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Outcomes in Pelvic Organ Prolapse Surgery in Women Using Chronic Antithrombotic Therapy

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Abstract

Introduction—Chronic antithrombotic therapy is common among patients requiring surgery for pelvic organ prolapse because of age and comorbidities. The impact of chronic anticoagulation on postoperative complications in pelvic organ prolapse surgery has not been investigated. This study aims to determine if patients on chronic antithrombotic therapy are at increased risk for postoperative complications.

Methods—This retrospective cohort study included women having prolapse surgery from 2012 to 2015, identified by Current Procedural Terminology codes, excluding patients undergoing concomitant major nonurogynecologic procedures. Baseline characteristics were compared and all procedures performed, operative duration, estimated blood loss, and length of hospitalization. Complications (blood transfusion, intensive care unit admission, reoperation, readmission, hematoma, thromboembolic event, and infection) were compared in women on chronic antithrombotic therapy and controls. Logistic regression determined odds ratio (OR) for complications in patients on chronic antithrombotics. Complications were graded by the Clavien-Dindo classification.

Results—A total of 388 charts were reviewed, and 386 patients met inclusion criteria. Twenty-one of the 386 patients were on chronic anti-thrombotic therapy. Chronic antithrombotic therapy increased overall complications (OR, 6.8; $P < 0.0005$), blood transfusion (OR, 165; $P < 0.001$), intensive care unit admission (OR, 19.10; $P < 0.004$), hospital readmission (OR, 20.7; $P < 0.0005$), vaginal hematoma (OR, 554.1; $P < 0.001$), infection (OR, 22.44; $P < 0.004$), and complications that required specific additional follow-up (OR, 9.42; $P < 0.0005$). There were no thromboembolic events. Antithrombotic therapy did not significantly increase reoperation rates (OR, 3.8; $P = 0.275$). Findings were maintained when adjusting for covariates of age and body mass index.

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Conclusions—Postoperative surgical complications after prolapse repair procedures are increased in patients who use chronic antithrombotic medication, the majority of cases are successfully managed conservatively.

Keywords

pelvic organ prolapse; postoperative complications; antithrombotic therapy

Pelvic organ prolapse (POP) has a negative impact on the quality of life for many women. With increasing awareness of pelvic floor disorders, surgeries for female pelvic prolapse are projected to increase by 45% over the next 30 years.¹ The incidence of prolapse increases with each decade of a woman's life, and by the eighth decade, it is estimated that 12% of women will have a procedure for POP.²

In addition to being a risk factor for POP, advanced age is a risk factor for venous thromboembolism (VTE) and pulmonary embolism.^{2–4} Women of advanced age are more likely to have co-morbidities, such as atrial fibrillation, coronary disease requiring stent placement, and history of stroke or VTE, which require chronic antithrombotic therapy.⁴ Because of advanced age and many reconstructive procedures being longer in duration, many women undergoing surgery for POP are categorized as high risk for VTE.⁵

These patients may pose a surgical dilemma for urogynecologic surgeons because risks of bleeding with surgery need to be balanced by the risk so their comorbidities.^{6,7} There is scant evidence of this specific patient population in the female pelvic medicine and reconstructive surgery literature. The primary aim of this study was to determine if perioperative complications are increased in women on chronic anticoagulation therapy undergoing female pelvic reconstructive surgery. The secondary aims were to characterize complications that more commonly occur in women on chronic antithrombotic therapy and to determine how these were managed.

MATERIALS AND METHODS

This is an institutional review board-approved retrospective cohort study from cases at Houston Methodist Hospital, Houston, Tex. This cohort included all patients who underwent POP surgery from 2012 to 2015. Cases were identified by Current Procedural Terminology code searches and review of surgeons' case logs. Surgeons of all cases were fellowship-trained female pelvic reconstructive surgeons (n = 3). Data were taken from paper charts from the clinic and from the hospital electronic medical record system. Patients were included if they underwent 1 or more of the following procedures: anterior or posterior repair (native tissue or augmented), laparoscopic or abdominal sacrocolpopexy, colpocleisis, sacrospinous ligament fixation, or uterosacral ligament suspension. It was noted if midurethral sling or concomitant hysterectomy were performed. Patients who underwent concomitant major surgery involving organs not in the female pelvic floor or urogenital system were excluded from the study. All gynecologic surgery patients at this institution wear intermittent pneumatic compression devices starting at anesthesia initiation until the patients are ambulating regularly. For patients who did not stay for overnight observation, sequential compression devices are discontinued before being discharged home.

