Proposal of a New Adverse Event Classification by the Society of Interventional Radiology Standards of Practice Committee

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ABSTRACT

Purpose: To develop a new adverse event (AE) classification for the interventional radiology (IR) procedures and evaluate its clinical, research, and educational value compared with the existing Society of Interventional Radiology (SIR) classification via an SIR member survey.

Materials and Methods: A new AE classification was developed by members of the Standards of Practice Committee of the SIR. Subsequently, a survey was created by a group of 18 members from the SIR Standards of Practice Committee and Service Lines. Twelve clinical AE case scenarios were generated that encompassed a broad spectrum of IR procedures and potential AEs. Survey questions were designed to evaluate the following domains: educational and research values, accountability for intraprocedural challenges, consistency of AE reporting, unambiguity, and potential for incorporation into existing quality-assurance framework. For each AE scenario, the survey participants were instructed to answer questions about the proposed and existing SIR classifications. SIR members were invited via online survey links, and 68 members participated among 140 surveyed. Answers on new and existing classifications were evaluated and compared statistically. Overall comparison between the two surveys was performed by generalized linear modeling.

Results: The proposed AE classification received superior evaluations in terms of consistency of reporting ($P < .05$) and potential for incorporation into existing quality-assurance framework ($P < .05$). Respondents gave a higher overall rating to the educational and research value of the new compared with the existing classification ($P < .05$).

Conclusions: This study proposed an AE classification system that outperformed the existing SIR classification in the studied domains.

ABBREVIATIONS

AE = adverse event, MSKCC = Memorial Sloan–Kettering Cancer Center, NSQIP = National Surgical Quality Improvement Program

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To measure the quality of care, several approaches and tools have been developed over a period of several decades (1). As a key component of the quality of care, procedural and surgical adverse events (AEs) have come under scrutiny (2). Several efforts have been made to create a valid and reliable system for classification of surgical and procedural AEs (3).

An optimal AE classification should have high accuracy, consistency, and practicality for clinical and research purposes. Most of the literature on AE classification regards surgical procedures. Although there is no universally accepted classification system, the most commonly used surgical classifications include the Clavien–Dindo classification (4,5), Memorial Sloan–Kettering Cancer Center (MSKCC) classification (6), Accordion classification (7), and National Surgical Quality Improvement Program (NSQIP) classification (8). In addition, there are classifications for AEs resulting from nonprocedural interventions, such as the National Cancer Institute Common Toxicity Criteria for cancer treatment (9).

Interventional radiology (IR) procedures are often distinguished from surgical procedures regarding invasiveness and types of AE. These differences have prompted the development of a unique IR classification of AEs. To that end, the Society of Interventional Radiology (SIR) developed its consensus-based classification between 1997 and 2003 (10–12). Although the current SIR classification has been widely used (**Table 1**) (12), its ability to provide additional differentiation of AE severity and less subjectivity in interpretation could be improved. For example, an AE "requiring therapy, [with] minor hospitalization (< 48 hours)" is classified in the same category ("major complication") as death. Although subcategories A/B and C–F provide more stratification, the accuracy of assigning severity or grade of an AE is limited. This lack of detail in reporting was illustrated by Degirmenci et al (13) in a comparison of a modified Clavien–Dindo classification versus the SIR classification for grading complications arising from ultrasound-guided percutaneous placement of nephrostomy tubes. The SIR classification underperformed compared with the modified Clavien–Dindo alternative as a result of a lack of detailed definitions and a resulting increased subjectivity in interpretation (13). In addition, moderate disagreement among interventional radiologists using only the SIR classification has been documented by Leoni et al (14).

A more detailed AE classification for IR procedures is needed to increase practicality for routine clinical use and precision for research applications. The purpose of the present study was to develop a new AE classification for IR procedures and evaluate its clinical, research, and educational value compared with the existing classification via an SIR member survey.

