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Bleeding risk assessment in interventional radiology.

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Bleeding Risk Assessment in Interventional Radiology

by

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Bleeding Risk Assessment in Interventional Radiology

Abstract

Background: Interventional Radiology (IR) procedures vary in their bleeding risk. Staff responsible for screening patients in the preprocedural setting may not have adequate education regarding specific factors associated with increased bleeding risk specific to IR patients. Society of Interventional Radiology (SIR) consensus guidelines recommend the use of screening tools, but no tools specific to IR are currently available.

Objectives: To evaluate confidence of staff assessing bleeding risk prior to IR procedures and identify areas where further education may be needed.

Methods: A prospective cohort study design was used to conduct a staff confidence screening tool specific to IR staff responsible for evaluating bleeding risk in patients undergoing percutaneous IR procedures.

Results: Following a training session covering the BSET-IR education tool, staff confidence assessing bleeding risk was significantly improved. Nurses were found to have the widest range of confidence based on the initial SCAB-IR assessment.

Discussion: The data collected from this project demonstrates the need for additional education in IR related to bleeding risk assessment. Bleeding risk associated with percutaneous IR procedures is multifactorial and requires heightened attention by staff when being assessed.

Key Words: *interventional radiology procedures, preprocedural, bleeding risk, assessment tool, bleeding, hemorrhage, screening, screening test, HAS-BLED, bleedMAP, and Bleemacs*

Introduction

Screening for bleeding risk in interventional radiology (IR) is multifactorial. The hematologic management of patients undergoing image-guided percutaneous intervention is complicated by the wide range of procedures performed in IR and an equally wide range of patient demographics and co-morbidities. Additionally, there has been a constant increase in the use of both short and long-term anticoagulation as well as antiplatelet agents (Malloy et al., 2009). The use of screening tools to predict adverse outcomes in the hospital setting has increased as America's healthcare system requires heightened attention to high-cost high-need (HCHN) patients. These patients account for only 5% of the population but 50% of the country's annual healthcare spending (Blumenthal et al., 2016). The American Heart Association predicts the number of patients using long-term anticoagulant medications to prevent and treat venous thromboembolism (VTE) will increase as Americans live longer (Raval et al., 2017). The use of anticoagulants among hospitalized patients is significant because most patients have at least one risk factor for venous thromboembolism (VTE) and roughly 40% have three or more risk factors. These risk factors include surgery, immobility, cancer, trauma, previous VTE, and increasing age (Geerts et al., 2008). It is estimated approximately 10% of patients on long-term anticoagulation will require an invasive procedure in a given year, however, there is limited data on the periprocedural management of patients diagnosed with coagulopathies or those taking anticoagulant medications (Kumar et al., 2016; Patel et al., 2019). The literature available is limited to retrospective studies from settings other than IR. Assessing nurses' and providers' confidence evaluating a patient's bleeding risk can provide feedback and data to ensure IR staff members are competent in factors that place a patient at increased risk of bleeding.

Literature Review

A database search was conducted using the University of Louisville Kornhauser library to find relevant publications via PubMed, CINAHL, Cochrane Library, and Medline which yielded 54 articles. Keywords/MeSH terms used included: *interventional radiology procedures, preprocedural, bleeding risk, assessment tool, bleeding, hemorrhage, screening, screening test, HAS-BLED, bleedMAP, and Bleemacs*. Articles were screened for appropriateness using: publication date prior to 2016 as an exclusion criterion; English language; accessibility of full text version; articles pertaining specifically to cardiac or neurologic interventions were excluded.

For the last 10 years, the Society of Interventional Radiology (SIR) has recognized and published/revised consensus guidelines emphasizing the importance of thrombotic and bleeding risk associated with IR procedures (Patel et al., 2019). Due to the low number of publications found using the database search, SIR Consensus Guidelines was used to find additional articles as references. Eight publications were reviewed using the above-mentioned screening requirements. A total of 13 articles were used in the integrative review. Two articles published prior to 2016 were used due to their relevance to the research topic and their mentioning in more recent publications. These articles and studies were used to formulate the staff confidence assessing bleeding risk in IR (SCAB-IR) tool, and bleeding staff education tool in IR (BSET-IR). These tools can be found in Appendix A and B.

Some helpful definitions were found during the literature review and used to guide this project. According to the International Society of Thrombosis and Haemostasis (ISTH), major bleeding is defined as fatal bleeding, symptomatic bleeding in a critical organ (intracranial, intraspinal, intraocular, retroperitoneal, intraarticular, pericardial, or intramuscular with compartment syndrome), bleeding causing a hemoglobin drop of 2g/dL or more, or bleeding

leading to a transfusion of two or more units of whole blood or packed red blood cells. Similarly, the authors responsible for creating the BleedMap tool define major bleeding as "overt bleeding and a hemoglobin decrease of ≥20 g L ^-1 after the procedure or transfusion of ≥2 units of packed red blood cells, or intracranial, intraspinal, intraocular, retroperitoneal, pericardial or fatal bleeding" (Tafur et al., 2011).

The literature review also demonstrated rationale for selecting the topics of confidence statement and education provided to staff. SIR guidelines recommend the use of two specific screening tools to assess bleeding risk in the pre-procedure setting. These screening tools have been studied in similar settings and proven to be helpful in identifying patients and procedures with a higher risk of bleeding complications. The HAS-BLED bleeding score consists of factors such as: hypertension, abnormal renal function, stroke, bleeding tendencies/predisposition, labile INR, elderly age, drugs, or excess alcohol use. Following lower limb revascularization, Freixo et al., (2019) found major bleeding occurred in 18.8% of patients at their one year follow up. 52.1% of these patients had a HAS-BLED score of ≥3. Mueller et al., (2016) found hemorrhagic incidence was significantly higher in the moderate-risk (0.53/patient) and high-risk (0.54/patient) patients compared to low-risk (0.08/patient) patients. There were 215 hemorrhagic event reports with 206 classified as minor and nine as major. This retrospective cohort study was conducted to determine whether the HAS-BLED risk tool was a good predictor of bleeding risk and warfarin control in deep vein thrombosis (DVT) patients. This study demonstrated a HAS-BLED score >3 was shown to accurately predict poor warfarin control with increasing risk category and bleeding risk with anticoagulant therapy. Similarly, Freixo et al., (2019) found a HAS-BLED score ≥3 showed a strong association with major bleeding risk which the authors defined using the ISTH definition of major bleeding. Patients with a HAS-BLED score > 3 had a major bleeding

incidence rate of 33.3% compared to ≤2 risk factors (4.2%). Tafur et al., 2011 found the use of BleedMAP accurately predicted major hemorrhage events related to periprocedural anticoagulation management and classified procedures into low and moderate-high bleeding risk. Patient factors were defined as: history of prior bleeding, mechanical mitral valve, active cancer, and low platelets. The score was calculated with one point for each 'yes'. Using this tool and a 95% confidence interval, the authors found patients with a score ≥3 had a 10% chance of experiencing a major bleeding event. The ability to categorize bleeding risk based on the type of bleeding, amount of blood loss, and the area where bleeding occurred provides a clearer picture for staff to better understand and retain the provided education. A complete evidence table can be found in Appendix C.