Baseline characteristics including patient age, number of postmenopausal years, body mass index (BMI), and Charlson Co-morbidity Index were collected. Charlson Comorbidity Index scores were assigned after reviewing the preoperative history and physicals, anesthesia preoperative evaluations, and medical records from the physicians who provided medical clearance for the procedure. Intraoperative information was obtained including estimated blood loss, procedures performed, and length of surgery. The length of hospital stay at the hospital was recorded as number of nights the patient was admitted. Overall complications were defined by Clavien-Dindo classification of surgical complications. By this classification, normal sequelae of surgeries and failure to cure are not graded as complications.⁸ Records were reviewed for events that occurred up to the time of the patients' second postoperative follow-up (4 to 6 weeks postoperative). Specific outcomes of hospital readmission, admission to intensive care unit (ICU), reoperation (requiring general anesthesia), need for blood transfusion, vaginal hematoma, infection, and thromboembolic events were noted.

For patients on chronic antithrombotic therapy, medical clearance letters, medication reconciliations, and preoperative assessments by anesthesia were used to determine the number of days the antithrombotic was discontinued. Charts were reviewed to identify the medication name, all indications for antithrombotic therapy, number of days preoperatively the antithrombotic therapy was held, bridging method, and when the antithrombotic was resumed. Use of any of the following medications before admission placed patients in the chronic antithrombotic use group: Coumadin (warfarin), Argatroban, Angiomax (bivalirudin), Fragmin (dalteparin), Iprivask (desirudin), Lovenox (enoxaparin), Arixtra (fondaparinux), heparin, Repludin (lepirudin), Eliquis (apixaban), Pradaxa (dabigatran), and Xarelto (rivaroxaban). Aspirin use alone was not included as an antithrombotic. All records of patients who had a bleeding-related complication (hematoma or blood transfusion) were screened specifically for use of fish oil or herbal supplements.

The primary aim was to determine if overall postoperative complications were more common in patients on chronic anti-thrombotic therapy compared with patients not on antithrombotic therapy. The secondary aims were to characterize complications that more commonly occur in women on chronic antithrombotic therapy and to determine how these were managed.

For data analysis, *t* test was used for continuous variables, χ^2 for categorical variables, and odds ratios (ORs) were assessed, with *P* values less than 0.05 considered statistically significant. Logistic regression curve was used to assess OR and 95% confidence intervals. At this time, there are no available data on perioperative complication rates in women on chronic antithrombotic surgery, thus sample size calculation was not done before the data collection.

RESULTS

A total of 388 patients met inclusion criteria. After 2 were excluded, 386 charts were fully reviewed. No patients in the study population had untreated malignancies or were undergoing treatment for malignancy. Demographics and perioperative data can be found in

Table 1. Patients with antithrombotic use were significantly older ($P < 0.0001$) and further postmenopausal than controls ($P < 0.0001$). Patients with antithrombotic use had significantly higher Charlson Comorbidity Index (2.33 vs 0.82; $P < 0.0001$), estimated blood loss (129 mL vs 81 mL; $P < 0.016$), and longer length of stay (2.6 days vs 1.3 days; $P < 0.0002$).

A total of 28 patients had complications, 12 of these complications were Clavien-Dindo grade II or higher (Table 2). Of the patients with complications, 24% ($n = 7$) were on chronic anti-thrombotic therapy. A total of 4 patients had complications related to bleeding, and all 4 patients were in the chronic antithrombotic group (Table 3). The complications related to bleeding included blood loss requiring blood transfusion, vaginal hematoma, and re-operation for persistent bleeding. All 4 patients had different combinations of procedures performed, but were similar in a way that each of these cases included a posterior repair. Three of 4 patients had vaginal hematomas successfully managed with continued observation and holding antithrombotic therapy, whereas the other 1 patient failed this management and required reoperation to stop vaginal bleeding. Three of the 4 patients had bleeding complications detected on postoperative day 2. The patient who required readmission and reoperation had clinically evident bleeding and hematoma on postoperative day 5 after being discharged home, and she required vaginal cuff revision on postoperative day 7 after failed conservative treatment. None of the patients with a bleeding complication reported taking fish oil or herbal supplements when admitted for surgery. None of the patients in the study (both groups) had a clinically evident thromboembolic event during the study period (Table 4).

