The Timing and Presentation of Major Hemorrhage After 18,947 Image-Guided Percutaneous Biopsies

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OBJECTIVE. The objective of our study was to characterize the temporal and clinical manifestation of major bleeding events after biopsy to guide clinicians in the institution of appropriate surveillance.

MATERIALS AND METHODS. We performed a retrospective review of percutaneous image-guided biopsies performed between September 1, 2005, and May 31, 2012, including 18,947 biopsy events. According to routine protocol, follow-up telephone calls were made to patients 24 hours after biopsy, and chart review was performed 3 months after biopsy. Bleeding complications were defined using the Common Terminology Criteria for Adverse Events (CTCAE, version 4.0) established by the National Cancer Institute. In patients with a grade 3 or greater bleeding complication, a retrospective chart review was performed to characterize the details of the complication including the timing of the complication and the primary clinical presentation of the event.

RESULTS. Grade 3 hemorrhage was associated with 64 of 18,947 (0.3%) procedures, and there were three deaths associated with the biopsy event (0.02% or ≈ 2/10,000). Hemorrhage was most commonly associated with biopsy of a native kidney (17/1407, 1.2%). Twenty patients (31%) presented with a bleeding complication within 1 hour of biopsy. Twenty-seven patients (42%) presented within 2 hours of biopsy. Fifty-two patients (81%) presented within 24 hours, and the remaining 12 patients (19%) presented more than 24 hours after biopsy. Pain was the most common presentation of patients with bleeding complications, occurring in 39 (61%) patients.

CONCLUSION. The incidence of major bleeding after percutaneous biopsies is very low, but delayed complications occur more frequently than anticipated. Pain is the most common clinical presentation of major bleeding complications.

Keywords: biopsy, complication, CT, hemorrhage, ultrasound

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Percutaneous core biopsy using image guidance provides an important, cost-effective option in the evaluation of neoplastic and intrinsic parenchymal disease processes. These biopsies are safe and are typically performed on an outpatient basis. These biopsy procedures will certainly increase in number with the growing evolution of targeted molecular and genetic therapies that rely on tissue sampling.

Although the general incidence of bleeding complications has been well established in the literature [1], thorough characterization of these bleeding events has been limited by the relatively small number of patients in whom these complications occur. Thus, the primary purpose of this study was to characterize the incidence, timing, and clinical manifestations of major bleeding complications after more than 18,000 image-guided core biopsies; a secondary goal was to provide radiologists with a foundation for defining an appropriate postbiopsy management strategy for their practice.

Materials and Methods

Approval for this retrospective study was obtained from our institutional review board (IRB). This study was HIPAA compliant. Informed consent was waived by the IRB.

Patient Selection

Patients in this study included those who underwent a percutaneous CT- or ultrasound-guided core biopsy during the period of September 1, 2005, through May 31, 2012; isolated fine-needle aspiration biopsies were not included. Although most patients were outpatients at the time of biopsy, inpatients were also included in the analysis. A variety of disease processes prompted the biopsies. In general, parenchymal biopsies were performed because of a suspicion of an under-

lying liver or renal disease. Transplant biopsies were performed both for surveillance reasons and for question of rejection. Mass biopsies were performed to assess for malignancy or infection.

In the time period between September 1, 2005, and May 31, 2012, 19,454 biopsies were performed in 14,425 patients; 488 biopsies in 383 patients were excluded from our analysis because the patients declined to participate in research. Nineteen biopsies were excluded because they occurred in patients who underwent more than one biopsy on a given day. Thus, 18,947 biopsies performed in 14,042 patients were available for review based on 24-hour follow-up. In addition, 3-month follow-up chart review was available for 18,556 biopsies (98%). This experience includes a cohort of 5740 patients (7033 biopsies) from a previously reported study regarding biopsy risk factors [1].

Biopsy events are tracked in a clinical database, including complications after biopsy. Specifically, the patient or a designated representative is contacted by a radiology department registered nurse (RN) 24 hours after biopsy to inquire about any possible complications. The RN inquires if the patient has any of the following: bleeding, pain, redness, tenderness, warmth, or abnormal drainage at the biopsy site; shortness of breath; and temperature of greater than 38.0°C. Patients are instructed to go to the emergency department if there is suspicion of bleeding based on these survey questions or other comments by the patient or his or her representative. If the initial telephone call attempt was unsuccessful, attempts to contact the patient were then made on day 2 and day 3 after biopsy; if these additional attempts were unsuccessful, no additional attempts were made, and a note documenting the calls was added to the patient's electronic medical record. A focused review of each patient's electronic medical record was then performed by an RN 3 months after biopsy to assess for biopsy-related complications.