Aims/Objectives

The aim of this project was to screen staff for confidence assessing bleeding risk in the preprocedural setting of interventional radiology at Clark Memorial Hospital and University of Louisville Hospital. Determining the confidence of the staff can aid in identifying areas where additional education is needed to improve patient safety outcomes and efficiency within the department. Currently, there is no education provided to assess bleeding risk associated with procedures in IR. This quality improvement project was completed to increase staff confidence assessing bleeding risk and improve safety by ensuring nurses and providers have the knowledge necessary when assessing patient in the preprocedural setting. The BSET-IR tool was formulated using consensus guidelines and studies completed in similar settings. The information provided is meant for staff to gain knowledge on topics known to affect bleeding risk specific to patients undergoing percutaneous IR procedures.

Study Design/Methodology

The project was set within the interventional radiology departments at Clark Memorial Hospital (CMH) and University of Louisville Hospital (ULH). The SCAB-IR tool was given to clinical staff to assess confidence prior to education, followed by a brief session using the BSET-IR tool, and the SCAB-IR tool again after the BSET-IR tool for reevaluation. The five topics on the tool were directly related to pertinent information needed to assess bleeding risk in IR patients. A Likert scale was used to obtain ordinal data and calculate each staff member's confidence. This allowed for comparison of topics individually as well as total confidence before and after the education.

This quality improvement (QI) project utilized a new middle-range nursing theory 'patient safety goal priming via safety culture'. Appendix D provides a visual of this framework. This theory centers around the use of priming or using stimuli to activate a particular construct outside of conscious awareness. Changing the culture of the nurses' behaviors about patient safety allows for (a) activation of a previously held patient safety goal of the nurses and (b) increases the perceived value of actions that nurses can take to achieve said goal. It is theorized that the nurse will subconsciously prioritize nursing tasks and risk assessment related to the desirable goal of patient safety (Groves & Bunch, 2018). Birkmeyer et al., found low levels of safety culture were associated with high incidences of adverse events in the surgical setting. The Patient Safety 2030 Report by the National Institute for Health and Research indicates more training in safe patient care should be provided to healthcare professionals to raise their awareness of issues to improve patient safety.

The primary investigator (PI) initiated contact with a designated person at each facility to schedule dates for project implementation. The initial SCAB-IR assessment was provided to staff

at each facility during the respective IR department's morning huddle on an agreed upon day. The surveys were then collected. The following week, study subjects were provided a brief education session covering the BSET-IR topics. Immediately after the education session, staff confidence assessing bleeding risk in IR using the SCAB-IR tool was tested again.

Inclusion & Exclusion

All nursing staff and providers were included in the sample. The use of contract or travel nurses is common practice within both departments so they were included in the project sample. These staff members stay for at least 3 months and were included to supplement the sample size. The clinical providers include attending physicians and APRNs. Clinical staff excluded from the study were those not responsible for reviewing clinical data such as scrub techs, unit secretaries, and staff who float from other departments of the facility such as cardiac catheterization lab.

Instruments

The SCAB-IR assessment tool included pertinent factors specific to each patient's care and pertinent to bleeding risk associated with IR procedures. As previously mentioned, there is currently limited data regarding the use of bleeding risk screening tools in IR, but SIR consensus guidelines recommend the use of tools for evaluation of bleeding and thrombus risk based on patient-specific factors. According to their updated consensus guidelines "Specific characteristics and comorbidities unique to a patient may increase their risk of bleeding or forming a clot and warrants pre-procedural evaluation" (Patel et al., 2019). Bleeding risk screening tools are commonly used in procedural areas including cardiac catheterization lab with an emphasis on the use of anticoagulants for patients with atrial fibrillation and following percutaneous coronary intervention. These tools have been shown to predict increased bleeding risk associated with invasive procedures in similar settings. The SCAB-IR tool was used to assess the confidence of

clinical staff in areas such as anticoagulants and their impact on IR procedures, the impact of a medication's half-life on IR procedures, identifying which IR procedures place a patient at higher risk for bleeding complications, identifying which lab values are concerning for bleeding risk, and what patient specific factors may increase bleeding risk associated with IR procedures. The BSET-IR tool provided staff with information to these specific topics as they are crucial in the assessment of bleeding risk associated with IR procedures. This does not include other common risks associated with procedures such as infection, pneumothorax, etc. Additionally, the information provided during the education session was only a brief overview of topics. A pamphlet version of the information was left at each site including references to additional information on all of the topics covered.

The classes of medications that place a patient at an increased risk of bleeding include anticoagulants, antiplatelets, and non-steroidal anti-inflammatory drugs (NSAIDs). A medication's half-life is especially important when evaluating a patient's bleeding risk. Recognizing medications with a longer or shorter half-life will ensure staff can confidently determine when it should be discontinued or held (Appendix E). Procedure-associated bleeding risk is categorized by SIR and broken into low risk and high risk, and by the Journal of Vascular and Interventional Radiology as low, moderate, and significant risk (Appendix F) (Malloy et al., 2009; Patel et al., 2019). Lab values commonly seen in IR that are indicative of bleeding risk are PT/INR, PTT, and platelet count (Appendix G). The patient factors drawn from bleeding risk screening tools recommended by SIR are HAS-BLED (hypertension, abnormal liver/renal function, stroke, bleeding history or predisposition, labile INR, elderly, drugs/alcohol concomitantly) (Appendix H) and BleedMAP (history of bleeding, mechanical heart valve, active cancer, and low platelet count) (Patel et al., 2019). The staff member's confidence on each

topic was assessed using a 5-point Likert scale (strongly disagree to strongly agree). The responses were compiled and evaluated to determine which topics require specific education or clarification.

Privacy/Confidentiality

The confidence screening tool posed no risk for patient information to be compromised as there were no patients or patient data included in this project. All of the participants were medical staff and no personal information was collected from participants. Completion of the survey implied consent. When completing the survey, the clinical staff were required to write the last four digits of their personal phone number at the top of the survey to compare data at pre and post analysis. This allowed staff to complete the screening tool in confidence. HIPAA policies for each facility were strictly followed. Approvals were granted by the director of cardiovascular services and the quality director from CMH and the nurse manager of IR at ULH. The project proposal was reviewed by the hospital policy committee and the medical advisory committee (MAC) board prior to implementation and approval was granted. This project was proposed as a Doctorate of Nursing Practice (DNP) project oral defense to the University of Louisville School of Nursing staff and faculty. Finally, the proposal was submitted to the respective internal review boards from each facility for final approval as well as, the ULH research office for tracking purposes.

Implementation

Initial staff confidence screening took place during the scheduled morning huddle at each facility on a designated day when all available clinical staff were scheduled. Staff were given 10 minutes to complete the SCAB-IR tool. Following the collection of the pre-education confidence screening tools, a second date was scheduled to allow for time to cover the BSET-IR education

tool. The second scheduled date at each facility was approximately two weeks after the initial confidence screening. A 10-minute education session over the BSET-IR information was followed immediately by the post-education SCAB-IR confidence tool.

