



ORIGINAL RESEARCH

Comparative analysis of apixaban vs. enoxaparin for thromboprophylaxis after radical cystectomy

A single-center, observational, before-after study

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ABSTRACT

INTRODUCTION: Radical cystectomy (RC) is the standard treatment for muscle-invasive and select high-risk non-muscle-invasive bladder cancer. Venous thromboembolism (VTE) is a common and preventable postoperative complication. Extended thromboprophylaxis with low-molecular-weight heparin, such as enoxaparin, is recommended, but direct-acting oral anticoagulants like apixaban are a possible alternative. This study evaluated the safety and efficacy of apixaban compared to enoxaparin for extended postoperative thromboprophylaxis following RC.

METHODS: A single-center, observational, before-after study of RCs performed between October 2021 and August 2024 was conducted. Patients receiving 28 days of post-discharge thromboprophylaxis with either enoxaparin or apixaban were included. The primary outcome was postoperative VTE within 30 days. Secondary outcomes included 90-day postoperative VTE, 30-day post-discharge emergency room (ER) visits, readmissions, complications such as bleeding, and 90-day postoperative mortality.

RESULTS: A total of 102 patients who received enoxaparin and 83 patients who received apixaban for VTE thromboprophylaxis were included. No significant differences were found in 30-day postoperative VTE rates (0 [0%] apixaban vs. 2 [2%] enoxaparin, $p=0.5$), 90-day VTE rates, 90-day overall survival, or 30-day post-discharge ER visits, readmissions, or hemorrhagic complications ($p>0.05$).

CONCLUSIONS: Apixaban appears to be a safe and effective alternative to enoxaparin for extended postoperative VTE prophylaxis following RC for bladder cancer.

INTRODUCTION

Bladder cancer is the fifth most common malignancy in Canada, with an estimated incidence of 12 300 and a projected death toll of 5500 in 2024.¹ The standard of care for both muscle-invasive bladder cancer and select high-risk non-muscle-invasive bladder cancer is radical cystectomy (RC).² RC is associated with substantial morbidity, with complication rates reaching as high as 64% within 90 days post-surgery.³

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and pulmonary embolism (PE), is the most common preventable cause of post-surgical morbidity and mortality.⁴ Recent studies have demonstrated that up to half of immediate postoperative mortality is attributable to VTE in the context of complex cancer surgery.⁵ Abdullah et al, in a systematic review of VTE rates following RC for bladder cancer that included 22 studies and 40 146 total patients, reported a 30-day range of 1.3–7.7% and a 90-day range of 2.5–6.3%. The heterogeneity was attributed to differences in length of followup, variations in study populations, use of pharmacologic VTE prophylaxis, and open or robotic approach.⁶

Furthermore, large-scale studies have demonstrated a mean time to VTE of 15.2 days postoperatively, which is most often after discharge.⁷ The Canadian Urological Association (CUA) strongly recommends a 28-day postoperative course of low-molecular-weight heparin (LMWH),

KEY MESSAGES

■ In a single-institution study, apixaban appears to be a viable alternative to enoxaparin for extended postoperative venous thromboembolism prophylaxis following radical cystectomy for bladder cancer.

■ Despite the potential limitations included in a retrospective cohort comparison, apixaban demonstrated a 0% (0/83) rate of 30- and 90-day deep vein thrombosis and pulmonary embolism, with no increase in bleeding events, supporting its efficacy as an alternative to enoxaparin.

such as enoxaparin, for any patient undergoing an open or robot-assisted RC (RARC), which is consistent with the European Association of Urology (EAU) guidelines;^{8,9} however, there is considerable variation among other published guidelines regarding the optimization of thromboprophylaxis, with recommendations varying based on risk categories, procedure types, and timing.¹⁰

Prior studies regarding RC have demonstrated the utility of extended 28-day postoperative thromboprophylaxis with enoxaparin, with 30- and 90-day VTE rates dropping from 12% to 5% and 17.6% to 5.06%, respectively, when compared to in-hospital-only heparin, with no increased risk of bleeding.^{11,12} Despite its demonstrated utility, limitations of enoxaparin, such as cost and need for subcutaneous injection, have led to poor patient adherence.¹³ This has prompted research into direct-acting oral anticoagulants (DOACs) such as apixaban for extended postoperative thromboprophylaxis.¹³ Studies in orthopedic surgery include several large-scale randomized controlled trials (RCTs) demonstrating the superiority of apixaban, with lower postoperative VTE rates as compared to enoxaparin;¹⁴⁻¹⁸ however, the CUA guideline does not recommend the use of DOACs as first-line agents, citing insufficient evidence in the context of urologic surgery.⁸

In this study, we investigated the safety and efficacy of apixaban compared to enoxaparin for extended postoperative thromboprophylaxis after RC for bladder cancer.

