

Anticoagulation management around percutaneous bedside procedures: Is adjustment required?

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BACKGROUND:	Percutaneous endoscopic gastrostomy (PEG) and percutaneous dilatational tracheostomy (PDT) are frequently performed bedside in the intensive care unit. Critically ill patients frequently require anticoagulant (AC) and antiplatelet (AP) therapies for myriad indications. There are no societal guidelines proffering strategies to manage AC/AP therapies periprocedurally for bedside PEG or PDT. The aim of this study is to evaluate the management of AC/AP therapies around PEG/PDT, assess periprocedural bleeding complications, and identify risk factors associated with bleeding.
METHODS:	A retrospective, observational study of all adult patients admitted from October 2004 to December 2009 receiving a bedside PEG or PDT was conducted. Patients were identified by procedure codes via an in-hospital database. A medical record review was performed for each included patient.
RESULTS:	Four hundred fifteen patients were included, with 187 PEGs and 352 PDTs being performed. Prophylactic anticoagulation was held for approximately one dose before and two doses or less after the procedure. There was wide variation in patterns of holding therapy in patients receiving anticoagulation via continuous infusion. There were 19 recorded minor bleeding events, 1 (0.5%) with PEG and 18 (5.1%) with PDT, with no hemorrhagic events. No association was found between international normalized ratio, prothrombin time, or activated partial thromboplastin time values and bleed risk ($p = 0.853$, 0.689 , and 0.440 , respectively). Platelet count was significantly lower in patients with a bleeding event ($p = 0.006$).
CONCLUSIONS:	We found that while practice patterns were quite consistent in regard to the management of prophylactic anticoagulation, it varied widely in patients receiving therapeutic anticoagulation. It seems that prophylactic anticoagulation use did not affect bleed risk with PEG/PDT. (<i>J Trauma</i> . 2012;72: 815–820. Copyright © 2012 by Lippincott Williams & Wilkins)
LEVEL OF EVIDENCE:	II, therapeutic study.
KEY WORDS:	Anticoagulation; percutaneous dilatational tracheostomy; percutaneous endoscopic gastrostomy; heparin; enoxaparin.

Percutaneous endoscopic gastrostomy (PEG) and percutaneous dilatational tracheostomy (PDT) traditionally performed in the operating room are now frequently being performed bedside in the intensive care unit (ICU).^{1–9} The purported advantages of bedside procedures over open surgical techniques include reduced risk of bleeding and infection, decreased procedure time, fewer postoperative complications, elimination of the inherent risk of transporting a critically ill patient, and decreased utilization and expense of an operating room and personnel.^{1–9}

Patients admitted to the ICU often require anticoagulant (AC) and antiplatelet (AP) therapies for myriad indications. There are societal guidelines proffering strategies to manage these AC and AP therapies periprocedurally in other surgical and nonsurgical procedures; however, no such consensus has been published for bedside PDTs or PEGs.^{10,11} The American Society for Gastrointestinal Endoscopy guidelines for the role of endoscopy in enteral feeding cite an uncorrectable coagulopathy as an absolute contraindication to PEG but do not offer recommendations on the management of these medications periprocedurally.⁷ There have been few published studies investigating the risk factors for bleeding associated with PEG or PDT, and none have directly investigated the impact of anticoagulation and/or AP therapies on this risk.^{1,2,4,12–16}

Major bleeding rates for PEG and PDT are generally considered to be quite low. Classification of bleeding complications in both procedures varies in definition and frequently reported as aggregate complication rates with other, unrelated complications.^{7,17,18} Fatal bleeding is exceedingly rare, but case reports of massive hemorrhage from PEG and PDT have been published.^{19–23} The true incidence of bleeding complications in these procedures, using a specific, widely accepted definition, has not been described.

The aim of this study was to evaluate practice patterns regarding AC and AP therapy management around the time of bedside PEG and PDT. Our secondary objectives were to

assess periprocedural bleeding in all patients who undergo bedside PEG and/or PDT and to identify risk factors associated with this complication. Our hypothesis is that there would be no increased incidence of bleeding in patients on prophylactic or therapeutic anticoagulation as compared with patients not receiving AC therapy.

