Incidence of Venous Thromboembolism and Safety of Perioperative Subcutaneous Heparin During Inflatable Penile Prosthesis Surgery

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OBJECTIVE To identify the incidence of venous thromboembolism (VTE) risk factors, postoperative VTE, and to assess the morbidity of perioperative pharmacologic VTE prophylaxis in men undergoing inflatable penile prosthesis (IPP) surgery.

METHODS We retrospectively reviewed 215 patients undergoing IPP surgery between July 2017 and June 2019. Univariate and multivariate statistical analyzes were performed to assess pre-operative Caprini risk score and compare post-operative day 0 scrotal drain output, scrotal hematoma formation, and VTE in men who received subcutaneous heparin (SqH) vs those who did not receive SqH.

RESULTS Of 215 IPP patients, 84% were classified as high or highest risk for VTE utilizing the Caprini risk score. A total of 119 (55%) received perioperative SqH with or without additional anti-thrombotics. Post-operative day 0 scrotal drain output was higher in those who received SqH compared to those who did not receive SqH, 99.9 mL vs 75.6 mL, respectively (P = .001). Minor scrotal hematomas occurred in similar rates in patients who received perioperative SqH vs those who did not, 3.8% vs 6.3%, respectively (P = .38). Similar results were found on subgroup analysis when eliminating patients who received SqH concurrently with other anti-thrombotics. The overall rate of postoperative VTE was 0.9%. No post-operative infections occurred.

CONCLUSION Patients undergoing IPP surgery are at elevated risk for VTE. To our knowledge, this is the first study showing SqH use in the perioperative IPP surgery setting is safe when used in conjunction with a scrotal drain. Preoperative VTE risk stratification may be performed and can be used to guide clinical decision making regarding pharmacologic prophylaxis. UROLOGY 00: 1–6, 2021. © 2021 Elsevier Inc.

Venous thromboembolism (VTE) following inflatable penile prosthesis (IPP) surgery is an understudied complication despite erectile dysfunction (ED) and VTE sharing a number of risk factors including smoking, advanced age, obesity, malignancy, and cardiopulmonary disease.[1,2] Two studies have attempted to characterize VTE risk in men undergoing IPP surgery utilizing the National Surgical Quality Improvement Database (NSQIP), however, significant limitations exist with use of this database, as NSQIP does not capture same-day discharge surgery, which reduces IPP surgical volume.[3,4] Owing to the absence of available literature, American Urologic Association (AUA) and European Association of Urology (EAU) perioperative VTE guidelines do not address VTE risk with IPP surgery and generally recommend against pharmacologic prophylaxis with outpatient surgery.[5,6]

Thus, we sought to better identify the incidence of VTE risk factors, postoperative VTE, and to assess the morbidity of perioperative pharmacologic VTE prophylaxis in men undergoing IPP placement.

MATERIALS AND METHODS

Data Source/Cohort Selection

After obtaining exempt status from the Institutional Review Board, we performed a retrospective cohort study of men undergoing IPP surgery by a single surgeon between July 2017 and June 2019. Adult patients undergoing primary or revision IPP surgery

Disclosures: Dr. Köhler is a consultant for Coloplast and Boston Scientific.

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Table 1. Cohort demographics and VTE risk factors

