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ORIGINAL CONTRIBUTIONS

The Safety and Efficacy of Apixaban (Eliquis) in 5017 Post-bariatric Patients with 95.3% Follow-up: a Multicenter Study

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Abstract

Background Thromboprophylaxis in bariatric surgery is widely debated; however, few large articles evaluate treatment plans and their efficacy. Herein, we make the first large-scale report of the safety and efficacy of apixaban (Eliquis) for thrombus prevention following bariatric surgery.

Purpose To evaluate the safety and efficacy of apixaban following bariatric surgery.

Setting Three private institutes, USA.

Materials and Methods Data from 5017 consecutive bariatric patients that were placed on postoperative apixaban for thromboprophylaxis were used for retrospective analysis. The dose prescribed to patients was 2.5 mg PO BID for a total of 30 days starting on day 3 postoperatively.

Results In total, of the 5017 patients, 59.7%, 31.2%, 4.4%, 2.5%, 1.8%, and 0.1% of the patients had undergone sleeve gastrectomy (SG), single-anastomosis duodeno-ileal bypass with SG (SADI-S), Roux-en-Y gastric bypass (RYGB), conversion from SG to SADI, small bowel reconstruction, and RYGB reversal, respectively. The 30-day follow-up rate was 95.3%. In total, 1.7% of patients experienced apixaban-related side effects. The most common side effects were menorrhagia and rash. Two (0.03%) side effects developed into Clavien-Dindo grade II complications. Overall, 10 (0.1%) patients experienced thromboembolic complications (five (0.09%) PVTs and five (0.09%) PEs). In each case, the protocol was not followed for extenuating circumstances. There were no deaths or thromboembolic events in cases where the protocol was able to be fully followed.

Conclusions In conclusion, 30 days of postoperative apixaban appears to be safe and effective with minimal side effects while preventing thromboembolic events.

Keywords Apixaban · Eliquis · Bariatric surgery · PVT · PE · Thromboprophylaxis

Key Points
- 1.7% of patients experienced apixaban-related minor side effects.
- 0.1% of patients experienced thromboembolic events.
- There were no deaths or thromboembolic events in cases where the protocol was able to be fully followed.

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Bariatric surgery aims to provide an interventional approach to weight loss and managing metabolic illness. However, undergoing bariatric surgery is accompanied by an inherent risk of postoperative thrombosis, specifically deep vein thrombosis (DVT), portal vein thrombosis (PVT) and mesenteric venous thrombosis (MVT), and pulmonary embolism (PE) [1]. While the exact mechanism is unknown, unintentional vessel injuries during surgery may explain the increased incidence of PVT and MVT reported following vertical sleeve gastrectomy (VSG). Furthermore, morbid obesity, insufflation for laparoscopy, and use of the reverse Trendelenburg position are all potentially harmful to venous flow and thus increase the risk of developing postoperative thrombosis [1–5].

Patients can take anticoagulant medication following surgery to minimize the risk of developing postoperative thrombosis. Anticoagulants prolong the time it takes for blood to clot, effectively preventing blood clots from causing undesirable thromboembolic events; one such anticoagulant is apixaban (Eliquis).

Apixaban was approved by the U.S. Food and Drug Administration (FDA) on the 8th of December 2012 [6]. This drug effectively "thins" the blood and prevents it from clotting by preventing factor X from functioning in the coagulation cascade [7]. Apixaban has several advantages over other anticoagulation medications. It does not require special storage, food restrictions or meal requirements, routine coagulation testing, and dose adjustments, especially in patients with renal impairment [8]. It is less costly and does not require an injection. There are even suggestions that it is more effective than low molecular weight heparin (LMWH) and has a lower rate of bleeding complications [8, 9]. It requires much less follow-up from healthcare professionals [10]. It also has a low bleeding risk. Moreover, it does not require regular international normalized ratio monitoring, thus requiring infrequent dose adjustments, compared to warfarin (Coumadin) [8, 11]. In addition, since it is taken orally, it has a much higher patient compliance rate than self-administered shots with unfractionated heparin or LMWH [12].

Current bariatric literature has not reported on the use of apixaban as a prophylactic anticoagulant medication following bariatric surgery [13–15]. This study evaluates the safety and efficacy of apixaban following bariatric surgery by evaluating the reported side effects and complications.

Methods

This study has been approved by the Quorum Institutional Review Board (QR# 31,353). It is a retrospective analysis of data from 5017 consecutive patients (inpatient and outpatient) who had undergone either a primary or revision laparoscopic sleeve gastrectomy (SG), single-anastomosis duodeno-ileal bypass with SG (SADI-S), Roux-en-Y gastric bypass (RYGB), SG to SADI-S, small bowel reconstruction, and RYGB reversal by five surgeons at three private institutes from October 2016 through December 2021.