Data Analysis

Using IBM SPSS version 29.0.0.0, an independent sample Mann-Whitney U test was performed to evaluate whether or not staff confidence assessing bleeding risk was improved following the BSET-IR education session. This non-parametric test was used due to the data being ordinal and not normally distributed. With a prior significance set at 0.05 the following assumptions were met: dependent variable is measured at the ordinal level; measurements for one subject do not affect measurements for another subject and each of the paired measurements must be obtained from the same subject. Using a 5-point Likert scale (1= strongly disagree, 5= strongly agree) each screening tool was given a score ranging from 5 to 25. The higher the score, the higher the confidence of that given staff member. Pre and post tests were paired using the last four digits of each participants phone number as a personalized identifier allowing for comparison of confidence following the BSET-IR education session. This was most appropriate as the same tool was used on the same subject at different times.

Results

The Cohort included 19 participants, 63.2% were registered nurses (RN), 26.3% physicians (MD), and 10.5% advanced practice providers (APRN). The results of the Mann Whitney-U test revealed staff confidence assess bleeding risk in IR was significantly lower in the pre-test group (*Md= 24.00, n=19*) compared to the post-test group (*Md=25.00, n=19*), *U= 85.5, p= <0.001,* Appendix I.

Prior to implementation of the BSET-IR education tool, a wide range of confidence scores were found. The majority of this skewness was RN confidence responses. Nurse confidence assessing bleeding risk ranged from 19.00 to 25.00. To further demonstrate this, a Mann Whitney-U test was performed evaluating only nurses confidence. This output included 12 nurses, the results revealed nurses confidence assessing bleeding risk was statistically significant. Confidence assessing bleeding risk was significantly lower in the pre-test group (*Md= 21.00, n=12*) when compared to the post-test group (*Md= 25.00, n= 12), U= 120.0, p= <0.001*. Specifically, staff confidence evaluating a medications half-life exhibited the widest range of confidence when analyzing the initial SCAB-IR data. Following the education session, staff reported significant increases in confidence evaluating a medication's half-life and the implication it has on the patient's bleeding risk (26.3% increase).

Discussion

These results represent a significant increase in staff confidence assessing bleeding risk in IR following an education session. It is crucial to accurately assess and identify the clinical staff's confidence in understanding bleeding risk. Previously published studies identified how to categorize bleeding risk, but no studies focusing on education for staff on their confidence when assessing said risk were uncovered. Mueller el al., (2016) and Frexio et al., (2019) found that using bleeding risk screening tools such as HAS-BLED allowed for categorization of patients into bleeding risk categories. These studies used the International Society of Thrombosis and Haemostasis (ISTH) major bleeding definition stating "major bleeding is fatal bleeding, symptomatic bleeding in a critical organ (intracranial, intraspinal, intraocular, retroperitoneal, intraarticular, pericardial, or intramuscular with compartment syndrome), bleeding causing a

hemoglobin of 2g/dL or more, or bleeding leading to a transfusion of two or more units of whole blood or packed red blood cells."

Further, registered nurses play an important role in the pre procedure assessment of patients undergoing IR procedures. This study demonstrates a larger gap in confidence assessing bleeding risk when analyzing nurse confidence specifically. The findings of this study suggest that once educated about the factors that may impact bleeding during IR procedures, nurses show increased confidence assessing bleeding risk. However, currently there are no standardized bleeding risk assessments specific to this population. Future work on this topic should include development of such tools.

The 'patient safety goal priming via safety culture' middle range nursing theory shows nurses care about the safety of patients. By evaluating their confidence assessing bleeding risk specific to IR procedures, we are able to create a safer environment for patients by identifying areas where additional education is necessary. Evaluating five different topics individually exposed areas of weakness in staff confidence where additional education may be necessary.

Conclusion

As our population ages and those requiring medical procedures continues to rise it is important to consider bleeding associated in IR as more considerable risk. The AHA predicts the continued increase in use of anticoagulants as Americans live longer but there is limited data on how this impacts IR procedures specifically. The Society of Interventional Radiology and Journal of Vascular and Interventional Radiology recognize the need for assessment of bleeding risk screening tools and acknowledge a lack of IR specific tools. Nurses working in IR have a very specialized role and are in a unique position to assess pre-procedure bleeding risk because they are commonly the pre-of staff evaluating patients.

Future Implications

This project will be helpful in the advancement of bleeding risk assessment and education related to interventional radiology procedures. In the future, this project can be used to compare to other confidence tools and staff education topics when evaluating risk of adverse events in the IR setting. The evaluation of bleeding risk confidence among staff opened the door for conversations among nurses, physicians, and advanced practice providers on topics necessary to complete a pre-procedural evaluation of each patient. It was found that experienced interventional radiologists had insight based on years of practice. For example, the BSET-IR tool includes common medications and their half-lives. Some physicians voiced their preference to calculate or reference the 'total elimination' of anticoagulant and antiplatelet medications which is approximately five times the half-life.

Bleeding risk screening related to IR procedures requires collaboration among the entire interdisciplinary team. It was found that staff from departments such as pre/post recovery could benefit from similar projects as they are commonly tasked with screening patients prior to procedures and recovering patients following IR procedures.

The sites for this project did not have resident physicians, fellows, or physician assistants (PA) on staff at the time of implementation, but these clinicians should be included in the sample size as they have an equal role in assessing bleeding risk. It was found that one of the facilities had compiled a list of varying lab value ranges and anticoagulant management for each of their clinicians. This could be confusing to nursing or ancillary staff trying to schedule patients for procedures if each provider has a different threshold for safety and bleeding risk. Specifically, some providers view on platelet count and risk of bleeding based on experience varied widely when compared to SIR consensus guideline data. By providing education pulled from consensus

guidelines, consistent practices will be found among providers and staff when evaluating bleeding risk.

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Appendix A: SBAR-IR

SCAB-IR tool:

1. I understand bleeding risk associated with anticoagulant medications in IR

Strongly disagree Disagree Neutral Agree Strongly Agree

2. I understand the significance of a medications half-life related to IR procedures

Strongly disagree Disagree Neutral Agree Strongly Agree

3. I understand which IR procedures have increased bleeding risk

Strongly disagree Disagree Neutral Agree Strongly Agree

4. I understand which lab values are concerning for bleeding risk associated with IR procedures

Strongly disagree Disagree Neutral Agree Strongly Agree

5. I understand what patient factors increase risk of bleeding associated with IR procedures

Strongly disagree Disagree Neutral Agree Strongly Agree

Appendix B: BSET-IR

BSET-IR

1. What IR procedure is ordered?

LOW risk	MODERATE risk	SIGNIFICANT risk
-Dialysis access intervention	-Angiography	-TIPSS
-Venogram	-Venous interventions	-renal biopsy
-Central line removal	-Chemoembolization	-biliary interventions
-IVC filter placement	-Uterine fibroid embolization	-nephrostomy tube placement
-PICC line placement	-Transjugular liver biopsy	-radiofrequency ablation (complex)
-Paracentesis	-Tunneled central venous catheter	
-Thoracentesis	-Subcutaneous port device	
-Superficial aspiration/biopsy	-Intraabdominal, chest wall, or retroperitoneal abscess drainage or biopsy	
-Superficial abscess drainage	-Lung biopsy	
-Drainage catheter exchange	-Transabdominal liver biopsy	
	-Percutaneous cholecystostomy	
	-Gastrostomy Tube	
	-Radiofrequency ablation	