Biopsy Technique

Our procedural guidelines suggest an international normalized ratio (INR) of less than 1.6 and a platelet count of greater than 50×10^9/L before biopsy; exceptions based on the clinical situation and radiologist preference were occasionally made. Patients are screened for the use of anticoagulants. Patients are asked to abstain from taking antiplatelet agents such as aspirin and clopidogrel for a minimum of 5 days before biopsy, although aspirin use is tolerated if the biopsy is requested for nonelective or urgent indications. All biopsies were performed by board-certified radiology staff or trainees supervised by radiology staff. All CT-guided biopsies were performed using a coaxial technique (Bard Monopty, CR Bard). Ultrasound-guided biopsies were routinely performed using real-time guidance without an introducer; however, on occasion, an introducer needle was used according to radiologist preference. The number of passes performed depends on the quality of the tissue obtained and radiologist preference; typically two or three 18-gauge core biopsy samples are obtained at parenchymal biopsies. Biopsy needle tract plugging was not performed for solid parenchymal organ biopsies. Frequently, at the discretion of the radiologist, a final set of images (CT without IV contrast material or focused ultrasound) was obtained immediately after the biopsy and before application of the sterile bandage to the puncture site to look for a discrete hematoma.

TABLE 1: Interventions Required for Common Terminology Criteria for Adverse Events (CTCAE), Version 4.0 [2], by Grade

CTCAE Grade (Definition)	Intervention Required
1 (Mild symptoms)	Intervention not indicated
2	Minimally invasive evacuation or aspiration indicated
3	Transfusion or radiologic, endoscopic, or elective operative intervention indicated
4 (Life-threatening consequences)	Urgent intervention indicated
5 (Death)	

Patients were routinely observed with regular assessments of vital signs for 2 hours after lung, liver, and transplant kidney biopsies and for 6 hours after native kidney biopsies. The duration of patient observation for other biopsies was dependent on radiologist preference. Patients were dismissed from the recovery area after the defined time period and in stable condition compared with baseline. Neither routine laboratory assessment nor imaging assessment was performed before patient discharge with the exception of routine chest radiographs 1 hour after lung biopsies. In patients with pain or other new symptoms after biopsy, additional imaging was performed at the discretion of the radiologist who performed the biopsy.

Our policy is for patients to remain within 30 miles of our institution the first night after lung and solid organ biopsies. Patients who undergo other biopsies may be asked to stay within 30 miles at the radiologist's discretion.

Data Review

For the study period of September 1, 2005, through May 31, 2012, a retrospective review of our department's existing internally maintained percutaneous biopsy database was conducted; this review included a cohort of patients who had been included in a prior study [1]. The biopsy technique did not change during the time period analyzed. Bleeding complications of grade 3 or greater as defined by the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE), version 4.0 (Vascular Disorders section, Hematoma), were reported at both the 24-hour and 3-month follow-ups [2] (Table 1). Specifically, grade 3 bleeding complications are defined as those requiring a transfusion or a radiologic, endoscopic, or elective operative intervention. Grade 4 bleeding complications are defined as those with life-threatening consequences that require urgent intervention. Grade 5 bleeding complications result in the death of the patient.

A single author reviewed all reported bleeding complications and identified the adverse events that fulfilled the criteria for a CTCAE grade 3 or greater complication. In cases in which the CTCAE grade of the adverse event was not immediately apparent, a second radiologist reviewed these cases and a decision was made by consensus. The site of biopsy was also recorded.

Of the patients with designated bleeding complications, a thorough chart review was performed to assess the time from the biopsy event (0 hours) to the patient's presentation with the bleeding complication and the specific sign or symptom with which the patient presented at the time of the bleeding event. Of those with delayed (> 24 hours) bleeding, anticoagulation therapy use after biopsy was recorded; regrettably, this information was not included in the prospective collection of data at the time of biopsy. Potential associations of bleeding with serum platelet count, INR, and periprocedural use of aspirin (within 7–10 days of biopsy) were measured for all biopsy events, native kidney biopsies, transplant kidney biopsies, and liver biopsies.