With logistic regression, all statistical findings were maintained when adjusting for covariates of age and BMI (Table 5). Chronic antithrombotic therapy users had significantly more overall complications (OR, 6.9; $P < 0.0005$). Chronic antithrombotic use showed a significant increase in blood transfusions (OR, 165.8; $P < 0.001$), ICU admission (OR, 22.2; $P < 0.004$), hospital readmission (OR, 20.8; $P < 0.0005$), vaginal hematoma (OR, 554.0; $P < 0.001$), and infections (OR, 22.44; $P = 0.004$). Patients on chronic antithrombotic therapy had greater odds of complications that required follow-up after discharge (OR, 7.96; $P < 0.0005$).

Despite the increasing complications related to bleeding, chronic antithrombotic therapy did not significantly increase reoperation rates (OR, 3.81; $P = 0.28$). Of the 5 patients who underwent reoperation, only 1 of the patients was on antithrombotic therapy. Three cases that required reoperation were for outlet obstruction from sling placement, and the other was for a cystotomy with delayed recognition. The chronic antithrombotic use patient required reoperation for vaginal hematoma and need for cuff revision after continued bleeding despite holding antithrombotic medications and packing.

DISCUSSION

This study shows an increased risk of perioperative complications, operating blood loss, and length of stay after pelvic floor reconstructive surgery in women on chronic antithrombotic therapy compared with women not on chronic therapy, even when controlling for age and

BMI. A prospective study evaluated 775 patients on chronic antithrombotic therapy (for previous VTE) having nonminor surgeries of many different types (orthopedic, gastrointestinal, cardiothoracic, urologic, plastic, vascular, cardiothoracic, and gynecologic).¹ Those patients were risk stratified and subsequently managed accordingly by published guidelines. Overall, there was a low cumulative incidence of thromboembolism (1.8%), major hemorrhage (1.8%), and mortality (1.7%).¹

Appropriate use of antithrombotic management and pharmacologic VTE prophylaxis is a quality measure that is closely evaluated in many hospitals.⁹ Death of secondary pulmonary embolism in the perioperative period is the most common cause of preventable death in hospitalized patients.¹⁰ Perioperative management of antithrombotic therapy requires assessment of patient risk for thromboembolism and weighing it against risk for perioperative bleeding.¹¹ American College of Obstetricians and Gynecologists (ACOG) provides risk assessment tools to assist in general VTE prophylaxis for all gynecologic surgery patients.¹² Procedure type, duration of surgery, age, and patient comorbidities such as malignancy or hypercoagulable state determine patient's level of risk.^{8,13} For management of antithrombotic therapy in gynecologic surgery patients, ACOG recommendations are derived from expert opinion and the 2012 American College of Chest Physicians (ACCP) Clinical Guidelines for Perioperative Management of Antithrombotics.¹¹

The Society of Gynecologic Surgeons' Systematic Review Group developed Clinical Practice Guidelines for VTE prophylaxis in women undergoing gynecologic surgery in 2011.⁵ Their systematic review found that mechanical prophylaxis alone is appropriate in benign gynecologic surgery patients considering the low incidence of VTE in these patients.⁵ In women of varied risk for VTE, there is a 0.25% to 0.3% incidence of VTE occurring up to 6 weeks postoperatively after use of intermittent pneumatic compression alone for prophylaxis.^{14,15} The guidelines by the ACCP and ACOG place the majority of benign gynecologic patients at "moderate" to "high" VTE risk.^{6,12,16} In contrast, the Society of Gynecologic Surgeons' Clinical Practice Guidelines suggest addition of pharmacologic prophylaxis only in patients with 2 of 3 risks (age 60 years or older, cancer history, or history of VTE).⁵ Our patient population differs from those studies, as they are on chronic antithrombotic medications because of other comorbidities and possibly a higher risk of VTE. There were no incidences of VTE within our population during this observed postoperative period. The patients on an antithrombotic in this study were generally managed within standards of care recommended by ACCP and institutional guidelines. Of note, 1 of the patients with a bleeding complication discontinued her Coumadin 3 days preoperatively while the physician managing her medications recommended discontinuation 5 days preoperatively.