(Malloy et al., 2009)

2. What patient specific factors need to be considered?

-Hypertension
-Abnormal renal function (dialysis, transplant, CKD)
-Abnormal liver function (cirrhosis or hyperbilirubinemia)
-Acute or chronic anemia
-Age >65
-History of alcohol or drug use (>8 drinks/week)
-Prior bleeding within 3 mo
OR with similar type of procedure
-platelet abnormality
-Mechanical mitral heart valve
-active cancer

(Patel et al., 2019)

Table 2. Assessment of Patient Bleeding Risk (3,21)

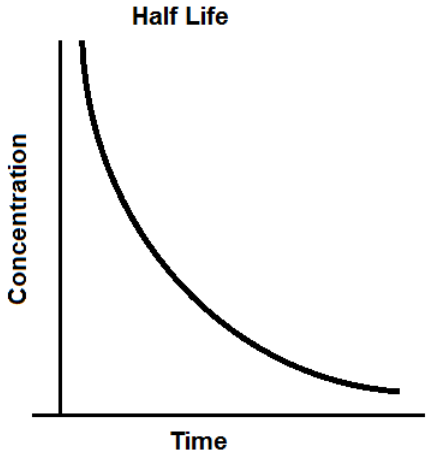
HAS-BLED Score (Score > 3 Predictive of Bleeding Events) Criteria	Points
Hypertension (systolic BP > 160 mm Hg)	1
Abnormal renal function (dialysis, renal transplantation, serum Cr > 200 μmol/L)	1
Abnormal liver function (cirrhosis or bilirubin > 2× ULN, AST or ALT > 3× ULN)	1
Prior stroke	1
History of major bleeding or predisposition to bleeding (anemia)	1
Labile INR (VKA) defined as time in therapeutic range < 60%	1
Age > 65 y	1
Concomitant use of antiplatelet agent or NSAID	1
History of alcohol or drug use (> 8 drinks per week)	1

Other Risk Factors for Bleeding
- Prior bleeding within 3 mo
- Prior bleeding with similar type of procedure
- Platelet abnormality
- INR above therapeutic range at time of procedure (VKA)
- Prior bleeding with bridging therapy
- Mechanical mitral heart valve
- Active cancer

Note–There are currently no well validated scoring systems that can be used to assess bleeding risk across interventional radiologic procedures. Similarly, the HAS-BLED score has not been designed to assess periprocedural bleeding risk. However, this score is often used in clinical practice as a general guide to aid clinicians in recognizing potential factors that may increase patient-specific bleeding risk and should be used for this purpose alone. History of bleeding, mechanical mitral heart valve, and active cancer are BleedMAP factors that may also indicate an increased propensity for a patient to experience bleeding; however, it should be noted that BleedMAP is not procedure-specific. Platelet counts lower than 20×10^9/L and lower than 50×10^9/L may be associated with increased risk of bleeding for low- and high-risk procedures, respectively (22).
ALT = alanine aminotransferase; AST = aspartate aminotransferase; BP = blood pressure; Cr = creatinine; mo = months; NSAID = nonsteroidal antiinflammatory drug; ULN = upper limits of normal; VKA = vitamin K antagonist; y = years.

3. What anticoagulant or antiplatelet medications is the patient taking?

Medication	half-life
Warfarin (Coumadin)	40h
Enoxaparin (Lovenox)/ delteparin (Fragmin)	2-6h
Heparin- unfractionated	1.5-2h
Argatroban (Acova)	50 min
Bivalirudin (Angiomax)	25 min
Dabigatran (Pradaxa)	12-17h
Apixiban (Eliquis)	15h
Fondaparinux (Arixtra)	17-21h
Rivaroxaban (Xarelto)	9-13h
Clopedigrel (Plavix)	6h
Prasurgrel (Effient)	3.7h
Ticagrelor (Brilinta)	7h
Aspirin	2-3h



(Davidson et al., 2019)

4. What lab values should be considered when assessing bleeding risk in IR patients?

INR/PT- can be abnormal with oral anticoagulant therapy, liver disease
-Low risk procedures: routinely recommended for patients on warfarin or with liver disease. **>2.0=threshold for treatment, correct to within range of ≤2.0-3.0**
-Moderate risk procedures: recommended, **correct if >1.5**
-Significant bleeding risk: routinely recommended, **correct if >1.5 with goal ≤ 1.5-1.8**

PTT- can be abnormal with IV heparin, von Willebrand disease, Factor VIII, Factor IX, or Factor XI deficiency
-Low risk procedures: routinely recommended for patients receiving IV unfractionated heparin **If on therapeutic low-molecular-weight heparin withhold one dose before procedure.**
-Moderate risk procedures: recommended in patients receiving IV unfractionated heparin. **If on therapeutic low-molecular-weight heparin withhold one dose before procedure. Withhold Plavix for 5 d prior to procedure.**
-Significant bleeding risk: recommended in patients receiving IV unfractionated heparin. **Stop or reverse heparin for values >1.5 times control. If on therapeutic low-molecular-weight heparin withhold 24h or 2 doses before procedure. Withhold Plavix for 5 d before procedure. Withhold ASA 5d before procedure.**

Platelet count- can be abnormal with known or suspected thrombocytopenia
-Low risk procedures: not routinely recommended BUT **if <20,000, transfusion recommended**
-Moderate risk procedures: not routinely recommended BUT **if <50,000, transfusion recommended**
-Significant risk procedures: routinely recommended, **transfuse if <50,000**

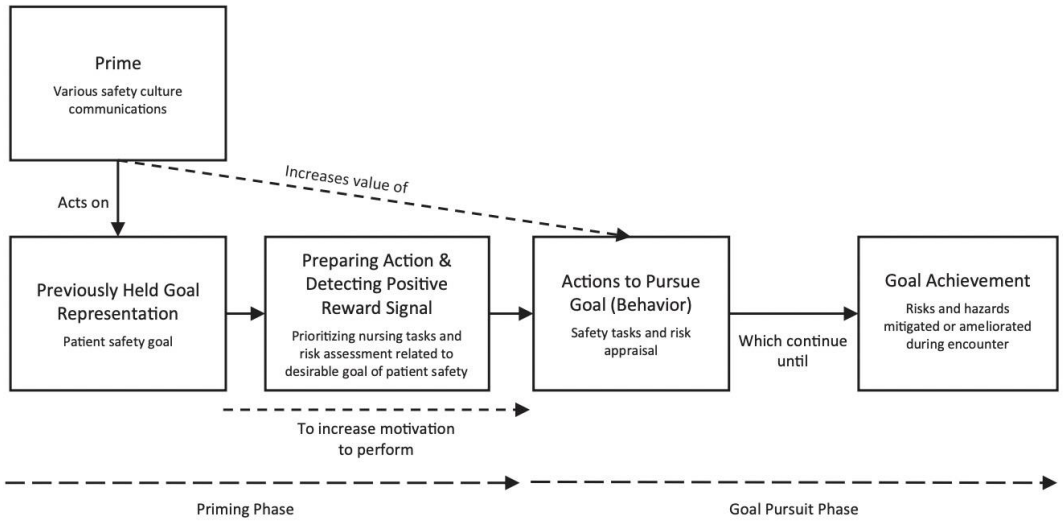
(Malloy et al., 2009; Patel et al., 2019)