Statistical Analysis

Descriptive statistics are reported for bleeding sites and clinical manifestations. Associations of aspirin use, INR, and platelet counts with bleeding at 24 hours or less after biopsy versus bleeding at more than 24 hours after biopsy were assessed for all biopsies and separately for native kidney biopsies, transplant kidney biopsies, and liver biopsies using logistic regression.

TABLE 2: Incidence of Bleeding Complications by Biopsy Site

Biopsy Type	No. of Biopsies	No. (%) of Bleeding Events (%)	No. (%) of Delayed (> 24 h) Events
Kidney (native)	1407	16 (1.1)	4 (0.28)
Kidney (transplant)	5220	12 (0.2)	3 (0.06)
Liver (parenchymal and mass)	4117	22 (0.5)	2 (0.05)
Pancreas (native and transplant)	255	2 (0.8)	0
Lung	1827	2 (0.1)	0
Adrenal	190	0	0
Other[a]	5931	10 (0.2)	3 (0.05)

[a]Other includes renal mass, retroperitoneal lymphadenopathy, pelvic sidewall mass, mesenteric mass, pelvic lymph node, gallbladder fossa mass, femoral bone, and spleen.

Results

Of the 18,947 core needle biopsies, there were 64 (0.3%) biopsy events in 64 patients that met the criteria for CTCAE grade 3 or greater bleeding complications within 3 months after biopsy, including one death that was remotely related to biopsy. The incidence of CTCAE grade ≥ 3 hemorrhagic complications is summarized by organ site in Table 2. The incidence of bleeding complications was greatest in native kidney parenchymal biopsies (17/1407, 1.2%).

For 53 of the 18,947 (0.3%) biopsies, the presence or absence of aspirin use was not recorded, including one of 64 (1.6%) patients with a bleeding complication. Otherwise, aspirin use within 10 days of biopsy was not associated with bleeding for the study population as a whole (p = 0.89; OR = 1.043; 95% CI, 0.58–1.87) and was not associated with bleeding after native kidney biopsies (p = 0.53; OR = 1.45; 95% CI, 0.45–4.67), transplant kidney biopsies (p = 0.60; OR = 1.38; 95% CI, 0.41–4.58), or liver biopsies (p = 0.69; OR = 1.23; 95% CI, 0.45–3.34). For these same biopsy groups, there was no significant ($p < 0.05$) association with INR. There was a significant association of a platelet count of 49 k/mL or less and bleeding for renal transplant biopsies (p = 0.04; OR = 0.04; 95% CI, 0.002–0.810) but not for the other biopsies.

Three deaths occurred after percutaneous biopsy, yielding a mortality rate of 0.02%. After undergoing an uneventful biopsy of a hepatic metastasis from renal cell carcinoma, the first patient was restarted on low-molecular-weight heparin (LMWH) the day after the procedure. She presented to her local emergency department 3 days after the biopsy with pain and a syncopal episode. Angiography showed active hepatic bleeding that was successfully embolized, but she ultimately died as a result of secondary multisystem organ failure related to the massive bleeding. The second patient, a woman with chronic obstructive pulmonary disease, underwent biopsy of a hepatic metastasis from newly diagnosed small cell lung carcinoma. She developed pain and hypotension 3 hours after biopsy and was found to have a large perihepatic hematoma. Subsequent angiography did not reveal a source of bleeding. The evening immediately after the biopsy, she became hypoxic and required intubation. After 12 days in the ICU with worsening pulmonary status and advanced untreatable malignancy, mechanical support was withdrawn at the request of her surrogate and she died. The third patient was a 93-year-old woman with ischemic cardiomyopathy and Alzheimer disease who presented for a workup of chest and abdominal pain. She underwent biopsy of a large pelvic mass, which was shown to be lymphoma. Therapeutic heparin infusion was started the day after the biopsy for ongoing myocardial infarction; she developed pain approximately 28 hours after the biopsy and was found to have a large hematoma on CT. Angiography did not show a source of bleeding. She became progressively more confused and was transitioned to comfort care; she died 15 days after the biopsy.

