Original Article

Highest risk of symptomatic venous thromboembolic events after radical cystectomy occurs in patients with obesity or nonurothelial cancers

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Abstract

Context: Venous thromboembolism (VTE) is a common cause of postoperative morbidity and mortality in cystectomy patients.

Aims: The aim of this study is to identify variables associated with risk of developing deep venous thrombosis (DVT) or pulmonary embolism (PE) within 90 days after radical cystectomy (RC).

Setting and Design: Retrospective chart review of patients undergoing RC from 2004 to 2011 at the University of Wisconsin.

Subjects and Methods: Clinical variables collected for all RC patients. All patients received mechanical prophylaxis, and routine heparin prophylaxis began in 2010.

Statistical Analysis Used: Univariate and multivariate analyses were used to evaluate VTE association with known risk factors.

Results: A total of 241 patients were identified with median age of 67.1 (interquartile range: 57.8-74.3) years. Body mass index (BMI) was ≥30 in 36.8% of patients. Median blood loss was 950 (600-1500) mL and 157/241 (65.2%) patients received a blood transfusion.

Within 90 days postoperatively, overall venous thromboembolic event (VTE) rate was 20/241 (8.3%). Of these, 13 (5 DVT, 8 PE) and 7 (3 DVT, 4 PE) were diagnosed on days 0-30 and days 31-90, respectively. After multivariate analysis, BMI ≥30 (odds ratio [OR] = 4.69, confidence interval [CI] = 1.70-12.92) and nonurothelial bladder cancer (OR = 4.01, CI = 1.33-12.07) were associated with significantly increased rates of VTE.

Conclusions: Patients with BMI ≥30 or nonurothelial cancer are at highest risk for postoperative VTE and should be considered for extended heparin prophylaxis.

Key Words: Cystectomy, deep vein thrombosis, nonurothelial, obesity, thromboembolism

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INTRODUCTION

According to the Agency for Healthcare Research and Quality, deep venous thrombosis (DVT) and pulmonary embolism (PE), or collectively, venous thromboembolism (VTE) is the number one cause of preventable hospital mortality.[1] Multiple randomized prospective trials of pharmacologic thromboembolism prophylaxis (PTP) have shown a decreased

risk of developing VTE with routine PTP in patients undergoing abdominal cancer surgery, major orthopedic, and gynecologic procedures. However, there are few data describing the benefit of PTP in patients undergoing urological surgery, and recommendations about the use of PTP in urology have largely been extrapolated from other fields.[2]

Several studies have noted that among urologic surgeries, radical cystectomy (RC) has the highest risk of postoperative VTE,[3-5] and PE is a common cause of morbidity and death after cystectomy.[6,7] However, a recent survey of American Urological Association members reported that 19-34% of respondents did not use routine PTP for patients undergoing cystectomy.[8] Many cystectomy patients may have multiple known risk factors for VTE, including: increased age, cancer diagnosis, obesity, and history of tobacco abuse, but it is unclear which patients are at highest risk to develop VTE after surgery. The purpose of this study was to evaluate the risk of symptomatic VTE after RC and to identify prognostic factors that predict the highest risk for postsurgical VTE.

SUBJECTS AND METHODS

After Institutional Review Board approval, an institutional database was used to identify consecutive patients with bladder cancer who underwent RC from January 2004 to May 2011. Comprehensive clinical and pathologic information was reviewed for each patient. Surgical technique for RC included prostatectomy or hysterectomy in male or female patients respectively. The template for pelvic lymphadenectomy (PLND) included: obturator, external iliac, internal iliac and common iliac lymph nodes. In symptomatic patients, PE was diagnosed using computed tomography angiogram or ventilation/perfusion scans, and DVT was diagnosed with lower extremity Doppler ultrasound. VTE was considered to be associated with surgery if diagnosed within 90 days after surgery. Univariate and multivariate logistic regression analysis was used to calculate an odds ratio (OR) and confidence interval (CI) corresponding to the risk of postoperative symptomatic VTE based on clinical and pathologic factors. A P (two-sided) <0.05 was considered as significant. All analyses were performed using SAS statistical software version 9.3 (SAS Institute Inc., Cary, NC, US). Kaplan–Meier analysis was used to predict risk of postoperative symptomatic VTE based on identified risk factors. Prognostic factors compared included: age, gender, race, smoking status, history of prior VTE, estimated blood loss, blood transfusion, neoadjuvant chemotherapy, preoperative statin medication use, type of bladder cancer, body mass index (BMI), 2009 American Joint Committee on Cancer clinical or pathologic stage, and the total anesthesia time. Patients were excluded on the basis of follow-up <90 days.