Appendix C

study	Purpose	Study type	Sample/setting	Major variables	Data analysis/ findings	Strength (LEGEND)
Mueller et al., 2016	HAS-BLED as predictor of bleeding, risk warfarin for DVT vs control	Retrospective cohort study	Australia, private practice, N=591	INR between 203, Incidence of bleeding (major or minor), HAS-BLED risk assessment score 0-<3	150 (28.1%) classified as low risk, 331 (62.1%) classified as moderate-risk and 52 (9.8%) high-risk. 43,033 INR tests with 71.8% in therapeutic range, 17.1% subtherapeutic and 11.1% supratherapeutic. 215 hemorrhagic events were reported with 206 classified as minor and nine as major (0.41% events per patient)	1a: Good Quality Systematic Review
Spiliopoulos et al., 2019	Peripheral bleeding score (PBS) to identify bleeding complications associated with endovascular therapy (EVT)	Prospective cohort study, single-center study	Greece, university hospital	HAS- BLED score, Bleeding events	Incidence of bleeding complications associated with peripheral EVT was low. PBS demonstrated statistically significant performance and could be considered for inclusion in the preprocedural endovascular checklist. HAS-BLED failed to predict 30-day bleeding events.	Level 3b Lesser Quality Prospective Cohort Study
Roldán et al., 2021	Predictive performance of ABD-bleeding score and HAS-BLED in AF	Retrospective cohort study	Spain, university hospital	CHA2DS2-VASc score, HAS- BLED, ABD-Bleeding score	HAS- BLED performed significantly better than ABC-Bleeding score in predicting major bleeding risk	4a Good Quality Retrospective Cohort Study
Rutherford et al., 2018	Using risk factors to derive a bleeding risk score for patients with AF	Retrospective cohort study	Norway, national patient registry, N=21,248	HAS-BLED, ATRIA, ORBIT	The new ABH-score showed a c-index of 0.66 (95% CI 0.65 to 0.67) compared to the modified HAS-BLED score showed a C-index of 0.62 (95% CI 0.60 to 0.63). The modified ATRIA score a C-index of 0.66 (95% CI 0.64 to 0.67) and the ORBIT score a C-index of 0.66 (95% CI 0.64 to 0.67)	4a Good Quality Retrospective Cohort Study
Fox et al., 2017	A tool for patients with AF to facilitate risk of mortality/bleeding and risks/benefits of anticoagulation	Prospective cohort study	International registry, N=39,898	CHA2DS2-VASc, HAS-BLED	CHA2DS2-VASc and HAS-BLED did not add any information over the GARFIELD-AF risk score for any endpoint in the lower risk cohorts (P values ranged from 0.087. to 1.00). For major bleeding over 1 year, the c- statistic was 0.66 for GARFIELD-AF patients on OACs and 0.61 for patients in ORBIT-AF	3a Good Quality Prospective Cohort Study
Fox at al., 2021	tool to predict mortality, non-hemorrhagic stroke/systemic embolism, major bleeding and to assess how the risk tool performs compared to CHA2DS2-VASc and HAS-BLED	Retrospective cohort study	International registry, N=52,080	Bleeding risk (major, minor/non-major), CHA2DS2-VASc, HAS-BLED	The GARFIELD-AF risk model for major bleeding risk performed well with a c-index of 0.68 compared to HAS-BLED for bleeding (c-index 0.56) in low-risk group.	4a Good Quality Retrospective Cohort Study
AlAmmari et al., 2021	to develop and validate a new model for the bleeding risk prediction score in patients using	Retrospective cohort study	Saudi Arabia, 3 medical centers, N=1722	Bleeding risk (major bleeding, CRNM)	The model had a c index of 0.75 which outperforms most of the other risk assessment scores as they score below 0.7 ‘c’ statistic	4b Lesser Quality Retrospective Cohort Study

	DOACs due to NVAF in the Arab population.					
Atzema et al., 2018	to create a decision instrument that predicts a composite outcome of 30-day mortality a subsequent hospitalization for a cardiovascular reason.	Retrospective cohort study	Canada, 24 emergency departments, N=3510	Cardiovascular condition, evidence of heart failure	2343 patients made up the derivation group (c statistic 0.73) and 1167 left in validation group (c statistic 0.69). The AFTER2 tool showed to stand up and be comparable to other screening tools to predict 30-day mortality rate in Emergency department AF patients with a c- statistic of 0.63.	4b Lesser Quality Retrospective Cohort Study
Freixo et al., 2019	to assess the efficacy of the HAS-BLED score in predicting bleeding risk after lower limb revascularization	Retrospective analysis		Major bleeding, HAS-BLED	Major bleeding occurred in 18.8% of patients at 1 year follow up. 52.1% of patients had a HAS-BLED score of ≥3. Patients with a HAS-BLED score over 3 had a major bleeding incidence of 33.3% compared to 0 risk factor (0%) and 2 risk factors (4.2%)	4b Lesser Quality Retrospective Cohort Study
Chang et al., 2020	to compare different bleeding assessment tools in terms of their accuracy in predicting major bleeding events	Meta-Analysis	Network Meta-analysis	Bleeding risk	European, ABC, mOBRI showed to be highly sensitive. ORBIT, GARFIELD, ATRIA, and Shireman showed to be highly specific. HAS-BLED proved to be balanced between sensitivity and specificity	1a Good Quality Meta-Analysis
Yoshida et al., 2019	To compare 4 bleeding scores regarding their ability to stratify bleeding risk within our cohort	Retrospective cohort study	Japan, municipal hospital, N= 3781	TIMI significant bleeding, Anemia, creatinine clearance, eGFR	c- statistic for HAS-BLED, ORBIT, and PRECISE-DAPT was 0.60 and 0.53 for PARIS using TIMI significant bleeding score. In patients taking OACs and undergoing PCI, HAS-BLED, ORBIT, and PRECISE- DAPT predict TIMI significant bleeding events better than PARIS.	4a Good Quality Retrospective Cohort Study
Beyth et al., 1998	To evaluate the accuracy and clinical utility of the Outpatient Bleeding Risk Index for estimating the probability of major bleeding in outpatients treated with warfarin.	Prospective cohort study	Ohio, University hospital, N=264	Bleeding	. Major bleeding occurred in 22/264 (8%). In the validation cohort there was a c index of 0.78 compared to the derivation cohort 0.72	3a Good Quality Prospective Cohort Study
Tafur et al., 2012	incidence and independent predictors of peri-procedural bleeding in chronically anticoagulated patients	retrospective cohort study	USA, Mayo clinics, N= 2182	Bleeding, procedures	Major bleeding occurred more frequently in patients receiving bridging therapy (3% vs. 1%; P = 0.017). Independent predictors (hazard ratio; 95% confidence interval) of major bleeding included mitral mechanical heart valve (2.2; 1.1–4.3), active cancer (1.8; 1.0–3.1), prior bleeding history (2.6; 1.5–4.5) and re-initiation of heparin therapy within 24 h after the procedure (1.9; 1.1–3.4)	4a Good Quality Retrospective Cohort Study