Of the three centers that participated in the study, one center placed patients on LMVH preoperatively (enoxaparin sodium 30 or 40 mg [Lovenox]). The other two centers used heparin 5000 U subcutaneous preoperatively. Mechanical prophylaxis with sequential compression device (SCD) was used in all centers intraoperatively and postoperatively until discharge. Early ambulation was encouraged.

Postoperatively, all 5017 patients that were included in the study were prophylactically placed on apixaban (Eliquis) from postoperative day 3 to day 33. The dose prescribed to patients was 2.5 mg PO BID for a total of 30 days.

The electronic health records in each center were used to determine follow-ups and the presence or absence of complications. If, for any reason, a patient stopped the medication prematurely, their reasoning was recorded and included as a potential side effect.

The side effects studied include rashes, postoperative bleeding, prolonged menstrual bleeding, epistaxis, mood issues, headaches, and any type of thromboembolism like DVT, PVT, and PE.

Results

In total, 5017 patients were included in the final analysis.

Of the 5017 surgeries, 3976 (79.2%) were inpatient and 1041 (20.7%) were outpatient surgeries. Of the 5017 patients, 59.7%, 31.2%, 4.4%, 2.5%, 1.8%, and 0.1% of the patients had undergone SG, SADI-S, RYGB, conversion from SG to SADI, small bowel reconstruction, and RYGB reversal, respectively. The mean age and preoperative body mass index (BMI) were 43.2 ± 12.1 years and 44.6 ± 8.5 kg/m2, respectively. The 30-day follow-up rate was 95.3%.

In total, 90 (1.7%) patients experienced apixaban-related side effects. The most common side effects were menorrhagia (44.4%) and rash (42.1%) (Table 1). Most patients that experienced any side effects had taken at least 1 week of apixaban before the appearance of the side effect.

Two (0.03%) side effects developed into Clavien-Dindo grade II complications. Of the two patients, one (0.01%) patient had an abortion several weeks prior to resleeve and conversion to SADI-S. Unknown to the patient, she had retained placenta and, when placed on apixaban, postoperatively developed menorrhagia and was hospitalized and required a dilation and curettage. The other patient was a young male that underwent an uneventful LSG. He had a change in symptoms and near syncope on POD 7.

Table 1 Side effects of prophylactic apixaban in post-bariatric patients

Side effect	Event (no.)	Percentage
Menorrhagia	40	0.7
Rash	38	0.7
Epistaxis	5	0.09
Hematuria	2	0.03
Hematemesis	2	0.03
Mood issue	1	0.01
Headache	1	0.01
Post-surgical bleed	1	0.01
Total	90	1.7%

He was admitted where a CT scan showed a large clot and required transfusion of three units of blood. He stabilized and was followed for several days and discharged without further intervention.

Overall, 10 (0.1%) patients experienced thromboembolic events. Of the 10 patients, five (0.09%) patients experienced PVT, and five (0.09%) patients experienced PE. In each case, the drug regimen was not followed for extenuating circumstances.

One patient experienced PVT. The patient had undergone an uneventful SG surgery. On day 7, the patient took all of the apixaban that the pharmacist had been given, not knowing the pharmacist had only given him part of the prescription since they had run out of apixaban in the pharmacy. The patient did not understand that he was supposed to come back and pick up the rest of the prescription. On day 14, the patient presented with abdominal pain and constipation. The patient was sent to the ER, where a CT scan revealed a PVT. They were admitted and treated with anticoagulation and discharged home on Coumadin. There was no sequela of the PVT. All the other patients with PVTs in the study did not pick up their prescription for unknown reasons (we could not tell from the chart if this was due to cost or inconvenience).

Of the five PEs, one (0.01%) PE led to the patient's death. The patient had undergone an uneventful SADI-S surgery. She started her apixaban on postoperative day 3. On postoperative day 6, the patient developed a postoperative partially obstructive trocar-site hernia. She lived 4 h away from the site where her surgery was performed. Rather than fixing it locally, the local surgeon deferred and sent them by ambulance for 4 h to the hospital where the SADI-S was originally performed. She was reoperated for a trocar-site hernia with a partial small bowel obstruction and received both chemical and mechanical prophylaxis for her surgery. Postoperatively, the patient also received heparin. She was discharged on postoperative day 1, eating, drinking, with normal mentation, and walking well. She stopped three times on the 4-h drive home to get out and walk to prevent blood clots. The evening of postoperative day 1, she suddenly collapsed and was rushed to the ER, where a CT scan revealed a PE. Shortly after admission, she was pronounced dead from hypoxia. The other patients with PEs in the study did not pick up their prescriptions for unknown reasons.

