Rivaroxaban for Venous Thromboembolism Prophylaxis in Abdominoplasty: A Multicenter Experience

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Abstract

Background: Abdominoplasty, a commonly performed aesthetic procedure, is considered to have an increased risk of venous thromboembolism (VTE) events. At present, routine VTE chemoprophylaxis following abdominoplasty remains controversial.

Objectives: This study evaluates the authors' experience with rivaroxaban, an oral Factor Xa inhibitor, for VTE prophylaxis in abdominoplasty patients.

Methods: A retrospective case series was conducted. All patients who underwent abdominoplasty and received rivaroxaban were included. The prophylactic dose was 10 mg daily for 7 days, beginning 12 hours postoperatively. Patient demographics, comorbidities, and type of surgery were recorded. The primary outcome measured was hematologic complication, including VTE, hematoma requiring operative evacuation, and need for blood transfusion.

Results: From September 2012 until July 2014, 132 patients (122 women and 10 men) underwent abdominoplasty surgery and received rivaroxaban postoperatively. Mean patient age was 43.7 years, and mean body mass index was 27.1. One hundred twenty-five patients also underwent abdominal muscle plication. Eleven patients underwent a fleur de lis vertical skin resection component. One hundred patients underwent concomitant abdominal liposuction, while 79 patients also had back liposuction. Only 1 patient had a symptomatic VTE event. Three patients had a hematoma requiring operative evacuation, and all went on to heal without sequelae. Two patients received a blood transfusion for anemia during their course of rivaroxaban.

Conclusions: Oral rivaroxaban administration for chemoprophylaxis in abdominoplasty patients is safe, with low rates of symptomatic VTE and hematoma formation. The authors continue routine use of the medication for patients at increased risk for VTE events.

Level of Evidence: 4

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Abdominoplasty, one of the most popular aesthetic procedures, was performed 160,077 times in 2013, according to statistics released by the American Society for Aesthetic Plastic Surgery.[1] A serious and potentially fatal complication of abdominoplasty is venous thromboembolism (VTE). A systematic review by Hatef et al demonstrated the rate of VTE was 0.34% for abdominoplasty-only patients, 0.67% for patients undergoing abdominoplasty with a concomitant plastic surgical procedure, and 3.4% for patients undergoing circumferential abdominoplasty.[2] Tracking Operations and Outcomes for Plastic Surgeons (TOPS) and CosmetAssure

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data over 4 years demonstrated deep vein thrombosis (DVT) and pulmonary embolism (PE) rates of 0.3% and 0.1%, respectively, for abdominoplasty as a single procedure.[3] Murphy et al reported 1 DVT and 2 PEs on 243 abdominoplasty and panniculectomy patients despite 100% compliance with Surgical Care Improvement Project (SCIP) VTE recommendations.[4] In a single institutional series, VTE was 5.0% in abdominoplasty patients and 7.7% in circumferential abdominoplasty patients.[5]

Despite the relative frequency of this serious complication, the accepted standard methods to prevent VTE in abdominoplasty patients, including chemoprophylaxis, remain a hot topic for debate.[6-11] Reasons for not incorporating chemoprophylaxis may be the low rate of VTE when patients are properly selected, anesthetic is limited in depth and duration, patients are properly positioned, mechanical prophylaxis is employed, and patients ambulate in the early postoperative period.[12-15] Additionally, because VTE chemoprophylactic agents block portions of the coagulation cascade to inhibit blood clot formation, the risk of bleeding complications is theoretically increased.

Rivaroxaban (Xarelto) is an oral Factor Xa inhibitor. The medication gained United States Food and Drug Administration (FDA) approval in 2011 for DVT prevention for patients undergoing hip or knee replacement surgery.[16] At the typical prophylactic dosage (10 mg administered once daily), measuring drug levels is not necessary, and no adjustments are needed for weight or creatinine clearance. We present the retrospective experience of 2 surgical centers that use rivaroxaban for routine VTE prophylaxis for patients undergoing abdominoplasty.