The primary clinical manifestations of CTCAE grade ≥ 3 bleeding complications are summarized in Table 3. More than half of the patients presented with more than one discrete manifestation of bleeding. The most common primary manifestation of bleeding was pain (61%) followed by hemodynamic instability or syncope (42%), In 16 of 64 (25%) patients, imaging findings in the immediate absence of signs or symptoms of bleeding led to the diagnosis of bleeding; these imaging findings included imaging performed at the time of biopsy. In eight of these patients, the bleeding complications ultimately progressed and the patients developed additional manifestations of major hemorrhage, including pain and hemodynamic instability. Additional patients were found to have anemia (5%), hematuria (8%), and soft-tissue bulge (2%), which precipitated the diagnosis of significant bleeding according to the CTCAE criteria.

The time after biopsy at which patients presented with a bleeding complication is summarized in Table 4. Bleeding complica-

TABLE 3: Manifestations of Common Terminology Criteria for Adverse Events (CTCAE) Grade ≥ 3 Hemorrhage[a]

Manifestation of CTCAE Grade ≥ 3 Hemorrhage	No. (%) of Patients (n = 64)
Pain	39 (61)
Imaging findings diagnostic of bleeding without clinical findings	16 (25)
Hemodynamic instability or syncope	27 (42)
Anemia	3 (5)
Hematuria	5 (8)
Soft-tissue bulge	1 (2)

[a]Twenty-six patients (41%) presented with multiple manifestations.

TABLE 4: Time to Presentation With Common Terminology Criteria for Adverse Events Grade ≥ 3 Hemorrhage

Time to Presentation	No. (%) of Patients With Grade ≥ 3 Hemorrhage (n = 64)
≤ 1 h after biopsy	25 (39)
≤ 2 h after biopsy	29 (45)
≤ 24 h after biopsy	52 (81)
> 24 h after biopsy	12 (19)

tions were evident within 1 hour of the biopsy event in 31% of patients and within 24 hours in 81%. Of the bleeding complications that occurred within 24 hours of biopsy, 29 of 64 (45%) occurred within 2 hours, 35 of 64 (55%) within 4 hours, and 46 of 64 (72%) within 8 hours of the biopsy event (Figs. 1–3).

Twelve of 64 (19%) patients presented with major bleeding more than 24 hours after the biopsy. Major bleeding was more common after biopsy of native kidneys (0.28%), although this organ site was not statistically significant compared with other sites ($p = 0.45$). In 10 of these 12 (83%) patients, pain was the presenting manifestation of bleeding. Six of the 12 (50%) patients with delayed bleeding had been started on therapeutic ($n = 3$) or prophylactic ($n = 3$) unfractionated heparin after biopsy. Two (17%) additional patients had been started on therapeutic LMWH, and a single (8%) patient had resumed warfarin therapy. Two of the 12 patients died (as detailed earlier).

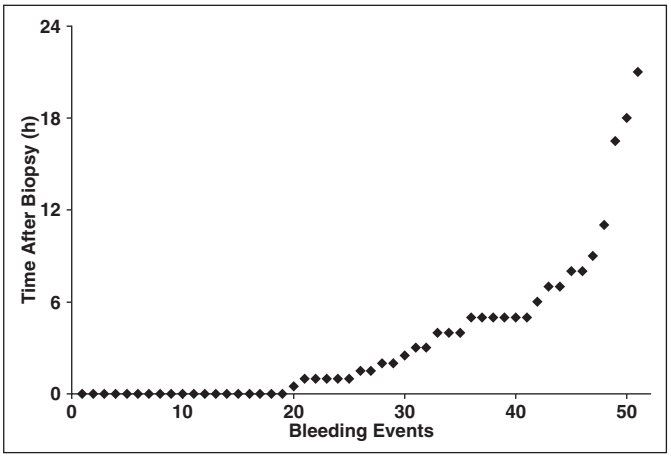

Fig. 1—Scatterplot shows timing of presentation with bleeding event after biopsy of any site within 24 hours of procedure ($n = 52$). Nineteen of 52 (37%) bleeding events were evident at time of biopsy.

