Consensus Guidelines for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions

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ABBREVIATIONS

aPTT = activated partial thromboplastin time, DIC = disseminated intravascular coagulation, DTI = direct thrombin inhibitor, FFP = fresh frozen plasma, INR = international normalized ratio, LMWH = low molecular weight heparin, LP = lumbar puncture, NSAID = nonsteroidal antiinflammatory drug, PT = prothrombin time

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies, as well as the institutional affiliations and professional credentials of the authors of this document, are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR produces its Standards of Practice documents by using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, complication rates, outcomes, and thresholds for prompting quality assurance reviews.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a modified Delphi consensus method (**Appendix**) (1). For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-d comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

INTRODUCTION AND BACKGROUND

Hematologic management in the patient undergoing percutaneous image-guided intervention is complex because of the wide range of procedures and equally wide range of patient demographics and comorbidities. Concurrent increases in the use of short- and long-term anticoagulation, as well as the increasing use of antiplatelet agents, further complicates the periprocedural management of these patients. Despite the continuing increase in the volume of percutaneous image-guided procedures, there is a general paucity of data regarding the periprocedural management of the patient with abnormal coagulation parameters. In the absence of data, clinicians may respond to the patient with abnormal coagulation parameters by canceling or postponing the procedure, altering an otherwise indicated procedure, or infusing blood products such as fresh frozen plasma (FFP) or platelets. Recommendations from open surgical experience can be extrapolated, but may not be completely applicable to interventional procedures because, in open cases, the operator is typically able to directly visualize and promptly control any bleeding complications. Finally, medicolegal factors may influence the management of the patient, as clinicians feel the

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Table 1. Tests of Hemostasis

Test	Indication	Normal Range
INR/PT	Extrinsic pathway (I, II, V,VII, X)	INR 0.9–1.1
	Oral anticoagulant therapy	
	Liver disease	
aPTT	Intrinsic pathway (VIII, IX, XI, XII)	aPTT 25–35 s
	Intravenous heparin therapy von Willebrand disease	
	Factor VIII, IX, or XI deficiency	
Platelet count	Known or suspected thrombocytopenia	150,000–450,000/μL
Bleeding time	No current indication before image-guided procedures	—

aPTT = activated partial thromboplastin time, INR = international normalized ratio, PT = prothrombin time.

need to "correct" an abnormal coagulation factor, despite the fact that studies of bleeding complications in percutaneous procedures have not shown a correlation between mild to moderate abnormality of preprocedural coagulation parameters and a higher incidence of bleeding complications.

The coagulation status of patients undergoing image-guided interventions should be assessed whenever the procedure involves direct entry into the arterial or venous system as an anticipated part of the procedure or whenever there is a possibility of inadvertent entry into the arterial or venous system with significant-sized interventional devices or tools. Patients are at increased risk for delayed detection of postprocedural hemorrhage when the site of the intervention is not easily assessed and poorly controllable, such as percutaneous intraperitoneal procedures. Coagulation status is complex; components of the intrinsic and extrinsic coagulation cascade and platelet function figure integrally into human hemostasis. The components of coagulation are evaluated by multiple tests of hemostasis. These tests and the component of coagulation function they assess are described later in this document and are summarized in **Table 1**, along with normal values for each test.

DEFINITIONS

Coagulation Parameters

Prothrombin time. The prothrombin time (PT) test measures the clotting time upon activation of the extrinsic and common coagulation pathway. It is used for monitoring oral anticoagulant therapy and is now widely reported as an international normalized ratio (INR). The degree of prolongation of the clotting time correlates to the degree of deficiency or inhibition of extrinsic or common pathway clotting factors I (fibrinogen), II (prothrombin), V, VII, and X, which are synthesized by the liver. When any of these factors is deficient, the PT is prolonged and the INR is elevated. The PT in a healthy adult is approximately 11–14 s. There is variation depending on the reagent used in the test (2).

International normalized ratio. The INR is an expression of the results of a PT in a standardized testing environment. It is calculated by using an international standard that corrects for laboratory variation. The INR allows for universal standardization anticoagulant therapy. In the following calculation, the ISI is the International Sensitivity Index of the thromboplastin reagent used in the assay: $\text{INR} = (\text{patient PT} / \text{control PT})^{\text{ISI}}$.

In this test, the patient's plasma is mixed with PT reagent containing thromboplastin and calcium chloride. The time to clot formation is measured. The degree of prolongation of the clotting time correlates to the degree of deficiency or inhibition of extrinsic or common pathway clotting factors I (fibrinogen), II (prothrombin), V, VII, and X, which are synthesized by the liver. When any of these factors is deficient or inhibited, the PT is prolonged and the INR is elevated. The INR results from different kits can vary by an average of more than 0.7 (3). This variation results from differing sensitivities to the various coagulation factors (4). The INR in a normal patient not undergoing warfarin therapy is 0.9–1.1.

A prolonged PT and elevated INR occur with warfarin therapy, vitamin K deficiency, lupus anticoagulants, extrinsic pathway coagulation factor deficiencies, disseminated intravascular coagulation (DIC), bile duct obstruction, malabsorption, malnutrition, and other conditions. Hirudin, argatroban, and heparin may prolong the PT. Because the coagulation factors are synthesized in the liver, the PT is elevated with severe liver failure and acute liver injury (5,6).

Activated partial thromboplastin time. The activated partial thromboplastin time (aPTT) measures the clotting time upon activation of the intrinsic coagulation pathways. In this test, the patient's plasma is mixed with reagent containing an activator, phospholipid, and calcium chloride. The time to clot formation is measured.

A normal aPTT in an adult is approximately 25–35 s. A therapeutic ratio of 1.5–2.5 times the control value is frequently employed in heparin therapy; however, this range varies depending on the reagent.

A prolonged aPTT occurs with factor deficiencies (especially of factors VIII, IX, XI, and/or XII), inhibitors (lupus anticoagulants), liver disease, DIC, vitamin K deficiency, or therapeutic anticoagulants such as heparin, hirudin, or argatroban). The aPTT is not useful in monitoring warfarin therapy (7). An isolated elevated aPTT is often the most common transient abnormal coagulation test result, with half of cases reverting to a normal result on subsequent testing (8). Furthermore, lupus inhibitors and factor XII deficiency are known to prolong the aPTT but do not cause excessive bleeding (8).

Thrombin time. Thrombin time provides an assay for fibrinogen concentration indirectly by measuring exogenous thrombin activated clotting times (9).

Bleeding time. Originally introduced in 1901 by Milian, bleeding time has been used to diagnose platelet disorders, assess patients for clinically significant bleeding tendencies before invasive procedures, and assess the effects of various therapies on bleeding tendencies and platelet function. The bleeding time is subject to reliability and reproducibility issues, with a number of studies showing that it is neither a specific nor a sensitive indicator of bleeding risk associated with surgery or other invasive procedures (10). Secondary to this, it has largely fallen out of favor in modern clinical practice as an assessment for bleeding tendencies because of conflicting data on its usefulness (11).

Platelet count. The platelet count is generally measured as a standard part of the complete blood count. It is commonly used to diagnose and follow bleeding disorders, thrombocytopenia, drug-induced thrombocytopenia, DIC, and neoplastic disorders, and to evaluate the response to platelet transfusions. The platelet count simply reflects the number of circulating platelets, not the platelet function. A normal adult platelet count is approximately 150,000–450,000 platelets per microliter of blood (12). A platelet count lower than 20,000/μL is a life-threatening event in which spontaneous bleeding may occur (12).

A small number of patients receiving heparin (including low-dose