Venous thromboembolism prophylaxis

Per hospital protocol all patients received mechanical thromboprophylaxis with intermittent pneumatic compression placed prior to surgery, and early ambulation was encouraged. Routine peri- and post-operative treatment with subcutaneous unfractionated heparin prophylaxis became protocol in September 2010.

RESULTS

Patients

A total of 241 were eligible for the study. Patient characteristics are displayed in Table 1. Open surgical procedure was utilized in 236/241 (97.9%) and 5/241 (2.1%) of patients had robot-assisted laparoscopic cystectomy. The median length of stay after surgery was 8 days (interquartile range = 6-9).

Venous thromboembolism events

Within 90 days postoperatively, 20/241 (8.3%) were diagnosed with VTE. Of these, 13 (5 DVT, 8 PE) and 7 (3 DVT, 4 PE) were diagnosed on days 0-30 and days 31-90, respectively.

Table 1: Patient and disease characteristics

Descriptive characteristic	
Median age in years (IQR)	67.1 (57.8-74.3)
Gender (%)	
Male	192 (79.7)
Female	49 (20.3)
Smoking	
Never	46 (19.2)
History	130 (54.4)
Current	63 (26.4)
Race	
White	228 (94.6)
African-American	6 (2.5)
Asian-American	1 (0.4)
Hispanic	2 (0.8)
Other	4 (1.7)
Prior VTE	9 (3.7)
Estimated blood loss in mL	950 (600-1500)
Transfused blood	157 (65.2)
Neoadjuvant chemotherapy	24 (10.0)
Taking statin preoperatively	83 (34.6)
Histological subtype	
Urothelial cancer	212 (88.0)
Other	29 (12.0)
Clinical stage	
Ta, T1, or CIS	57 (24.3)
T2	166 (70.6)
T3 and T4	12 (5.1)
ASA class	
1 and 2	131 (54.8)
3 and 4	108 (45.2)
BMI	
<30	151 (63.2)
≥30	88 (36.8)
Median anesthesia time (min)	477 (355-595)

IQR: Interquartile range, VTE: Venous thromboembolic event, BMI: Body mass index, ASA: American Society of Anesthesiologists, CIS: Carcinoma *in situ*

The symptomatic PE incidence was 12/241 (5.0%) and resulted in a fatality in 2/20 (10%) patients with VTE. Shortness of breath was the most common presenting symptom 7/12 (58.3%). The average time from symptoms to diagnosis was 1.3 (0-11) days.

Pharmacologic prophylaxis

Preoperative heparin prophylaxis was given in 27/241 (11.2%) patients, but was not associated with decreased VTE rate ($P = 0.58$) or increased blood loss ($P = 0.15$). Twenty patients were given prophylaxis per institutional protocol developed in September 2010. Seven patients were given preoperative heparin based on physician assessment of an increased risk for VTE.

Risk factors for venous thromboembolism events

After multivariate analysis, BMI ≥30 (OR = 4.69, CI = 1.70-12.92) and nonurothelial bladder cancer subtype (OR = 4.01, CI = 1.33-12.07) were associated with significantly increased rates of VTE [Table 2]. Kaplan-Meier curves were constructed and show the risk of VTE over time for those with a BMI ≥30 kg/m^2 [Figure 1], those with nonurothelial histopathological subtype [Figure 2], and those with both BMI ≥30 kg/m^2 and nonurothelial histology [Figure 3]. Of patients with a VTE and nonurothelial cancers, five patients had squamous cell carcinoma, two had adenocarcinoma, and one had rhabdomyosarcoma.

DISCUSSION

Venous thromboembolism is a common cause of postsurgical morbidity and mortality following RC for bladder cancer [Table 3].