	Total (215)	No Heparin (96)	Heparin (119)	*P* value
Age, mean	63.5	62.7	64.1	.37
BMI, mean	30.5	30.7	30.2	.53
CHF, n (%)	32 (14.9)	23 (23.9)	9 (7.5)	**<.001**
CAD, n (%)	66 (29.8)	35 (36.5)	29 (24.4)	.054
Atrial fibrillation, n (%)	27 (12.6)	19 (19.8)	8 (6.7)	**.003**
HTN, n (%)	141 (65.6)	69 (71.9)	72 (60.5)	.08
Sepsis, n (%)	3 (1.4)	3 (3.1)	0 (0.0)	**.02**
DM, n (%)	66 (30.7)	37 (38.5)	29 (24.4)	**.02**
Pneumonia, n (%)	2 (0.9)	1 (1.0)	1 (0.8)	.88
SOB, n (%)	16 (7.4)	11 (11.5)	5 (4.2)	**.04**
Leg fracture, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Stroke/CVD, n (%)	18 (8.4)	10 (10.4)	8 (6.7)	.33
Trauma, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
SCI, n (%)	1 (0.5)	1 (1.0)	0 (0.0)	.2
Varicose veins, n (%)	1 (0.5)	1 (1.0)	0 (0.0)	.2
Venous insufficiency, n (%)	12 (5.6)	11 (11.4)	1 (0.84)	**<.001**
Central venous access, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Pulmonary embolism, n (%)	7 (3.3)	3 (3.1)	4 (3.3)	.92
DVT, n (%)	15 (7.0)	9 (9.4)	6 (5.0)	.21
Family history thrombosis, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Factor V leiden deficiency, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Lupus anticoagulant, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Anticardiolipin, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	1
Inflammatory bowel syndrome, n (%)	5 (2.3)	4 (4.1)	1 (0.8)	.1
BMI >25, n (%)	185 (86.0)	84 (87.5)	101 (84.9)	.58
Myocardial infarction, n (%)	17 (7.9)	12 (12.5)	5 (4.2)	**.02**
Chronic obstructive pulmonary disease, n (%)	21 (9.8)	9 (9.4)	12 (10.1)	.86
Malignancy, n (%)	82 (38.1)	32 (33.3)	50 (42.0)	.19
Antithrombotic during surgery, n (%)				
Aspirin 81 mg	60 (27.9)	30 (31.2)	30 (25.2)	.32
Aspirin 325 mg	7 (3.3)	3 (3.1)	4 (3.4)	.92
clopidogrel 75 mg	5 (2.3)	1 (1.0)	1 (0.8)	.10
apixaban 5 mg	3 (1.4)	3 (3.1)	0 (0.0)	**.02**
rivaroxaban 20 mg	2 (0.9)	2 (2.1)	0 (0.0)	.07
warfarin	6 (2.8)	5 (5.2)	1 (0.8)	**.04**
Ectopic reservoir, n (%)	64 (29.7)	24 (25.0)	40 (33.6)	.23
Preoperative Caprini Score, mean (SD)	5.96 (1.63)			
Preoperative Caprini Score, median (IQR)	6 (5, 7)			
Preoperative Caprini Score, Low risk (%)	2 (0.9)			
Preoperative Caprini Score, Moderate risk (%)	33 (15.3)			
Preoperative Caprini Score, High risk (%)	168 (78.1)			
Preoperative Caprini Score, Highest risk (%)	12 (5.6)			

BMI, body mass index; CAD, coronary artery disease; CHF, congestive heart failure; DM, diabetes mellitus; DVT, deep vein thrombosis; HTN, hypertension; SCI, spinal cord injury; SOB, shortness of breath.

were included. Revision IPP surgery was defined as complete device explantation and replacement during the same operation. Malleable devices were excluded. Medication administration records (MAR) were reviewed to determine if perioperative subcutaneous heparin (SqH) was administered. Preoperative risk factors for perioperative venous thromboembolism were collected in a retrospective fashion (Table 1) allowing calculation of preoperative Caprini Score.[7,8] During the study period, a departmental perioperative policy change regarding SqH led to initiation of SqH administration (5,000 units every 8 hours for duration of admission) in men undergoing IPP surgery. Thus, patients were not administered SqH based on risk factors or Caprini Score, but rather as a result of the policy change resulting in two consecutive cohorts without and with SqH.

Perioperative Course

Primary and revision IPP surgery at our institution is performed in the outpatient overnight setting (ie patients are discharged within 24 hours) via a penoscrotal approach. Bilateral corporotomies were made after preplacement of 2-0 vicryl stay sutures. The IPP reservoir was placed in a retropubic or subrectus location depending on prior surgical history. A 10 Fr Jackson Pratt scrotal drain (Cardinal Health, Dublin, OH) left to bulb suction overnight without a holding suture is our standard practice as this has not been shown to affect infection rates. The scrotal drain was removed on post-operative day 1 if output was <50 cc per shift. Our prostheses are left inflated at 40%-60% for 3 weeks and a Henry mummy wrap is left in place for 2 days.[9] All patients utilize sequential compression devices (SCDs) perioperatively and begin ambulation on post-operative day 0. We routinely prescribe a 5-day course of oral antibiotics.[10] Patients follow up 3 weeks after surgery for surgical site assessment and device activation.

