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Gastrointestinal Complications Following Abdominal Sacrocolpopexy for Advanced Pelvic Organ Prolapse

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Abstract

OBJECTIVES—The aims of this secondary analysis of the “Colpopexy And Urinary Reduction Efforts” (CARE) study were to estimate the incidence of post-operative gastrointestinal complications and identify risk factors.

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STUDY DESIGN—We prospectively identified gastrointestinal complications and serious adverse events (SAE) for 12 months after sacrocolpopexy. Two surgeons independently reviewed reports of ileus or small bowel obstruction (SBO).

RESULTS—Eighteen percent of 322 women (average age 61.3 years) reported "nausea, emesis, bloating, or ileus" during hospitalization and 9.8% at 6 weeks. Nineteen women (5.9%; CI 3.8%, 9.1%) had a possible ileus or SBO that generated SAE reports: four (1.2%, CI 0.5%,3.2%) were re-operated for SBO, 11 (3.4%, CI 1.9%,6.1%) were readmitted for medical management, and four had a prolonged initial hospitalization. Older age ($p<0.001$) was a risk factor for ileus or SBO.

CONCLUSIONS—One in twenty women experiences significant gastrointestinal morbidity after sacrocolpopexy. This information will aid pre-operative counseling.

Keywords

Ileus; Small bowel obstruction; Nausea; Sacrocolpopexy

Introduction

Abdominal sacrocolpopexy is an effective procedure commonly performed for apical pelvic organ prolapse. As other procedures and surgical approaches are also recommended for treating apical prolapse,[1] it is important to understand complications in addition to efficacy when selecting the best procedure or procedures for an individual patient.

A recent review of the published literature on abdominal sacrocolpopexy included a summary of reported intraoperative and postoperative complications.2 Among the complications occurring in more than 1% of patients were gastrointestinal complications, including postoperative ileus in a median 3.6% (range 1.1% to 9.3%) of patients and re-operation for small bowel obstruction (SBO) in a median 1.1% (range 0.6% to 8.6%). Most of the studies identified in this review were small and data were generally collected retrospectively. Little is known about risk factors for gastrointestinal complications following abdominal sacrocolpopexy. The Colpopexy And Urinary Reduction Efforts (CARE) study,[3] a randomized trial of Burch colposuspension to prevent urinary incontinence vs. no colposuspension in patients undergoing abdominal sacrocolpopexy for pelvic organ prolapse, provides an opportunity to study postoperative complications using prospectively collected data in a large series of surgeries from multiple sites and multiple surgeons. The objectives of this study were to (1) describe the occurrence of postoperative gastrointestinal complications after sacrocolpopexy, including ileus, SBO, and nausea and vomiting, and (2) identify potential risk factors for ileus and SBO.

Materials and Methods

This study analyzes data collected from the 322 subjects who were enrolled in the CARE trial from March 7, 2002 to February 7, 2005. The methods and primary outcomes of the CARE trial have previously been reported.[3;4] While aspects of the surgical technique were standardized (3), we did not standardize peri-operative bowel care, i.e., bowel preparations, diet, or post-operative bowel regimens. The study was conducted by the Pelvic Floor Disorders Network, a cooperative agreement network sponsored by the National Institute of Child Health and Human Development (NICHD).

Adverse events (AEs), defined as untoward medical occurrences during the clinical trial, were recorded according to Food and Drug Administration regulations. Adverse events can be expected (consistent with current standard of care or the risk information provided during informed consent) or unexpected. A serious adverse event (SAE) was defined as an

untoward medical occurrence that was life threatening or resulted in death; required unplanned hospitalization or prolonged hospitalization for the index surgery; resulted in persistent or significant disability or incapacity; or necessitated an unplanned additional procedure not specified by the study protocol. SAEs were reported to the data coordinating center's Safety Monitor, the NICHD Project Scientist, and the local Institutional Review Board. AEs were included with the monthly reports to the data coordinating center. The Data and Safety Monitoring Board (DSMB) for the Pelvic Floor Disorders Network received notification of each SAE on a continuing basis and reviewed all adverse events (SAE and AE) during regularly scheduled meetings. In addition, DSMB meetings could be convened on an expedited basis, if necessary, for any SAEs. A case report form with a full description of the event was required for all SAEs and unexpected AEs.