Pharmacologic prophylaxis with heparin or similar agents has shown to reduce VTE risk in cancer patients undergoing major abdominal surgeries,[15] but the optimal timing and duration has not been studied in bladder cancer patients. In the current study, we identify risk factors for postoperative VTE in bladder cancer patients after RC. Increased BMI (≥30 kg/m^2) and nonurothelial bladder cancer were independently associated with postoperative VTE. RC patients with BMI ≥30 kg/m^2 and nonurothelial histology should be considered at highest

Table 2: Logistic regression analysis of risk factors for VTE

Risk factor	Univariate OR (CI)	Multivariate OR (CI)
Age (years)	1.00 (0.96-1.04)	
Gender	1.77 (0.64-4.88)	
Smoking		
Never	Reference	
History	0.61 (0.19-1.93)	
Current	0.71 (0.19-2.60)	
Race	2.12 (0.44-10.32)	
Prior VTE	3.40 (0.66-17.57)	
Blood type		
A	Reference	
AB	1.12 (0.13-9.69)	
B	1.91 (0.47-7.80)	
O	1.34 (0.48-3.72)	
Preoperative heparin	1.45 (0.40-5.31)	
Estimated blood loss (per 100 mL)	1.02 (0.99-1.04)	
Transfused blood	0.99 (0.38-2.59)	
Neoadjuvant chemotherapy	1.01 (0.22-4.62)	
Taking statin preoperative	1.02 (0.39-2.67)	
Histological subtype		
Urothelial	Reference	
Other	3.69 (1.29-10.54)	4.01 (1.33-12.07)
Clinical stage		
Ta, T1, or CIS	Ref	
T2	1.79 (0.50-6.42)	
T3 and T4	1.64 (0.16-17.23)	
ASA class		
1 and 2	Ref	
3 and 4	0.79 (0.31-2.02)	
BMI≥30	4.57 (1.69-12.38)	4.69 (1.70-12.92)
Total anesthesia time (per 60 min)	1.21 (1.02-1.43)	

VTE: Venous thromboembolic event, OR: Odds ratio, CI: Confidence interval, CIS: Carcinoma *in situ*, ASA: American Society of Anesthesiologists, BMI: Body mass index

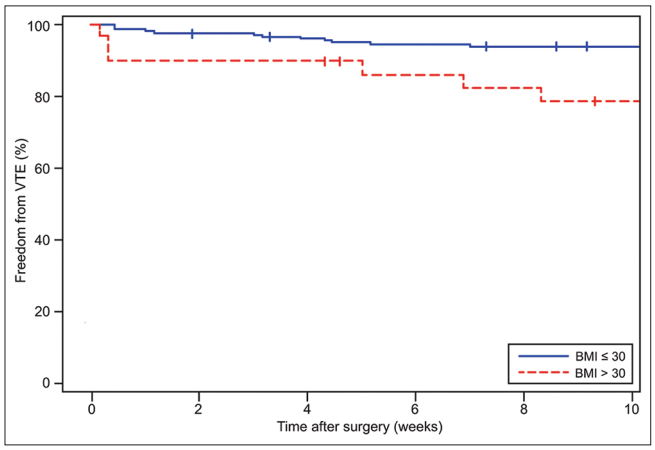

Figure 1: Kaplan–Meier curves demonstrating the risk of venous thromboembolism over time for those with a body mass index ≥30 kg/m^2

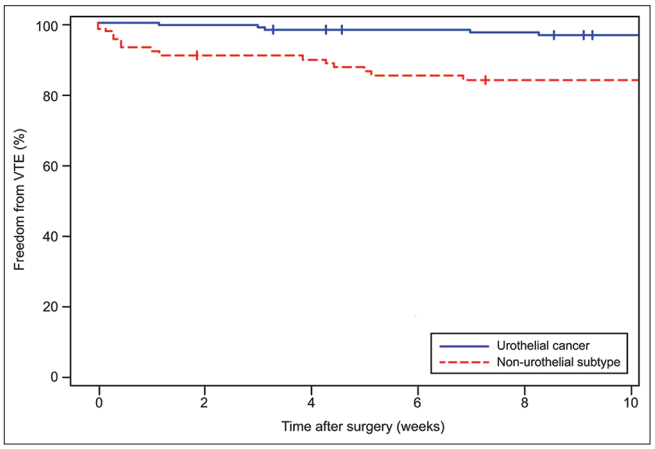

Figure 2: Kaplan–Meier curves demonstrating the risk of venous thromboembolism over time for those with nonurothelial histopathological subtype