MATERIALS AND METHODS

Development of the New AE Classification System

A new classification (**Appendix A** [available online at *www.jvir.org*]) was proposed. This was developed through conference calls and email correspondence by a total of 18 members of the SIR Standards of Practice Committee between 2013 and 2015. The Clavien–Dindo (4,5), MSKCC (6), Accordion (7), NSQIP (8), and Common Terminology Criteria for Adverse Events (15) classifications, as well as the Office for Human Research Protections (16) and Food and Drug Administration (17) reporting guidelines, were used as resources to develop the new SIR AE classification. The following considerations were used to guide the classification development process: practicality of use of the AE classification; educational value; potential to improve quality, accuracy, and consistency; completeness of AE reporting; potential for incorporation into existing quality-assurance framework; comparability/compatibility with AE classification systems used by other medical specialties; and utility for scientific research.

Table 1. SIR Existing AE Classification (12)

Category/Class	Definition
Minor complications	
A	No therapy, no consequences
B	Nominal therapy, no consequence; includes overnight admission for observation only
Major complications	
C	Requires therapy, minor hospitalization (< 48 h)
D	Requires major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h)
E	Permanent adverse sequelae
F	Death

AE = adverse event.

Clinical Scenarios Evaluated

To evaluate the new AE classification system, 12 clinical case scenarios regarding AEs related to IR procedures were selected (**Appendix B** [available online at *www.jvir.org*]). The cases were selected to encompass a broad spectrum of procedural anatomy, IR techniques and complexity, as well as all levels of potential AE severity and preventability. Complexity levels of interventional procedures were based on number and cost of supplies used, the degree of technical skill and training required, procedural preparation, periprocedural and intraprocedural operator time commitment required, and postprocedural monitoring requirements (similar to stratifications previously established by the SIR Standards of Practice Committee) (18). Each scenario was selected from a pool of AE case scenarios previously drafted by senior SIR Standards of Practice Committee members (Curtis Bakal and David Sacks) as well as from additional ones proposed by 18 members of the SIR Standards of Practice Committee. Case selections and finalizations were made by committee consensus through conference calls. The case scenario topics were on AEs related to the following topics: tunneled hemodialysis catheter placement, excessive moderate sedation, inadvertent arterial placement of central venous catheter, review of patient allergies, pediatric interventional care, sepsis following nephrostomy tube placement, inferior vena cava filter retrieval, hemobilia after percutaneous biliary drainage, bronchial artery embolization, wire fracture creating a soft-tissue foreign body, intraprocedural cardiac arrest, and requirement of repeat biopsy (**Appendix B** [available online at *www.jvir.org*]).

Survey and Study Participants

A survey was developed via 15 conference calls by a group of 18 members of the SIR Standards of Practice Committee and Service Lines. A total of 140 SIR members were invited to complete the survey between October 2016 and March 2016 via online survey links, of whom 68 (49%) participated in the study. Each participant was instructed to classify the 12 AE clinical scenarios twice, once by using the existing classification and once by using the proposed classification, followed by completion of a questionnaire on each assessment (ie, 24 surveys; **Figs 1**, **2**). The survey comprised questions designed to evaluate the educational value, unambiguity, consistency of AE reporting, potential for incorporation into institution's quality-assurance framework, and utility for scientific research (**Appendix B** [available online at *www.jvir.org*]). The participants gave a rating of 1–5 for each question (1, strongly disagree; 3, neutral; 5, strongly agree).

Statistical Analysis

Statistical analysis was performed with R, version 2.13 (R Foundation for Statistical Computing, Vienna, Austria). Internal consistency (ie, interrater reliability) of the proposed and existing classifications was measured with the Cronbach α. The intraclass correlation coefficients between the existing and the proposed classification grades were calculated. Survey data for the proposed and existing classifications were compared by χ^2 analysis, McNemar test, or paired-sample *t* test as appropriate. Overall comparison between the two surveys was performed by using multivariate generalized linear modeling employing maximum-likelihood estimating methods.