Surgeons provided data about intra-operative complications immediately following the surgery. Other gastrointestinal complications (besides ileus and SBO) were recorded at the time of hospital discharge and at the 6 week follow-up appointment. At those times, research nurses reviewed the medical record to identify the occurrence of (1) intestinal, rectal, or bowel injury; (2) hepatitis, jaundice, or liver failure; or (3) gastrointestinal bleeding; and (4) they queried each subject about symptoms of nausea, emesis, bloating, or ileus. A positive response to any of the first 3 questions required an AE report but symptoms of "nausea, emesis, bloating, or ileus" did not because nausea, emesis, and bloating were expected adverse events.

To evaluate the frequency of ileus and SBO, we first identified all SAEs and AEs that listed ileus or SBO either as a diagnosis or a possible diagnosis. The full SAE and AE reports for these events were reviewed by two surgeon investigators independently and masked to treatment assignment, in order to classify the event as ileus, SBO, or indeterminate; and to characterize the management and outcome of the event. Disagreements were subsequently resolved by discussion between the two raters. We recorded length of index hospital stay, management of complication including duration of any readmission, and elapsed time from the original surgery to diagnosis of the SAE. Based on this information, these events were categorized into one of three management categories: re-operation, readmission for medical management, and prolongation of initial hospitalization.

To assess possible risk factors associated with ileus or SBO, we used baseline demographic and medical history variables as well as data collected from the index operation. The Cumulative Illness Rating Scale for Geriatric Patients (CISR-G),[5] with minor adaptations, was used to estimate comorbidity, i.e., the total burden of illness. The CISR-G lists common illnesses, categorized into 14 organ systems, and assigns severity weightings to the illnesses that are present. A severity weight of 1 is reflects mild severity, 2 is used for moderate severity requiring treatment, 3 is for severe or constant disability, and 4 is for an extremely severe or urgent clinical problem. The total score is the sum of severity ratings in the 14 organ systems. It is a valid predictor of mortality6 and morbidity.5

Statistical analysis

For analysis of risk factors, ileus and SBO reports were combined because (1) it was judged not possible to reliably distinguish between these two categories of events unless re-operation was required; and (2) there were few events overall to assess risk factors. We assessed other gastrointestinal complications; however, we did not attempt to assess risk factors for these other gastrointestinal complications because there were no events other than nausea, emesis, bloating, and ileus reported. It was not possible to disaggregate nausea, emesis, bloating, and ileus because they were asked together, although they may have different causes and different clinical implications. Chi-square analysis was used for categorical variables (presented as proportions), Mann-Whitney was used for skewed data

(presented as medians and interquartile ranges), and student t-test for continuous variables (presented as mean ± standard deviation [SD]). Body mass index (BMI) in kg/m^2 was defined by categories: normal (<25), overweight (25.0–29.9) and obese (≥30). Logistic regression was used to evaluate the association of risk factors with the outcome of having ileus or SBO. We regarded the analysis of risk factors as exploratory because the small number of events limited statistical power. It should be noted that since there were only 19 subjects with ileus or SBO, there would have to be an expected difference of 2/3 of a standard deviation between the group means of continuous measures to have 80% power to identify a difference between subjects with vs. those without this adverse event. Similarly, for dichotomous measures, there would have to be an expected absolute difference greater than 0.25 in rates if the rate in the sample without an adverse event was 0.10 or larger.

Institutional Review Board

The Institutional Review Board (IRB) at each clinical site and at the data coordinating center approved this trial and informed consent was obtained from each subject.