METHODS

Study population

This study was approved by the University of British Columbia Clinical Research Ethics Board (H24-00803

and H23-04134). This was a single-center, observational, before-after study of adverse events in patients who underwent open or robotic RC at our tertiary care center between October 2021 and August 2024 based on an anticipated sample size of 100 patients for each group. All procedures were performed by four surgeons (MG, MM, MP, and PB). Only patients who were prescribed 28 days of postoperative thromboprophylaxis after undergoing RC for bladder cancer were included. Patients were excluded if they were on therapeutic anticoagulation, had a contraindication for receiving thromboprophylaxis, or underwent RC without a primary bladder oncologic indication.

Thromboprophylaxis regimen

All patients were treated under the same enhanced recovery after surgery (ERAS) protocol, as described previously.¹⁹ The ERAS protocol included 5000 units of subcutaneous heparin intraoperatively after epidural catheter insertion, sequential compression devices, and encouragement of early postoperative ambulation. Additionally, all patients received 40 mg of subcutaneous enoxaparin daily, beginning the morning of postoperative day 1.

Before May 1, 2023, all eligible patients were discharged with a 28-day prescription of 40 mg/day of subcutaneous enoxaparin for VTE prophylaxis, with nursing staff providing proficiency training in self-injection. After May 1, 2023, all eligible patients received 2.5 mg of oral apixaban twice daily for up to 28 days postoperatively instead of enoxaparin, starting the day after discharge. Ineligible patients had contraindications to apixaban, such as significantly impaired kidney function. In parallel to this change in ERAS protocol on May 1, 2023, perioperative methylnaltrexone was added to enhance postoperative bowel function.

Data sources

All patient information was obtained from patient medical records via paper charts from October 2021 to November 2022 and thereafter from the electronic medical record (EMR). Information after discharge, such as emergency room (ER) visits, imaging, labs, and consult notes, was obtained from the hospital or urology clinic's EMR, relying on followups and referral notes for non-local patients. Data collection was performed from May to December 2024, with review from the date of RC to 90 days postoperative.

Outcome measures

Data collected included demographics, clinical data, surgical data, and postoperative clinical outcomes. Our

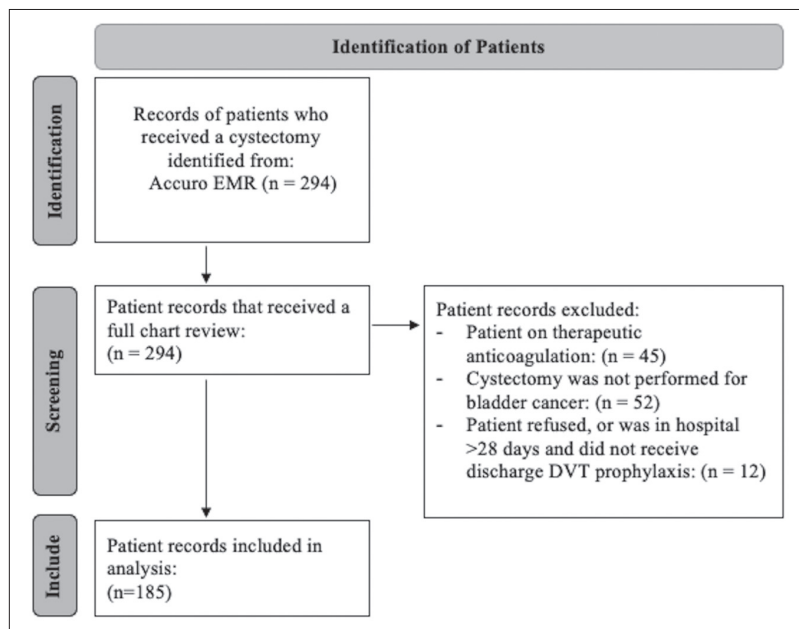


Figure 1. PRISMA diagram. DVT: deep vein thrombosis; EMR: electronic medical record.

