




Postmastectomy Breast Reconstruction is Safe in Patients on Chronic Anticoagulation

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Abstract

Background Postmastectomy breast reconstruction (PMR) increases patient satisfaction, quality of life, and psychosocial well-being. There is scarce data regarding the safety of PMR in chronic anticoagulated patients. Perioperative complications can reduce patient satisfaction; therefore, it is important to elucidate the safety of PMR in these patients.

Methods A retrospective case–control study of patients who underwent PMR with implants and were on chronic anticoagulation was performed at our institution. Inclusion criteria were women ≥ 18 years old. Exclusion criteria included autologous reconstructions, lumpectomy, and oncoplastic procedures. Two controls for every one patient on anticoagulation were matched by age, body mass index, radiotherapy, smoking history, type of reconstruction, time of reconstruction, and laterality.

Results From 2009 to 2020, 37 breasts (20 patients) underwent PMR with implant-based reconstruction and were on chronic anticoagulation. A total of 74 breasts (40 patients) who had similar demographic characteristics to the cases were defined as the control group. Mean age for the case group was 53.6 years (standard deviation [SD] = 16.1), mean body mass index was 28.6 kg/m² (SD = 5.1), and 2.7% of breasts had radiotherapy before reconstruction and 5.4% after reconstruction. Nine patients were on long-term warfarin, six on apixaban, three on rivaroxaban, one on low-molecular-weight heparin, and one on dabigatran. The indications for anticoagulation were prior thromboembolic events in 50%. Anticoagulated patients had a higher risk of capsular contracture (10.8% vs. 0%, $p = 0.005$). There were no differences regarding incidence of hematoma (2.7% vs. 1.4%, $p = 0.63$), thromboembolism (5% vs. 0%, $p = 0.16$), reconstructive-related complications, or length of hospitalization (1.6 days [SD = 24.2] vs. 1.4 days [SD = 24.2], $p = 0.85$).

Conclusion Postmastectomy implant-based breast reconstruction can be safely performed in patients on chronic anticoagulation with appropriate perioperative management of anticoagulation. This information can be useful for preoperative counseling on these patients.

Keywords

- ▶ postmastectomy reconstruction
- ▶ breast reconstruction
- ▶ anticoagulation
- ▶ warfarin
- ▶ heparin

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Breast cancer remains the most common cancer and second most common cause of cancer-related death in women in the United States.¹ One surgical option for the treatment of breast cancer includes mastectomy. Overall 5-year survival rate from breast cancer is 90% in the United States.¹ With the increasing number of women surviving breast cancer, there is a growing population dealing with the sequela after mastectomy. Breast reconstruction is a procedure that restores the breast shape after mastectomy, and has been shown to improve patient satisfaction, psychological, emotional, social, and sexual well-being.² Use of immediate and delayed postmastectomy breast reconstruction (PMR) continues to increase since the implementation of the Women's Health and Cancer Rights Act in 1998, which required insurance coverage of any type of reconstruction after mastectomy.³ In 2018, at least 101,657 breast reconstructions were performed in the United States.⁴ Nonetheless, only around 40% of patients who underwent mastectomy pursued breast reconstruction.⁵

Approximately 6 million people in the United States are on anticoagulation treatment and 2.83 million office visits per year are made regarding its use.⁶ This number is rising as the incidence of conditions such as atrial fibrillation continues to increase due to early detection and treatment.⁷ In the last decade, direct oral anticoagulants (DOACs) such as rivaroxaban, apixaban, and dabigatran have been offered as an alternative to the traditional vitamin K antagonists such as warfarin. DOACs offer more favorable risk-benefit profile in the treatment of atrial fibrillation which is the most common reason for anticoagulation. They also provide a better risk-benefit profile compared with low-molecular-weight heparin (LMWH) in the prevention of deep vein thrombosis (DVT).⁸ In addition, they have a rapid onset of action, relatively short elimination half-lives, predictable pharmacokinetic characteristics, and few drug-to-drug interactions.⁸

To our knowledge, there are only a few studies evaluating the outcome of breast reconstruction in chronic anticoagulated patients. A case-control study of seven anticoagulated patients reported a higher risk of hematoma, blood transfusion, infection, and longer hospital length-of-stay in patients on anticoagulation.⁹ However, other small cohort studies, including a case series of seven patients with chemotherapy line-induced thromboembolism requiring anticoagulation at the time of breast reconstruction,¹⁰ and a case report,¹¹ showed no increased risk of complications due to anticoagulation. Potential consequences of postoperative bleeding can be detrimental to the results of implant-based breast reconstruction since it is a known risk factor for capsular contracture. But more importantly, adjuvant cancer therapy may be delayed if any complications occur.¹² The literature on the outcomes of PMR in patients on chronic anticoagulation is scarce; therefore, the goal of this study was to address this knowledge gap. Our study is the largest case-control study evaluating the safety of PMR in patients who require chronic anticoagulation.