Per ACCP guidelines,¹¹ vitamin K antagonist (ie, Coumadin) should be discontinued 5 days before surgery. For low-risk surgeries, there would be no bridging recommended, and for high-risk surgeries (ie, mechanical heart valve, atrial fibrillation, or VTE at high risk for thromboembolism), bridging anticoagulation should be received. Therapeutic dose of unfractionated heparin should be discontinued 4 to 6 hours before surgery, and therapeutic dose of low molecular weight heparin (Lovenox) should be discontinued 24 hours before surgery. Bridging agents and Coumadin may be resumed 12 to 14 hours after surgery if there

is adequate hemostasis. Patients on antiplatelet therapy (ie, aspirin, clopidrel, prasugrel) should discontinue 7 to 10 days before surgery in most cases. If they have had a coronary stent placed, surgery should be deferred at least 6 weeks after bare-metal stent placement, and 6 months after drug-eluting stent placement. If surgery cannot be delayed, antiplatelet therapy should be continued perioperatively. General recommendations for postoperative hours to resume antithrombotic medications vary depending on medication type. Guidelines state that medications may be resumed only if hemostasis is certain,¹¹ leaving the weight of the decision on the surgeon as they compare their certainty of hemostasis against risks of VTE.

The ACCP has not made guidelines yet for management of novel anticoagulants (ie, rivaroxaban, apixaban, dabigatran). A review of current evidence and consideration of their pharmacokinetics recommend that in low-risk bleeding surgeries, states that it may be reasonable for low-risk bleeding patients to hold their doses of Rivaroxaban or Dabigatran starting two days preoperatively. In presence of renal insufficiency they should be held three days preoperatively. No particular guidelines had been established regarding novel antithrombotic agents and research is ongoing.¹⁷

For the pelvic reconstructive surgeon, when dealing with patients on chronic antithrombotic therapy, the risks of surgery and bleeding complications need to be weighed against the risk of thromboembolic disease or cardiovascular disease when off with their medications. The pelvic reconstructive surgeon should work together with the patient's primary care physician or cardiologist to determine the optimal perioperative management of their medication, including time of discontinuing medication, bridging, and resuming their antithrombotic medication. This population of women showed no incidences of VTE in a population of women on chronic antithrombotic therapy. Although bleeding complications were increased in this cohort of patients, these complications were successfully managed with vaginal packing and temporarily holding antithrombotic therapy or pharmacologic VTE prophylaxis.

The strength of this study is the ability to compare complications within 1 institution, with a thorough review of medical records available for both inpatient and at outpatient follow-up. Information gained by this study can help in preoperative counseling of patients on chronic antithrombotic medications regarding risk of overall complications and types of management if complications arise. This study is limited by the great difference in sample sizes (patients on antithrombotics and patients not on antithrombotics), and thus poor precision when evaluating perioperative complications. The reporting of complications was limited to 6 weeks postoperatively, when patients have attended at least 1 to 2 of their routine postoperative follow-up appointments. Although no patients in this study had clinical VTE evident within this period, it is possible that thromboembolic events occurred at a later date. With the low prevalence of VTE found in benign gynecology patients in previous studies, an increased sample size could increase the power of this study. Given the small sample size of the study, there is a low number of postoperative complications. Conclusions cannot be made regarding outcomes after specific procedures (laparoscopic vs vaginal) or outcomes with use of specific antithrombotic agents. A larger study with controls matched to cases would be helpful in improving the precision of these results. The information gained by this study can help female pelvic reconstructive surgeons in preoperative counseling of

patients on chronic antithrombotic medications with regards to overall risks and complications.

