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Procedure-specific venous thromboembolism prophylaxis: A paradigm from colectomy surgery

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Abstract

Background—Colectomy patients are at high-risk for venous thromboembolism (VTE), but associated risk factors and best prophylaxis in this defined population are only generalized.

Methods—Fifteen hospitals prospectively collected pre-, peri-, and postoperative variables related to VTE and prophylaxis, in addition to the variables defined by the National Surgical Quality Improvement Program between 2008 and 2009 concerning open and laparoscopic colectomy patients with 30-day outcomes. Symptomatic VTE was the primary outcome, and risk factors were tested for association with VTE using multiple logistic regression.

Results—The cohort included 3,464 patients with a mean age of 65; 53% were female. Overall, the 30d incidence of VTE was 2.2%. VTE prophylaxis included sequential compression devices (SCDs, 11%) alone; pharmacologic prophylaxis alone (15%); and both SCDs and pharmacologic prophylaxis (combined prophylaxis, 74%). VTE was associated with each additional year of age (OR, 1.05; 95% CI 1.02–1.06, $P < .001$); increased body mass index (OR 1.03; CI 1.01–1.05; $P = .02$); preoperative anemia (OR 2.4; CI 1.2–4.8; $P = .011$); contaminated wound (OR 3.4; CI 1.6–7.3; $P < .01$); postoperative surgical site infection (OR 2.5; CI 1.2–5.2; $P < .011$); and postoperative sepsis/pneumonia (OR 3.6; CI 1.9–6.7; $P < .01$). Postoperative factors alone accounted for 32% of VTE risk. When controlling for all other factors, only combination prophylaxis was protective against VTE (OR 0.48; CI 0.27–0.9; $P = .02$). Operative time, presence of disseminated malignancy, anastomotic leak, transfusion, urinary tract infection, and laparoscopic procedure were not significantly associated with VTE. Propensity matching showed that unfractionated heparin was equivalent to low molecular weight heparin, and the transfusion rate was not increased with pharmacologic prophylaxis compared to SCDs alone.

Conclusion—Regardless of preoperative factors, VTE prophylaxis using a combination of SCDs and chemoprophylaxis was associated with significant reduction in VTE and should be standard care for patients after colectomy.

Venous thromboembolism (VTE) is a high-profile patient-safety issue highlighted by the recent Surgeon General's call to action and by many high-quality groups.[1,2] Although information about VTE prophylaxis has been widely published and compliance has likely

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increased, overall postoperative VTE incidence has not changed substantially over the past decade.[3,4]

The risk for VTE in patients depends on multiple factors, including personal history of VTE, family history of VTE, hypercoagulable states, obesity, and age. Procedure type, particularly orthopedic, neurosurgical, and abdominal-pelvic major operations, are associated with increased risk for VTE.[3,5] The relative weight of each risk factor against VTE occurrence is not as well delineated; that is, do certain comorbidities outweigh the procedure's effect, or vice versa?[6,7] Colectomy is inherently a higher risk surgery than other procedures.[8] However, more colectomies are being done via a laparoscopic approach, and in some series, they have been associated with decreased risk for VTE.[9,10]

The American College of Chest Physicians' (ACCP) evidence-based guidelines suggest that VTE risk be categorized into 1 of 4 levels.[11] Which level is appropriate is based on a general consideration of surgical type and presence of other VTE risk factors. Other systems promote calculation of individual risk, which involves an exhaustive history and physical examination followed by completion of a weighted risk-stratification tool.[12] The resultant aggregated risk score has been shown to be predictive of postoperative VTE.[13] Further, the benefit of VTE prophylaxis in potentially low-risk patients has also raised questions about whom best to treat, because major bleeding can occur,[14] not to mention the cost. A recent multicenter database review suggests many postoperative patients may not need any prophylaxis and, in general, the rate of postoperative VTE is very low.[4]

Suggested prophylaxis strategies accompany most risk-assessment guidelines, but correlations with specific prophylaxis regiments are not as well defined. Venous thromboembolism prophylaxis includes 2 primary modes, mechanical and pharmacologic. Effective mechanical means are sequential compression devices (SCDs) that act to provide calf-muscle contraction.[15] Pharmacologic therapies are primarily heparin-based anticoagulation, including unfractionated heparin (UFH), low molecular weight heparin (LMWH), and fondaparinux.

In this context, we used a statewide prospectively maintained database in a defined set of patients undergoing left or right colectomy to assess risk for, and best prophylaxis against, VTE.