METHODS

A retrospective chart review was conducted on all patients who received postoperative rivaroxaban (Xarelto) after having undergone a procedure for removal of excess abdominal skin at 1 of the 2 clinical sites. Most patients also underwent additional interventions to contour the torso including muscle plication, fleur de lis vertical skin resection, liposuction, and excision of excess back skin (circumferential abdominoplasty or bra line back lift). All procedures were performed under general anesthetic at the American Association for Accreditation of Ambulatory Surgery Facilities- or Joint Commission-accredited ambulatory surgical facilities associated with the practices. Both centers initiated rivaroxaban independently of each other following informal discussion with community hematologists, as ease of administration and patient compliance were felt likely to be improved with rivaroxaban over injectable prophylactic measures. A dose of 10 mg, initiated 12 hours postoperatively, was recommended. Since this medication was administered in abdominoplasty patients, the usage was technically off-label as rivaroxaban has been FDA approved for VTE prophylaxis in hip and knee replacement patients. Because the medication was approved for a related (but not identical) indication, a specific formal written consent regarding its use following abdominoplasty was not obtained. The routine consultation and surgical consent process incorporated the discussion regarding the risks and benefits of rivaroxaban use, as well as notification of its off-label administration. The study conformed to the World Medical Association Declaration of Helsinki.[17] As this was a retrospective chart review of previously established postoperative protocols, formal Institutional Review Board approval for this study was not sought.

All clinical and operative notes and laboratory and radiographic data were utilized for data collection. Data on demographics, comorbidities, body mass index (BMI), Factor V Leiden mutation, operation performed, length of anesthetic, and postoperative complications were recorded. Patients were included in the analysis if there was a follow-up of at least 30 days, or if follow-up was less than 30 days but a complication was noted. A subset of our patients were deemed high risk for VTE based on personal or family history of blood clots and were referred to a hematologist preoperatively; these patients were included in our review if they received rivaroxaban 10 mg daily for prophylaxis as recommended by the hematologist.

At 1 center, formal risk stratification using the 2004 Davison-Caprini Scale[18] was employed; prophylactic rivaroxaban 10 mg was prescribed for 14 days if indicated (high risk, 3 factors or more). The decision to use this scale was made because of its relative ease of interpretation and completion compared with other scales. At the other center, rivaroxaban was administered routinely for all abdominoplasty patients, as they were deemed high risk based on the procedure type as cited in the ASPS VTE task force recommendations (which utilized the 2005 Caprini scale),[19] and was prescribed for 7 days. As a standard practice at both centers, the first dose was given 12 hours post-procedure if there was no concern for postoperative bleeding. Additional prophylaxis including perioperative sequential compression devices, knee flexion when supine, early ambulation, and maintaining adequate hydration, was standard practice.

Follow-up was the time from surgery until the most recent visit to the practice. A patient was considered a current smoker if they endorsed smoking at the preoperative visit (typically within 4 weeks of surgery) and was not considered a smoker if they reported a negative smoking history or had a negative urine cotinine test preoperatively. A patient was considered positive for contraceptive medication or hormone replacement therapy if they endorsed taking those medications in any form (pill, cream, ring, intrauterine, injection) at the preoperative visit; patients on these medications were encouraged to discontinue usage 2 weeks prior to surgery (with the exception of low-dose intrauterine devices).