Methods

After institutional review approval, a retrospective case-control study of patients who underwent PMR and who

were on chronic anticoagulation was performed from January 2009 to 2020 at our institution. Patients' information was obtained by retrospective chart review. Inclusion criteria were female patients ≥ 18 years old who underwent mastectomy secondary to breast cancer or cancer prophylaxis and underwent immediate or delayed breast reconstruction with implant-based reconstruction (IBR). Exclusion criteria were a revision of prior breast reconstruction, lumpectomy, oncoplastic procedures, and autologous reconstruction. Chronic anticoagulation was defined as continuous anticoagulation use for at least 6 months prior to breast reconstruction.

Study Design

A case-control study was designed with a ratio of 1 case to 2 controls. Controls were randomly selected for each patient from all PMR cases at our institution, after matching for age (± 10 years), category of body mass index (BMI) according to the World Health Organization classification, pre-mastectomy and adjuvant radiation therapy, smoking history, type of reconstruction, time of reconstruction, and laterality.

Data Extraction

The patient demographics including age, BMI, smoking status, anticoagulation use, reason for anticoagulation, antiplatelet use, radiation and chemotherapy treatments, timing of reconstruction, type of reconstruction, laterality (unilateral or bilateral), and reason for reconstruction (cancer or prophylaxis) were collected. Patient's comorbidities including hypertension, hyperlipidemia, coronary artery disease, diabetes, smoking status, and antiplatelet use were recorded. Complications associated with chronic anticoagulation were assessed with bleeding and thrombotic-related perioperative complications such as acute bleeding, hematoma, DVT, and pulmonary embolism. Complications related to the mastectomy/breast reconstruction were recorded, including Baker grade III-IV capsular contracture, seroma, cellulitis, abscess, wound necrosis, wound dehiscence, unplanned surgical intervention, and hospital length-of-stay. Surgical outcomes were recorded for the entire reconstructive process including second-stage surgeries.

Statistical Analysis

Categorical comparisons between the case and control groups were evaluated using the Fisher's exact test and continuous values were compared using the Wilcoxon test. All statistical analyses were performed using JMP Statistical Software version 14 JMP (SAS Institute Inc., Cary, NC). A *p*-value of < 0.05 was considered statistically significant.

Results

Between January 2009 and 2020, over 5,000 breast reconstructions were performed at our institution. A total of 41 breasts (22 patients) underwent PMR and were on chronic anticoagulation. Of all, 80.5% of breast mounds underwent IBR with tissue expanders, 9.8% were reconstructed with Goldilocks closure with direct implants, 4.9% with

Table 1 Patient demographics

Demographics	No. of patients (%)		p-Value
	Case (n = 20 [37 breasts])	Control (n = 40 [74 breasts])	
Age (y), mean ± SD	53.6 ± 16.1	52.9 ± 12.1	0.8645
BMI (kg/m ²), mean ± SD	28.6 ± 5.1	28.6 ± 5.1	0.5425
Hypertension	9 (45.0)	13 (32.5)	0.3804
Diabetes	1 (5.0)	1 (2.5)	0.2907
Coronary artery disease	4 (20.0)	0	0.0038 ^b
Hyperlipidemia	6 (30.0)	15 (35.0)	0.5205
Smoking history			
Current	0	0	
Former	8 (40.0)	9 (22.5)	0.1687
Never	12 (60.0)	28 (70.0)	0.1687
Radiation therapy ^a			
Prior to reconstruction	1 (2.7)	1 (1.4)	0.7679
Adjuvant	2 (5.4)	6 (8.1)	0.5827
Chemotherapy			
Prior to reconstruction	7 (35.0)	5 (12.5)	0.0451 ^b
Adjuvant	3 (15.0)	5 (12.5)	0.8169
Timing of reconstruction ^a			
Immediate	31 (83.8)	60 (81.1)	0.0863
Delayed	7 (18.9)	14 (18.9)	0.0863
Type of reconstruction ^a			
IBR-TE	33 (89.2)	66 (89.2)	0.1146
DTI	4 (10.8)	8 (10.8)	0.1146
Laterality			
Unilateral	3 (15.0)	6 (15.0)	0.9710
Bilateral	17 (85.0)	34 (85.0)	0.9710
Reason for reconstruction ^a			
Prophylactic mastectomy	4 (10.8)	8 (10.8)	0.6697
Cancer resection	33 (89.2)	66 (89.2)	0.6697

Abbreviations: BMI, body mass index; DTI, direct to implant; IBR-TE, implant-based reconstruction with tissue expander; SD, standard deviation.