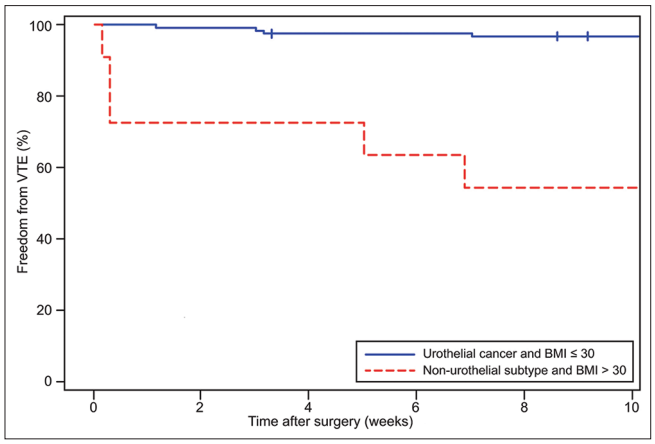

Figure 3: Kaplan–Meier curves demonstrating the risk of venous thromboembolism over time for those with both body mass index ≥30 kg/m² and nonurothelial histology

Table 3: Selected radical cystectomy series with published VTE rates

Reference	*n*	Pharmacologic prophylaxis	% PE	% DVT	% VTE
Clément *et al.*[3]	86	Yes	5	19	24
Hammond *et al.*[4]	446	Unknown	-	-	8.3
De Martino *et al.*[5]	306	Unknown	3.1	2.8	4.9
Ali-el-Dein *et al.*[9]	192	Unknown	1	2.6	3.7
Novotny *et al.*[10]	516	Yes	1.7	4.7	6.4
Rosario *et al.*[11]	101	Unknown	-	-	5.9
Chang *et al.*[12]	304	Unknown	0.7	0.7	-
Novara *et al.*[13]	358	Yes	-	-	4
Shabsigh *et al.*[28]	1142	Unknown	2.9	4.9	7.8
Current series	241	Partial	5.0	3.3	8.3

VTE: Venous thromboembolic event, PE: Pulmonary embolism, DVT: Deep venous thrombosis

risk for VTE and extended medicinal prophylaxis should be considered in these patients.

Despite the absence of large prospective studies evaluating VTE risk after cystectomy, there are compelling retrospective and population based data demonstrating increased postsurgical VTE risk. Hammond *et al.* reviewed 20,762 cases of VTE after major cancer surgery from a non-Medicare database and found cystectomy patients (8.3%) to have the second highest rate of postoperative VTE among all cancers studied.[4] In contrast, prostatectomy had the lowest VTE rate for the cancer operations for which data was collected (1.8%).[4] De Martino *et al.* demonstrated similar findings using the National Surgical Quality Improvement Program database.[5] In 2011, Clément *et al.* published a prospective series identifying the incidence of and risk factors for VTE in a group of 583 urological cancer patients.[3] This cohort received heparin and mechanical prophylaxis and underwent nephrectomy, cystectomy, or prostatectomy. They found an overall incidence of VTE in 10% of urological cases and in 24.4% of cystectomy patients. Of several patient characteristics included in their multivariate analysis, only a personal history of VTE (OR = 5.16, $P = 0.02$) and RC (OR = 3.47, $P = 0.002$) were found to be significant risk factors. The authors proposed routine DVT screening postoperatively in those patients who have undergone major urological cancer procedures.

Current recommendations on PTP for urological surgery from urology associations are limited and frequently cite the minimal urology specific data on VTE. However, nonurological sources are resolute in their recommendations for urology patients, based largely on the increased risk from data extrapolated from general surgical, gynecological, and orthopedic data. In the most recent guidelines from the American College of Chest Physicians, routine pharmacological thromboprophylaxis is recommended for all patients undergoing major, open urological surgery. Mechanical prophylaxis is also uniformly recommended, as an adjunct to heparin prophylaxis, or as the primary measure only in patients with high bleeding risk.[2]

The lack of adherence to clinical guidelines on VTE prophylaxis may stem from the perception of increased adverse events (AE) associated with heparin-related thromboprophylaxis.[8] Although minimal data exists in RC, several studies have assessed AE in prostatectomy patients treated with heparin prophylaxis. In a prospective study of patients undergoing prostatectomy, Koch and Smith found a significantly higher rate of bleeding risk in those receiving low-molecular weight heparin (LMWH) compared to those with only elastic stockings (7.8% vs. 0%, $P < 0.001$). However, VTE rates were significantly lower in the group that received LMWH (0% vs. 33%, $P = 0.026$).[16] In nonurological literature, Leonardi *et al.* reviewed 33 randomized control trials from general surgery patients and found low rates of complications, including a <3% chance of bleeding requiring a change in care.[17] Two patients (0.7%) in the current study required repeat operation for bleeding, and neither of these patients received preoperative heparin.