METHODS

From October 1, 2004, through December 31, 2009, all patients aged 18 years and older admitted to Fletcher Allen Health Care, a university-affiliated Level I trauma center, who had PEGs and/or PDTs performed at the bedside were included for analysis. Patients were identified from a hospital database via current procedural terminology codes (43246, 31600, and 37620) for PEG and PDT. This study was approved by the University of Vermont Committees on Human Research. According to criteria set by this committee, a waiver to abstain from obtaining informed consent was granted. This study was developed and conducted in accordance with the STROBE statement for cohort studies.²⁴

Exclusion criteria included undocumented timing of administration of AC or AP therapies, procedure performed in an open or surgical manner, and premorbid history of coagulopathy, as defined by any diagnosed hypercoagulable or hypocoagulable state documented in the admission history and physical note, hematology consult note, or periprocedural note in the patient's medical record during the admission in which the procedure was performed. The protocol was approved by the Fletcher Allen Health Care/University of Vermont Committees on Human Research.

All data were collected via extensive medical record review. Age, gender, number of days hospitalized before each procedure, in-hospital AC and/or AP use data, procedural complications, and type of intervention performed to induce hemostasis (none, packing inserted at the site of procedure, stitch placed, and pressure held) were obtained.

PDTs were placed using a Seldinger approach after administration of local anesthesia.²⁵ Multiple, progressive dilators were used to place the appropriate size of tracheostomy tube.²⁵ PEG tubes were placed with the use of endoscopy via the “pull” method after administration of local anesthesia of the abdominal wall at the site of transillumination.^{26,27} Once the PEG tube was in place, the position was confirmed with endoscopy assuring no tension on the flange.^{26,27}

In-hospital AC and/or AP use data obtained included agents, doses, frequency, time last dose was administered preprocedure, time first dose was administered postprocedure, indication for anticoagulation, or reason for lack of AC therapy. The laboratory values assessing coagulation status obtained on the day of procedure and closest to the time of procedure included international normalized ratio (INR), platelet count, prothrombin time (PT), and/or activated partial thromboplastin time (aPTT). For patients having additional bedside procedures on a different date or time than the first procedure, these data were collected for each procedure.

Patients were classified as “unanticoagulated,” “prophylactically anticoagulated,” or “therapeutically anticoagulated” for each procedure. Unanticoagulated patients were either not receiving ACs, had subcutaneous (SQ), intermittent prophylactic anticoagulation agents held for one or more doses, or had therapeutically dosed anticoagulation held for ≥ 4 half-lives of the AC (i.e., enoxaparin 1 mg/kg SQ administered twice daily held for ≥ 2 doses). Prophylactically anticoagulated patients were either receiving prophylactically dosed anticoagulation that was not held periprocedurally or therapeutically dosed anticoagulation that was held ≤ 4 half-lives of the AC (i.e., enoxaparin 1 mg/kg SQ administered twice daily held for 1 dose). Therapeutically anticoagulated patients were receiving therapeutically dosed anticoagulation that was continued periprocedurally.

Bleeding complications were classified by estimated amount of blood loss either as minor or hemorrhagic. Minor bleeding was any documented bleeding that did not meet the definition of a hemorrhagic complication. Blood-tinged pulmonary secretions were not considered to be a PDT bleeding complication. Hemorrhagic complications were defined as overt bleeding that was associated with a decrease in hemoglobin level of at least 2 g/dL, the requirement for transfusion of two or more units of packed red blood cells, or the need for surgical intervention.²⁸ Bleeding complications were assessed up to 4 days after the procedure was performed.

Nominal data, including demographics and potential predictors for bleeding, were explored using summary measures. Continuous variables, such as age and days after admission procedure performed, were compared using the Student's *t* test for normally distributed variables and the Mann-Whitney *U* test for variables that were not normally distributed. Dichotomous data were compared using the χ^2 statistic or Fisher's exact test where appropriate. A two-sided *p* value < 0.05 was considered statistically significant. All data management and statistical analysis were computed using Stata/MP, Version 11 (College Station, TX).

RESULTS

There were a total of 449 patients identified who received a PEG (*n* = 204) and/or PDT (*n* = 365) during the study period. Thirty-four patients met exclusion criteria; 24 lacked appropriate documentation of medication administration, 9 had procedures performed in an open manner, and 1 PEG procedure was aborted after a failed attempt. A total of 415 patients were included with 187 PEGs and 352 PDTs being performed.

The demographics of included patients are displayed in Table 1. The mean anticoagulation laboratory values obtained on the day of the procedure were elevated above our institutional reference ranges in both procedure groups, with the exception of platelet count (Table 1).