Results

Demographics

The 322 women who participated in the study averaged 61.3 ± 10.2 (mean ± SD) years of age, with mean BMI of 27.0 ± 4.5 kg/m^2. The majority were overweight (243, 75.5%) or obese (74, 23.0%), with only 5 subjects (1.5%) of normal weight. Race was reported as Caucasian by 299 (92.9%), African American by 17 (5.3%), and “Other” by 6 (1.8%). Ethnicity was listed as Hispanic by 9 (2.8%). One hundred seventy (52.8%) had attended college, and 239 (74.7%) were married or living as married. The median number of births was 3 (range 1–11). Twelve months of follow-up had been completed in 304/322 (94.4%) of subjects at the time of this report.

Rates of ileus and SBO

Nineteen patients (5.9% of operations; 95% CI 3.8%, 9.1%) were identified on SAE or AE reports as having, or suspected of having, ileus or SBO. Table 1 lists these 19 cases and reports the results of the independent review of these events by two surgeons. Based on their review, the events were classified by management categories and probable clinical diagnoses. Four patients (1.2%; 95% CI 0.5%, 3.2%) required re-operation (cases 1–4 in Table I). All four had small bowel entrapment in or adhesion to the abdominal wall incision. One of the four (case 3 in Table 1) had sacrocolpopexy performed through a midline vertical incision and three through a low transverse incision. All four patients requiring re-operation were judged to have SBO.

Eleven patients (3.4%; 95% CI 1.9%, 6.1%) required readmission to the hospital for management (Table I), and two others (0.6%) required prolonged initial hospitalization (lengths of stay for these two cases were 9 and 12 days). Surgeon reviewers classified 7 of these 13 subjects as having ileus, two as SBO, and two as indeterminate for either ileus or SBO. One patient was readmitted for nausea related to medication, and one for fecal impaction. The median time from operation to presentation of these adverse events was 5 days (range 2 to 193 days). The last two cases (numbers 18 and 19 in Table I) were initially reported as SAEs because of delayed hospital discharge. However, both were discharged on postoperative day 4 (i.e., without significant delay), and the surgeon reviewers judged both to have slow return of bowel function, not ileus or SBO.

Based on the review of adverse event reports by two surgeons, 6/322 patients were categorized as definite SBO and 2 others were judged indeterminate, with features of both

SBO and ileus. The surgeon reviewers concluded that 7/322 patients had definite ileus. Thus, the rate of SBO was estimated to be 1.9% to 2.5%, and the rate of ileus was estimated to be 2.2% to 2.8%.

Nausea, emesis, bloating, or ileus

Positive responses were obtained from 58/322 women (18.0%; 95% CI 14.2%, 22.7%) at hospital discharge, and from 31/316 (9.8%; 95% CI 7.0%, 13.7%) at 6 weeks follow-up. (Data for 6 subjects were missing at 6 weeks.) Only 7 of 58 women (12.1%) with these symptoms at hospital discharge had them at 6 weeks follow-up; conversely, 24 of 31 with these symptoms at 6 weeks did not have them during their index hospital stay (Chi square = 1.8, p=0.42).

Other gastrointestinal complications

No subject (0/316; 95% CI 0, 1%) experienced intestinal, rectal, or bowel damage during surgery (data missing for 6); hepatitis, jaundice, or liver failure (data missing for 1); or gastrointestinal bleeding during the hospital stay (data missing for 1 patient), or at the 6 week follow-up (data missing for 6).

Risk Factors for Ileus or SBO

Table II lists characteristics investigated as possible risk factors for ileus or SBO. Only age showed a significant association with ileus or SBO. However, prior abdominal surgery (p=. 054) showed possible associations. None of the surgical procedure variables investigated (Table III) showed a significant association with ileus or SBO.