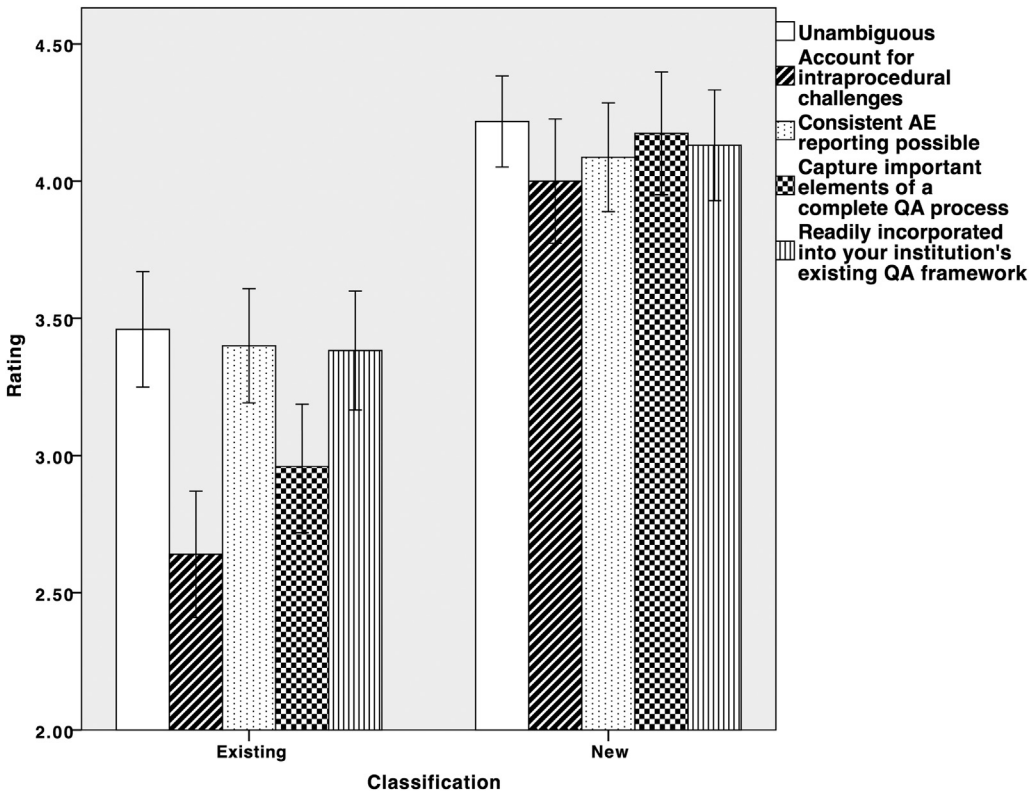

Figure 1. The average rating (range, 1–5) for the 12 AE case scenarios was significantly higher ($P < .05$ for each pairwise comparison) for the new classification compared with the existing classification in the 5 different domain questions listed: unambiguity, accounts for intraprocedural challenges, consistent AE reporting possible, capture of important elements of a complete quality-assurance process, and ready incorporation in an institution's existing quality-assurance framework. The bars represent mean, and the handles represent standard error of the mean. Note that the exact wording of questions used in the survey is provided.

P values $< .05$ were considered to indicate a statistically significant difference.

RESULTS

There was a good level of interobserver consistency for classification of the case scenarios based on the existing system (Cronbach $\alpha = 84\%$; $P < .01$) or the proposed AE classification system (Cronbach $\alpha = 85\%$; $P < .01$). There was an excellent intraclass correlation between the existing and the proposed classification grades ($r > 0.8$ and $P < .01$ for each of the 12 different case scenarios).

Respondents gave significantly higher ratings ($P < .05$) for the new classification compared with the existing classification in terms of unambiguity, consistency of reporting, ability to capture important elements of a complete quality-assurance process, and potential for incorporation into institutions' quality-assurance framework (**Fig 1**). Respondents also gave a higher rating to the questions related to educational and research value of the new classification compared with the existing classification (**Fig 2**). On multivariate analysis, the proposed classification outperformed the existing SIR classification in different domains (**Table 2**). In addition, taking together the effects of all the studied domains, the overall performance of the new classification system was superior to the existing classification (Wald $\chi^2 = 65.81$; $P < .01$).