METHODS

The Michigan Surgical Quality Collaborative (MSQC) represents a partnership between 2 entities: Blue Cross and Blue Shield of Michigan/The Blue Care Network (BCBSM/BCN) and 34 Michigan hospitals, of which 24 participated in this study.[16,17] BCBSM/BCN has funded hospital participation in the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) for participating hospitals. The MSQC uses the basic data platform of the ACS-NSQIP to standardize data collection and outcomes and has also developed new process and outcome measures that pertain specifically to the colectomy procedure.

Participating centers captured defined colectomy cases when they fell within the ACS-NSQIP sampling framework and added additional colectomy cases outside the ACS-NSQIP sampling methodology. All standard ACS-NSQIP preoperative, operative, and postoperative variables were collected.[18] Additional data were collected on the type of bowel preparation, diabetic management, VT prophylaxis, surgical-site prevention practices (ie, normothermia and antibiotic dosing), operative techniques, the incidence of *C. difficile* colitis, anastomotic leak, ileus, ureteral injury, and need for splenectomy.[19] Cases selected for study were open segmental colectomy (44,140), laparoscopic segmental colectomy (44,204), ileocolic resection (44,160), and laparoscopic ileocolic resection (44,205). Over the study period (January 2008 to December 2009) data were entered for 3,464 colectomy operations.

We used chi-square cross-tabulation to compare variables associated with postoperative VTE. We used multivariate logistic regression models to evaluate overall pre-, peri-, and postoperative factors associated independently with postoperative VTE. Models were created at the patient level over the entire study period.

Covariates in the logistic regression model included the following preoperative variables: blood urea nitrogen, creatinine, bilirubin, serum glutamic oxaloacetic transaminase (SGOT), white blood cell count, alkaline phosphatase, platelet count, prothrombin time, partial prothrombin time, albumin, race, age, sepsis, functional status, cancer diagnosis, chronic obstructive pulmonary disease, congestive heart failure, hemiparesis, previous stroke, steroid use, recent weight loss, bleeding diathesis, coronary artery disease, alcohol use, peripheral vascular disease, preoperative dyspnea, preoperative smoking status, relative value units in the patient (a measure of case complexity), gender, diabetes status, compliance with bowel preparation, and insurance status. In addition, the logistic regression model included the following colectomy-specific perioperative variables: preoperative ureteral stents, postoperative wound left open, intraoperative fecal contamination, intraoperative ureteral injury, perioperative glucose levels, preoperative and intraoperative antibiotic administration, epidural catheter utilization, intraoperative transfusion, and operative duration.

Propensity score matching was used to adjust for factors statistically associated with receiving 1 of 2 types of anticoagulant prophylaxis, namely, LMWH or UFH. The propensity score was calculated using a standard multivariate logistic regression analysis, the primary outcome measure being type of anticoagulant. Once the propensity score was derived, it was used to match patients (1 patient receiving UFH and 1 patient not receiving LMWH). We used the Statistical Analysis System (SAS, Cary, NC) greedy matching algorithm to do the case matching, yielding a case-controlled subset of the data. Of the 3,464 patients in the initial study, 1,835 received UFH, and 957 received LMWH. To test the success of the matching, we compared preoperative and intraoperative factors using a McNemar chi-square test to determine whether there were statistical differences between the anticoagulants before and after the propensity matching. The propensity matching was deemed successful if there was no longer any statistical difference in the clinical factors between the 2 groups. After the propensity analysis, we ended up with 503 matched patients in the group. The McNemar chi-square test was also used to test for differences in outcomes

between the 2 groups using our adjusted (matched) dataset, with VTE occurrence as the primary outcome.

Except for the SAS (version 9.1) matching algorithm, all analyses were performed with SPSS version 17.0 (IBM, Armonk, NY). University of Michigan Institutional Review Board approval was obtained.

RESULTS

The cohort undergoing colectomy was elderly and there were slightly more women than men (Table I). The comorbidities were typical for patients in this age group, with a slight majority having hypertension but a minority having diabetes mellitus and active smoking. Colectomy-specific variables showed a low rate (<5%) of anastomotic leak, fecal contamination, or open wound at operative completion. Disseminated malignancy was not common, with only 4% diagnosed prior to the procedure. Mechanical bowel obstruction was present in 14% of patients at presentation. Prior history of weight loss was present in ~4%, and greater than 90% had independent functional status.