Comment

The most important findings of this analysis are the quantification of gastrointestinal adverse events collected prospectively and judged independently. For women in the CARE trial[3;4], the incidence of gastrointestinal complications reported as SAEs resulting in re-operation, prolonged hospitalization or readmission was 19/322 or 5.9% within one year after abdominal sacrocolpopexy (95% CI 3.8%, 9.1%). The rate of occurrence of SBO in our series was 1.9% to 2.5%, and the rate of ileus was 2.2% to 2.8%. By comparison, Nygaard and colleagues reviewed published reports from other surgeons performing sacrocolpopexy and found a median rate for SBO requiring re-operation that was 1.1% (range, 0.6% to 8.6%) and a median rate for ileus of 3.6% (range, 1.1% to 9.3%). The rates for SBO and ileus observed in our prospectively followed population were well within the range of these other published series.

We suggest it may be more useful to categorize postoperative gastrointestinal adverse events into management categories – re-operation vs. prolonged hospitalization or readmission for medical management – rather than SBO vs. ileus because: (1) the differentiation between ileus and SBO in the immediate postoperative period is difficult and possibly unreliable, and (2) the likelihood of these outcomes (management categories) provides a more meaningful basis for counseling patients about the risks of the operation. This approach may also provide third party payers with a better basis for estimating costs. In our study, 4/322 patients (1.2%; 95% CI 0.5%, 3.2%) required re-operation within one year, 11/322 patients (3.4%; 95% CI 1.9%, 6.1%) required readmission to the hospital for medical management, and 2 others (0.6%) required prolonged initial hospitalization.

Our data are based on one year of follow up after abdominal sacrocolpopexy and may underestimate the long term risk of SBO requiring re-operation. The most common cause of SBO is the occurrence of intra-abdominal adhesions.7 In one series of 262 patients with

SBO,[8] the median interval between surgery and development of SBO was 5.3 years (range, 1 month to more than 20 years). For the 6 cases of SBO in our study, the median interval from surgery to presentation was 11 days (range, 5 to 159 days). We will continue to assess the incidence of SBO remote from surgery in our subjects.

Nausea, vomiting and bloating are commonly experienced after all surgical procedures, ranging from 20% to 30% after balanced general anesthesia9. Women may be more likely to have these symptoms.[10] In our study, nausea, emesis, bloating, or ileus were reported by 18% of subjects undergoing sacrocolpopexy during their initial hospital admission and in 9.8% at their 6 week return visit (including 7.5% who had not reported these symptoms during their hospital stay). The symptoms of nausea, emesis, and bloating are common in population-based samples; 11.9% report nausea, 3.4% report vomiting, and 12.9% report bloating within the last month[11]. Thus, the rate of new-onset symptoms in our study reported 6 weeks following the index surgery are unlikely to reflect delayed reactions to abdominal sacrocolpopexy. Though unpleasant, these gastrointestinal symptoms rarely resulted in prolongation of hospitalization, readmission or intervention with medicine or surgery. However, given the large number of patients with these unpleasant symptoms, further attention is merited to determine whether peri-operative interventions such as pre-operative bowel preparation and post-operative bowel regiments influence such gastrointestinal symptoms.

We did not observe other gastrointestinal adverse events including injuries to the intestines or rectum during surgery, gastrointestinal bleeding, hepatitis, jaundice, or liver failure. Thus, patients considering open sacrocolpopexy can be reassured that these events are highly unlikely.

Technical aspects of surgery and patient characteristics other than age did not appear to contribute much, if at all, to the risk of ileus and SBO. Although age was found to be an independent risk factor for ileus or SBO, this association is not unique to abdominal sacrocolpopexy; advanced age is associated with a higher rate of surgical complications for other procedures including bariatric surgery[12] and cardiac surgery[13]. Ileus or SBO may be related to prior abdominal surgery. This association was not statistically significant, but in view of the small number of adverse events, statistical power was limited. Lack of a statistically significant association should not be construed to mean the lack of a potential clinically significant association. These associations warrant further investigation in studies with more subjects or with high-risk study populations who are expected to experience more gastrointestinal complications.