primary outcome measure was the incidence of VTE, including DVT or PE, confirmed by imaging, within 30 days postoperatively. Patients were evaluated for VTE only based on clinical suspicion. Secondary outcomes included the incidence of 30-day postoperative bleeding and 90-day postoperative VTE, as well as the number of ER visits and readmissions within 30 days post-discharge and overall survival (OS) at 90 days postoperatively. VTE was defined as a description of DVT on peripheral ultrasound or PE on computed tomography (CT) angiogram or ventilation-perfusion scan. Bleeding was defined as any post-discharge bleeding event, including the development of a new hematoma confirmed by imaging, or any bleeding requiring intervention, such as a transfusion.

Statistical analysis

No sample size calculation was made, and convenience sampling was used. Descriptive statistics were used to summarize baseline patient characteristics, surgical data, and postoperative outcomes. Medians and interquartile range (IQR) were used to summarize continuous variables, while categorical variables were reported as counts and percentages. Risk difference and the 95% confidence interval (CI) using Wilson score interval method were used. P-values were calculated using Fisher's exact test and Barnard's exact test for variables that had no events in a group. P-values <0.05 were considered statistically significant.

The Cox proportional hazards model was used to estimate hazard ratios (HRs) for 90-day OS, with adjust-

ment for type of thromboprophylaxis at discharge, age at surgery, sex, and American Society of Anesthesiologists (ASA) physical status classification. No other regression analyses were performed due to the small number of events in the outcomes measured.²⁰ All analyses were performed using RStudio version 4.1.2.

RESULTS

A total of 294 RCs were performed during the study period. Following chart review, 109 were excluded, leaving 185 patients for analysis (Figure 1). Of these, 102 (55.1%) received enoxaparin while 83 (44.9%) received apixaban. There were 174 (94%) RCs performed using an open approach and 11 (6%) that were RARC, 10 of which were in the apixaban group and one in the enoxaparin group. The median age was 70 years (IQR 64–76) and 77% were male. Table 1 presents the baseline characteristics and demographics of each group. Additional perioperative outcomes, such as transfusions received and pre-discharge complications, are presented in Supplementary Table 1 (available at cuaj.ca).

The total incidence of VTE at 30 days postoperative was two (2.0%) for patients who received enoxaparin and zero (0%) for apixaban. The small number of events resulted in an imprecise estimate rate and wide CI (risk difference 2%, 95% CI -8.8–1.3, $p=0.5$) (Table 2). The 90-day postoperative total VTE rate was four (3.9%) for enoxaparin and zero (0%) for apixaban (risk difference 3.9%, 95% CI -8.6–1.6, $p=0.13$).

A total of 57 (31%) patients visited the ER at least once within 30 days after discharge, and 39 (21%) were readmitted at least once. There were no significant differences in the secondary outcomes between groups ($p>0.05$), and the risk difference had wide 95% CIs for 30-day postoperative hemorrhage, 90-day postoperative VTE, and 30-day post-discharge ER visits and readmissions (Table 2). Of the patients who consulted the ER, the most common Clavien-Dindo complications were grade 1–2 ($n=44$, 24%), with only 13 (7%) grade 3–4 complications.²¹

There were two deaths in each group within 90 days postoperatively (risk difference -0.4%, 95% CI -1.4–1.4, $p=1.0$). Univariable Cox regression showed that the type of thromboprophylaxis at discharge (reference: enoxaparin) was not significantly associated with OS (HR 0.42, 95% CI 0.12–1.49, $p=0.18$). After adjusting for age, sex, and ASA score, the association remained non-significant (adjusted HR 0.37, 95% CI 0.10–1.32, $p=0.13$), although older age at surgery was independently associated with worse survival (HR 1.07 per year increase, 95% CI 1.02–1.13, $p=0.006$).

DISCUSSION

We compared VTE rates in patients receiving extended VTE thromboprophylaxis with enoxaparin or apixaban following RC for bladder cancer. In this observational, before-after study, there were very low rates of 30- and 90-day VTE post-RC with either agent. Additionally, there were no differences in rates of bleeding or other complications, including ER visits and readmissions.