Appendix D



(Groves & Bunch, 2018)

Appendix E

Table 3. Properties of Anticoagulant Medications

Drug (Brand Name)	Mechanism of Action	Half-Life	Drug Elimination (h)*	Test to Detect Drug Effect or Presence	Reversal Agent (Brand Name)
Vitamin K antagonist					
Warfarin (Coumadin)	Inhibits function of factors II,VII, IX, and X	40 h	200	PT/INR or chromogenic factor X	4F-PCC (Kcentra), plasma†
Heparins					
Low molecular weight: enoxaparin (Lovenox) and dalteparin (Fragmin)	Indirect factor Xa inhibition	2–6 h‡	10–30	Anti-Xa assay	Protamine
Unfractionated	Inhibits thrombin more than factor Xa	1.5–2 h‡	7.5–10	PTT, anti-Xa assay	Protamine
Direct thrombin inhibitors					
Argatroban (Acova)	Direct thrombin inhibitor	50 min	4	PTT or TT	None
Bivalirudin (Angiomax)	Direct thrombin inhibitor	25 min	2§	PTT or TT	None
Dabigatran (Pradaxa)	Direct thrombin inhibitor	12–17 h	60–85§	TT, ecarin clotting time	Idarucizumab (Praxbind)
Factor Xa inhibitors					
Apixaban (Eliquis)	Direct factor Xa inhibitor	15 h	75§	Anti-Xa assay, apixaban assay where available	Andexanet alfa (Andexxa) PCC
Betrixaban (Bevyxxa)	Direct factor Xa inhibitor	37 h	185§	Anti-Xa assay	Andexanet alfa (Andexxa)
Edoxaban (Savaysa)	Direct factor Xa inhibitor	9–14 h	45–70§	Anti-Xa assay	Andexanet alfa (Andexxa) PCC
Fondaparinux (Arixtra)	Indirect factor Xa inhibitor	17–21 h	85–105§	Fondaparinux assay	Andexanet alfa (Andexxa)
Rivaroxaban (Xarelto)	Direct factor Xa inhibitor	9–13 h	45–65§	Anti-Xa assay, rivaroxaban assay where available	Andexanet alfa (Andexxa) PCC

4F-PCC = 4 factor–prothrombin complex concentrate; INR = International Normalized Ratio; PT = prothrombin time; PTT = partial thromboplastin time; TT = thrombin time.
*The plasma concentration of a drug is halved after 1 elimination half-life. After 5 half-lives, the amount of drug remaining is approximately 3%, which is considered to be negligible with regard to therapeutic effect for most classes of drug. However, complete drug elimination may not always reflect the time to return to normal hemostasis for all drug classes, and specific drug-withholding recommendations are provided in table 6 of part II of this document.
†Plasma only if 4F-PCC is unavailable
‡The range of half-life times presented for the heparin classes of drugs reflect times for intravenous and subcutaneous administration.
§Time to normal hemostasis may vary with these drugs in patients with renal failure as a result of renal excretion of the medications.

Table 2. Properties of Antiplatelet Agents

Drug (Brand Name)	Mechanism of Action	Half-Life	Drug Elimination (h)*	Test to Detect Drug Effect
Thienopyridines				
Cangrelor (Kengreal)†	Thienopyridine (reversible)	3.6 min	0.33	Platelet aggregometry, VerifyNow P2Y12‖
Clopidogrel (Plavix)†	Thienopyridine (irreversible)	6 h	30	Platelet aggregometry, VerifyNow P2Y12‖
Prasugrel (Effient)†,§	Thienopyridine (irreversible)	3.7 h	20	Platelet aggregometry, VerifyNow P2Y12‖
Ticagrelor (Brilinta)†	Thienopyridine (reversible)	7 h	35	Platelet aggregometry, VerifyNow P2Y12‖
Ticlopidine (Ticlid)†	Thienopyridine (irreversible)	13 h	65	Platelet aggregometry, VerifyNow P2Y12‖
NSAIDs				
Aspirin†	COX-1 inhibitor	2–3 h	10–15‡	PFA-100, platelet aggregometry, VerifyNow ASA‖
Aspirin/dipyridamole (Aggrenox)†	COX-1 and phosphodiesterase inhibitor	13 h	65‡	PFA-100
Celecoxib (Celebrex)	COX-2 inhibitor	8–12 h	40–60	NA
Diclofenac (Voltaren)	COX-2 inhibitor	1–2 h	5–10	NA
Diflunisal (Dolobid)	COX-1 and -2 inhibitor	8–12 h	40–60	NA
Ibuprofen (Motrin)	COX-1 inhibitor	2–4 h	10–20‡	NA
Indomethacin	COX-1 inhibitor	5–10 h	25–50	NA
Ketorolac (Toradol)	COX-1 and -2 inhibitor	5–6 h	25–30‡	NA
Ketoprofen (Orudis)	COX-1 and -2 inhibitor	2–5 h	10–25‡	NA
Meloxicam (Mobic)	COX-2 inhibitor	15–20 h	75–100	NA
Nabumetone (Relafen)	COX-2 inhibitor	22–30 h	110–150	NA
Naproxen (Aleve)	COX-1 and -2 inhibitor	12–17 h	60–85‡	NA
Piroxicam (Feldene)	COX-1 and -2 inhibitor	45–50 h	225–250	NA
Sulindac (Clinoril)	COX-1 and -2 inhibitor	16 h (active metabolite)	80	NA
Glycoprotein IIb/IIIa inhibitors				
Abciximab (ReoPro)†	Glycoprotein IIb/IIIa inhibitor	10–30 min	2.5	PFA-100
Eptifibatide (Integrilin)†	Glycoprotein IIb/IIIa inhibitor	2.5 h	12.5	PFA-100
Tirofiban (Aggrastat)†	Glycoprotein IIb/IIIa inhibitor	2 h	10	PFA-100
Phosphodiesterase inhibitors				
Cilostazol (Pletal)	Phosphodiesterase inhibitor	10 h	50‡	NA
Dipyridamole (Persantine)	Phosphodiesterase inhibitor	10 h	50	NA

