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ORIGINAL SCIENTIFIC REPORT

Safety of Prophylactic Anticoagulation During Bedside Procedures: A Prospective Multicenter Observational Study

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Abstract

Background Bedside percutaneous dilatational tracheostomy (PDT) and percutaneous endoscopic gastrostomy (PEG) are common procedures performed in the intensive care unit (ICU). Venous thromboembolism (VTE) prophylaxis is frequently prescribed to ICU patients and it remains unclear whether pre-procedure discontinuation is necessary.

Methods This multi-center prospective observational study aimed to describe bleeding rates in patients undergoing bedside PEG or PDT who did or did not have VTE prophylaxis held. Decision to hold prophylaxis was made by the operating physician. The primary endpoint was the rate of peri-procedural bleeding complications. Secondary endpoints included quantification of held doses in the peri-procedural period, rate of venous thromboembolism, and characteristics associated with having prophylaxis held.

Results 91 patients were included over a 2-year period. Patients were on average aged 54 years, 40% female, mostly admitted to the trauma service (59%), and most commonly underwent bedside PDT (59%). Overall, 21% of patients had doses of pre-procedure prophylaxis held. Bleeding events occurred in 1 patient (1.4%) who had prophylaxis continued and in 1 patient (5.0%) who had prophylaxis held, a rate difference of 3.6% (95% CI–9.5%, 16.7%). One bleeding event was managed with bedside surgical repair and one with blood transfusion. There were 10 VTE events, all of whom had prophylaxis continued during the pre-procedure period but 3 had prophylaxis held after the procedure.

Conclusions Bleeding complications were rare and did not significantly differ depending on whether prophylaxis was held or not. Future research is required to confirm the lack of risk with continuing prophylaxis through bedside procedures.

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Introduction

Percutaneous dilatational tracheostomy (PDT) and percutaneous endoscopic gastrostomy (PEG) are procedures that may be safely completed at the bedside in the intensive care unit (ICU) [1–5]. Bleeding is the most common early complication of tracheostomy [6], occurring in up to 5% of patients, and occurs in up to 2.5% of PEG placements [7–11].While bedside procedures offer shorter operative time, fewer adverse events from anesthesia, and lower resource utilization compared to procedures completed in the operating room (OR), it is unclear whether patients continued on anticoagulation or antiplatelet agents are at increased risk for bleeding during these procedures [12].

Patients admitted to the ICU are frequently placed on anticoagulant or antiplatelet medications for a number of indications. Nearly all ICU patients are indicated for chemical venous thromboembolism (VTE) prophylaxis with subcutaneous low molecular weight heparin (LMWH) or unfractionated heparin (UH) [13]. Variation in practice exists in whether prophylactic anticoagulation requires temporary discontinuation prior to bedside operations. A retrospective review of bleeding complications on prophylactic anticoagulation in patients undergoing bedside PEG or PDT did not reveal increased risk of bleeding complications, but this has yet to be prospectively confirmed [14]. In this prospective cohort study, we aimed to describe the difference in rates of bleeding complications between patients who did and did not have prophylactic anticoagulation held prior to bedside PEG or PDT.

Methods

This was a prospective multicenter observational trial conducted from February 2017 to February 2019 at two Level I trauma centers in the USA. Patients aged 16 years or older undergoing bedside percutaneous endoscopic gastrostomy (PEG) and/or percutaneous dilatational tracheostomy (PDT) who were receiving prophylactically dosed anticoagulation with subcutaneous heparin, low molecular weight heparin, or a direct acting anticoagulant (DOAC) were eligible for inclusion. Patients were identified by investigators who reviewed the surgical and ICU procedural schedules or by receiving direct report from the clinician completing the procedure. Patients were excluded if they were receiving therapeutically dosed anticoagulation, were prisoners, pregnant, were decisionally impaired, or if the procedure was conducted in an open or surgical manner. Eligible patients were asked for informed consent to be included in the cohort and data were collected prospectively after the procedure. Decision to hold or continue prophylactic anticoagulation was made by the individual surgeon completing the procedure and was not influenced by study personnel. The study was reviewed and approved by both participating sites' Institutional Review Boards.

