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Risk Mitigation: Identifying and Creating Evidence-Based Periprocedural Screening and Anticoagulation Guidelines to Reduce Interventional Radiology Bleeding Risks

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A B S T R A C T

As image-guided therapeutic and diagnostic procedures have increased in demand, the specific risk factors for periprocedural complications have been poorly defined. To identify risk factors for bleeding because of interventional radiology procedures and for quality assurance purposes, the staff in the Department of Radiology at Mayo Clinic in Rochester, Minnesota, created a detailed procedural database in 2003. In addition to documentation of baseline demographic characteristics and procedural details, patients were monitored for 3 days to document any postprocedural complications. The data, including patient follow-up, were collected by radiology registered nurses. Analysis of these data has provided opportunity to identify risk factors for bleeding and to create evidence-based periprocedural screening and anticoagulation guidelines in the practice.

Introduction

In recent years, technological advances in ultrasonography and computed tomography (CT) have guided such therapeutic and diagnostic procedures as paracentesis, thoracentesis, drain placements, fine needle aspirations, and deep organ biopsies into routine outpatient procedures. As demand for these procedures increases, screening guidelines to identify patients at risk for bleeding are constantly evolving to assess the possibility of periprocedural bleeding. Laboratory values and anticoagulant use are among the data evaluated to determine a patient's relative risk of bleeding. The Society of Interventional Radiology (SIR) concedes that although the number of percutaneous image-guided procedures has increased over the years, there continues to be a low volume of data regarding the management of abnormal coagulation parameters (Patel et al., 2012). Although cases are evaluated individually, general parameters must be developed with consideration for the patient population served.

In the Department of Radiology at Mayo Clinic in Rochester, Minnesota, the patient population encompasses a broad spectrum of ages and comorbidities and includes inpatients, outpatients, and emergency department patients. Mayo Clinic in Rochester is a teaching hospital where the Department of Radiology has approximately 21 CT scanners and 50 ultrasound (US) machines. Indications for radiologic procedures commonly include chronic liver disease, malignant pleural effusions, abscess, and metastatic cancer. Serious comorbidities include congestive heart failure, chronic liver disease, renal dysfunction, diabetes mellitus, and cancer. In addition, many patients have coagulopathies because of these comorbidities or therapeutic agents such as anticoagulants and chemotherapy. The increased use of novel anticoagulants also presents a challenge because research evaluating periprocedural laboratory values and bleeding risk does not provide a consensus on management of these relatively new agents (Atwell et al., 2017).

In the radiology practice, guidelines have been generally based on parameters established by internal clinical experience and anecdote, by the internal “Ask Mayo Expert” panel, and by societal recommendations, including those of the SIR. Importantly, guidelines have been frequently generalized to the broad practice without specific evidence to direct a patient's care. Such a practice approach results in confusion among nursing staff on which information requires additional consideration by radiologists. Therefore, in many ways, our guidelines match those of SIR but with more defined thresholds to aid in patient triage through scheduling.

When radiologic procedures are scheduled, registered nurses (RNs) screen patients to ensure appropriate indication and order; briefly review the electronic health record for pertinent diagnosis and comorbidities and for risk factors such as history of bleeding

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after procedures; and consider prescribed and over-the-counter medications, abnormal vital signs, and laboratory values. An expectation at our practice is that procedural RNs understand relative bleeding risk and are familiar with generic and trade names of common anticoagulants, the mechanisms of action, and the relationship to comorbidities because these details are necessary to help identify high-risk patients. If a concern is noted by the RN, the concern is brought to the attention of the radiologist performing the procedure before the patient enters the procedural suite.

Before the procedure, the radiologist reviews the planned technique and applies established guidelines, as well as personal clinical expertise, to determine whether (1) the technique can be performed safely, (2) a correction of abnormal laboratory studies is indicated, or (3) the procedure should be postponed or canceled because of increased patient risk. Patients are contacted by a radiology RN at 1 and 3 days after their procedures, to capture any clinical bleeding manifestation. Historically, this capture has included pain, syncope, hypotension, and bruising. Because of the available clinical studies, the internal database, and lack of knowledge, the practice needs to standardize screening guidelines and pertinent findings to improve patient safety and workflow processes and to streamline the approach to performing or canceling a procedure.