COX = cyclooxygenase; NA = not applicable; NSAID = nonsteroidal antiinflammatory drug; PFA-100 = platelet function analyzer-100 (this test has replaced bleeding time to assess primary hemostasis, ie, platelet function and von Willebrand disease).
*The plasma concentration of a drug is halved after 1 elimination half-life. After 5 half-lives, the amount of drug remaining is approximately 3%, which is considered to be negligible with regard to therapeutic effect for most classes of drug. However, complete drug elimination may not always reflect the time to return to normal hemostasis for all drug classes (eg, abciximab and aspirin), and specific drug-withholding recommendations are provided in table 6 of part II of this document.
†In cases of antiplatelet-associated life-threatening bleeding requiring reversal, there are no specific antidotes to the medications themselves; however, platelet transfusions may help control bleeding/symptoms.
‡Time to drug elimination may vary with these drugs in patients with renal failure as a result of renal excretion of the medications.
§The US Food and Drug Administration issued a Black Box Warning for prasugrel, which should not be used in patients with active pathologic bleeding, history of ministrokes or stroke, or those requiring an urgent need for surgery, including coronary artery bypass graft surgery.
‖VerifyNow P2Y12 and VerifyNow ASA are point-of-care devices that can detect a patient's resistance to thienopyridines or acetylsalicylic acid (ASA). If a patient is resistant to these medications, the normal recommended withholding times may not apply.

Appendix F

Table 2
Category 1: Procedures with Low Risk of Bleeding, Easily Detected and Controllable

Procedures	Preprocedure Laboratory Testing	Management
Vascular Dialysis access interventions Venography Central line removal IVC filter placement PICC line placement Nonvascular Drainage catheter exchange (biliary, nephrostomy, abcess catheter) Thoracentesis Paracentesis Superficial aspiration and biopsy (excludes intrathoracic or intraabdominal sites): thyroid, superficial lymph node Superficial abscess drainage	INR: Routinely recommended for patients receiving warfarin anticoagulation or with known or suspected liver disease Activated PTT: Routinely recommended for patients receiving intravenous unfractionated heparin. Platelet count: Not routinely recommended Hematocrit: Not routinely recommended	INR >2.0: Threshold for treatment (ie, FFP, vitamin K) PTT: No consensus Hematocrit: No recommended threshold for transfusion Platelets: Transfusion recommended for counts <50,000/UL Plavix: Do not withhold Aspirin: Do not withhold Low-molecular-weight heparin (therapeutic dose): Withhold one dose before procedure DDAVP: Not indicated

There was an 80% consensus for each of these recommendations unless otherwise stated.
The management recommendations for each coagulation defect and drug assume that no other coagulation defect is present and that no other drug that might affect coagulation status has been administered.

Table 3
Category 2: Procedures with Moderate Risk of Bleeding

Procedures	Preprocedure Laboratory Testing	Management
Vascular Angiography, arterial intervention with access size up to 7 F Venous interventions Chemoembolization Uterine fibroid embolization Transjugular liver biopsy Tunneled central venous catheter Subcutaneous port device Nonvascular Intraabdominal, chest wall, or retroperitoneal abcess drainage or biopsy Lung biopsy Transabdominal liver biopsy (core needle) Percutaneous cholecystostomy Gastrostomy tube: initial placement Radiofrequency ablation: straightforward Spine procedures (vertebroplasty, kyphoplasty, lumbar puncture, epidural injection, facet block)	INR: Recommended Activated PTT: Recommended in patients receiving intravenous unfractionated heparin Platelet count: Not routinely recommended Hematocrit: Not routinely recommended	INR: Correct above 1.5 (89% consensus) Activated PTT: No consensus (trend toward correcting for values >1.5 times control, 73%) Platelets: Transfusion recommended for counts <50,000/uL Hematocrit: No recommended threshold for transfusion Plavix: Withhold for 5 d before procedure Aspirin: Do not withhold Low-molecular-weight heparin (therapeutic dose): Withhold one dose before procedure DDAVP: not indicated

There was an 80% consensus on each of these recommendations unless otherwise stated.
The management recommendations for each coagulation defect and drug assume that no other coagulation defect is present and that no other drug that might affect coagulation status has been administered.

Table 4
Category 3: Procedures with Significant Bleeding Risk, Difficult to Detect or Control

Procedures	Preprocedure Laboratory Testing	Management
Vascular Transjugular intrahepatic portosystemic shunt Nonvascular Renal biopsy Biliary interventions (new tract) Nephrostomy tube placement Radiofrequency ablation: complex	INR: Routinely recommended Activated PTT: Routinely recommended in patients receiving intravenous unfractionated heparin infusion. No consensus on patients not receiving heparin Platelet count: Routinely recommended Hematocrit: Routinely recommended	INR: Correct above 1.5 (95% consensus) Activated PTT: Stop or reverse heparin for values >1.5 times control) Platelets <50,000: Transfuse Hematocrit: No recommended threshold for transfusion Plavix: Withhold for 5 d before procedure Aspirin: Withhold for 5 d Fractionated heparin: withhold for 24 h or up to two doses DDAVP: Not indicated

There was an 80% consensus on each of these recommendations unless otherwise stated
The management recommendations for each coagulation defect and drug assume that no other coagulation defect is present and that no other drug that might affect coagulation status has been administered.

Appendix G

Table 3. Procedure-Associated Bleeding Risk Categorization (4,32–38)

Screening Coagulation Laboratory Test	Procedures
Low bleeding risk	
PT/INR: not routinely recommended*	Catheter exchanges (gastrostomy, biliary, nephrostomy, abscess, including gastrostomy/gastrojejunostomy conversions)
Platelet count/hemoglobin: not routinely recommended	Diagnostic arteriography and arterial interventions: peripheral, sheath < 6 F, embolotherapy‡
Thresholds†	Diagnostic venography and select venous interventions: pelvis and extremities
INR: correct to within range of ≤ 2.0–3.0‡	Dialysis access interventions
Platelets: transfuse if < 20 × 10^9/L	Facet joint injections and medial branch nerve blocks (thoracic and lumbar spine)§
	IVC filter placement and removal‖
	Lumbar puncture¶
	Nontunneled chest tube placement for pleural effusion
	Nontunneled venous access and removal (including PICC placement)
	Paracentesis
	Peripheral nerve blocks, joint, and musculoskeletal injections§
	Sacroiliac joint injection and sacral lateral branch blocks§
	Superficial abscess drainage or biopsy (palpable lesion, lymph node, soft tissue, breast, thyroid, superficial bone, eg, extremities and bone marrow aspiration)
	Thoracentesis
	Transjugular liver biopsy#
	Trigger point injections including piriformis§
	Tunneled drainage catheter placement‡
	Tunneled venous catheter placement/removal (including ports) ‡

continued

Table 3. Procedure-Associated Bleeding Risk Categorization (4,32–38) *(continued)*