DISCUSSION

In the present study, we proposed a new AE classification system, which received higher ratings in terms of clinical, research, and educational values compared with the existing classification. The typically minimally invasive approach and unique features of IR procedures in comparison with surgical procedures drive the need for an IR-specific AE grading classification system. However, the proposed AE classification is intended to be comparable with the surgical Clavien–Dindo scale (4,5) and the National Cancer Institute Common Terminology Criteria scale (9), such that similar AE severities resulting from IR or surgical procedures receive the same grade. By approximating the Clavien–Dindo classification for surgical AEs, the proposed AE classification may facilitate comparisons between related IR and surgical procedures. On the contrary, simply using the Clavien–Dindo classification itself would not be sufficiently specific for IR procedures. Indeed, even within surgical specialties, the classification is believed to be inadequate without modification (19).

Within the surgical literature, there are several classifications currently in use. The Clavien–Dindo classification (20) has five grades and two subgrades, and is based on the therapy used to mitigate the complication (**Table 3**) (4). The majority of other surgical classifications used are derived from the Clavien–Dindo system, presumably in view of its versatility and simplicity. The MSKCC classification was developed as a modification of the Clavien–Dindo classification specific to oncologic surgery (6,21). It incorporates five-tiered grading similar to the Clavien–Dindo classification, but focuses more on physiologic systems involved (**Table 4**) (7). The Accordion classification offers a contracted and expanded version with 4 or 6 grades (7), which are intended to be applicable and useful for small and large studies, respectively (**Tables 5**, **6**) (7). The NSQIP classification is a more complex classification developed in the Veterans Administration hospital system of the United States. It adjusts for patient preoperative risk and assesses for AEs (8,22).

The proposed AE classification system allows for greater detail than the existing approach. Additional detail on the severity of the AE is provided by using a 5-grade severity scale classification. For example, the existing classification would categorize a minor hospitalization (< 48 h) and a prolonged hospitalization (> 48 h) as major complications. The proposed classification would categorize the former as grade 1 or 2 ("mild"

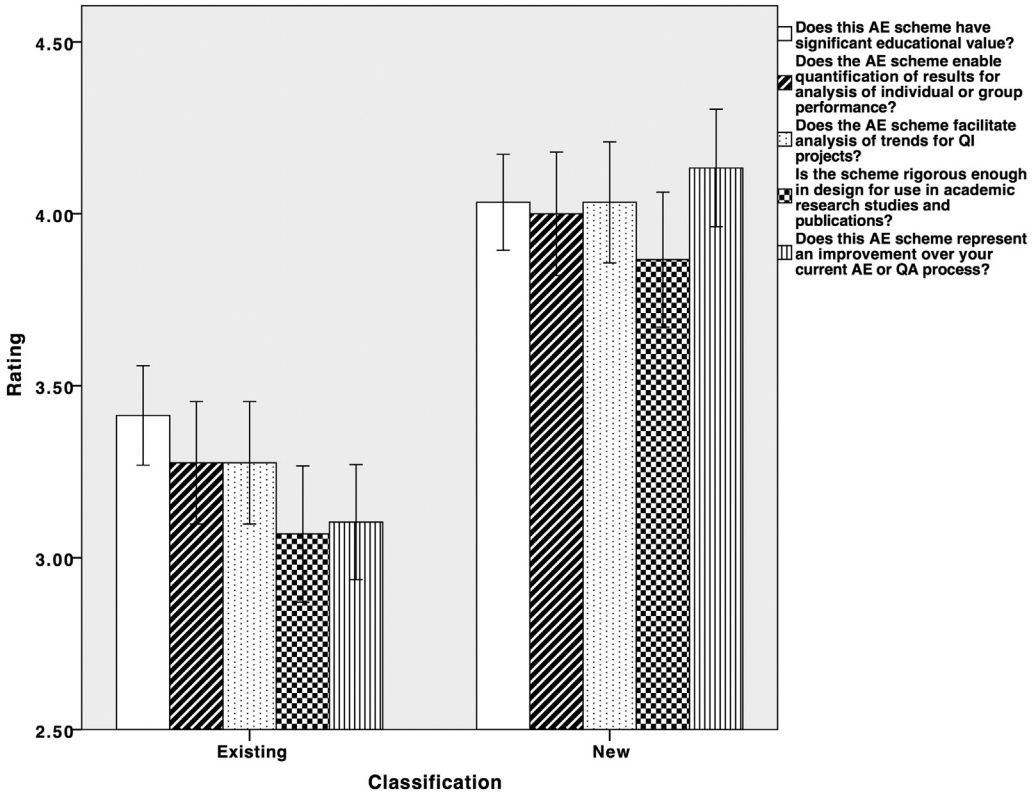

Figure 2. The average rating (range, 1–5) for the 12 AE case scenarios was significantly higher ($P < .05$ for each pairwise comparison) for the new classification compared with the existing classification in the 5 different domain questions related to educational/research value of the AE classification. The bars represent mean, and the handles represent standard error of the mean. Note that the exact wording of questions used in the survey is provided.