In total, one (0.01%) death was noted during the study period. None of the patients experienced any isolated DVT event.

Discussion

Obesity is a known, independent risk factor for new-onset and recurrent thromboembolic events [16]. The main pathophysiological background of the elevated thrombotic risk in obesity is represented by inflammation [17]. The risk increases even more with high BMI and advanced age [18]. Individuals with BMI > 35 kg/m^2 may present a sixfold greater risk than those with normal BMI [17]. The risk is even higher in surgical patients [19]. The reported incidence of PVT, DVT, and PE following bariatric surgery ranges from 0.3 to 1%, 0 to 6.4%, and 0 to 5.4%, respectively [13, 14, 20–24, 24, 26]. That means according to published literature, of the 5017 patients that were included in the final analysis of the present study, at least 15 to 50 patients were at the risk of developing PVT, 0 to 321 patients were at the risk of developing DVT, and 0 to 271 patients were at the risk of developing PE. However, none of the patients who completed the postoperative prophylactic 30-day apixaban course experienced PVT, DVT, or PE.

Data from the multicenter prospective Longitudinal Assessment of Bariatric Surgery (LABS) study reported a 30-day incidence of thromboembolic events of 0.4% [27]. In the present study, the 30-day thromboembolic event rate was 0.1%. Stein et al., in 2013, found that the prevalence of thromboembolic events following bariatric surgery appeared to be 2.2% [4]. This study was instrumental in determining a baseline rate of VTE following bariatric surgery and showing the higher risk of DVT for the patients with morbid obesity. If our group had experienced a 2.2% rate of thromboembolic events, we would have seen 110 blood clots postoperatively; instead, we saw zero in patients who were able to complete the protocol.

Post-discharge mortality following bariatric surgery is rare. PE that usually occurs in the post-discharge phase has an even higher mortality rate [28]. It is the leading cause of death in the post-discharge phase in bariatric patients, around 20.7% [28]. In the present study, one patient (0.01%) experienced PE leading to death. PVT is another rare but potentially fatal post-discharge complication [21, 29, 30]. The reported incidence of mortality caused by PVT is 1.3% [21, 29]. None of the patients in the study died from PVT or even experienced PVT. These findings are extremely promising.

All medications can cause side effects. When weighing the severity of side effects of apixaban experienced by our patients with the dramatic decrease in the likelihood of developing thromboembolic events, the conclusion is clear; mild reactions to apixaban experienced by approximately 1.7% of patients are well worth the benefit of reducing the rate of postoperative thromboembolic events. Reactions were mild, with menorrhagia (44.4%) and rashes (42.2%) accounting for almost 86.6% of all side effects.

A paucity of data exists; hence, when reading this article, possible questions may arise regarding diagnosing of thromboembolic events, dosage, duration, or absorption of apixaban in post-bariatric patients.

According to the American College of Chest Physicians evidence-based clinical practice guidelines, the patients undergoing hip or knee arthroplasty or hip fracture surgery (HFS) should receive thromboprophylaxis for a minimum of 10 days (grade 1A [grade 1 recommendations are strong and indicate that the benefits do or do not outweigh risks, burden, and costs]) [1]. For hip arthroplasty and HFS, they recommend continuing thromboprophylaxis > 10 days and up to 35 days (grade 1A). New oral anticoagulant like apixaban is currently available for prophylaxis against VTE in patients undergoing total hip or knee replacement surgery [8]. The level of risk for postoperative thrombosis depends largely on the type of surgery performed. The incidence of DVT after general surgical procedures is about 20 to 25%, with almost 2% of these patients having a clinically significant PE [31], whereas the risk for DVT after hip surgery and knee reconstruction ranges from 45 to 70% without prophylaxis, and clinically significant PE occurs in 20% of patients undergoing hip surgery [32]. Orthopedic surgical specialty is one of the top 5 high-risk surgeries for postoperative thromboembolic events [33, 34]. The effectiveness and safety of apixaban have already been evaluated in these patients. As per the recommended dosing, a standard dose of 2.5 mg BID for 35 days starting from 12 to 24 h effectively prevents any thromboembolic events postoperatively [8]. In addition, in patients with a history of DVT/PE, the chances of recurrence are higher; however, the recommended dose in such cases remains the same, which is 2.5 mg BID [8].