Screening Coagulation Laboratory Test	Procedures
High bleeding risk	
PT/INR: routinely recommended	Ablations: solid organs, bone, soft tissue, lung
Platelet count/hemoglobin: routinely recommended	Arterial interventions: > 7-F sheath, aortic, pelvic, mesenteric, CNS†,‡
Thresholds†	Biliary interventions (including cholecystostomy tube placement)
INR: correct to within range of ≤ 1.5–1.8	Catheter directed thrombolysis (DVT, PE, portal vein)**
Platelets: transfuse if < 50 × 10^9/L	Deep abscess drainage (eg, lung parenchyma, abdominal, pelvic, retroperitoneal)
	Deep nonorgan biopsies (eg, spine, soft tissue in intraabdominal, retroperitoneal, pelvic compartments)
	Gastrostomy/gastrojejunostomy placement
	IVC filter removal complex**
	Portal vein interventions
	Solid organ biopsies
	Spine procedures with risk of spinal or epidural hematoma (eg, kyphoplasty, vertebroplasty, epidural injections, facet blocks cervical spine)§
	Transjugular intrahepatic portosystemic shunt††
	Urinary tract interventions (including nephrostomy tube placement, ureteral dilation, stone removal)
	Venous interventions: intrathoracic and CNS interventions

CNS = central nervous system; DVT = deep vein thrombosis; INR = International Normalized Ratio; IVC = inferior vena cava; PE = pulmonary embolism; PT = prothrombin time.

*Screening coagulation laboratory testing before low bleeding risk procedures should be considered for patients with risk factors for bleeding or those receiving warfarin or heparin drip if there is concern for supratherapeutic levels.

†Thresholds for laboratory parameters are based largely on scientific consensus established in the literature from limited-quality studies and the consensus of the Writing Group and Standards Committee volunteers. INR ranges, reflecting the upper limits of thresholds, have been provided in the recommendations, as the varying degrees of bleeding risk within procedural categories should be taken into consideration. For example, an INR < 1.8 may be acceptable for a liver biopsy but an INR < 1.5 may be preferred before an aortic intervention, as the strategies and success of controlling unanticipated bleeding differ between the 2 procedure types. Similarly, an INR < 2.0 may be preferred for catheter placement procedures in which a subcutaneous tunnel is planned. Recommendations for patients with cirrhosis differ and are specified in Table 4.

‡Low bleeding risk procedures involving percutaneous and venous access have been performed safely at INRs within the range of 2.0–3.0 (32–34). For low bleeding risk procedures that require arterial access, the recommended INR thresholds are < 1.8 for femoral access and < 2.2 for radial access (4). Interventions involving the creation of a subcutaneous tunnel (eg, pacemaker insertion, pleural or venous catheter placement) have traditionally been grouped into the low bleeding risk category (35–37). Preprocedure DOAC interruption > 24 h vs < 24 h was not identified as a potential risk factor for major bleeding events (36).

§Injection and pain-management procedures follow the classification outlined by the American Society of Regional Anesthesia and Pain Medicine, the European Society of Regional Anesthesia and Pain Therapy, the American Academy of Pain Medicine, the International Neuromodulation Society, the North American Neuromodulation Society, and the World Institute of Pain (32). These guidelines consider spine procedures with risk of spinal or epidural hematoma to be high bleeding risk procedures given that bleeding in this area could be difficult to manage and be associated with morbid consequences for the patient.

‖IVC filter placements and uncomplicated IVC filter removals would fall into the low bleeding risk category. For IVC filter removal, consider the anticipated technical complexity of the procedure (ie fractured legs, legs penetrating outside of IVC, tilt) and dwell time.

¶See discussion in text: *Laboratory Parameters for High Bleeding Risk Procedures* and *Recommendation 3*.

#Ref. 38 sets a platelet threshold of > 30 × 10^9/L for transjugular liver biopsy.

**Clinical and technical nuances involved in catheter-directed lysis procedures and complex IVC filter retrieval cases should govern the target thresholds for INR and platelet count on an individual patient basis. For example, the INR target for complex IVC filter retrieval may be higher for patients in whom the interventionalist chooses to maintain anticoagulation medications during the case. Similarly, the bleeding risk for planned overnight lysis with lytic agents may be different than the bleeding risk in which only mechanical removal of clot is planned. However, both procedures are listed in the high bleeding risk category given that advanced techniques and/or medications will be used that may increase the complexity and procedural bleeding risk.

††Transjugular intrahepatic portosystemic shunts are classified as high bleeding risk procedures, as tearing of the portal vein may be a fatal complication. Most patients who undergo transjugular intrahepatic portosystemic shunt creation will have chronic liver disease, and the suggested laboratory parameters for this patient population are listed in Table 4.

Table 1
Tests of Hemostasis

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

Appendix H

Table 2. Assessment of Patient Bleeding Risk (3,21)

HAS-BLED Score (Score > 3 Predictive of Bleeding Events)

Criteria	Points
Hypertension (systolic BP > 160 mm Hg)	1
Abnormal renal function (dialysis, renal transplantation, serum Cr > 200 μmol/L)	1
Abnormal liver function (cirrhosis or bilirubin > 2× ULN, AST or ALT > 3× ULN)	1
Prior stroke	1
History of major bleeding or predisposition to bleeding (anemia)	1
Labile INR (VKA) defined as time in therapeutic range < 60%	1
Age > 65 y	1
Concomitant use of antiplatelet agent or NSAID	1
History of alcohol or drug use (> 8 drinks per week)	1

Other Risk Factors for Bleeding

- Prior bleeding within 3 mo
- Prior bleeding with similar type of procedure
- Platelet abnormality
- INR above therapeutic range at time of procedure (VKA)
- Prior bleeding with bridging therapy
- Mechanical mitral heart valve
- Active cancer

Note–There are currently no well validated scoring systems that can be used to assess bleeding risk across interventional radiologic procedures. Similarly, the HAS-BLED score has not been designed to assess periprocedural bleeding risk. However, this score is often used in clinical practice as a general guide to aid clinicians in recognizing potential factors that may increase patient-specific bleeding risk and should be used for this purpose alone. History of bleeding, mechanical mitral heart valve, and active cancer are BleedMAP factors that may also indicate an increased propensity for a patient to experience bleeding; however, it should be noted that BleedMAP is not procedure-specific. Platelet counts lower than 20×10^9/L and lower than 50×10^9/L may be associated with increased risk of bleeding for low- and high-risk procedures, respectively (22).

ALT = alanine aminotransferase; AST = aspartate aminotransferase; BP = blood pressure; Cr = creatinine; mo = months; NSAID = nonsteroidal antiinflammatory drug; ULN = upper limits of normal; VKA = vitamin K antagonist; y = years.

Appendix I

Independent-Samples Mann-Whitney U Test Summary

Total:		RNs:	
Total N	38	Total N	24
Mann-Whitney U	85.500	Mann-Whitney U	120.000
Wilcoxon W	275.500	Wilcoxon W	198.000
Test Statistic	85.500	Test Statistic	120.000
Standard Error	26.451	Standard Error	14.446
Standardized Test Statistic	-3.592	Standardized Test Statistic	-3.323
Asymptotic Sig.(2-sided test)	<.001	Asymptotic Sig.(2-sided test)	<.001
Exact Sig.(2-sided test)	.005	Exact Sig.(2-sided test)	.005