RESULTS

The operative database was queried on July 11 2014. The chart review included all patients undergoing abdominal skin excision surgery during the time period from September 20, 2012 (the first patient to receive the medication) until the date of the query. One hundred eighty-seven patients had some form of abdominal skin resection during the study. Twenty-six patients were part of a trial involving tissue glue being evaluated for FDA approval and, therefore, did not receive chemoprophylaxis. Four patients had simple scar revisions, while 3 patients had limited surgeries where chemoprophylaxis was not felt to be indicated based on surgeon judgment. Three patients had surgeries at a local hospital not affiliated with the surgery centers and were excluded. Fifteen patients received enoxaparin (5 because of a hematologist's recommendations for a hypercoagulable state, 10 because the prescriptions were given to the patient preoperatively prior to the switch to rivaroxaban). Two patients underwent operative hematoma evacuation prior to receiving rivaroxaban and were excluded. One hundred thirty-four patients, therefore, underwent abdominoplasty and received at least 1 dose of rivaroxaban. Two patients had follow-up of less than 30 days without a complication and were, therefore, excluded. The remaining 132 patients who received rivaroxaban and had adequate follow-up were included in the analysis.

Demographic, body mass index (BMI), and comorbidity data are summarized in Table 1. For the 132 patients, there were 122 females (92%) and 10 males (8%). Mean patient age was 43.7 years (range, 19.8-71.5 years). Mean BMI was 27.1 (range, 17.3-45.9), and 33 patients (25%) had a BMI > 30. Ten patients were current smokers, 2 patients had diabetes, and 15 patients reported hypertension. Thirty-four patients were on oral contraceptives or hormone replacement therapy at the preoperative visit. Ten patients reported a family history of blood clots, and 3 patients had a personal history of DVT. Of the 112 patients for which we obtained preoperative Factor V Leiden data, 2 were heterozygous for the mutation. There were no patients who were homozygous for the Factor V Leiden mutation included in the analysis. Mean follow-up was 7 months (range, 1-20 months).

Operative details may be found in Table 2. As mentioned, all 132 patients had excision of excess abdominal skin. One hundred twenty-five patients (95%) also had a muscle plication. Eleven patients (8%) had a fleur de lis vertical skin resection. One hundred patients (76%) had abdominal liposuction. Twenty-two patients (17%) also had excision of back skin (either circumferential abdominoplasty/lower body lift or a bra line backlift). Seventy-nine patients (60%) had liposuction of their back. Ninety-three patients (70%) underwent additional procedures. Table 3 lists the procedures performed on individual patients, amount resected, and operative time. Additional procedures (eg, extremity contouring, fat grafting, breast or facial procedures) are also included. Mean resection weight was 10.6 lbs (range, 0.1-34.8 lbs), and 37 patients (28%) had more than 15 pounds removed. Mean length of anesthetic was 353.8 minutes (range, 137-640 minutes).

Complication data may be found in Table 4. Of our 132 patients who received postoperative rivaroxaban, 1 patient (0.76%) had a DVT/PE. The patient was a 61 year old woman, BMI 27.4, Factor V Leiden negative, who underwent abdominoplasty with muscle plication and circumferential trunk liposuction. On the fourth visit, on postoperative day (POD) 18, she reported a 2-day history of calf pain affecting her ambulation and shortness of breath

Table 1. Demographic Data

	Number (%) ± SD	Range
Total cases	132	NA
Mean age (years)	43.7 ± 10.2	19.8-71.5
Gender		
Women	122 (92.4%)	NA
Men	10 (7.6%)	NA
BMI	27.1 ± 5.5	17.3-45.9
Diabetic patients	2 (1.5%)	NA
Current smokers	10 (7.6%)	NA
HTN	15 (11.4%)	NA
Contraceptives/HRT	34 (25.8%)	NA
Family h/o VTE	10 (7.6%)	NA
Personal h/o VTE	3 (2.3%)	NA
Factor V Leiden heterozygous	2 (1.5%)	NA

BMI, body mass index; HRT, hormone replacement therapy; h/o, history of; HTN, hypertension; NA, not applicable; VTE, venous thromboembolism.

