

The Commonwealth of Massachusetts
Board of Registration in Medicine
Quality and Patient Safety Division

Interventional Radiology Complications

REVIEW OF INTERVENTIONAL RADIOLOGY COMPLICATIONS

Over the last several years, the Quality and Patient Safety Division (QPSD) has reviewed an increasing number of Safety and Quality Review (SQR) reports of serious complications associated with Interventional Radiology (IR) procedures. Some of the cases involved significant bleeding complications. This advisory is issued to draw providers' attention to this concern, to share some of the lessons learned by the reporting hospitals, and to support hospitals in the development of protocols, credentialing standards and other processes to ensure the safety of IR procedures. While some references are provided, this advisory does not include a comprehensive review of the literature; nor is it intended to provide specific recommendations for evidence-based practice.

These cases, serious unexpected complications of IR procedures, typically meet the QPSD's Type 4 Event criteria for reporting unexpected patient outcomes.

QPSD received seventy SQRs over the past several years that involved complications of IR procedures. Nineteen of these events resulted in patient death.

Twenty-seven of the SQRs (38.5%) were bleeding complications during or following the IR procedure. Of these reports, twelve reports involved bleeding complications following biopsy of the liver (7), kidney (2), lung (2) or breast (1). Common themes in these cases were: the presence of liver disease (hepatitis or cirrhosis); issues with anticoagulant/anti-platelet medications; or an absence of pre-procedure information regarding the patient's clotting status.

Fifteen of the bleeding complications involved disruption of a vessel or organ during the procedure, including three intracranial hemorrhages in patients on Alteplase and/or Heparin.

CASE STUDIES

Case One

A patient with hepatitis underwent a liver biopsy for evaluation of a hepatic mass. The patient complained of severe pain after the liver biopsy and the CT showed hemorrhage in the peri-hepatic region. An arteriogram did not identify the bleeding site, but the hepatic artery was embolized. The patient was transfused and a second angiogram was done several hours later that showed active bleeding from more distal vessels. The gastro-duodenal artery was embolized and the bleeding stopped.

Learning

It is vital that Interventional Radiologists and their staff are aware of patients' medical histories and work closely with referring physicians in monitoring patients before, during and after interventional procedures, including discussion of risk categorization and consideration of risk/benefit prior to the biopsy.^{1,2} Guidelines for obtaining INR, PTT and/or platelet levels prior to biopsy, particularly in patients with a history of liver disease, cancer and/or anti-coagulation or anti-platelet use, are essential, as is the need for INR parameters for cutoff and reversal.

Case Two

A patient was undergoing ultrasound guided renal biopsy when they complained of back pain and became bradycardic and hypotensive. A chest tube was placed for a hemothorax, and the patient underwent VATS (video-assisted thoracoscopic surgery) procedure and hematoma evacuation.

Learning

The needle tip was not well visualized during the biopsy; training of Renal Fellows was identified as an issue, including a discussion of approach in order to have the best visualization on ultrasound and the best outcome. The practice had been for the Renal Fellow to maneuver the biopsy needle, guided by the Renal and Radiology Attendings (ultrasound division), who were watching the ultrasound imaging and providing instruction. A new command set of “advance/stop/biopsy” and a revised “safety pause” were developed to include maximum needle depth.

PREVENTION STRATEGIES

Protocols

- IR procedural guidelines should promote the recognition of those patients at increased risk for bleeding complications by stressing the importance of effective communication between services and obtaining a thorough past medical history on **all** patients, including medication use. Recommendations for pre-procedure testing should be clear, and INR parameters for cutoff and reversal discussed.
- Guidelines for procedures on anticoagulated patients should address the following elements:
 - Clear, consistent (between services and providers) verbal and written patient instructions regarding anti-coagulation, anti-platelet or NSAID (non steroidal anti-inflammatory) use prior to procedure.
 - Whenever possible, surgery in a chronically anticoagulated patient should be done on an elective basis to allow for planned anticoagulant reversal, driven by the patient’s risk categorization and guided by best practice recommendations.³
 - Discontinuation of warfarin for percutaneous needle procedures (including organ biopsies) in non-compressible sites.³
 - For all patients receiving thrombolytics, monitoring of vital signs, including neuro signs, is recommended for 24 hours.
 - Vigilance for signs or symptoms of bleeding in patients at risk for retroperitoneal hematoma.
- Protocols should alert providers to any contraindications to the procedures. For example, the American College of Radiology and Society of Interventional Radiology guidelines indicate that two of the relative contraindications for percutaneous needle biopsy include significant coagulopathy that can’t be corrected and lack of a safe pathway to the lesion.⁴

Skill, Technique & Credentialing

- Physicians must perform a sufficient number of percutaneous needle biopsies to maintain their skills with acceptable success and complication rates. Continued competence should depend on participation in a quality improvement program that monitors these rates and utilizes indicator thresholds. When performance falls below a minimum threshold or complications exceed a maximum threshold, a review should be done.³
- Consider use of smaller biopsy needles in at-risk patients.⁴
- Prior to removal of trocar and insertion of biopsy needle, reconfirm the location of the tip to ensure that the needle is still in the correct location.
- If Physician Assistants are utilized, their credentialing, education, supervision and monitoring requirements should be similarly standardized and clearly stated, including whether credentialing includes the performance of high risk procedures.⁵

Additional Measures

- There should be a designated area for patient preparation prior to the IR procedure and observation post-procedure that has immediate access to emergency resuscitation, trained personnel and equipment.¹
- Consider having IR patients co-managed by anesthesia in the Operating Room and admitted to the Surgical Service; the Attending Interventional Radiologist should conduct a follow-up exam and write a discharge note prior to the patient leaving the Post Anesthesia Care Unit.
- Safe IR practice requires clear coverage and communication between providers and an on-call system for post-IR patients.

- The adoption by IR of standardized protocols and checklists such as those used in the OR (universal protocol) is strongly recommended.^{6,7}

RESOURCES

1. Morris A., “Bleeding Risks in Interventional Radiology,” *Radiologic Technology*, 81, (2010 July/Aug):6.
2. Malloy P. et al., “Consensus Guidelines for Periprocedural Management of Coagulation Status and Hemostasis Risk in Percutaneous Image-guided Interventions,” *J Vasc Interv Radiol*, 20 (2009): 240-209. Available at http://www.sirweb.org/clinical/cpg/Consensus_Guidelines_for_Periprocedural_Management_of_Coagulation_Malloy.pdf Accessed June 14, 2011.
3. “Warfarin Therapy – Management During Invasive Procedures and Surgery,” Oct 2010, Available at <http://guideline.gov/content.aspx?f=rss&id=24512> Accessed June 14, 2011.
4. Gupta S. et al., *Society of Interventional Radiology (SIR) Standards of Practice*, “Quality Improvement Guidelines for Percutaneous Needle Biopsy,” *J Vasc Interv Radiol*, 21(2010):969–975, Available at <http://www.sirweb.org/clinical/cpg/0810-5.pdf> Accessed June 14, 2011.
5. Rosenberg S. et al., “Position Statement: The Role of Physician Assistants in Interventional Radiology,” *J Vasc Interv Radiol*, 19 (2008): 1685-1689, Available at http://www.sirweb.org/clinical/cpg/JVIR_PA.pdf Accessed June 14, 2011.
6. “Applying the Universal Protocol to Improve Patient Safety in Radiology Services,” *Pennsylvania Patient Safety Advisory*, 8, 2 (June 2011):63-9.
7. “WHO surgical safety checklist: for radiological interventions only,” 2010, Available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=73612> Accessed June 14, 2011.