Prophylactic anticoagulation given for the prevention of venous thromboembolism was held for an average of one dose before and two doses or less after the procedure (Table 2). There was wide variation in practice patterns of holding or not holding anticoagulation in patients receiving continuous infusion anticoagulation (i.e., heparin, lepirudin, or argatroban) (Table 2).

There were 19 recorded bleeding events, one (0.5%) was associated with PEG and 18 (5.1%) with PDT (Fig. 1). There were no documented hemorrhagic complications. Fourteen (73.7%) of the patients with minor bleeds were considered unanticoagulated, 4 (21.1%) were prophylactically anticoagulated, and 1 (5.3%) was therapeutically anticoagulated. The bleeding was controlled by placing packing material around the wound site in nine patients, a stitch was required in three patients, pressure was applied to the bleeding site in six patients, and one bleed resolved without intervention. All bleeding complications occurred at the procedure site. Six patients who had a bleeding complication were not receiving any anticoagulation medication periprocedurally.

The majority of patients were considered unanticoagulated at the time of the procedure (PEG 147 [78.6%], PDT 260 [73.9%]) followed by a level of prophylactic anticoagu-

TABLE 1. Baseline Characteristics*

Characteristic	PEG (<i>n</i> = 187)	PDT (<i>n</i> = 352)
Age	54.6 (19.3)	56.9 (18.4)
Male, <i>n</i> (%)	123 (65.8)	216 (61.4)
Days until procedure [†]	16.6 (13.6)	16.6 (14.6)
International normalized ratio	1.2 (0.2)	1.3 (0.4)
Prothrombin time (s)	15.8 (3.5)	16.6 (4.3)
Activated partial thromboplastin time (s)	37.8 (21.0)	40.2 (23.1)
Platelet count (K/cmm)	332 (161)	308 (172)
Intensity of anticoagulation, <i>n</i> (%)		
Unanticoagulated	83 (44.4)	114 (32.4)
Prophylactic	89 (47.6)	178 (50.6)
Therapeutic	15 (8.0)	60 (17.0)

* Not all laboratory values were collected on each patient on the day of the procedure.

[†] Number of days after admission procedure was performed.

Values are given as mean (SD) unless otherwise noted.

TABLE 2. Duration Anticoagulation Regimens Were Held Periprocedurally

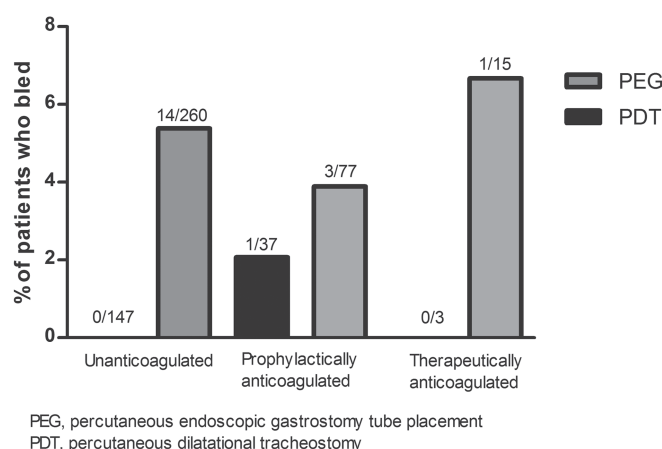
Anticoagulant	n	PEG		n	PDT	
		Duration Held Prior*	Duration Held After*		Duration Held Prior*	Duration Held After*
Heparin 5,000 units SQ every 12 h	7	0.6 (0–3)	1.4 (0–10)	19	0.9 (0–2)	0.1 (0–1)
Heparin 5,000 units SQ every 8 h	32	1.2 (0–6)	1.2 (0–10)	82	1.3 (0–6)	0.9 (0–10)
Heparin 7,500 units SQ every 12 h	1	2	0	1	1	0
Enoxaparin 30 mg SQ every 24 h	6	0.7 (0–1)	0.7 (0–4)	4	1.3 (1–2)	1.0 (0–4)
Enoxaparin 40 mg SQ every 24 h	16	0.8 (0–2)	0.9 (0–10)	33	0.7 (0–2)	0.8 (0–10)
Enoxaparin 30 mg SQ every 12 h	27	0.9 (0–3)	0.3 (0–4)	34	0.9 (0–3)	0.4 (0–10)
Enoxaparin 20 mg SQ every 12 h	0			1	1	0
Enoxaparin 40 mg SQ every 12 h	0			4	0.8 (0–1)	0 (0)
Heparin CI†	5	7.6 (0–13)	7.6 (0–30)	30	6.3 (0–24)	8.0 (0–30)
Enoxaparin‡	8	1.0 (0–2)	0.8 (0–3)	22	1.0 (0–2)	0.3 (0–2)
Warfarin‡	0			3	0 (0)	0.7 (0–2)
Lepirudin CI†	1	3	6	2	1.5 (0–3)	3.0 (0–6)
Argatroban CI†	1	0	0	3	2.5 (0–6.5)	1.5 (0–4)