Table 2. Multivariate Analysis Comparing the Ratings on Different Domains for the Proposed versus Existing AE Classification

Domain	Wald χ^2	*P* Value
Unambiguity	23.19	< .01
Account for intraprocedural challenges	20.78	< .01
Consistent AE reporting possible	16.91	< .01
Capture important elements of a complete QA process	12.02	< .01
Readily incorporated into your institution's existing QA framework	6.29	.02
Does this AE scheme have significant educational value?	6.65	.02
Does the AE scheme enable quantification of results for analysis of individual or group performance?	5.99	.04
Does the AE scheme facilitate analysis of trends for QI projects?	9.87	< .01
Is the scheme rigorous enough in design for use in academic research studies and publications?	9.96	< .01
Does this AE scheme represent an improvement over your current AE or QA process?	14.45	< .01

The proposed classification outperformed ($P < .01$) the existing SIR classification in different domains.
Note–The exact wording of questions used in the survey is provided.
AE = adverse event; QA = quality assurance; QI = quality improvement.

or "moderate" AEs) and the latter as grade 2 or 3 ("moderate" or "severe" AEs) depending on the specifics of the case. The existing SIR system tends to "upgrade" some AEs that were not clinically severe into the "major" category. As another example, in the existing classification, an AE resulting in mitigating therapy and a resultant 2-day admission would be categorized as "major" complication, whereas the proposed classification would force authors to provide additional detail and categorize the AE as grade 2 or 3 in severity (moderate or severe AE). Although the current SIR AE classification does allow for subcategorization (minor as A or B; major as C–F), authors may simply choose to report minor versus major complications.

The proposed AE classification has two main parts: part A refers to AE description and severity characterization, and part B provides a more detailed analysis of the risk modifiers, causality, preventability, and management of the AEs. Part A could be used on a stand-alone basis to provide a short descriptive AE report within a practice. Nonetheless, part B is recommended to be used as a supplement to part A to provide a more detailed analysis of the AE. The modifiers (**Appendix A** [available online at *www.jvir.org*]) defined in the proposed classification system—although they may add complexity—are intended to provide a framework for quality-improvement programs by assessing key issues of probable causality, preprocedural risk, preventability, and complication management. Patient comorbidities and other preprocedural factors can have a large impact on outcomes. The risk modifiers help account for these factors. The analysis scoring may also allow for intra- and interinstitutional comparisons. The

Table 3. Clavien–Dindo Complication Classification (4)

Grade	Definition
Grade I	Any deviation from normal postoperative course without need for pharmacologic treatment or surgical, endoscopic, and radiologic interventions
Grade II	Allowed therapeutic regimens are drugs as antiemetic, antipyretic, analgesic, diuretic agents, electrolytes, and physiotherapy; this grade also includes wound infections opened at bedside
Grade III	Requiring surgical, endoscopic, or radiologic intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications*) requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix "d"	If a patient experiences a complication at time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication; this label indicates the need for follow-up to fully evaluate complication

CNS = central nervous system; IC = intermediate care; ICU = intensive care unit.
*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.

Table 4. Memorial Sloan–Kettering Cancer Center Complication Classification (7)

Grade	Definition
1	Complications with no intervention or minor interventions such as oral antibiotic treatment, bowel rest, or basic monitoring
2	Complications are those requiring moderate interventions such as intravenous medications (eg, antibiotic or antiarrhythmic drugs), total parenteral nutrition, prolonged tube feeding, or chest tube insertion
3	Complications requiring hospital readmission, surgical intervention, or radiologic intervention
4	Complications producing chronic disability, organ resection, or enteral diversion
5	Complications resulting in death

Clavien–Dindo system and the current SIR system do not include a structured analysis component (20). It would be a task for future research to evaluate the added value of including part B in the new classification at the expense of adding to time and details.