The overall 30-day VTE rate was 2.2% and was most common in those undergoing an open left hemicolectomy (Table II). Rates of VTE were significantly lower in those undergoing laparoscopic rather than open colectomy, and emergent colectomy cases had a twofold higher rate of VTE than nonemergent cases.

Overall, VTE prophylaxis was documented in 92% (3,185) of the patients in this study population (Table III). Mechanical prophylaxis (SCD) rates were similar in 2008 and 2009, whereas pharmacologic-only VTE prophylaxis decreased slightly. Pharmacologic plus mechanical prophylaxis predominated throughout the study period at >75%. Comparing rates of postoperative transfusion in the VTE prophylaxis modalities, those with only SCDs had a higher rate of postoperative transfusion than did those who did not have SCDs only (Table IV). Similarly, those patients who did not have combined mechanical and pharmacologic prophylaxis had a higher rate of postoperative transfusion, whereas pharmacologic-only prophylaxis was associated with low and similar rates of postoperative transfusion.

We used a subset of patients in this cohort for whom we had complete data so we could perform multivariable analysis. This resulted in 2,263 patients of whom 52 suffered a VTE (2.2%), a rate essentially the same as that of the larger cohort. Considering the pre-, peri-, and postoperative variables, multiple factors were independently correlated with VTE as shown (Table V). The highest absolute rates of VTE were observed in those with angina and postoperative infection. Independent factors associated with increased VTE occurrence included increased age, increased body mass index (BMI), presence of anemia, presence of surgical-site infection, wound classification of contaminated, and infection bundle (sepsis, septic shock, organ space infection, pneumonia). Factors associated with lower occurrence of VTE included a lack of angina history and a lack of weight-loss history. Combined mechanical and pharmacologic prophylaxis was the only modifiable risk factor in the regression analysis (Table VI). Receipt of combined mechanical and pharmacologic

prophylaxis was significantly protective against 30d VTE. The Hosmer-Lemeshow goodness-of-fit statistic was $P = .80$, and the C-statistic was 0.81 for this multivariable model. Of the model variables, pre- and perioperative variables accounted for 61% of the predictability, and postoperative occurrences accounted for 39% of predictability. Of note, operative time, presence of disseminated malignancy, anastomotic leak, transfusion, urinary tract infection, laparoscopic technique, and emergent procedure were not independently associated with VTE.

To determine whether 1 type of pharmacologic agent was associated with a lower VTE rate, a propensity matched analysis was done to equalize factors that were initially significantly different in groups. These included anemia, race, type of approach (laparoscopic versus open), and whether they received a transfusion (Table VII). Comparison of UFH and LMWH showed similar VTE rates, at 1.6% and 1.4%, respectively ($P = .5$) (Table VIII).

DISCUSSION

Abdominal-pelvic surgeries are associated with higher baseline risk for VTE as compared with other surgeries.[20] This may be due to increased venous stasis because of body positioning, longer duration of operations, and systemic inflammation if performed in the setting of infection or inflammatory bowel disease. This study suggests that the most effective VTE prevention strategy for patients undergoing laparoscopic and open colectomy is using both pharmacologic and mechanical prophylaxis, regardless of other risk factors that may or may not be present. Major bleeding was low and was not associated with pharmacologic heparin-based prophylaxis.

The overall rate of postoperative symptomatic 30-day VTE was low, at 2.2%, and is similar to other reports concerning patients undergoing colectomy.[4,10,21] However, this rate is higher than that of most other surgical procedures, including orthopedic procedures, as abstracted from large prospective-obtained data sets.[3,7] Other studies of colectomy patients and VTE occurrence show VTE rates ranging from 2% to 18%.[8] However, these rates are often determined by how the VTE is diagnosed. For example, many prospective therapeutic trials studies report higher rates of deep venous thrombosis (DVT) if all patients are prospectively imaged by duplex ultrasonography than if only symptomatic patients are imaged. In the current cohort, only symptomatic patients were abstracted, as defined by standard NSQIP definitions.[3,7]