Study limitations

Our estimates of the magnitude of risk for gastrointestinal complications may be impacted by the methods used to collect gastrointestinal complication data. At discharge, research staff extracted data regarding the incidence of nausea, emesis and bloating from the hospital progress notes, and the data may be influenced by their subjective understanding of what constitutes “normal or expected” degrees of post-operative nausea and emesis. At the 6 week follow-up visit, research staff specifically queried women about gastrointestinal symptoms using a standardized format. In addition, “Adverse Event” reports were completed at follow-up research visits or at any time an adverse event came to the attention of the site investigator. While our data may therefore underestimate the true incidence of immediate postoperative gastrointestinal symptoms, we believe they accurately record concrete events such as readmissions and re-operations. Future trials would benefit from standardized, a priori guidelines for defining adverse events, including the expected duration of uncomplicated postoperative nausea and vomiting.

Additional limitations included the following: (1) Preoperative bowel preparation and perioperative bowel care was not standardized; this may have impacted the frequency of symptoms such as nausea, emesis, and bloating but is unlikely to have affected reports of ileus or SBO. (2) Only 1.5% of our subjects were of normal weight; the rest were overweight (75.5%) or obese (23.0%). We believe this reflects the fact that obestity is a risk factor for pelvic organ prolapse[14].

Our report suggests that the number of serious adverse gastrointestinal events that result in prolongation of hospital stay, rehospitalization or re-operation is within the range of other gynecologic procedures by laparotomy.[15] The enhanced risk associated with age and possibly with prior laparotomy provides surgeons with data for counseling their patients about sacrocolpopexy and other approaches to prolapse repair. At 12 months following the operation, the primary indication for re-operation was small bowel entrapment in the ventral incision. Awareness of this potentially modifiable serious risk inspires further exploration of surgical technique.

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Table I

Severe Adverse Event Reports for Possible Ileus and Small Bowel Obstruction

Case Number	Management Category Based on SAE Report	Postoperative Days to SAE Onset* (days)	Duration of Initial Hospitalization (days)	Duration of Readmission (days)	Reviewers Comments
1	Re-operation	5	3	7	SBO Treatment: Exploratory laparotomy on postoperative day 8. Procedure: Lysis of adhesions, freeing small bowel incarcerated between rectus muscles. (abdominal wall fascia intact)
2	Re-operation	10	2	11	SBO Treatment: Exploratory laparotomy on postoperative day 15. Procedure: Small bowel resection and hernia repair for small bowel incarcerated in abdominal wall fascial closure.
3	Re-operation	12	5	5	SBO Treatment: Exploratory laparotomy on postoperative day 12. Procedure: Lysis of adhesions, freeing small bowel adherent to fascia under abdominal incision.
4	Re-operation	159	2	10	SBO Treatment: Exploratory laparotomy on postoperative day 161. Procedure: Small bowel resection for small bowel herniated through fascial incision.
5	Readmission	3	2	3	Ileus Treatment: no oral intake
6	Readmission	3	2	3	Ileus Treatment: no oral intake, nasogastric tube drainage
7	Readmission	4	3	3	Ileus vs. Partial SBO Treatment: no oral intake; Abdominal radiographs suggest partial SBO
8	Readmission	4	3	13	Ileus and Clostridium dificile colitis Treatment: no oral intake, nasogastric tube drainage, antibiotics
9	Readmission	5	3	2	Nausea related to medications Treatment: no oral intake
10	Readmission	6	4	4	Ileus Treatment: no oral intake
11	Readmission	6	3	2 and 6	SBO Admission to local hospital followed by transfer to PFDN clinical site; Treatment: no oral intake, nasogastric tube drainage; CT scan shows SBO with “transition point” in mid-ileum
12	Readmission	7	2	3	Ileus Treatment: no oral intake
13	Readmission	9	3	5	Ileus Treatment: no oral intake