This study contributes to a growing body of evidence demonstrating apixaban as a safe and effective alternative to LMWH for extended VTE thromboprophylaxis after RC.

Numerous retrospective studies have demonstrated the efficacy of DOACs, including apixaban, in comparison to LMWHs in urologic cancer surgery.^{22,23} To date, four studies including 246 total patients receiving apixaban have demonstrated apixaban as a viable alternative to enoxaparin in RC for bladder cancer specifically.²⁴⁻²⁷

Ortiz et al reported no significant differences in VTE events or bleeding complications in their study of 66 patients, with 29 patients in the DOAC group; however, their study consisted of only RARC, and there was no standardization of which DOAC patients received on discharge, which included 30-day postoperative apixaban, rivaroxaban, or dabigatran. Further, patients received either heparin or enoxaparin immediately postoperatively, and the time to DOAC implementation varied.²⁴

Rosen et al reported no VTE or major bleeding events in their 72-patient cohort of RC patients receiving 28 days of apixaban post-discharge; however, they did not compare with LMWHs, nor did they include whether the procedure was an open or RARC.²⁷ In the largest study to date, Rich et al found no significant difference in VTE rates in their cohort of 374 RARC patients, 124 of whom had received apixaban. In their study, thromboprophylaxis was administered for 21 days postoperatively, and apixaban was initiated on the first postoperative day rather than on the first day of discharge.²⁶

Aside from its safety and efficacy, perhaps the most appealing aspects of apixaban are its oral administration and cost. LMWHs, though efficacious, have been found to have a rate of non-compliance ranging from 20–40% in the postoperative cancer-related setting.²⁷ Common reasons given for non-compliance are cost, pain, and needle aversion.^{13,27,28} In a study comparing 161 patients receiving enoxaparin and 154 receiving apixaban following abdominopelvic oncologic surgery, Westerman et al reported compliance events in 33.5% of the enoxaparin group vs. 14.3% in the apixaban

Table 1. Baseline characteristics by type of VTE prophylaxis received at discharge

Variable		Enoxaparin (n=102)	Apixaban (n=83)
Sex, n (%)	Female	20 (19.6)	22 (26.5)
	Male	82 (80.4)	61 (73.5)
Median (IQR) age, years		70.0 [64.0, 75.0]	71.0 [65.0, 77.0]
Median (IQR) BMI, kg/m ²		27.1 [24.2, 31.2]	26.2 [22.2, 28.5]
Median (IQR) CCI score		5.0 [4.0, 7.0]	5.0 [3.0, 6.0]
History of DVT/PE, n (%)		3 (2.9)	0 (0.0)
Received NAT, n (%)		40 (39.2)	30 (36.1)
Smoking status, n (%)	Never	34 (33.3)	36 (43.4)
	Former	55 (53.9)	34 (41.0)
	Current	13 (12.7)	13 (15.7)
cTNM stage, n (%)	≤cT1	43 (42.2)	37 (44.6)
	cT2	46 (45.1)	41 (49.4)
	≥cT3	13 (12.7)	5 (6.0)
Type of urinary diversion, n (%)	Ileal conduit	79 (77.5)	64 (77.1)
	Other (Indiana pouch, neobladder)	23 (22.5)	19 (22.9)
Median (IQR) EBL, mL		500.0 (400.0, 700.0)	400.0 (300.0, 700.0)
Median (IQR) LNs removed		15.0 (9.0, 22.0)	14.0 (8.0, 17.5)
Histology, n (%)	Primary UC	98 (96.1)	78 (94.0)
	Pure squamous	3 (2.9)	1 (1.2)
	Pure adeno	1 (1.0)	4 (4.8)
pTNM, n (%)	≤(y)pT1	48 (47.0)	41 (49.4)
	(y)pT2	14 (13.7)	10 (12.0)
	(y)pT3	26 (25.5)	24 (28.9)
	(y)pT4	13 (12.7)	8 (9.6)
pN positive, n (%)		22 (21.5)	13 (15.7)

Adeno: adenocarcinoma; BMI: body mass index; CCI: Charlson comorbidity index; cTNM: clinical tumor stage; DVT: deep vein thrombosis; EBL: estimated blood loss; IQR: interquartile range; LNs: lymph nodes; NAT: neoadjuvant chemotherapy; PE: pulmonary embolism; pN: pathologic nodal stage; pTNM: pathologic tumor stage; UC: urothelial carcinoma.