Table 2. Operative Data By Procedure

Procedure	No. (%)
Abdominal skin resection	132 (100)
Muscle plication	125 (94.7)
Abdominal liposuction	100 (75.8)
Back liposuction	79 (59.8)
Fleur de lis vertical skin resection	11 (8.3)
Back skin resection (lower body or bra line backlift)	22 (16.7)
Additional procedures	93 (70.5)

Table 3. Operative Data by Patient

Procedure	Number n = (%)	Add Proc n=	Weight removed mean lbs ± SD	Case length mean min ± SD
MP	13 (9.8%)	7	1.81 ± 2.54	207 ± 65.4
MP, ALipo	19 (14.4%)	8	8.45 ± 7.6	340.1 ± 130.6
MP, ALipo, FDL	1 (7.6%)	1	14.3	312
MP, ALipo, FDL, BSkin	2 (1.5%)	2	22.8 ± 4.5	489.5 ± 13.4
MP, ALipo, FDL, BSkin, BLipo	1 (0.76%)	1	11.9	483
MP, ALipo, BSkin	4 (3.3%)	4	12.6 ± 15.2	396.5 ± 44.9
MP, ALipo, BLipo	68 (51.5%)	50	12.6 ± 5.8	375 ± 70.9
MP, FDL	1 (0.76%)	0	27.9	263
MP, FDL, BSkin	5 (3.8%)	3	19.0 ± 7.3	448.6 ± 92.2
MP, FDL, BSkin, BLipo	1 (0.76%)	1	19.6	390
MP, BSkin	6 (4.5%)	6	4.7 ± 3.0	344.7 ± 79.2
MP, BSkin, BLipo	1 (0.76%)	1	9.7	407
MP, BLipo	3 (2.3%)	3	3.8 ± 2.7	363.3 ± 47.5
ALipo	1 (0.76%)	0	1.8	307
ALipo, BLipo	4 (3.0%)	4	8.1 ± 2.4	349.2 ± 37.9
ALipo, BSkin	1 (0.76%)	0	2.8	250
BLipo, BSkin	1 (0.76%)	1	4.6	258

All patients had abdominal skin resected. Add Proc, had additional procedures performed; ALipo, abdominal liposuction; BLipo, back liposuction; BSkin, excision of excess back skin, either a lower bodylift/circumferential abdominoplasty or a bra line backlift; FDL, fleur de lis vertical skin resection; MP, muscle plication.

Table 4. Complications

	No (%)
VTE event	1 (0.76)
Hematoma with operative evacuation	3 (2.3)
Blood transfusion POD 0-14	2 (1.5)
Blood transfusion POD ≥15	1 (0.76)
Wounds with dressing changes	33 (25.0)
Seroma with needle aspiration	38 (28.8)
Infections (including cellulitis)	27 (20.5)

POD, postoperative day; VTE, venous thromboembolism.

with normal conversation and sat for an extended time during a trade show shortly before the symptoms began. Ultrasound confirmed a left popliteal vein DVT, and a CT scan confirmed a PE, moderate-large clot burden affecting all lobes. She then began a therapeutic dose of enoxaparin and was transitioned to a therapeutic dose of Xarelto (20 mg daily) for DVT/PE treatment. While she indicated a family history of blood clots preoperatively, further inquiry postoperatively determined an extensive family history with multiple family members affected that had not been disclosed prior to surgery. She recovered uneventfully.

Three patients (2.3%) had a hematoma requiring operative evacuation. One patient (35 year old woman, BMI 19, using oral contraceptives, underwent a non-liposuction abdominoplasty with muscle plication and subfascial breast augmentation) had a hematoma at the abdominoplasty site evacuated on POD 2. One patient (28 year old woman, BMI 26.6, using oral contraceptives, underwent abdominoplasty with muscle plication and abdominal liposuction) had a hematoma at the abdominoplasty site evacuated on POD 3. One patient (37 year old woman, BMI 20.8, underwent abdominoplasty with muscle plication with abdominal liposuction, and a mastopexy) had a hematoma of the left breast site evacuated on POD 2.