Case Number	Management Category Based on SAE Report	Postoperative Days to SAE Onset* (days)	Duration of Initial Hospitalization (days)	Duration of Readmission (days)	Reviewers Comments
14	Readmission	19	3	5 and 4	Probable intermittent SBO Two readmissions (POD 19 and 41); 1st: treatment: no oral intake; 2nd: treatment: no oral intake, nasogastric tube drainage
15	Readmission	193	3	3	Fecal impaction Treatment: no oral intake, laxatives
16	Prolonged initial hospitalization	2	9	--	Ileus Treatment: no oral intake, nasogastric tube drainage
17	Prolonged initial hospitalization	4	12	--	Ileus vs. Partial SBO Treatment: no oral intake, nasogastric tube drainage, total parenteral nutrition; Abdominal radiographs suggest partial SBO
18	Prolonged initial hospitalization	3	4	--	Slow return of bowel function Treatment: slow advancement of diet; passed flatus POD 3, bowel movement POD 4
19	Prolonged initial hospitalization	3	4	--	Slow return of bowel function Treatment: no oral intake, laxative, antiemetics, antibiotic; Discharge home delayed by 1 day because of nausea, vomiting and low-grade fever.

* Not counting the day of operation

SAE- Severe adverse event

SBO- Small bowel obstruction

POD- Postoperative day

PFDN- Pelvic Floor Disorder Network

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Table II

Subject Characteristics Evaluated as Possible Risk Factors for Ileus or Small Bowel Obstruction

Variables Tested	Ileus or SBO		# P-value
	Yes N=19	No N=303	p-value
Age, years (mean ± SD)	70.6 ± 5.5	60.8 ± 10.2	<0.0001
BMI, kg/m^2 (mean ± SD)	26.6 ± 4.5	27.1 ± 4.5	0.68
Prescription Medications (Median, Interquartile Range)	4 (2 – 5)	3 (2 – 5)	0.78
Prior Abdominal Surgery	19 (100%)	247 (82%)	0.054
Comorbidity Index*	5.0 ± 3.3	3.9 ± 3.0	0.09
Current Smoker	2 (10.5%)	21 (7.0%)	0.64

SD = Standard Deviation

BMI = Body Mass Index

#Student t-test were used for continuous variables (e.g., age, BMI, comorbidity index), Mann-Whitney test was used for skewed data (e.g., for number of medications), and Chi-square analysis was used for categorical variables (e.g., prior abdominal surgery, current smoker).

*Comorbidity Index: the total score is the sum of severity ratings 1 to 4 (mild to very severe) in each of 14 organ-specific categories.

Table III

Procedure Variables Evaluated as Possible Risk Factors for Ileus or Small Bowel Obstruction

Variables Tested	Ileus or SBO	Without Ileus or SBO	# P-value
Duration of Surgery (minutes) (mean ± SD)	176 ± 65	180 ± 58	0.78
Estimated Blood Loss (ml) (mean ± SD)	230 ± 155	228 ± 198	0.96
Vertical Orientation of Incision (N, %)	5 (26.3%)	45 (14.9%)	0.19
Peritoneal Closure over Graft (N, %)	11 (57.9%)	228 (75.3%)	0.11
Graft Type: (N, %)			NS
Synthetic	17 (89.5%)	250 (82.8%)	
Cadavaric	1 (5.3%)	25 (8.3%)	
Other	1 (5.3%)	27 (8.9%)	
Culdoplasty (N, %)	5 (26.4%)	106 (35.1%)	0.62
Burch (N, %)	11 (57.9%)	146 (48.2%)	0.48

SD = Standard Deviation

Student t-tests were used for continuous variables (e.g., duration of surgery, blood loss), and Chi-square analysis was used for categorical variables (e.g., proportion with vertical orientation of incision, peritoneal closure, different graft types, culdoplasty, and burch procedure).