)	3.2 (7)	0.02*
Pulmonary complication	3.4 (11)	6.5 (7)	1.9 (4)	0.03*
Cardiac complication	1.5 (5)	2.8 (3)	0.9 (2)	0.20
Surgical-site infection	10.2 (33)	10.2 (11)	10.2 (22)	1
Hematoma	0.6 (2)	0 (0)	0.9 (2)	0.32
Neurologic injury	0.6 (2)	0.9 (1)	0.5 (1)	0.62
Venous thromboembolism	1.9 (6)	2.8 (3)	1.4 (3)	0.38
Radiology (excluding staging)	11.4 (37)	15.7 (17)	9.3 (20)	0.08
Enterotomy/perforation	0.3 (1)	0	0.5 (1)	0.48
Small bowel obstruction	0.3 (1)	0	0.5 (1)	0.48
Postoperative Ileus	2.8 (9)	5.6 (6)	1.4 (3)	0.03*
Lower urinary tract injury	0.9 (3)	0	1.4 (3)	0.22
Renal failure	0.9 (3)	2.8 (3)	0	0.01*
Urinary tract infection	13.6 (44)	25.9 (28)	7.4 (16)	<0.0001
Emergency room evaluation	1.9 (6)	0.9 (1)	(5)	0.38
Urinary retention	0.6 (2)	1.9 (2)	0	0.04
Mesh erosion	0.3 (1)	0.9 (1)	–	–
Intensive care unit admission	1.5 (5)	0.9 (1)	1.9 (4)	0.52
Sepsis/bacteremia	0.3 (1)	0.9 (1)	0	0.16

SD standard deviation

*Not statistically significant on multivariate analysis

Table 5 Comparison of postoperative complications by Clavien-Dindo grade

Complication grade, % (*n*)	All cases $N = 324$	Combined surgery $N = 108$	Oncology only $N = 216$	*P* value
Grade 1	1.2 (4)	0.9 (1)	1.4 (3)	0.72
Grade 2	27.5 (89)	43.5 (47)	19.4 (42)	<0.0001
Grade 3	17.0 (55)	22.2 (24)	14.4 (31)	0.08
Grade 4	2.5 (8)	2.8 (3)	2.3 (5)	0.80
Grade 5	2.8 (09)	1.9 (2)	3.2 (7)	0.47

radiation therapy or when there is an increased risk of associated surgical complications.

While we believe this matched cohort study design is robust, there are some inherent limitations. First, many patients had benign pathology despite undergoing surgery for suspected malignancy, which means that we did not look only at patients undergoing combined surgery with known preoperative cancer diagnoses. However, pathologic diagnoses are often unknown during surgical planning, and as a result, inclusion of these patients makes our findings more applicable to real clinical decision making. As this study spans >13 years, practice patterns for urogynecology and oncology surgery have evolved, including a preference toward minimally invasive surgery; however, this effect should have been minimized with cohorts matched by surgical date and route. Finally, while this study is underpowered to report on specific AEs, the summative comparison based on Dindo classification is a widely accepted evaluation of postoperative complications. To mitigate the limitations inherent in a retrospective chart review, including inter- and intrarater reliability, we used a standardized electronic abstraction form with a priori definitions of AEs, and data were collected by only two individuals and crosschecked for accuracy in the electronic medical record.

The study's findings provide meaningful information for surgeons and patients who are considering a combined urogynecologic and gynecologic oncologic surgery. Overall, combined surgery does not seem to pose a higher risk for serious AEs compared with performing the oncologic surgery alone. To improve patients' postoperative QoL and minimize multiple episodes of anesthesia and hospitalization, it is reasonable to consider planning concurrent surgery for pelvic floor disorders and suspected gynecologic malignancy. It remains important to counsel patients about their increased risk of postoperative UTI and voiding symptoms, which are inherent to all urogynecologic surgeries, and to inform them of the 10% chance that their preoperative urogynecologic plan may change intraoperatively.

Compliance with ethical standards

Conflicts of interest The authors declare that they have no direct conflicts of interest for this work. Dr. Ferrando is an author for and receives royalties from UpToDate® and has unrestricted research grants from Coloplast and Caldera.

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