Outcomes of Interest

Pre-operative VTE risk factors were assessed. Using this data, a preoperative Caprini Score was calculated, and preoperative

VTE risk was determined.[7,8] Perioperative outcomes evaluated included post-operative day 0 scrotal drain output, post-operative hematoma formation, post-operative infection rate, and perioperative venous thromboembolism complications. Swelling and/or bruising which precluded device activation by the patient at 3-week follow-up was considered a hematoma.

Statistical Analysis

Medians/standard deviation (SD) and frequency counts/percentages were used to report differences in baseline characteristics. Outcomes of interest were summarized using frequency counts/percentages and were compared depending on administration of SqH at time of IPP surgery. Multivariable logistic regression analyzes were used to evaluate the association of SqH administration with the perioperative end points after adjusting for baseline characteristics significant on univariate analysis. Statistical analyzes were performed using JMP version 14.1 (SAS Institute Inc, Cary, NC) with $P < .05$ considered statistically significant.

RESULTS

A total of 215 patients underwent IPP surgery including 42 (19%) patients undergoing revision surgery. Using a Caprini score calculator preoperative Caprini scores and overall risk were assessed.[7] Of the entire cohort (215 patients), mean and median Caprini score was 5.96 (SD, 1.63) and 6 (IQR, 5, 7), respectively (Table 1). Stratification of risk based on the Caprini system revealed 0.9% low risk, 15.3% moderate risk, and 83.7% high or highest risk (Table 1).

Of 215 patients, 119 (55%) received intraoperative SqH and made up our primary cohort. Preoperative risk factors for venous thromboembolism based on the Caprini Score system were assessed in those who received SqH vs those not receiving SqH (Table 1).[7] Prior history of VTE (DVT or PE) was seen in 17 (8%) patients, with 5 (2%) having prior history of DVT and PE. Patients who received SqH had a similar history of DVT (5% vs 9.4%) and PE (3.3% vs 3.1%) when compared to those not receiving SqH, respectively (Table 1).

Primary Analysis

Patients who received perioperative SqH had higher post-operative day 0 scrotal drain output (99.9 mL vs 75.6 mL), $P = .001$ (Table 2). However, rates of post-operative scrotal hematomas were similar 3.4% vs 6.3%, respectively ($P = .38$). No patient experienced a postoperative hematoma requiring surgical drainage. The overall rate of postoperative VTE in this cohort was 0.9% (2/215).

Subgroup Analysis (SqH Alone vs No SqH or Anti-Thrombotic)

A subgroup analysis was performed to control for confounders including concurrent administration of anti-thrombotics (anti-platelets or anti-coagulation) by excluding patients on any anti-thrombotic (AT) at the time of surgery. Patients who received SqH alone (without concurrent AT use) were compared to patients who received no SqH or AT. Of 215 patients, 84 patients received SqH without concurrent AT and 54 patients received no SqH or AT at the time of surgery. SqH administration alone was associated with high postoperative day 0 drain output compared to those not receiving SqH or AT, 104.5 mL vs 71.6 mL, respectively, $P = <.001$ (Table 3). One VTE was identified in a patient who did not receive SqH. No VTE events were identified in the SqH cohort. No difference in hematoma formation was seen between each group (Table 3).

Subgroup Analysis (SqH ± Antithrombotic vs No SqH or Antithrombotic)

A second subgroup analysis was performed to assess if concurrent use of AT with SqH at the time of surgery increased scrotal drain output, hematoma rates, or VTE events compared to those not receiving SqH or AT. Of 215 patients, 119 received SqH ± AT. Patients receiving SqH ± AT had higher postoperative day 0 scrotal drain output compared to patients who did not receive SqH or antithrombotic, 99.9 mL vs 71.6 mL, respectively, $P = .001$ (Supplement Table 1). Each subgroup had a patient that experienced a VTE event. No difference in hematomas was identified (Supplement Table 1).

Multivariable analysis of the effect of concurrent administration of antiplatelet therapy (aspirin, clopidogrel) and anticoagulation (warfarin, rivaroxaban, apixaban) revealed no effect on postoperative on drain output or hematoma rate.