Data collection

After consent, data were prospectively collected from the electronic medical record into a pre-specified Research Electronic Data Capture (REDCap) form [15, 16]. Demographic information included the age, weight, gender, and admitting service (trauma, medical, surgical, or other) of each patient. The hospital and ICU lengths of stay prior to the procedure, type of prophylactic anticoagulation name, dose, frequency, and whether dose adjustments had been made, and type of antiplatelet agent ordered, if any, were also collected. The procedure performed, number of doses of prophylactic anticoagulation held before the procedure, markers of renal function, including serum creatinine (SCr) and blood urea nitrogen (BUN) on the day of the procedure, and any laboratory coagulation values (international normalized ratio [INR], platelet count, fibrinogen, anti-Xa activity, or activated partial thromboplastin time [aPTT]) on the day of the procedure were also recorded. Outcome variables included any peri-procedure bleeding complications requiring intervention which occurred within 48 h of the procedure, whether an intervention was performed to address the bleeding (blood product transfusion, bedside surgical intervention, open surgical intervention, or other), whether a venous thromboembolism occurred post-procedure during the index hospital admission, and whether any doses of prophylactic anticoagulation were held after the procedure. 48 h was selected to minimize the likelihood of non-operative confounders contributing to bleeding events post-operatively.

Bleeding events were defined as any bleeding during the procedure that required more than direct pressure to manage or any post-procedure bleeding that required any intervention (direct pressure, topical hemostatic agent, suture control, or re-exploration). Thromboembolic events were defined as any venous or arterial thromboembolism detected after the procedure during the index admission. One site performed routine, surveillance venous duplex ultrasounds on hospital day 3 then weekly to screen for VTE while one site did not complete routine Doppler ultrasounds but did perform whole leg sonography when clinical suspicion for lower extremity VTE was high.

Outcomes

The primary objective of this study was to describe the rates of peri-procedural bleeding events after bedside PDT or PEG in patients whose VTE prophylaxis was or was not

held. Secondary endpoints included quantification of held doses in the peri-procedural period, predictors of having prophylaxis held, identification of risk factors for bleeding events, and the incidence of VTE events in either group.

Statistical analysis

Baseline characteristics were reported as frequencies and percentages or medians and interquartile ranges (IQR) and continuous and ordinal variables were compared between groups with the Mann–Whitney *U* test or Student's t-test as appropriate. The difference in the rates of events was compared using the chi-squared test or Fisher's exact test as appropriate and 95% confidence intervals for rate differences were calculated using the proportion test. Predictors of bleeding events or whether anticoagulation was held was completed using univariable logistic regression with age, gender, serum creatinine, BUN, platelet count, INR, procedure performed, and prophylactic anticoagulant agent used as variables. Predictors of whether VTE prophylaxis was held included the same predictive variables used for bleeding events. Analysis was completed using R version 4.0.0 (R Core Team, R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 91 patients were included in the cohort with 48 from site 1 and 43 from site 2. The baseline characteristics of the cohort are listed in Table 1 and were well-matched between sites**.** Patients who did or did not have prophylactic anticoagulation held prior to PEG or PDT were similar with no major differences between groups. Overall, patients were more commonly male (60%), most likely to be admitted by the trauma service (59%), and had been in the hospital for a median of 12 days and in the ICU for 11 days prior to the procedure. Both procedures were performed within 12 h of each other in 35% of patients, whereas 59% of patients only received a PDT and 6.6% of patients only received a PEG at bedside.

Details on the characteristics of prophylactic anticoagulation and antiplatelet agents prescribed are listed in Table 2**.** Three patients received higher doses of prophylaxis, all adjusted for body mass index (BMI). None of these patients had prophylaxis held. 21% of patients were receiving low-dose aspirin (81 mg) and there was no difference in the rate of antiplatelet use between patients who did and did not have anticoagulation held (25% vs 20%).

There were two bleeding events in the cohort, one in the continuation group (1.4%) and one in the held group (5%) for a rate difference between continuing and holding prophylaxis of -3.6% (95% CI–9.5%, 16.7%) (Table 3). This was also found to be non-significant via Fisher's exact test ($p = 0.54$). In response to the bleeding event, one patient had the bleeding surgically repaired at bedside and one required only blood transfusion. The patient who received a transfusion had cardiovascular comorbidities and received a transfusion based on higher transfusion goals after the procedure. Overall, 18% of patients had at least one dose of prophylaxis held after the procedure, with 33% of patients whose prophylaxis was held pre-procedure having dosing held after the procedure compared to 14% of patients whose prophylaxis was not held ($p = 0.07$). Specific characteristics of each patient who experienced a bleeding event is listed in Table 4. Both patients had doses of prophylaxis held after the bleeding event in response to the bleeding.