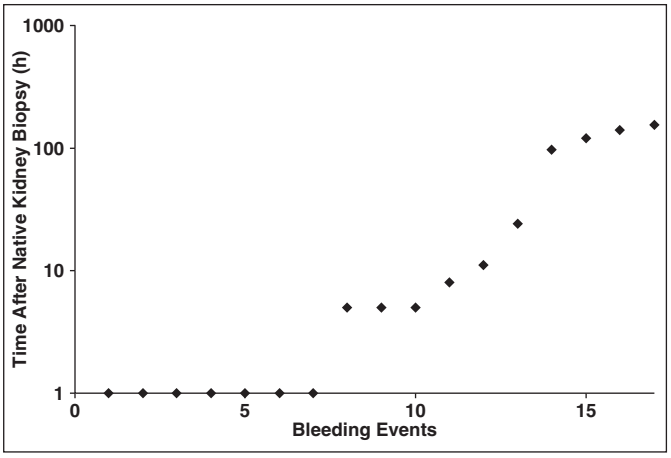

Fig. 2—Scatterplot shows timing of presentation with bleeding event after biopsy of native kidney ($n = 17$). Seven of 17 (41%) patients who bled presented within 6 hours after biopsy; these patients represent 0.5% (7/1407) of all patients who underwent native kidney biopsy.

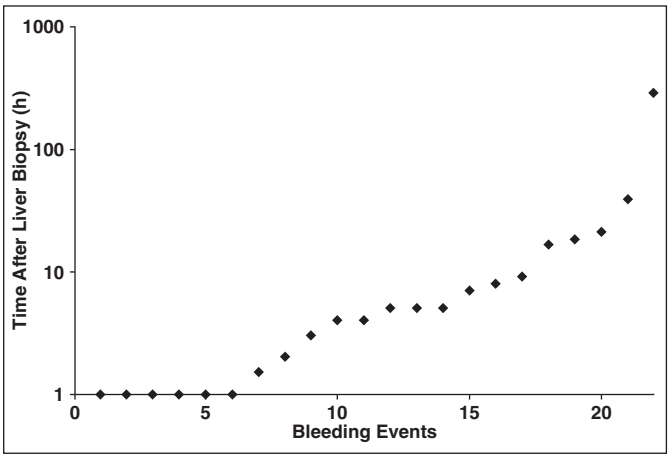

Fig. 3—Scatterplot shows timing of presentation with bleeding event after liver biopsy ($n = 22$). Fourteen of 22 (64%) patients who bled presented within 2 hours after biopsy; these patients represent 0.3% (14/4117) of all patients who underwent liver biopsy.

Discussion

Image-guided percutaneous biopsies are integral to providing minimally invasive cost-effective diagnosis of malignancy and parenchymal disease, particularly involving solid organs such as the liver and kidney. Fortunately, complications after these biopsies, including hemorrhage, are exceedingly rare. The overall incidence of significant bleeding in this study was very low, far less than 1%. This incidence compares favorably with prior major complications rates of 0–6.4% after biopsies of solid organs [3–7], including our previously published experience [1]. Similar to our prior study, we again did not find an association between recent aspirin use and major bleeding complications [1].

In planning patient care during and after a biopsy procedure, it is important to recognize and manage potential complications. Although complications are infrequent, the consequences can be devastating. Thus, the radiology care team needs to have a process in place to adequately monitor patients after biopsy and adequately educate patients about self-surveillance for potential complications.

With respect to monitoring patients in an era of cost-containment and efficient resource allocation, identifying an optimum window of direct patient observation is necessary. To our knowledge, only a single published standard exists regarding a suggested period of observation after percutaneous biopsy. A consensus article published on behalf of the American Association for the Study of Liver Diseases recommended a 2- to 4-hour observation period after liver biopsy but qualified that the optimal time will vary depending on local expertise and practice [8]. In support of this relatively short period of observation, Firpi et al. [9] found no significant difference in major complication rates after liver biopsy in patients observed for 1 hour after biopsy (0.7%) compared with those observed for 6 hours after biopsy (1.7%).

A single-center experience of kidney biopsies has suggested an observation period of 24 hours after biopsy. Specifically, in a review of 750 kidney biopsies performed in patients who were on bed rest for 23–24 hours after biopsy, a total of 98 (13%) complications were identified [7]. These complica-

tions occurred in 42% of the patients within 4 hours of biopsy, 67% within 8 hours of biopsy, and 89% within 24 hours of biopsy [7]. Others have found that a 6-hour period of observation is sufficient after kidney biopsy [10, 11]. In a review of 330 kidney biopsies, complications were no different in those treated as inpatients versus outpatients [11]. After 475 kidney biopsies, Jiang et al. [10] found that minor complications occurred at a mean of 2.5 hours after biopsy, and four of six major complications occurred within 4 hours of the biopsy; delayed major complications at 12 and 62 hours after biopsy were safely managed. In our experience, we have found the incidence of bleeding after biopsy of a kidney transplant to be quite low (possibly because of scarring, secondary tamponade effect, and occasional ability to compress the needle tract), so patients are observed for 2 hours after biopsy of a kidney transplant compared with 6 hours after biopsy of a native kidney.