Compared with the old classification that mainly focuses on safe patient preparation and procedure performance, the new classification includes all AEs occurring within 30 days of a procedure, regardless of the causality. This recognizes the understanding that the interventional radiologist's responsibility extends to the immediate follow-up after the procedure, as is understood in surgery (23).

Table 5. Contracted Accordion Complication Classification (7)

Grade	Definition
1	Mild complication; requires only minor invasive procedures that can be done at the bedside such as insertion of intravenous catheters, urinary catheters, and nasogastric tubes, and drainage of wound infections; physiotherapy and the following drugs are allowed: antiemetic, antipyretic, analgesic, diuretic agents, electrolytes, and physiotherapy
2	Moderate complication; requires pharmacologic treatment with drugs other than such allowed for minor complications, such as antibiotic therapy; blood transfusions and total parenteral nutrition also included
3	Severe complication; all complications requiring endoscopic or interventional radiologic procedures or repeat operation as well as complications resulting in failure of one or more organ systems
4	Death; postoperative death

Table 6. Expanded Accordion Complication Classification (7)

Grade	Definition
1	Mild complication; requires only minor invasive procedures that can be done at the bedside such as insertion of intravenous catheters, urinary catheters, and nasogastric tubes, and drainage of wound infections; physiotherapy and the following drugs are allowed: antiemetic, antipyretic, analgesic, diuretic agents, electrolytes, and physiotherapy
2	Moderate complication; requires pharmacologic treatment with drugs other than such allowed for minor complications, such as antibiotic therapy; blood transfusions and total parenteral nutrition also included
3	Severe complication; invasive procedure without general anesthesia; requires management by an endoscopic, interventional procedure, or repeat operation without general anesthesia
4	Severe complication; operation under general anesthesia; requires management by an operation under general anesthesia
5	Severe complication; organ system failure
6	Death

Any AE classification system adopted as a standard should ideally be validated. The Clavien–Dindo classification has been validated by multiple studies across several surgical subspecialties (4,13,19). Similar validation has been performed for the other major classifications in use (24,25). Initial validation has been performed for the proposed classification in the present study; however, additional studies are recommended before widespread use.

The present study has some limitations. As with any survey study, there is potential for respondent bias, a cognitive bias whereby respondents' answers are different from what the answers should be considering the facts and circumstances of reporting. Survey participation rate is a potential source of selection bias. The response rate of the current study (68/140, or approximately 50%) is considered good to excellent for a long e-mail

survey with 12 case scenarios and more than 100 questions (26). In the present study, we surveyed performance of the proposed and existing AE classification systems across 12 different hypothetical case scenarios considered representative of the spectrum of IR clinical case scenarios. Future studies are necessary to evaluate the performance and consistency of the proposed classification system in comparison with the existing system for evaluation of the AEs related to different real-world IR case scenarios and procedures.In conclusion, the present study proposed and evaluated a new AE classification for IR, with a comparison versus the current SIR AE classification. The proposed AE classification performed better than the existing SIR classification in the domains evaluated.

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APPENDIX A. ADVERSE EVENT CLASSIFICATION

The classification system has two parts (A and B). Part A refers to adverse event (AE) description and severity characterization. It is suitable for scientific use (eg, presentations, publications), as well as for AE reviews within a practice, practice group, facility, or specialty.

Part B pertains to AE analysis. It is designed to enable a confidential and constructive review of any AE within an interventional radiology (IR) practice. Applicability of part B for scientific publications is limited, and there is none for other public use. The part B is meant to provide a strictly confidential, legally nondiscoverable, nonpunitive, objective, consistent, and clinically constructive analytic guide that may result in quality-improvement in IR.