Three patients (2.3%) received blood transfusions following their procedures after taking at least 1 dose of rivaroxaban. One patient underwent abdominoplasty with muscle plication and circumferential trunk liposuction

along with fat grafting to her buttocks and face. On POD 3 she developed symptomatic anemia with a Hgb of 8.5 g/dL, received a blood transfusion, and was discharged the following day. One patient had a circumferential abdominoplasty with rectus plication and liposuction to her inner thighs. On POD 1, she developed symptomatic anemia with a Hgb of 6.9 g/dL; she was discharged on POD 3 following blood transfusion. Both of these patients resumed their prophylactic dose of rivaroxaban once their hemoglobin stabilized without further issues with bleeding or anemia. Another patient, a 56 year old man, underwent a fleur de lis abdominoplasty with muscle plication. In the initial postoperative period, he did well but developed a wound in the vertical limb of his abdominoplasty that underwent serial debridement in clinic. Three weeks postoperatively (2 weeks after the rivaroxaban course) the wound began bleeding at home; he presented to a local emergency department where he received a blood transfusion for anemia. His wound subsequently healed with serial dressing changes.

Additional complications included seroma formation with needle aspiration (n = 38, 28.8%), wounds with dressing changes at any operative site (n = 33, 25%), and infections (n = 27, 20.5%). We attribute the relatively high seroma rate to frequent use of concomitant liposuction with a large volume of tumescent and aggressively aspirating even very small fluid collections. We attribute our relatively high infection rate to our low threshold for starting antibiotics for patients with a possible early cellulitis.

DISCUSSION

Regarding the decision to employ VTE chemoprophylaxis, Trussler and Tabbal stated, "The precarious balance of the coagulation cascade is the pivot point for two of the most common surgical complications: bleeding and thrombosis."[20] Hematomas requiring operative evacuation, and DVTs requiring prolonged anticoagulation to minimize propagation or post-thrombotic syndrome, are not pleasant events. A fatal PE is a nightmare scenario, as is massive postoperative hemorrhage leading to incapacitation or death. Postoperative complications, while difficult to tolerate for all patients, are perhaps more difficult to come to terms with for the healthy patient undergoing an entirely elective procedure. Continued study of methods to reduce complications while not causing a compensatory increase in others (eg, bleeding vs clotting) is imperative.

Ideally, chemoprophylaxis should: (1) be effective at preventing VTE, (2) have a low risk of adverse events such as hematoma formation, (3) be inexpensive, (4) be without the need for monitoring levels or adjusting doses based on weight or creatinine, (5) be easily administered and tolerated by the patient, and (6) be administered as part of a regular patient protocol without consulting a risk-stratification scale. At this time, no agent is ideal, and one must continue to weigh the risks and benefits of chemoprophylactic administration for any patient. Clinicians should consult a recommendation or risk-assessment scale that they find useful to help guide this decision.

Rivaroxaban has demonstrated effectiveness for VTE prophylaxis for patients undergoing hip and knee replacement (initial FDA indications), and bleeding rates were found to be similar to enoxaparin.[21,22] Regarding cost compared with enoxaparin, rivaroxaban demonstrated a cost savings in patients with total hip and total knee replacements.[23] Our patients report paying approximately $90 for a 1 week course if insurance does not cover the medication. If the typical prophylactic dosing is utilized, measuring drug levels is not necessary, and no adjustments are needed for dosage based on weight or creatinine clearance. Regarding compliance, no patients in our series reported difficulty tolerating the medication or were burdened by its administration.