DISCUSSION

There is an absence of data on VTE risk prior to IPP surgery despite significant overlap in risk factors for development of VTE and erectile dysfunction being present. To our knowledge, this manuscript is the first to address the risk of VTE in men undergoing IPP surgery using a validated scoring system while also assessing perioperative morbidity associated with SqH administration at time of IPP surgery.

Urologic VTE risk has been well studied in urologic oncology with the highest post-operative risk occurring in the cystectomy population (3.96%-5.5%).[4,11] However, outpatient urologic surgery has been considered low risk for VTE and as a result, has been less studied. Review of NSQIP data has yielded a lower risk of VTE in outpatient surgeries including female sling, hydrocelectomy, and ureteroscopy at 0.08%, 0.13%, and 0.33%, respectively.[4] Our incidence of 0.9% in this cohort is based on two events and should not be compared with the before mentioned studies due to the small sample size of our study. However, a higher incidence of VTE in the IPP surgery population may be expected compared to those undergoing female slings, hydrocelectomy, and ureteroscopy as patients

Table 2. Primary cohort univariate analysis comparing scrotal drain output, hematoma, and DVT/PE in patients who received SqH +- antithrombotics vs no SqH +-antithrombotics

	No Heparin ± AT (96)	Heparin ± AT (119)	*P* value
Drain output Day 1, mL	75.6	99.9	**.001**
Hematoma, n (%)	6 (6.32)	4 (3.36)	.38
DVT/PE, n (%)	1 (1.0)	1 (0.84)	.87

Table 3. Univariate analysis comparing scrotal drain output, hematoma, and DVT/PE in patients who received SqH alone vs no SqH or any antithrombotics

	No Heparin Without AT (58)	Heparin Without AT (84)	*P* value
Drain output Day 1, mL	71.6	104.5	**<.001**
Hematoma, n (%)	1 (1.72)	2 (2.38)	.78
DVT/PE, n (%)	1 (1.72)	0 (0.0)	.18

undergoing IPP surgery often have significant vascular disease, advanced age, and/or previous or active cancer diagnosis. Although early ambulation has been shown to decrease the risk of perioperative DVT in the outpatient surgical setting,[12] ambulation following IPP surgery can also present unique challenges if the device is left in the inflated position and may be a source of study in the future in high risk patients undergoing IPP surgery.

We hypothesize that VTE risk is elevated following IPP surgery due to an increased likelihood of VTE risk factors being present in men with erectile dysfunction as well as specific anatomic considerations related to IPP placement. First, a preponderance of well-studied risk factors for both VTE and ED including endothelial dysfunction, arterial occlusive disease, diabetes, spinal cord injury, inadequate venous occlusion, hyperlipidemia, hypertension, malignancy, obesity may predispose patients to VTE.[7,13-15] In our cohort, these risk factors were common: obesity (86%), hypertension (65%), malignancy (38%), diabetes (30%), coronary artery disease (30%), stroke (8%), and venous insufficiency (5%) (Table 1). Similar rates of comorbidities have been shown in other studies assessing pre-operative comorbidities of men undergoing IPP surgery.[16,17]

The Caprini score was first developed in 1991 by Dr. Joseph Caprini to stratify risk of postoperative VTE events and has been further validated in patients undergoing surgery.[18-21] Overall perioperative risk is stratified into low, moderate, high, and highest risk which corresponds to minimal, 0.7 %, 1.8%-4.0%, and 10.7% risk of a VTE event, respectively.[20] Assessment of VTE risk in our cohort using Caprini score showed a staggering 83% of patients where high or highest risk for a VTE event which corresponds to a 1.8%-10.7% risk for VTE in the postoperative period (Fig. 1).[7] Furthermore, we suspect this cohort is representative of most patient populations encountered by IPP surgeons. For example, a 62-year-old patient with a BMI of 27 and a history of prostate cancer with no additional comorbidities would be considered high risk (Age +2 points, BMI +1 point, history of malignancy +2 points). In this cohort, patients were more likely to be highest risk (5.6%) vs low risk (1.0%) and 99% of the cohort qualified for moderate risk which conferred at minimum a VTE risk of 0.7%. Additionally, 8% of patients in our cohort had a personal history of DVT and/or PE prior to IPP surgery. Furthermore, the retrospective nature of our study and its dependence on accurate CPT coding, likely resulted in under documentation of risk factors, thus this cohort's risk assessment is likely higher than shown in our assessment.