Part A: Adverse Event Description

A. Description narrative of adverse event (AE; including sedation and anesthesia).

B. AE severity assessment*: escalation of level of care.

1. Mild AE: No therapy or nominal (nonsubstantial) therapy (post-procedural imaging performed and fails to show manifestation of AE); near miss (eg, wrong site of patient prepared, recognized and corrected before procedure, wrong patient information entered for procedure);
2. Moderate AE: moderate escalation of care, requiring substantial treatment, eg, intervention (description of intervention and result of intervention) under conscious sedation, blood product administration, extremely prolonged outpatient observation, or overnight admission after outpatient procedure not typical for the procedure (excludes admission or hospital days unrelated to AE);
3. Severe AE: marked escalation of care, ie, hospital admission or prolongation of existing hospital admission for $>$ 24 hours, hospital admission that is atypical for the procedure, inpatient transfer from regular floor/telemetry to intensive care unit, or complex intervention performed requiring general anesthesia in previously nonintubated patient (generally excludes pediatrics or in circumstances in which general anesthesia would primarily be used in lieu of conscious sedation, eg, in mentally challenged or severely uncooperative patients);
4. Life-threatening or disabling event: eg, cardiopulmonary arrest, shock, organ failure, unanticipated dialysis, paralysis, loss of limb or organ;
5. Patient death or unexpected pregnancy abortion.

The Society of Interventional Radiology (SIR) AE Severity Scale is intended to approximate the surgical Clavien–Dindo scale and the National Cancer Institute Common Terminology Criteria for Adverse Events scale. The SIR scale is tailored toward the procedures and AEs encountered in IR practices. The grading of interventional oncology AEs can selectively incorporate relevant AE grading definitions published in the current Common Terminology Criteria for Adverse Events for oncologic interventions, which may be particularly relevant in the context of research publications. All AEs occurring within 30 days of a procedure should be included in the AE description and analysis, regardless of causality, in the interest of objectivity. The AE scale itself does not assess operator performance.

Note: A marker of "M" is used to indicate multiple AEs, each of which is counted and evaluated separately if possible.

Part B: AE Analysis

A. Causality

Category 1: AE not caused by the procedure.

Category 2: Unknown whether AE was caused by the procedure.

Category 3: AE caused by the procedure.

B. Patient and procedural risk modifier

Category 1: High-risk patient and technically challenging procedure.

Category 2: High-risk patient (eg, American Society of Anesthesiologists [ASA] status 4, uncorrectable coagulopathy, poor functional status [Eastern Cooperative Oncology Group performance status of 3/4], polypharmacy/polyintravenous therapy and transfusion, septicemia, hemodynamic instability, recent catastrophic event/intensive care unit admission/major surgery or interventions) or low-risk patient and technically challenging procedure (eg, transjugular intrahepatic portosystemic shunt with occluded portal vein, percutaneous biliary drain placement in nondilated biliary system).

Category 3: No modifier.

C. AE preventability

Category 1: Rarely preventable, ie, well-described and "typical" for the procedure and occurring despite adequate precautionary and preventive measures.

Category 2: Potentially preventable.

Category 3: Consistently preventable, eg, inappropriateness of procedural indication (may use checklist; see below).

D. AE management

Category 1: Most operators would have handled the AE similarly.

Category 2: Some operators would have handled the AE differently.

Category 3: Most operators would have handled the AE differently.

Examples of Consistently Preventable Event.

- Wrong patient
- Absolute contraindication for procedure
- Wrong side for procedure
- Wrong procedure
- Wrong medication/contrast agent/blood product (dose/administration route)
- Exposure to known allergens
- Intraarterial placement of catheter meant to be intravenous or nonvenous placement of inferior vena cava filter
- Failure to follow up or communicate laboratory, pathology, or radiology results
- Use of known malfunctioning equipment or patient monitoring system
- Lack or inappropriate use of monitoring equipment during sedation

APPENDIX B. CLINICAL CASE SCENARIOS

Tunneled Hemodialysis Catheter Placement

A 58-year-old hemodialysis-dependent patient with end-stage renal disease is referred for tunneled hemodialysis catheter placement. He is classified as ASA status 3 because of a history of stroke, known coronary artery disease, and a cardiac ejection fraction of 15%. A tunneled hemodialysis catheter is inserted from a right internal jugular approach, with the catheter tip terminating at the lower superior vena cava. After placing the catheter, the operator does not aspirate and flush the catheter to assess the flow rate and attempt to determine its adequacy for performance of hemodialysis. During the patient's dialysis session the next day, the catheter flow rates are poor. The dialysis staff is told to reverse the lumens for performance of hemodialysis, and the dialysis session is continued but abbreviated. The patient returns the next day for catheter exchange with a serum potassium level of 5.5 mg/dL and pulmonary edema. During the catheter exchange, the patient experiences a fatal arrhythmia. No code is called and no resuscitation is attempted, as patient is classified as do not resuscitate/do not intubate.