* Mean dose (range) unless otherwise noted.

† Mean hours (range).

‡ Dosed to achieve therapeutic anticoagulation.

CI, continuous infusion; PDT, percutaneous dilatational tracheostomy; PEG, percutaneous endoscopic gastrostomy tube placement; SQ, subcutaneous.

**Figure 1.** Coagulation status at the time of procedure and bleed risk.

lation (PEG 37 [19.8%], PDT 77 [21.9%]) and by therapeutic anticoagulation (PEG 3 [1.6%], PDT 15 [4.3%]). Anticoagulation was not administered to 43.9% of patients undergoing PEG and 34.1% of patients undergoing PDT, with the most common contraindications for anticoagulation being intracranial hemorrhage (68.3% and 51.7%, respectively) or active bleed (8.5% and 19.2%, respectively).

No association was found between INR, PT, or aPTT values obtained on the day of procedure and bleed risk (Table 3). Platelet count was found to be significantly lower in those patients who experienced a bleeding event ($p = 0.006$) (Table 3). Neither the use of any specific AP agent ($p = 0.360$) nor level of anticoagulation on the day of procedure appeared to be associated with bleed risk (Fig. 1, Table 4).

DISCUSSION

PEG and PDT have gained widespread acceptance as methods for creating elective enteral access and surgical

TABLE 3. Anticoagulation Laboratory Values and Risk of Bleed

	No Bleed (n = 520)	Bleed (n = 19)	p
International normalized ratio	1.3 (0.4)	1.4 (0.4)	0.853
Prothrombin time (s)	16.4 (4.1)	17.3 (3.6)	0.689
Activated partial thromboplastin time (s)	39.6 (22.7)	38.3 (18.1)	0.440
Platelet count ($\times 10^3$ per μL)	319 (169)	220 (112)	0.006
Coagulation status, n (%)			
Unanticoagulated	393 (75.6)	14 (73.7)	
Prophylactically anticoagulated	110 (21.2)	4 (21.0)	0.686
Therapeutically anticoagulated	17 (3.2)	1 (5.3)	

Values are given as mean (SD) unless otherwise noted.

TABLE 4. Bleed Risk With Antiplatelet Regimen (N = 539)

Antiplatelet Regimen*	No Bleed† (n = 520)	Bleed† (n = 19)
Aspirin 81 mg	395 (73.3)	16 (3.0)
Aspirin 325 mg	54 (10.0)	1 (0.2)
Aspirin 25 mg/dipyridamole 200 mg twice daily	60 (11.1)	1 (0.2)
Aspirin 81 mg/clopidogrel 75 mg	4 (0.7)	0 (0)
Aspirin 325 mg/clopidogrel 75 mg	3 (0.6)	1 (0.2)
Clopidogrel 75 mg	3 (0.6)	0 (0)

* Administered once daily, unless otherwise noted.

† n (% of all procedures).

airway in patients who require long-term enteral nutrition and mechanical ventilation, respectively.^{1–7,13–17,29,30} Complications of these procedures include bleeding, infection, cardiopulmonary complications related to sedation/analgesia, aspiration, and blunt organ injury due to physical

manipulation. The true risk of bleeding is hard to define based on currently available literature, as reported rates are often combined with other outcomes, such as infection, and tube dislodgement. Moreover, “bleeding” itself is not uniformly defined. In PDT, the most common complication is tracheobronchial bleeding (22%) demonstrated in the form of bloody secretions.^{21,22}

The majority of patients in the ICU have risk factors for thromboses necessitating venous thromboembolism chemoprophylaxis with AC or AP therapies.⁴ Unfortunately, no guidelines exist for the management of these therapies periprocedurally for PEG and/or PDT. In general, prolonged or complex major surgery is thought to be more likely to cause significant bleeding problems, as compared with short, minor procedures. It is therefore theorized that PEG and/or PDT would be considered a “low bleeding risk procedure,” similar to cataract surgery, coronary arteriography, and other minor outpatient procedures. In such procedures, it is reasonable to not alter the patient’s anticoagulation regimen.