From a surgical perspective, reservoir placement in a retropubic location may also contribute to VTE risk. The external inguinal ring and transversalis fascia are violated during retropubic reservoir placement. In a cadaveric study by Henry et al, the average distance from the external ring to the external iliac vein was only 3.23 cm which is similar to the diameter of many IPP reservoirs.[22] DVT from implant reservoir compression of the iliac vein is a described complication, with asymmetric leg swelling on the side of reservoir necessitating high index of suspicion for DVT.[23] The reservoir diameter and its proximity to the external iliac vein could theoretically lead to

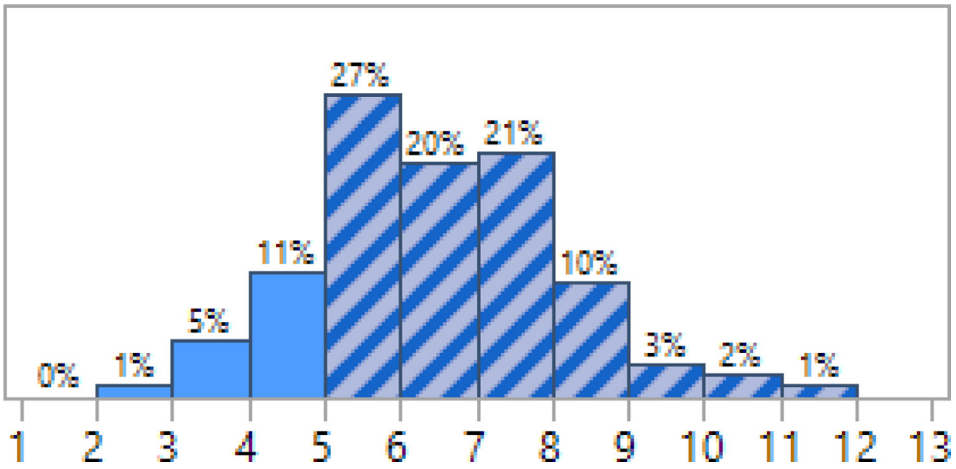

Figure 1. Bar graph showing distribution of preoperative Caprini Score with diagonal filled bars indicating high or highest risk. (Color version available online.)

increased resistance of lower extremity venous return. In our cohort, this is a less likely contributor as our devices are partially inflated (reservoir is deflated) in the immediate post-operative period.

The International Society for Sexual Medicine (ISSM) guideline for IPP surgery in 2016 does not address mechanical or pharmacologic VTE prophylaxis.[24] The American Urologic Association (AUA), European Association of Urology (EAU), and Canadian Urological Association (CUA) have published VTE prophylaxis guidelines for urologic surgery with the CUA guideline being a variant of EAU guidelines.[5,6,25] The EAU guideline recommendations R20-23 address non-oncological urological surgery which recommends against the use of both mechanical and pharmacologic prophylaxis in ambulatory day surgery and transurethral resection of the prostate (TURP).[6] IPP surgery specific recommendations are absent. AUA guidelines use a risk stratification model adapted from Geerts et al[26] While the IPP surgery population is not specifically addressed, anti-incontinence and pelvic reconstructive surgery guidelines recommend single or multimodal prophylaxis via mechanical and/or pharmacologic means based on patient risk factors, age, and post-operative bleeding risk.[5] The Caprini score recommends patients with moderate risk to receive chemoprophylaxis for the duration of hospitalization (in addition to compression stocking and mechanical prophylaxis), high risk to receive 7-10 days of chemoprophylaxis, and highest risk to receive 30 days of chemoprophylaxis.[7] For most surgeons, the main deterrent for pharmacologic prophylaxis in IPP surgery is post-operative scrotal hematoma which can occur in 0.5% to 3.6% of IPP cases.[27,28] Studies utilizing closed suction drains during IPP surgery have shown reduction of hematoma rates ranging from 0% to 0.5% without an increased risk of infection.[29,30] However, the true incidence of hematoma formation is difficult to discern as it is a subjective finding without clear definition.