There are myriad risk assessment modules and institutional guidelines to assist the surgeon with the choice of employing chemoprophylaxis,[18,19,24-30] sometimes with conflicting recommendations. In our series, the average abdominoplasty patient (age 43.7 yrs, BMI 27.1, operative time 353 minutes), has a 2004 Davison-Caprini Score of 3, 2005 Caprini Score of 4, 2010 Caprini Score of 6, and a Patient Safety Committee Score of "high". One center utilized the 2004 Davison-Caprini scale to guide rivaroxaban administration,[18] and another routinely administered rivaroxaban based on the heightened VTE risk for abdominoplasty patients, as cited in the American Society of Plastic Surgeons VTE task force recommendations (which utilized the 2005 Caprini scale).[19] As there is no VTE risk-assessment scale that has been formally validated in the outpatient abdominoplasty patient population, the choice of a particular scale is currently at the discretion of the surgeon. This is not the first published study on rivaroxaban in abdominoplasty patients. Dini and colleagues evaluated rivaroxaban for postoperative VTE prophylaxis in abdominoplasty patients.[31] In a prospective, randomized, double-blinded, placebo controlled study, 40 patients considered high risk were randomized to receive either rivaroxaban 10 mg or placebo daily for 10 days. The drug was first administered 8 hours after surgery. After 27 surgeries, the study was stopped due to a high complication rate; it was noted that all 8 hematomas up to that point had occurred in the study (rivaroxaban) group. While the increased bleeding rate may have resulted from the timing of the first dose being only 8 hours after surgery, we believe that it was likely the routine postoperative use of tenoxicam (a nonsteroidal anti-inflammatory drug [NSAID]) that potentiated bleeding when used in combination with rivaroxaban. When patients are instructed to avoid NSAIDs while on rivaroxaban, and when giving our first dose 12 hours after surgery, we have not experienced unacceptably high rates of bleeding complications.

While we are unhappy with any VTE event, our 1 patient with a DVT/PE (0.76%) in this study is consistent

with the incidence in the literature. This patient also had an extensive family history of blood clots, and it would have been the practice at the institution where she was treated to have her referred to a hematologist preoperatively, and perhaps keep her on DVT chemoprophylaxis for a longer period of time (she developed symptoms of a DVT 9 days after she would have stopped her rivaroxaban). Regarding hematoma, Stewart et al published their experience with 278 abdominoplasties and reported a 3% hematoma rate (and 1 patient had a pulmonary embolus).[32] Specific VTE prophylactic measures were not mentioned in this series; however, upon communication with Mr. Stewart, he relayed that heparin administration was not a standard practice at that time. Out of our 132 patients, the hematoma formation requiring operative evacuation in 3 patients (2.3%) is also acceptable, with 2 hematomas at the abdominal site (therefore, a 1.5% rate of hematoma evacuation for the abdominoplasty portion) and 1 at a breast site. All patients went on to heal and were pleased with their operative results. When compared to reoperative hematoma rates in the plastic surgery population in general, our use of rivaroxaban is consistent with previously published data. Studying 3681 patients having a wide array of surgical procedures, Pannucci et al reported an overall reoperative hematoma rate of 2.65% when enoxaparin was not administered and 3.38% when enoxaparin was administered (not significant) in this study of 1567 patients at moderate to high risk for VTE events according to the 2005 Caprini scale and 2114 matched historical control patients.[8]

A potential limitation of our study is that we only included patients receiving rivaroxaban during the study period. The exclusion of patients that did not receive the medication (ie, the 5 patients that had enoxaparin recommended by a hematologist) could introduce bias by selecting out the highest risk patients. Additionally, since this study reports on a patient series without a comparison group, we cannot make conclusions regarding superiority or inferiority of rivaroxaban use for abdominoplasty patients with respect to VTE prevention or complication rates. The strengths of the study include the large number of patients and our inclusion of all consecutive patients during our study period who took rivaroxaban with adequate follow-up for relevant hematologic and surgical complications. In our experience, rivaroxaban has a low rate of adverse events such as hematoma formation and is well tolerated by patients without a large burden of cost. Further study with a larger series of patients and comparison with other VTE prophylactic regimens (medication-based or otherwise) is warranted. While currently considered an off-label indication, the 2 surgical centers continue to prescribe oral rivaroxaban routinely to patients undergoing abdominoplasty for VTE chemoprophylaxis.

CONCLUSIONS

Routine chemoprophylaxis with rivaroxaban (Xarelto) for high-risk abdominoplasty patients has a low rate of VTE events. This oral medication is well tolerated and has an acceptable complication profile.

Disclosures

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