There were 10 thromboembolic events identified in the cohort. None (0% vs. 30%, $p = 0.11$) of the patients with diagnosed thromboembolism had VTE prophylaxis held prior to their procedure but 3 (30% vs. 17%, $p = 0.40$) had prophylaxis held after the procedure (Fig. 1). Nine of the thromboembolic events occurred at one site which conducted routine surveillance venous duplex ultrasounds (16.4% event rate) compared to one at one site which did not conduct surveillance ultrasounds (2.7% event rate), a significant difference ($p = 0.04$). One thromboembolic event was a pulmonary embolism, eight were deep vein thromboses, and one was a middle cerebral artery occlusion.

Factors predicting the decision to hold prophylactic anticoagulation prior to procedure were analyzed and are listed in Table 5. Of the factors evaluated (age, gender, SCr, BUN, platelet count, procedure type, and prophylaxis type), only type of prophylaxis was found to be associated with the decision to hold prophylaxis. Compared to enoxaparin 30 mg every 12 h, patients receiving enoxaparin 40 mg every 24 h were less likely (OR 0.77, 95% CI 0.62–0.97) to have doses held prior to the procedure. Other regimens were not found to confer significantly different odds of having prophylaxis held.

Discussion

In this prospective multicenter observational study of patients undergoing bedside PEG or PDT, the overall rate of bleeding events was found to be 2.2% and was unaffected by whether prophylactic anticoagulation was held pre-procedure. Bleeding events were managed by either bedside intervention or blood transfusion and did not require transition to open procedure. Neither procedure was more likely to result in held prophylactic anticoagulation, nor did any patient-specific factor including age, gender, renal function, or coagulation status. Patients receiving

Table 1 Baseline characteristics

Characteristic	Overall, $N = 91$	Not Held, $N = 71$[1]	Held, $N = 20$[1]	P-value
Age, years	54 (41, 69)	56 (42, 70)	48 (30, 66)	0.11
Gender				0.64
Female	36 (40%)	29 (41%)	7 (35%)	
Male	55 (60%)	42 (59%)	13 (65%)	
Admitting Service				0.73
Medical service	15 (16%)	13 (18%)	2 (10%)	
Surgical service	22 (24%)	17 (24%)	5 (25%)	
Trauma service	54 (59%)	41 (58%)	13 (65%)	
Procedure				0.23
Both (within 12 h)	31 (34%)	21 (30%)	10 (50%)	
PDT	54 (59%)	45 (63%)	9 (45%)	
PEG	6 (6.6%)	5 (7.0%)	1 (5.0%)	
Pre-procedure Hospital Length of Stay, days	12 (8, 18)	13 (8, 17)	12 (9, 18)	0.92
Pre-procedure ICU Length of Stay, days	11 (8, 16)	11.0 (8, 16)	11.5 (8.5, 14.5)	0.84
Serum Creatinine, mg/dL	0.70 (0.54, 0.91)	0.70 (0.52, 0.90)	0.67 (0.55, 0.92)	0.86
BUN, mg/dL	26 (21, 38)	28 (21, 42)	24 (21, 26)	0.19
INR	1.20 (1.10, 1.30)	1.20 (1.10, 1.30)	1.20 (1.02, 1.30)	0.86
Platelet Count, cells $\times 10^9$	340 (204, 426)	347 (209, 434)	306 (206, 408)	0.70
Fibrinogen, mg/dL	536 (294, 636)	488 (310, 631)	585 (414, 618)	0.99
aPTT, seconds	30 (26, 33)	30 (27, 35)	28 (26, 31)	0.43

[1]Statistics presented: median (IQR); *n* (%)

Table 2 Characteristics of prophylaxis regimens

Characteristic	Overall, $N = 91$	Not Held, $N = 71$[1]	Held, $N = 20$[1]
Prophylactic anticoagulation regimen			
Enoxaparin 30 mg every 12 h	23 (25%)	15 (21%)	8 (40%)
Enoxaparin 40 mg every 12 h	4 (4.4%)	4 (5.6%)	0 (0%)
Enoxaparin 40 mg every 24 h	31 (34%)	28 (39%)	3 (15%)
Heparin 5000 units every 12 h	2 (2.2%)	1 (1.4%)	1 (5.0%)
Heparin 5000 units every 8 h	31 (34%)	23 (32%)	8 (40%)
Antiplatelet Agent Used	88	68	20
Aspirin 81 mg once daily	19 (21%)	14 (20%)	5 (25%)

[1]Statistics presented: *n* (%)

enoxaparin once daily, however, were less likely have doses held than other regimens. These results help confirm prior results suggesting that holding prophylactic anticoagulation is unnecessary prior to bedside PEG or PDT in the ICU [14].