However, when deciding whether to hold anticoagulation and/or AP therapy, the risk of bleeding must be weighed against the risk of thrombosis. Just as procedures are considered low or high risk, the indications for which patients are prescribed ACs can be stratified into low or high risk based on probability of thrombosis.^{14,17} Ultimately, the surgeon must consider both the underlying indication for anticoagulation and the inherent risk of bleeding of the scheduled procedure in deciding whether or not to hold AP therapy or anticoagulation.

Indeed, considering PEG and PDT as low-risk procedures, it is reasonable to continue prophylactic anticoagulation around these procedures. Unfortunately, there were too few therapeutically anticoagulated patients in our study to draw conclusions on how these patients’ AC regimens are generally handled, and practice seemed to vary widely in the duration of therapy held both pre- and postprocedure.

The risk of holding AP therapy is likely more of a value judgment based on the class of AP being given, the patients current platelet count, and the original indication. For example, a patient on nonsteroidal anti-inflammatory medications does not need to have therapy held for low-risk procedures, whereas prasugrel or clopidogrel have more profound, long-lasting AP effects, possibly justifying withholding therapy. From a risk standpoint, a patient who had recent cardiac stents placed is more likely to significant morbidity and potentially mortality if AP therapy is withheld than a patient administered low-dose aspirin for primary prevention of stroke.¹⁷ Similarly, a patient with a platelet count <50 K/cmm on AP therapy likely poses more of a bleed risk than a patient who is on therapy but not thrombocytopenic. The duration one must hold these AP agents must also be considered, as clopidogrel must be held for 5 days to 7 days before the pharmacological effects are considered to be normalized. However, this may not be a reasonable duration to defer the procedure. In this study, there was no association between the use of AP agents and bleed risk, although we did not have a large enough sample size to detect this difference.

No association was found between specific AC used; the level of anticoagulation at the time of procedure; aPTT, PT, or INR values obtained preprocedure and bleed risk. This may be hard to interpret across our population, as we did not collect all laboratory values on every patient the day of procedure. This could also skew our data to make it look as though our patients were more coagulopathic on the whole, because these values were more likely to be obtained for patients with previously abnormal values or in those bleeding is anticipated. A statistical association between platelet count and bleed risk was found. In prior studies, it has been reported that platelet counts <50 K/cmm is associated with increased bleeding in PDT.¹⁶

This study has limitations. First, this study was retrospective in nature. Current procedural terminology codes were used to identify patients, and given the limitations of procedural coding, it is possible that we excluded some patients who would have met study criteria. Second, documentation and description of bleeding events was subjective and may have varied by the recording clinician. Third, patients only had to have one laboratory value on the day of procedure to be included in our study. It is therefore possible that there was a bias to obtain these values on patients who were at an increased risk of bleed, had previous bleeding diatheses, or had previous abnormal values. In addition, documentation of a medical history coagulopathy may have been inadequate.

Our study is the first of its kind to describe practice patterns regarding the management of anticoagulation around bedside PEG and PDT and to assess bleeding risk with different AP and AC therapies. We found that our clinicians appear to adequately assess global bleeding risk and manage anticoagulation accordingly, as shown by our low bleeding incidence. Practice patterns were quite consistent in regard to the management of prophylactic anticoagulation, while they varied widely in patients receiving therapeutic anticoagulation. As a randomized, prospective, placebo-controlled trial addressing this topic will likely never be conducted, retrospective reports such as this one likely represent the most robust data presented on the topic.

AUTHORSHIP

C.A.B., W.D.M., W.E.C., P.A.I., N.C.B., J.J.A., and J.B.F. designed this study. C.A.B. conducted the literature search. C.A.B., W.D.M., and N.C.B. collected data; T.O. and W.E.C. analyzed the data; and C.A.B., W.D.M., T.O., P.A.I., N.C.B., J.J.A., and J.B.F. interpreted the data. C.A.B., W.D.M., T.O., W.E.C., and N.C.B. wrote the manuscript, for which C.A.B. and W.D.M. prepared figures.

DISCLOSURE

The authors declare no conflicts of interest.

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