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TABLE 1

Demographics and Perioperative Data

	No Antithrombotic Use (n = 365)	Antithrombotic Use (n = 21)	Total (N = 386)	P
Age, y	60.6 (11.7)	71.4 (8.)	61.2 (11.8)	<0.0001 *
BMI	28.4 (5.81)	29.6 (5.72)	28.4 (5.80)	0.3332 *
Postmenopausal age, y	10.8 (11.5)	23.7 (9.08)	11.5 (11.8)	<0.0001 *
Charlson Comorbidity Index [†]				
0	234 (64)	0	234 (61)	<0.001 *
1	61 (17)	7 (33)	68 (18)	
>1	70 (19)	14 (67)	84 (21)	
Duration of surgery, min	184.5 (88.2)	169 (72.1)	183.9 (87.4)	0.44 *
Estimated blood loss, mL	80.9 (82.8)	129 (161)	83.5 (89.2)	0.016 *
Length of stay, d	1.331 (0.920)	2.619 (2.617)	1.401 (1.115)	<0.0001 *

Data are shown as mean (standard deviation) unless otherwise specified.

*
t test.

[†]
Data are shown as n (%).

TABLE 2**Clavien-Dindo Classification of Postoperative Complications**

Clavien-Dindo Grade*	No Antithrombotic Use (n = 21)	Antithrombotic Use (n = 7)	Total (n = 28)
I	14 (67)	2 (29)	16 (57)
II	1 (0.5)	1 (14)	2 (7.0)
IIIa	0	1 (14)	1 (3.6)
IIIb	5 (23)	0	5 (18)
IVa	1 (0.5)	1 (14)	2 (7.0)
IVb	0	2 (29)	2 (7.0)
V	0	0	0
VI	0	0	0
d [†]	19 (90)	7 (100)	26 (93)

Data are shown as n (%).

* Clavien Dindo Classification⁸: Grade I, Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This also includes wound infections opened at the bedside; Grade II, Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included; Grade III, Requiring surgical, endoscopic, or radiological intervention (A) not under general anesthesia (B) under general anesthesia; Grade IV, Life-threatening complication (including CNS complications) requiring IC/ICU management (A) single organ dysfunction (including dialysis) and (B) Multiorgan dysfunction; Grade V, Death of a patient.

[†] Suffix “d”(for “disability”): If the patient suffers from a complication at the time of discharge, suffix “d” is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

TABLE 3

Patients With Complications Related to Bleeding

Patient	1	2	3	4
Antithrombotic	Plavix	Eliquis	Plavix, Coumadin	Coumadin
No. d medication discontinued (preoperative)	6	6	5	3
Bridging medication	Heparin		Lovenox, therapeutic dose	Lovenox, therapeutic dose
Time postoperatively bridging started, h	8		12	12
Time postoperatively	2 d	8 h	2 d	1 d
Antithrombotic resumed				
Postoperative day of complication	2	2	2	5 *

* Patient symptomatic after being discharged home, readmitted 2 days after discharge.

TABLE 4

Specific Postoperative Complications

Complication	No Antithrombotic Use (n = 21)	Antithrombotic Use (n = 7)	Total (n = 28)
Blood transfusion	1 (0.2)	3 (14)	4 (1.0)
ICU admission	2 (0.5)	2 (9.5)	4 (1.0)
Infection	7 (1.9)	1 (4.8)	8 (2.1)
Hematoma	1 (0.2)	3 (14)	4 (1.0)
Thromboembolic event	0	0	0
Small bowel obstruction	0	1 (4.8)	1 (0.3)
Readmission	7 (1.9)	4 (19)	11 (2.8)
Reoperation	4 (1.1)	1 (4.8)	5 (1.3)

Data are shown as n (%).

TABLE 5

Multivariate Analysis of Postoperative Complications in Chronic Antithrombotic Use

Complication	OR (95% CI)	P
Overall complications	6.90 (2.4–20.0)	<0.0005
Blood transfusion	165.8 (7.5–3670)	0.001
Readmission	20.8 (4.20–102)	<0.0005
Vaginal hematoma	554.0 (11.5–26817)	0.001
Reoperation	3.81 (0.35–42.0)	0.275
ICU admission	22.2 (2.71–182)	0.004
Infection	22.4 (2.74–184)	0.004