^aValues are presented as the number of breasts (%).

^bStatistically significant, $p < 0.05$.

immediate deep inferior epigastric perforator flap, and 4.9% with delayed free transverse rectus abdominis myocutaneous flap. In our study, only the 20 patients (37 breasts) who underwent IBR and were on chronic anticoagulation were included in the case group. Of them, 79.4% had immediate IBR. The mean age for the case group was 53.6 years (standard deviation [SD] = 16.1), mean BMI was 28.6 kg/m² (SD = 5.1). In total, nine patients had hypertension, six had hyperlipidemia, four had coronary artery disease, and one

Table 2 Anticoagulant medication

Variable	No. of patients (%) (n = 20)
Anticoagulant	
Warfarin	9 (45)
Apixaban	6 (30)
Rivaroxaban	3 (15)
LMWH	1 (5)
Dabigatran	1 (5)
Reason for anticoagulation	
DVT/PE	10 (50)
Cardiac	4 (20)
Coagulation disorder	4 (20)

Abbreviations: DVT, deep venous thrombosis; LMWH, low-molecular-weight heparin; PE, pulmonary embolism.

had diabetes. Of all breasts, 2.7% of breasts had radiotherapy before reconstruction, 5.4% after reconstruction, 35% had chemotherapy prior to reconstruction, and 15% after reconstruction. A case-control study was designed with a ratio of 1 case to 2 controls. Controls were randomly selected for each patient from all PMR cases at our institution, after matching for age (± 10 years), category of BMI according to the World Health Organization classification, premastectomy and adjuvant radiation therapy, smoking history, type of reconstruction, time of reconstruction, and laterality. A total of 74 breasts (40 patients) that had similar demographic characteristics to the cases were defined as the control group. Cases and controls were not matched for chemotherapy since many studies have reported that it does not influence breast reconstruction outcomes (**Table 1**).^{13,14}

Nine patients were on long-term warfarin, six on apixaban, three on rivaroxaban, one on LMWH, and one on dabigatran. The indications for anticoagulation were prior DVT/pulmonary embolism ($n = 10$, 50%), hereditary coagulation disorders ($n = 4$, 20%), and cardiac indications ($n = 4$, 20%). In addition, 16.7% of patients ($n = 3$) were on low-dose aspirin, which was stopped within a week before surgery (**Table 2**). Perioperative management of DOACs consisted of stopping the anticoagulation approximately 48 hours before the surgery and resuming it at 24 to 48 hours after surgery. Bridging with LMWH was performed in patients on chronic warfarin and the patient on LMWH was asked to discontinue it the night prior to surgery.

Cases and controls showed no statistically significant difference in hospital length-of-stay (mean \pm SD: 1.6 \pm 0.6 days vs. 4.0 \pm 0.6 days; $p = 0.18$) or follow-up time (28.8 months [range 3–135.3] vs. 28.0 months [range 3.3–73], $p = 0.85$). In terms of bleeding-related perioperative complications, no significant differences were reported between cases and controls. Hematoma was reported in one (2.7%) breast mound in the case group versus one (1.4%) in the control group ($p = 0.63$). All hematomas were described in different patients and resolved with surgical drainage. No acute bleeding within the immediate perioperative period

up to 30 days after surgery was reported in either group. With respect to thromboembolic events, one patient (5%) in the case group developed DVT on postoperative day 7 that resolved with medical treatment versus none in the control group ($p = 0.16$). Regarding reconstructive-related complications, there was no significant difference on the incidence of seroma in the case group versus the control group (10.8% vs. 4.2% reconstructed breasts mounds; $p = 0.18$), cellulitis (2.7% vs. 4.2%; $p = 0.70$), other surgical site infections (0% vs. 1.4%; $p = 0.47$), or fat necrosis (5.4% vs. 2.8%; $p = 0.49$). One reconstructed breast mound (2.7%) in the case group developed full-thickness wound necrosis which required debridement versus two (1.4%) in the control group ($p = 0.33$). One breast mound (2.7%) in the case group developed superficial wound dehiscence that resolved with dressing changes and one (1.4%) in the control group developed full-thickness wound dehiscence ($p = 0.29$). Additional complications were unplanned revision surgery (10.8% vs. 6.9%; $p = 0.49$) and reconstruction loss (4.9% vs. 5.6%; $p = 0.97$). Of all IBR in the case group, two reconstructed breast mounds developed clinically significant capsular contracture with grade III