In this series, a difference in post-operative day 0 scrotal drain output was noted in those who received SqH (99.9 mL) vs those who did not receive SqH (75.6 mL), $P = .001$. This remained significant when sub-stratifying for those who only received SqH in the absence of other AT. However, this did not translate into a difference in likelihood post-operative hematoma with scrotal drain utilization. We considered a post-operative hematoma to be present if bruising, swelling precluded device activation by the patient at 3-week follow-up which likely overestimated the incidence of actual hematomas. Using this definition, 4.6% patients in our cohort experienced a hematoma with no difference between those who received SqH vs those who did not receive SqH. Again, after sub-stratifying our cohort to those who received SqH alone or SqH ± AT compared to patients who received no form of AT, no difference in hematoma rates were seen (**Table 3** and Supplement Table 1). Although a difference in scrotal drain output of 24.3 mL did not meet statistical significance in this study, it should be noted that this may be clinically significant in the absence of scrotal drain use. This series showed no significant morbidity with SqH utilization. It should be stressed that all hematomas that did occur were self-limited and only resulted in delay of device activation by 1 or 2 weeks. No post-operative infections or hematoma evacuations occurred. While no interventions were necessary in those who experienced a hematoma, we acknowledge that any deviation in standard post-operative care could be considered significant by some patients or providers.

Two post-operative VTE events occurred in our series including a sub-segmental PE (did not receive SqH, peri-operative SCDs used) and DVT (received SqH and peri-operative SCD). The first patient (retropubic reservoir) called our overnight call service due to post-operative pain and was noted to be audibly short of breath. He was directed to his local ED where a subsegmental PE was noted on CT angiogram of the chest. The second patient (ectopic reservoir) noted unilateral leg swelling and presented to the ED where a lower extremity ultrasound revealed an acute DVT. Both patients were successfully treated with apixiban. The first patient's Caprini Score was 4 (moderate risk) while the second patient's Caprini Score was 6 (high risk). Although each patient was treated successfully without significant morbidity, these findings highlight the potential catastrophic outcome of an elective outpatient surgery.

While our study is the first to evaluate VTE and scrotal hematoma risk in the IPP surgery population receiving SqH, several questions remain unaddressed and should direct future studies. First, due to the low overall rate of VTE, additional multi-institutional studies with higher patient volumes are necessary to validate the true incidence of VTE following IPP surgery. Additionally, this cohort's calculated VTE incidence was based on symptomatic VTE events and thus may represent an underestimation of the true incidence. Second and most importantly, no benefit of pharmacologic over mechanical prophylaxis was shown in this study or in the literature, which should limit widespread implementation of SqH. However, this data does support risk stratification and consideration of combined pharmacologic and mechanical prophylaxis in well counseled patients with prior history of VTE or if elevated risk is noted on preoperative Caprini score assessment.

Our study is not without limitations inherent to small retrospective datasets. Our primary cohorts had statistically significant differences in rates of prior MI, CHF, atrial fibrillation, and venous insufficiency which could impact our findings. Additionally, preoperative risk factors for VTE were assessed via retrospective review, thus it is likely that risk factors were underrepresented in this study. The Caprini scoring system is dependent on some risk factors being present within 1 month of surgery which was difficult to determine.[7] Likewise, the Caprini Score should be calculated during a face-to-face encounter with the patient and not in a retrospective fashion which limits this method of data collection.[7] We acknowledge that our

findings occurred in an academic setting with a high-volume implanter and may not be applicable to all providers. Finally, these findings were in the setting of outpatient overnight surgery and scrotal drain use; thus, this should be interpreted with caution in practice settings where patients are discharged same day without a drain. While, our findings support the safety of SqH, it does not prove a benefit of SqH use in IPP surgery and should be utilized at the discretion of the surgeon after preoperative discussion with the patient.

CONCLUSION

In this contemporary assessment, perioperative VTE risk in patients undergoing IPP surgery was alarmingly high according to the Caprini scoring system. Two VTE events occurred following IPP surgery. Peri-operative administration of SqH during IPP surgery did not increase post-operative morbidity in the setting of a scrotal drain. Due to the low number of VTE events in this cohort, increased efficacy of SqH over mechanical prophylaxis in the IPP surgery population was not shown and should be a focus of future, higher volume prospective studies. Our findings, which are the first to address VTE risk and Caprini scores in the IPP population, should serve as a baseline for a currently unaddressed area of perioperative IPP surgical management.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2021.08.002.

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