Bedside PEG and PDT have been known to be safe and effective for over two decades and are common practice in many ICUs [5, 17–21]. Among the most serious complications of bedside procedures are peri- and post-operative bleeding events. While variably defined in studies comparing bedside to open procedures, rates of bleeding range from 0 to 10% [7, 8, 22]. Bleeding events described include stoma site bleeding or other minor bleeding and can often be managed with minimally invasive surgical repair. While the risks of the procedures are low, concern still remains over whether it is safe to continue prophylactic anticoagulation in the periprocedural time period. Patients receiving anticoagulation have been described as being high-risk candidates for bedside procedures [7], but the distinction between therapeutic and prophylactic doses

Table 3 Primary and secondary endpoints

Characteristic	Overall, $N = 91$	Not Held, $N = 71$[1]	Held, $N = 20$[1]	Rate difference	P-value[2]
Bleeding event	2 (2.2%)	1 (1.4%)	1 (5.0%)	− 3.6% (95% CI–9.5%, 16.7%)	0.39
Response					
bedside surgical repair	1 (1.1%)	1 (1.4%)	0 (0%)		
Taken to OR	0 (0%)	0 (0%)	0 (0%)		
Blood transfusion	1 (1.1%)	0 (0%)	1 (5.0%)		
Other procedure	0 (0%)	0 (0%)	0 (0%)		
Had doses held after procedure	17 (19%)	10 (14%)	7 (35%)		0.09

[1]Statistics presented: *n* (%), [2] Fisher's exact test, Chi-squared

Table 4 Specific characteristics of patients experiencing periprocedural bleeding

	Patient 1	Patient 2
Age	69	74
Gender	Female	Female
Admitting Service	Medical	Trauma
BUN	20	34
INR	1.4	Not Available
Platelet Count	402	843
Procedure	Both (Bleeding occurred at PDT site)	PDT
Regimen	Heparin 5000 units every 8 h	Enoxaparin 40 mg every 24 h
Antiplatelet Agents	None	None
Doses Held Prior	1	0
Doses Held After	6	1
Treatment	Blood transfusion	Bedside surgical repair
VTE?	No	No

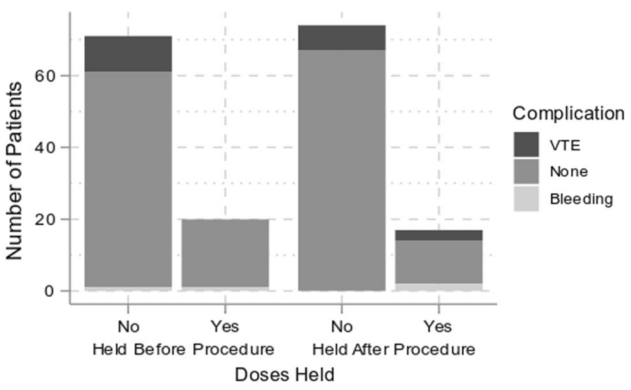

Fig. 1 Rate of Complications by Held Prophylactic Anticoagulation Status Rates of complications based on whether prophylactic doses were held before or after the procedure. Both patients who experienced bleeding had doses held post-procedure in response to the bleeding event. VTE: Venous thromboembolism

of anticoagulation is not always made. Prior single-center retrospective analyses of prophylactic anticoagulation use prior to bedside procedures have failed to detect a significant signal of harm [14, 23].

Holding prophylactic anticoagulation in patients undergoing bedside PEG or PDT is not without risk. Patients undergoing bedside procedures are most commonly admitted to the ICU and likely have substantial risk factors for thromboembolic events [24, 25]. A prospective observational study evaluating the effect of missing prophylactic anticoagulation doses in a surgical ICU reported a linear relationship between missed doses of prophylaxis and risk of venous thromboembolism, with patients who missed between 2 and 4 doses of prophylaxis being at an 8.49 times increased odds of experiencing deep vein thrombosis compared to patients without interruption [26]. A different cohort study of two national registries of patients