($n = 3$) and grade IV ($n = 1$) capsular contracture. Of them, two breasts underwent revision with capsulectomy and implant exchange. No capsular contractures were described in the control group ($p = 0.005$). All patients in the case group completed second-stage surgery and the reconstruction was successful in 95.9% of patients versus 94.4% in the control group ($p = 0.97$) (– **Table 3**).

Discussion

PMR has been shown to improve patients' satisfaction, quality of life, and emotional, psychological, and sexual well-being after mastectomy.² Although there is data on short-term perioperative anticoagulation for thromboembolism prophylaxis, there is a lack of information regarding the safety of PMR in patients on chronic anticoagulation. This is a problem that many surgeons face and it is estimated to affect approximately 250,000 patients annually in North America.¹⁵ There is a delicate balance between the risk of thrombosis and bleeding that must be achieved to avoid any complications. In the last decade, only 0.8% of the total breast reconstructions at our institution were performed in patients on chronic anticoagulation. This data highlights the importance of this study in surgical planning and patient counseling in this subset of patients. We present the largest case–control study on the safety of PMR with implants in patients on chronic anticoagulation.

The type of reconstruction should be taken into account when deciding whether to proceed with breast reconstruction in a patient on chronic anticoagulation. The study by Wilkins et al¹⁹ based on the Mastectomy Reconstruction Outcomes Consortium data, reported that autologous reconstruction had higher rates of complications (45%) than tissue expander/implant reconstruction (25%).¹⁶ It is for this reason that we only included PMR with implants in this study. In this case–control study, low complication rates for PMR in patients on chronic anticoagulation were reported. No significant difference was found on the incidence of bleeding-related, thrombotic-related, or reconstructive-related complications. Based on these results, it is encouraging to see that, with appropriate perioperative management of anticoagulation, PMR with implants can be safely performed in patients on chronic anticoagulation without an increase in complications. Capsular contracture is not an uncommon complication after implant-based breast reconstruction; Baker grade III/IV capsular contracture has been described in up to 37.5%.¹⁷ Bleeding, hematoma, and seroma have also been identified as risk factors for capsular contracture.^{12,18,20} In our study, patients on anticoagulation had a higher risk of developing capsular contracture than those without anticoagulation. Even though no hematoma or acute bleed were reported in those patients, anticoagulated patients might have had a subclinical bleed that increased their risk of developing capsular contractures.

Patients undergoing PMR can have multiple risk factors for the development of thromboses such as advanced age, high BMI, cancer, hormone therapy, oral contraceptives, smoking, general anesthesia, and prolonged surgery.^{21–24}

Table 3 Perioperative complications

Perioperative complications	No. of breasts (%)		p-Value
	Cases (n = 37)	Controls (n = 74)	
Hematoma	1 (2.7)	1 (1.4)	0.6284
DVT/PE, no. of patients (%)	1 (5.0)	0	0.1611
Seroma	4 (10.8)	3 (4.2)	0.1803
Cellulitis	1 (2.7)	3 (4.2)	0.7003
Other infections	0	1 (1.4)	0.4714
Fat necrosis	2 (5.4)	2 (2.8)	0.4896
Full-thickness wound necrosis	1 (2.7)	1 (1.4)	0.3302
Wound dehiscence			0.2917
Superficial	1 (2.7)	0	
Full	0	1 (1.4)	
Capsular contracture			0.0045 ^a
Grade III	3 (8.1)	0	
Grade IV	1 (2.7)	0	
Unplanned revision surgery	4 (10.8)	5 (6.9)	0.4874
Reconstruction loss	2 (4.1)	4 (5.6)	0.9740
Hospital length-of-stay (d), mean ± SD	1.6 ± 0.6	1.4 ± 0.6	0.1768
Follow-up time (mo), mean ± SD	28.8 ± 24.2	28.0 ± 24.2	0.8541

Abbreviations: DVT, deep vein thrombosis; PE, pulmonary embolism; SD, standard deviation.

^aStatistically significant, $p < 0.05$.