We chose postoperative day 3 because the joint replacement literature suggests postoperative bleeding complications fall to 0. Moreover, in post-bariatric patients, acute postoperative bleeding usually occurs within 12–48 h after a surgical procedure [35]. Additionally, the usual occurrence day for DVT following bariatric surgery is usually greater than a week. The third day was chosen as a compromise of these two competing factors.

Bariatric surgery may alter the absorption of oral anticoagulants to an extent. It may be true for some DOACs; however, it may or may not be true for apixaban. A few articles in the literature suggest that apixaban appears to be most readily absorbed in the upper small intestine with some gastric absorption; however, as per the document by the FDA, apixaban is absorbed throughout the gastrointestinal tract with the distal small bowel and ascending colon also contributing to the absorption [36]. Rottenstreich et al., in their article on the effect of bariatric surgery on direct-acting oral anticoagulants (DOACs), assessed the blood levels of DOACs in post-bariatric patients through a cross-sectional, matched cohort study [37]. Data were obtained by matching every bariatric patient to a healthy patient of the same age, sex, BMI, and serum creatine. The drug peak levels of post-bariatric patients were compared to the control group taking the same drug. They found that the drug levels were below the expected range in post-bariatric patients who used rivaroxaban; however, the peak drug levels were within the expected range in all apixaban patients. The peak levels for apixaban did not differ in the post-bariatric surgery group compared to the control group (median 207 [164 to 271] vs. 212 [126 to 238] ng/mL, $P = 0.92$).

Our study has some limitations. First, it is retrospective and not prospective. This means we cannot comment on "the correct day to start postoperative Apixaban." Second, some of the known risk factors for VTE are prior VTE, age, immobility, smoking, oral contraceptives, estrogen treatment for hormone replacement therapy, family history of VTE, and clotting disorders. In the present study, we did not evaluate for any of the predisposing risk factors (patient-related and procedure-related); however, not evaluating these patients for these risk factors did not change the outcome of the study. Additionally, as this was a standard of care study, only the outcomes were measured, not patient compliance. Third, some of the reported side effects may or may not be associated with apixaban. This is especially true for menorrhagia following bariatric surgery. Fourth, apixaban was discontinued in any patients with side effects, and with the exception of menorrhagia, they were prescribed rivaroxaban 10 mg PO QD. Fifth, a few studies have reported the first 90-day outcomes after surgery [38]. Like most thromboprophylaxis-related articles in the literature, the present study also evaluated the first 30 days after surgery. Around 80% of thromboembolic events occur within the first 30 days after surgery, and that is why the patients in the present study received a 30-day course of apixaban postoperatively [15, 39]. Furthermore, a few patients may or may not have received extended prophylactic. The present study did not evaluate the effect of extended prophylactic in such patients.

There is no class I evidence to guide specific recommendations regarding dosing or duration in post-bariatric patients. Also, the study did not prospectively look for thromboembolic events with ultrasounds or CT scans. This was a standard of care retrospective study looking for symptomatic thromboembolic events, and as such, there may have

been subclinical thromboembolic events that we did not appreciate. Our 95.3% follow-up also means that our data are very accurate, but we cannot exclude the possibility that in 4.7% of the patients, there may have been a thromboembolic event. Lastly, this study is our 5-year experience of using prophylactic apixaban in bariatric patients. In our opinion, proper patient selection and adherence to the protocol may minimize the risk of post-discharge thromboembolic events but would not eliminate them.

Conclusions

In conclusion, preoperative heparin, intraoperative use of SCD, postoperative early ambulation, and a 30-day postoperative course of apixaban have a positive outcome regarding thromboembolic events, regardless of the type of bariatric surgery. Furthermore, prospective studies are required to make any definitive conclusion on the effectiveness of this novel therapy.

Declarations

Ethics Approval For this type of study, formal consent is not required.

Consent to Participate Does not apply.

Conflict of Interest Amit Surve, M.D., has no conflict of interest. James Potts, MA, has no conflict of interest. Daniel Cottam, M.D., reports personal fees and others from Medtronic and GI Windows outside the submitted work. Mitchell Roslin, M.D., F.A.C.S., F.A.S.M.B.S., is an educational consultant at Johnson & Johnson Inc., Covidien Ltd., and W. L. Gore & Associates and receives compensation from these companies. Additionally, he is on the scientific advisory board at SurgiQuest and ValenTx and has stocks options in these companies. Walter Medlin, M.D., F.A.C.S., has no conflict of interest. Miro Uchal, M.D., F.A.C.S., has no conflict of interest. Christina Richards, M.D., F.A.C.S., has no conflict of interest. Legrand Belnap, M.D., has no conflict of interest.

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