In a recent review, pulmonary hemorrhage was found to occur in 4–27% of lung biopsies [12]. This incidence contrasts considerably with our incidence of 0.1% (Table 2). It is important to recognize how one defines a complication when reviewing complications; we adhered to a strict definition of the term "complication" using standardized guidelines. In fact, the same review by Winokur et al. [12] noted that 86% of pulmonary bleeding is only minor alveolar hemorrhage along the needle tract; these events were not considered as bleeding complications in our series because they do not meet the criteria for a CTCAE grade ≥ 3 complication.

In reviewing our experience, we found that delayed bleeding complications occurred more frequently than we had anticipated. These bleeding complications were most frequent in patients who had undergone kidney biopsy, in whom the overall risk of bleeding was greatest. Nearly half of the patients with delayed bleeding had been restarted on some sort of anticoagulation therapy. Regrettably, we are unaware of how many patients without a bleeding complication were taking anticoagulation therapy after biopsy, so characterization of a specific risk is not possible.

Management guidelines related to heparin therapy after invasive procedures have been published. In a review of periprocedural anticoagulation bridging with LMWH, Douketis et al. [13] proposed that therapeutic LMWH could be reinstituted the day after biopsy in patients who had undergone a "non–high-bleeding-risk procedure," as subjectively defined by the patient's care team. In patients who had undergone a "high-risk-bleeding procedure," LMWH bridging was not administered after the procedure. Baron et al. [14] suggest that bridging therapeutic heparin should be withheld for at least 48 hours after an invasive procedure, noting that organ biopsy constitutes a high-risk procedure. These same authors suggest that prophylactic anticoagulation therapy may be resumed "once hemostasis is secured." Suffice it to say, the time to reinitiate anticoagulation therapy needs to be based on the patient's thrombotic risk and risk of bleeding from the biopsy.

Patient education is important in recognizing important signs and symptoms of bleeding. As expected, we found that pain and manifestations of hemodynamic instability (e.g., syncope) were the most common clinical presentations of bleeding. Unfortunately, pain is a nonspecific symptom and is often associated with clinically insignificant bleeding. Nevertheless, pain after biopsy warrants evaluation for clinically important hemorrhage.

Hemodynamic instability may be associated with more nonspecific symptoms, occasionally presenting in a delayed fashion and validating the need for a companion to accompany the patient after biopsy. For example, the Patient Care Committee of the American Gastroenterological Association has proposed that the liver biopsy patient must stay within 30 minutes of the hospital in which the procedure was performed and be accompanied by a responsible adult the first night after the biopsy [15]. This recommendation seems appropriate for most patients after general invasive image-guided biopsy.

This study differs from our earlier review of biopsy complications [1] in that the focus of this study is on clinical presentation of bleeding after biopsy rather than on the incidence of bleeding events. This study also includes a larger and more contemporary cohort derived from our biopsy registry. As opposed to the earlier study, additional sources of patient events since 2008 were not available, and it is reasonable to suppose that some complications were overlooked in the current single review process. Thus, the more contemporary cohort and sources of data likely account for the small difference in overall bleeding incidence and mortality incidence between the two reports.

There are limitations to this study of bleeding complications. First, imaging findings independently precipitated the cascade of events leading to the diagnosis of a major bleeding complication in more than a quarter of our patients. This finding is particularly notable in that clinically insignificant bleeding frequently occurs after needle biopsy [16, 17]. Thus, one is required to make a full assessment of both patient and imaging factors. Second, we considered biopsies from multiple sites in the body, recognizing that some sites will be more prone to bleeding than others. Although general organ-specific bleeding complication rates are provided, we did not investigate more specific details of the biopsies; organ-specific studies, including risk factors, are currently in progress.

In conclusion, clinically important bleeding after percutaneous biopsy is exceedingly rare. Routine contact with the postbiopsy patient and chart review are valuable means of ensuring patient care and quality in a biopsy practice. Delayed bleeding complications, particularly after initiation of anticoagulation therapy, can occur, and appropriate clinical prudence and patient education about the recognition of these events are warranted to allow timely management.

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