The main modalities of VTE prophylaxis include anticoagulation and mechanical methods (SCDs). In this study, most patients underwent prophylaxis according to current ACCP evidence-based guidelines,[20] although we did not know the specifics of risk factor assessment and individual patient decisions at any given hospital. For example, the Caprini VTE risk-scoring system is useful for stratifying patient risk when all the preoperative risk variables are known.[13] However, in this cohort of patients, most were at moderate to high risk based on the incidence of 2% to 4%. In fact, most patients in this cohort received combined pharmacologic and mechanical prophylaxis, suggesting excellent adherence to ACCP guidelines and the Surgical Care Improvement Project criteria.[1] Combined pharmacologic and mechanical prophylaxis is recommended for patients at highest risk, but

colorectal patients are not often listed in this group.[7,13,20] Other studies have shown significant benefit of combined pharmacologic and mechanical prophylaxis in colorectal patients. For example, the APOLLO trial randomized patients undergoing colorectal surgery to fondaparinux plus SCDs or SCDs alone and found a ~70% reduction in postoperative DVT rates in those who had undergone combined prophylaxis.[22]

The laparoscopic approach as compared to open colectomy was not independently associated with a protective effect against VTE, in contrast to other studies.[9,10] Although it may have been a power issue (type II error) in our cohort, it is more likely the colectomy-specific variables not present in other studies may have negated the operative-approach effect. For example, the study by Shapiro et al[10] included a broader range of colorectal procedures, and that might have affected risk for VTE, and they used only standard NSQIP variables for analysis.

These data also highlight factors that are associated with postoperative VTE in a group of patients receiving prophylaxis, so-called breakthrough VTE. Our findings in the >90% prophylaxed cohort are in contrast to other studies, in which high-risk patients may be underprophylaxed.[5,21,23] High-risk patients who suffer a VTE may not always receive the adequate prophylaxis dosage due to body weight; dosing may be refused or missed; or the SCDs may not be on the patient.[1] Nonetheless, high-risk patients should be carefully followed for adherence to both modalities of prophylaxis, once they have been prescribed.

Counter to other studies,[7,10] typical risks in our cohort that were not associated with VTE included disseminated malignancy, emergent procedure, operative time, anastomotic leak, UTI, and transfusion. However, the effect of postoperative infection was predominant, with surgical site infection (SSI) and systemic infection bundle conferring a 2.5-and 3.5-fold increased risk, respectively. Infection is a known risk factor for VTE and has been confirmed in inpatient[3,10,13] and outpatient settings,[24] although varying prophylaxes were used in these study cohorts. Why infection and inflammation increase the risk for VTE is not defined but may be due to increased remote vein wall procoagulant reactivity, increased circulating procoagulant active phase reactants, and/or increased activated leukocytes. In particular, neutrophils may play a direct role,[25,26] but few data are available from humans. Colectomy patients with major infectious complications may be better served by either prospective duplex assessment or increased levels of anticoagulant prophylaxis. However, further study is needed.

The type of heparin anticoagulant does not seem to be as important as that pharmacologic therapy be used. Although we did not analyze or capture specific prophylaxis-dosing regimens, we recommend using UFH 5000U TID; LMWH 40 mg (lovenox) or 5000U qD (deltaparin), or fondaparinux 2.5 mg qD. The equivalence of LMWH and UFH has also been found in a prospective cohort of critically ill patients.[27] Importantly, this strategy was not associated with increased major bleeding, as defined by the NSQIP standard definition. In pharmacologic colorectal trials, the bleeding rates range from 1.6% to 11.5%, depending on how major bleeding is defined.[14,22] Bleeding postoperatively often is not caused by prophylactic levels of anticoagulation but by other inherent factors in patients.[28] Overall, the postoperative bleeding rate was low (<3%), even considering that emergent cases were

included. Indeed, a higher bleeding occurrence was found in those receiving SCDs alone. This is probably because these patients were deemed to be at high risk by their treating physicians. In general, contraindications to anticoagulation are documented in ~8% of surgical patients.[29]

The limitations of this study include that VTE was clinically diagnosed and was not prospectively determined by defined criteria. Thus, practitioners at different hospitals may have different thresholds for obtaining a venous duplex scan or computed tomography scan. This study did not abstract for variables highly associated with VTE, including hypercoagulable states or a personal history of VTE.[20] However, even if independently associated with postoperative VTE, it is likely that the number would have been small[29] and that the combined prophylaxis regimen is still protective.[5] The prophylaxis type was determined by direct chart abstraction, but we do not know the rate of compliance with administration of VTE pharmacologic agents to that of SCDs. Anecdotally, patient compliance with SCDs may be less than optimal. We did not assess patients for development of heparin-induced thrombocytopenia (HIT) or capture those with a known history of HIT. However, current guidelines suggest using fondaparinux 2.5 mg qD for prophylaxis, with platelet-count monitoring.[30] Last, recent studies suggest elevated VTE risk beyond the 30-day catchment of the NSQIP, as shown by Pannucci et al[31] and whether the defined factors at 30 day are predictive at 90 days is not able to be determined.