Table 5 Predictors of having prophylaxis held pre-procedure

Factor	Odds ratio	95% CI
Age, years	0.99	0.99, 1.00
Male Gender	1.04	0.87, 1.24
SCr < 1.5 mg/dL	0.99	0.77, 1.27
BUN < 30 mg/dL	1.20	1.01, 1.43
Platelet count < 100,000	1.12	0.69, 1.82
PDT vs Both procedures	0.85	0.71, 1.02
PEG vs Both procedures	0.85	0.59, 1.22
Enoxaparin 40 mg every 12 h	0.70	0.45, 1.08
Enoxaparin 40 mg every 24 h	0.77	0.62, 0.97
Heparin 5000 units every 12 h	1.16	0.64, 2.10
Heparin 5000 units every 8 h	0.91	0.73, 1.14

undergoing colostomy found that in high-risk patients missing at least 1 dose of VTE prophylaxis significantly increased the odds of experiencing a VTE (OR 2.41, 95% CI 1.27–4.57) [27]. Similarly, PDT has been demonstrated to be safe even in patients with coagulopathy (INR > 1.3 or platelet count < 80,000), with rates of bleeding complications occurring in 1.22% of coagulopathic patients compared to 0.94% of noncoagulopathic patients ($P > 0.99$) [28]. While our study did not reveal an increased risk of VTE events with holding pre-procedure prophylaxis, patients with prophylaxis post-procedure tended to develop more VTEs, although this was not significant. One arterial thrombus was detected in our sample (an MCA stroke); while this is not exclusively related to held prophylaxis dosing, it demonstrates the pro-thrombotic state of these patients. A larger sample size would be needed to accurately estimate the risk of developing a VTE when prophylaxis is held before or after bedside procedures.

The decision to hold prophylactic anticoagulation was left to the discretion of the surgeons in this study. An attempt to identify factors which led surgeons to hold anticoagulation did not identify any significant patient-specific factor, including age, gender, renal function, BUN, or platelet count. Not enough patients had an INR available at the time of the procedure to make accurate predictions. Neither procedure individually nor combined was found to be associated with the decision to hold doses. The only regimen found to have been held less often was enoxaparin 40 mg once daily (OR 0.70, 95% CI 0.62–0.96). Antiplatelet agents (exclusively aspirin 81 mg) were commonly used in this cohort (21%), but none of these patients developed bleeding events after their procedure.

This study has several limitations. First, while patients were included prospectively, they were not randomized to either group, thus introducing the potential that patients at higher risk of bleeding may have been ordered to have prophylaxis held. This introduces the potential that rates of bleeding did not differ between groups because of external confounding. Second, manual patient identification limited the number of patients available for screening, which led to a slower than usual enrollment rate and lower sample size than was expected. This may introduce selection bias, as patients undergoing bedside procedures who were not identified for data collection may not have randomly occurred. We also did not retrospectively review all PEG/PDT cases that were not included in prospective data collection, so a true proportion of procedures included could not be reported. The small sample size reduced the power of the study to detect an uncommon event (bleeding). Third, specific factors which led to the decision to hold prophylaxis revealed enoxaparin 40 mg once daily was less likely to be held than other regimens. Patients also may have been less likely to have this held because the wide dosing interval may be less worrisome to operating physicians. This may lead to patients who otherwise would have had prophylaxis held if the interval was shorter to be allocated to the not held group independent of patient-specific risk factors for bleeding. Fourth, we did not have an open surgical group to compare rates of bleeding to the bedside group. This may have helped further elucidate differences in the safety of these two operative techniques. Screening for VTE occurred differently between sites, as well, with one site conducting routine VTE surveillance scans and one not, which is reflected in the significantly higher rate of VTE in the site 1 patients compared to site 2.

This study does have several strengths, however. The prospective, multi-center nature of the design helps to address practice variation between sites and also allowed investigators to actively screen for bleeding events. The broad inclusion criteria also produced an externally valid, generalizable population to both medical and surgical practitioners. This study also described specific prophylaxis regimens which are often missing from similar reports. While few patients had their prophylaxis regimens adjusted for patient-specific factors, we did collect these variables as well in case this influenced the primary outcome.

Conclusion

Our prospective cohort study found that rates of bleeding between groups did not differ significantly. We conclude that holding prophylactic anticoagulation is likely not necessary before bedside PEG or PDT, although randomized studies would serve to validate this conclusion. Additional research is needed to make conclusions on the

impact of antiplatelet therapy or treatment anticoagulation and the risk of bleeding for these procedures.

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Declarations

Conflicts of interests The authors have no conflicts of interest to disclose.

Ethical approval This study was approved by the IRB at each participating institution.

Consent informed Informed consent was obtained for all participants in this study.

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