group. Compliance events were defined as stopping or missing doses due to medical contraindications, physical inability to administer the medication, patient preference, or cost.¹³

Studies conducted in both the Canadian and American healthcare systems have analyzed the cost-effectiveness of thromboprophylaxis options by accounting for medication costs, adherence rates, and event rates. These studies consistently show that apixa-

Table 2. Post-discharge clinical outcomes by type of VTE prophylaxis received at discharge

Variable	Enoxaparin (n=102)	Apixaban (n=83)	Risk difference (95% CI)	p
30-day postoperative VTE (%)	2 (2.0)	0 (0.0)	2% (-8.8–13)	0.5
90-day postoperative VTE (%)	4 (3.9)	0 (0.0)	3.9% (-8.6–16)	0.13
30-day postoperative hemorrhage (%)	1 (1.0)	1 (1.2)	-0.2% (-12–11)	1.0
Visited ER (%)	27 (26.5)	30 (36.1)	-9.7% (-47–27)	0.2
Re-admission (%)	19 (18.6)	20 (24.1)	-5.5% (-39–28)	0.4
90-day postoperative overall mortality	2 (2.0)	2 (2.4)	-0.4% (-14–14)	1.0

CI: confidence interval; ER: emergency room; VTE: venous thromboembolism.

ban is more cost-effective than enoxaparin in the setting of orthopedics and gynecologic cancer surgery.^{28–30}

Strengths and limitations

A strength of this study is its size relative to similar studies in the literature and the evaluation of extended VTE thromboprophylaxis in the setting of primarily open RC, which is commonly performed in the Canadian setting, as compared to RARC. The choice to maintain patients on enoxaparin while in hospital, in contrast to other studies, was based on ease of reversibility, as well as the ability to give VTE thromboprophylaxis to patients not tolerating oral intake.

The main limitation of this study is its retrospective nature and observational, before-after design. The overall 30-day and 90-day VTE rate (1.1% and 2.2%) in our study was low, but within the margin of similar studies comparing enoxaparin and apixaban after RARC or open RC, which ranged from 0–1% for 30-day VTE and 0–6.1% for 90-day VTE.^{13,24–26,31}

Furthermore, unpublished data available from the National Surgical Quality Improvement Program³² at our institution showed a postoperative VTE rate between 2018 and 2020 (1.5%, 4/264) that was comparable to our retrospective review. Since data was abstracted from medical records, it is possible that information from rural centers was not relayed to the treating urologist. Asymptomatic VTE cases were likely missed, but we believe that these are of low clinical relevance.

Additionally, information regarding adherence to treatment and patient satisfaction was not captured in

our analysis. Other limitations include the potential bias from the before-after design, including historical and information bias, and the Hawthorne effect. Further, the historical period included the introduction of methylaltrexone in May 2023, and the transition to an EMR system in November 2022, which may have influenced data collection. This was also a single-institution study at a tertiary teaching center, limiting the generalizability of our findings to all patient populations. Finally, the small number of events resulted in imprecise estimates for between-group differences, so we cannot statistically rule out an increased rate of VTE events with apixaban.

To address these limitations, a prospective, large-scale RCT would be needed to validate our findings and assess whether apixaban is superior to enoxaparin for extended thromboprophylaxis following RC for bladder cancer. One could speculate that DOACs will have improved efficacy by increasing patient compliance and therefore reducing treatment failure. The ongoing phase 4 RCT (NCT06243510), which compares enoxaparin and apixaban in the setting of RC for bladder cancer, will provide further insight on the use of apixaban and compliance to treatment.³³

CONCLUSIONS

This single-institution study adds to the existing evidence of the safety and efficacy of apixaban for extended VTE thromboprophylaxis following both open and RARC. While historical cohort comparisons are subject to bias and our sample size is modest, we observed no VTE events with apixaban. Given prior evidence supporting the safety and efficacy of DOACs, such as apixaban, in post-surgical thromboprophylaxis in urology and other specialties, along with its lower cost and potential higher patient adherence, apixaban appears to be a safe and effective alternative to enoxaparin for extended VTE thromboprophylaxis following RC for bladder cancer.

COMPETING INTERESTS: The authors do not report any competing personal or financial interests related to this work.

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