In conclusion, in a highly selected group of patients undergoing colon surgery, combined pharmacologic and mechanical prophylaxis is protective against VTE and is associated with low risk for bleeding. Focusing on procedure-associated VTE risk rather than on separate patient factors may simplify VTE prophylaxis in specific high-risk procedures.

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Table I

Demographics of study cohort

Age (years)	64.7 ± 15
Male/female	47%/53%
Tobacco use	20%
Hypertension	57%
Angina	1%
Anemia	11%
Malignancy	4%
Functional status-dependent	7.5%
Weight loss	4.2%
Anastomotic leak	2.2%
Fecal contamination	2.2%
Prolonged ileus	8.6%
Open wound	1.2%
Wound class	
Clean contaminated	81%
Contaminated	10%
Dirty	9%

Table II

Rate of venous thromboembolism stratified by procedure type and activity*

***n* = 3,464**	**Rate of VTE**	
VTE	2.2%	
Open L (1,334)	3.1%	*P* = .011
Open R (838)	2.3%	
Laparoscopic L (897)	1.7%	
Laparoscopic R (395)	0.5%	
Emergent (377)	4.0%	*P* = .017
Nonemergent (3,078)	2.0%	

* Comparison of categories was made by using the cross-tab function.

L, Left; *R*, right; *VTE*, venous thromboembolism.

Table III

Type of prophylaxis stratified by year

	2008	2009
SCD only	13%	13%
Pharm only	16%	10%
Pharm + SCD	71%	77%

Pharm, Pharmaceuticals; *SCD*, sequential compression device; *VTE*, venous thromboembolism.

Table IV

Rates of postoperative transfusion stratified by prophylaxis type

	Postoperative transfusion?		
	Yes	**No**	***P***
SCD only	1.6%	0.4%	.009
Pharm only	0.6%	0.7%	.45
SCD + Pharm	0.3%	1.3%	.005

Pharm, Pharmaceuticals; *SCD*, sequential compression device.

Table V

Risk factors for and rate of venous thromboembolism

	VTE%		
Factor	**Present**	**Absent**	***P***
Age (years)	65 ± 15	62 ± 13	<.001
BMI	31 ± 7	28 ± 7	.009
Anemia	6.1	1.8	<.001
SSI	6.3	1.9	<.001
Wound class			
Clean	1.8	—	.001
Clean contaminated	3.6	—	
Dirty	6.1	—	
Infection bundle*	9.3	1.4	<.001
Angina	13.6	2.2	.013
Weight loss	6.3	2.1	.021
No combined prophylaxis	3.7	1.9	.013

* Infection bundle = sepsis, septic shock, pneumonia, organ space infection.

BMI, Body mass index; *SSI*, surgical site infection; *VTE*, venous thromboembolism.

Table VI

Independent factors associated with venous thromboembolism from a multivariable regression model

Factor	OR	95% CI	*P*
Age	1.05	1.02–1.06	<.001
BMI	1.03	1.004–1.05	.016
Anemia	2.4	1.2–4.8	.011
SSI	2.52	1.23–5.17	.011
Wound class (dirty/infected relative to clean/contaminated)	3.4	1.6–7.3	.001
Infection bundle	3.6	1.9–6.7	<.001
(-) h/o angina	0.18	.05–.68	.011
(-) h/o weight loss	0.33	.13–.86	.024
Combined prophylaxis	.48	.27–.89	.02

h/o, history of; *infection bundle*, sepsis, sepsis shock, organ space infection, pneumonia; *SSI*, surgical site infection.

Table VII

Propensity matching factors

Factor	UFH (*n* = 503)	LMWH (*n* = 503)	*P*
Anemia	45.8%	54.2%	.238
African American	49.3%	50.7%	.50
Laparoscopic procedure	49.8%	50.02%	.475
Transfusion	51.4%	48.6%	.500

LMWH, Low molecular weight heparin; *UFH*, unfractionated heparin.

Table VIII

Type of anticoagulant and VTE incidence

	VTE		
Anticoagulant	**No**	**Yes**	***P***
UFH	495 (98.4)	8 (1.6)	
LMWH	496 (98.6)	7 (1.4)	.5

LMWH, Low molecular weight heparin; *UFH*, unfractionated heparin; *VTE*, venous thromboembolism.