Increased rate of postoperative lymphoceles is another concern for patients receiving thromboprophylaxis. Whether thromboprophylaxis increases lymphoceles risk is debated, and conflicting data has been published for patients undergoing prostatectomy with PLND. Several early publications suggested an increased risk of lymphocele formation after lymphadenectomy in patients who received heparin prophylaxis.[18-23] However, larger contemporary series have not found a difference in lymphocele incidence or intra-operative blood loss in patients receiving heparin prophylaxis.[16,21] Sieber *et al.*, in a study of 579 men undergoing PLND, found no difference in bleeding complications or lymphocele incidence when comparing those who received heparin versus those who did not.[22] Further confounding this data is the observation

that the presence of a pelvic lymphocele itself is associated with VTE, possibly by compression of the large pelvic veins.[23] When considering the potential risks and benefits of VTE prophylaxis, the risk of minor AE does need to be carefully balanced with the possible reduction in serious AE. In our study, 26 patients (9.6%) developed a radiographically-confirmed lymphocele. Of these, only 4 (15.4%) received preoperative heparin and 6 (23.1%) patients received postoperative heparin while in the hospital. In contrast, 20 patients developed VTE after surgery and two patients died as a result of VTE.

In patients with high-risk of VTE, the optimal timing, duration and type of pharmacologic prophylaxis is important to consider. Bergqvist *et al*. conducted a prospective, double-blinded, placebo-controlled trial of 332 patients undergoing surgery for abdominal and pelvic cancers. The authors found a VTE-prevention benefit with prolonged (4-week) LMWH prophylaxis, without imposing any increased bleeding or other complication risk.[15] Raskob *et al*. also found that the period of risk of significant VTE may extend to 90 days and high-risk patients may benefit from LMWH during that time.[24] In the current series, seven patients had a VTE event detected after 30 days.

Elevated BMI and nonurothelial cancers represent a very high-risk population that may potentially benefit from prolonged thrombo-prophylaxis. Our institution developed a standard post-cystectomy protocol in 2010 which includes a 4-week long course of heparin prophylaxis after cystectomy, with patients receiving subcutaneous heparin preoperatively for a single dose, which continues during inpatient hospitalization. At discharge, patients begin LMWH and continue until 30 days postoperatively.

Multiple studies have demonstrated that VTE are morbid for patients and costly for health care.[25] Heparin-based prophylaxis may significantly reduce these costs,[26] and aggressive extended thromboprophylaxis is suggested for those patients who are at highest risk.[15] In prior studies, risk factors for VTE risk have included: advanced age, malignancy, recent surgery, ABO blood type, previous VTE, obesity, cardiac or respiratory failure, and smoking status.[27] Several of the known risk factors are typically present in bladder cancer patients.[28] Furthermore, in the current study we demonstrate that BMI >30 and nonurothelial type bladder cancers are independently associated with VTE after cystectomy. These important predictors can be used to identify patients at highest risk to consider extended heparin prophylaxis, which may reduce this significant postsurgical cause of morbidity and mortality.

The current study has the inherent limitations of a retrospective study at a single, tertiary referral center. Since routine radiologic screening of asymptomatic patients for VTE was not performed, the actual VTE rate is likely higher than reported. However, given the lack of randomized prospective data on this topic, retrospective data is critical to improve our practice. The incidence of late VTE (after 30 days) is difficult to estimate in retrospective studies because some patients may delay presentation that delays diagnosis. However, similar incidences of late developing VTE have been demonstrated in prospective trials where screening was performed, and VTE were found to develop weeks after surgery.[14,15]

CONCLUSIONS

Venous thromboembolism events are common in bladder cancer patients undergoing RC, and are a potentially preventable cause of postsurgical morbidity and mortality. Patients with BMI ≥30 or nonurothelial cancer are at highest risk for postoperative VTE and should be considered for aggressive pharmacologic prophylaxis. Future prospective evaluation is necessary to evaluate the optimal thromboprophylaxis regimen for patients undergoing RC for cancer.

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