Materials and methods

No institutional board review was needed for this quality improvement project because it was a literature review that included a retrospective review of an established database. A collaborative effort was established between the radiology clinical resource nurse, staff nurses, and radiologists working in CT- and US-guided procedural settings. A literature review was conducted to identify peer-reviewed research performed by similar institutions and professional organizations. In addition, current SIR guidelines for periprocedural management of coagulation status were reviewed. Internal reviews of retrospective studies performed from patient electronic health records or from the department-maintained biopsy database were also considered. The database contained limited patient information, such as procedural indication, medications, vital signs (e.g., blood pressure), laboratory results (e.g., platelets, international normalized ratio [INR], activated partial thromboplastin time), and clinical history (i.e., surgery, bleeding history, and other important comorbidities).

The relatively low occurrence of complications after procedures performed by trained radiologists using CT or US guidance limited the availability of evidence. Because of the relatively low risk of bleeding for patients with normal laboratory values and coagulation, the review focused primarily on patients with coagulopathies and abnormal laboratory values for development of practice guidelines.

After examining available data, literature, and evidence, we categorized procedures as low- or medium-risk bleeding procedures (paracentesis, thoracentesis, superficial aspiration/fine needle aspiration/musculoskeletal, superficial biopsy [body wall/neck], superficial aspiration, or drain placement, or a combination) and high-risk bleeding procedures (e.g., deep/organ biopsy, deep/retroperitoneal drainage catheter, intra-abdominal biopsy, bone biopsy, lung biopsy). Guidelines were established for procedures with and without high risk of bleeding for holding medications on the basis of consideration of drug class, mechanism of action, half-life, and implications of withholding anticoagulant therapy (Tables 1 and 2). Of note, these guidelines apply to most, but not all, patients, with clinical decisions made by the supervising radiologist. Parameters for acceptable laboratory values were determined, as was a time frame of values within 30 days of procedure or within 14 days because of increased risk of platelet dysfunction or coagulopathy, if the patient had known or suspected kidney or liver disease or recent chemotherapy.

Table 1
Guidelines[a] for values and medications of procedures that have a low to medium risk of bleeding

Variable	Applicability to procedure
Laboratory value[b]	
Hematocrit	NA
Platelets	NA However, if result is available within 30 d and is <50,000/μL, notify the radiologist
INR	NA However, if patient is taking warfarin or result is available within 30 days and is >2.5, notify the radiologist
aPTT	NA
Medication	
IV heparin	Hold 4 hr
Therapeutic LMWH	Hold 24 hr
Prophylactic SQ heparin	NA
Warfarin	NA
Aspirin (including aspirin-containing medication)	NA
Prasugrel	NA
Clopidogrel	NA
Ibuprofen	NA
Naproxen	NA
Cilostazol	NA
Ticagrelor	NA
Oral direct thrombin inhibitors	NA
Direct factor Xa inhibitors	NA
Angiogenesis inhibitors	NA

NA = not applicable; INR = international normalized ratio; aPTT = activated partial thromboplastin time; IV = intravenous; LMWH = low-molecular-weight heparin; SQ = subcutaneous.
[a] Table data are guidelines only. Clinical decisions are made by the supervising radiologist, who may incorporate additional information that may result in a variation from these guidelines.
[b] If a particular laboratory value is required for the procedure, the result must be available within 30 days of the test; 14 days, if known or suspected kidney or liver disease, or chemotherapy was administered recently.

The project was developed as a guideline instead of a policy. As a result, physicians may evaluate other factors to determine bleeding risk and can use their clinical expertise and discretion to proceed.

Results and findings

An early lesson derived from our experience was the appropriate recognition of a bleeding complication. On the basis of follow-up phone calls made by radiology RNs, we identified those patients with a major bleeding complication and described the specific clinical manifestations of such bleeding. In our practice, pain accounted for clinical findings related to major bleeding of more than one-half (61%, n = 39) of patients (Atwell et al., 2015). We recognized that patients often present with more than one symptom, and 42% (n = 27) of our patients presented with syncope or hypotension because of bleeding. Interestingly, 25% (n = 16) of the patients were treated for major bleeding on the basis of imaging findings and in the absence of specific clinical signs of bleeding. Other less common findings associated with bleeding included hematuria, laboratory evidence of anemia, and changes in physical examination.

In assessing risks for bleeding, we observed that hypertension was eliminated as a risk factor for most procedures (Atwell et al., 2015). A comparison of hypertensive and normotensive patients showed no statistically significant difference in risk level, except