Radiotherapy has been shown to negatively affect the outcomes of PMR; however, chemotherapy has been reported to have no effect.^{13,14} In this case-control study, controls were matched to cases according to age, BMI, and radiotherapy, as well as surgery-related characteristics such as type of surgery, time of reconstruction, and laterality. Mixed results have been reported regarding the safety of perioperative anticoagulation. A previous case-control study reported that PMR had higher rates of hematoma, requirement for transfusion and infection, in patients on chronic anticoagulation.⁹ However, the study consisted of a very small number of patients. Some of the reasons that may explain the increased incidence of complications in that study are that the patients had higher BMI and four patients had class 1 obesity versus our study (mean \pm SD, 28.7 ± 4.9 kg/m²). In addition, 42.9% of patients had autologous breast reconstruction with free flaps which could have increased the rate of surgical complications. Pannucci et al²⁵ reported that prophylactic postoperative LMWH was associated with a reduction in the development of venous thromboembolism in patients with Caprini score ≥ 5 , without increased rates of hematoma, compared with no prophylaxis. Moreover, Keith et al²⁶ reported no increased risk of bleeding with the use of preoperative enoxaparin in autologous and implant-based breast reconstruction. The Venous Thromboembolism Prevention Study included more than 3,000 patients and concluded that postoperative chemoprophylaxis with enoxaparin, after controlling for the type of surgery, was not associated with an increase in reoperative hematoma rates.²⁷ To minimize hematoma, meticulous hemostasis, use of compression bras, and appropriate perioperative anticoagulation management can be useful. Close monitoring aids in the prompt detection and management of hematoma.

Many scales have been described to help classify patients based on their risk of developing DVT, the most popular being the Caprini Risk Assessment Model score which is currently endorsed by the American Society of Plastic Surgeons and the American Association of Plastic Surgeons for use in surgical patients. It is based on 20 different patient-specific risk factors and it gives recommendations on the best perioperative prophylaxis method.²⁸ In our study, all patients had a Caprini score ≥ 5 , reflecting higher risk of developing thrombosis. Thus, the American College of Chest Physicians²⁸⁻³⁰ recommends the perioperative use of LMWH or unfractionated heparin in addition to mechanical prophylaxis such as graduated elastic compressions stockings or intermittent pneumatic compression devices. Regarding antiplatelet use, aspirin should be stopped around 7 to 10 days before surgery. However, for patients at high risk of cardiovascular event who are undergoing a noncardiac procedure, continuation of aspirin is recommended.¹⁵

Our study shows that PMR with implants is safe in patients on chronic anticoagulation. However, both the risk of bleeding due to perioperative continuation of anticoagulation and the risk of thrombosis if the anticoagulation is withheld should be discussed between patients and providers to allow for informed decision making. Additionally, the number of times that disruption of anticoagulation may

be required to complete the reconstructive process should also be considered and discussed with the patient. Careful selection of patients and type of reconstruction is crucial to obtain the best outcomes possible. As shown in our study and in the literature, many surgeons are reluctant to offer breast reconstruction in patients with chronic anticoagulation. This information can be useful during perioperative counseling and risk stratification.

The limitations of this study include its retrospective nature, small sample size, and single institution. Additionally, these were patients on anticoagulation who were selected to proceed with PMR and do not include patients where the risk was thought to preclude PMR, this is a potential for selection bias. Future multicenter studies with a bigger sample size are encouraged. In addition, propensity score matching was not performed; however, our controls were randomly selected from the entire cohort of PMR patients at our institution. To our knowledge, this is the largest case-control study to report safety of PMR in patients on chronic anticoagulation.

Author Contributions

Conceptualization: M.Y., M.T.N. Data curation: M.Y. Formal analysis: M.Y. Funding acquisition: M.Y. Methodology: M.Y., M.T.N. Project administration: M.Y., M.T.N. Visualization: M.Y., M.T.N. Writing - original draft: M.Y., M.T.N. Writing - review and editing: M.Y., D.K., J.C.B., O.J.M., N.V.T., C.A.H., J.M.-J., M.T.N. All authors read and approved the final manuscript.

Ethical Approval

The study was approved by the Institutional Review Board of Division of Plastic Surgery, Mayo Clinic (IRB No. IRB 19-012716) and performed in accordance with the principles of the Declaration of Helsinki. The informed consent was waived because this study design is a retrospective chart review.

Prior Presentation

This study was presented at Plastic Surgery The Meeting, American Society of Plastic Surgery, October 16-19, 2020.

Conflict of Interest

None declared.

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