Excessive Moderate Sedation

An 89-year-old woman with numerous comorbidities that include diabetes mellitus, coronary artery disease, peripheral arterial disease, and a left ventricular ejection fraction of 25% was classified as ASA status 3. During attempted percutaneous transhepatic cholangiography, apnea develops after

she receives 2 mg of midazolam and 75 μg of fentanyl. Her peripheral oxygen saturation decreases to 50% for several minutes before bag mask ventilation is initiated. Although she receives naloxone to reverse the effects of the narcotic drugs, a disabling stroke occurs as a result of the apneic event.

Arterially Placed Peripherally Inserted Central Catheter

An extreme low-birth-weight neonate is brought to the IR service for peripherally inserted central catheter (PICC) placement. She is intubated, ventilated, and managed by the neonatal intensive care team. Detailed informed parental consent is obtained. A right-arm tourniquet is applied to provide venous distension of the < 1-mm veins, and ultrasound-guided vascular access is obtained in an upper right arm vessel that is assumed to be the right basilic vein. Under fluoroscopy, it is noted that the course of the guide wire is slightly medial at the mediastinal level, but is otherwise unremarkable, and a 1.9-F PICC is then successfully introduced and placed. On completion of the procedure, a small contrast medium injection shows arterial flow and opacification of the aorta, indicating that an arterial rather than a venous catheter had been placed. The PICC is immediately removed. The limb subsequently becomes ischemic, despite conservative measures of anticoagulation and nitroglycerin paste. After several days of progressively worsening ischemia, an upper-limb amputation is required. Eventually, the infant dies from sequelae of her prematurity, unrelated to the vascular event.

Review of Patient Allergies

A 50-year-old woman with known heparin-induced thrombocytopenia and end-stage renal disease undergoes elective placement of a hemodialysis catheter without preprocedural review of her medication allergies. The procedure is uncomplicated, but both lumens of the catheter are locked with 1,000 U/mL of heparin. This goes unrecognized until a floor nurse accidently flushes the intraluminal heparin into the systemic circulation. The patient sustains a platelet count decrease of 50% versus baseline count, and iliac-vein deep vein thrombosis (DVT) subsequently develops after 3 days. She is treated for the condition and administered systemic anticoagulation with a direct thrombin inhibitor.

Pediatric AE Scenario

An 8-year-old girl presents with fever and malaise following a bone marrow transplant. Computed tomography (CT) reveals a 3-cm mass in the posterior left lower lobe with central cavitation and surrounding vessels. The lesion is believed likely to be infectious, and a diagnostic biopsy of this lesion by the interventional radiology service is requested to determine whether the lesion is bacterial or fungal in origin and plan appropriate treatment. Although the patient has leukocytosis and compromised renal function with an estimated glomerular filtration rate of 35 mL/min/1.73 m^2, her serum electrolyte levels, coagulation parameters, and platelet count are normal. The patient is intubated with a standard endotracheal tube and placed in prone position for CT-guided percutaneous needle biopsy. During biopsy with an 18-gauge needle, blood suddenly pours from the endotracheal tube after the second pass. Despite aggressive suctioning, the patient's oxygen saturation rapidly decreases to 65%. She is turned to the supine position for emergency placement of a double-lumen endotracheal tube. However, attempts to place the tube are unsuccessful because of massive hemoptysis, and therefore significant bleeding continues, with spillage into the contralateral lung. Eventually the patient's condition is sufficiently stabilized for transfer to the intensive care unit, where resuscitation continues. However, 2 days later, the patient dies of multiorgan failure. The biopsy specimen reveals hyphae and angioinvasive *Aspergillus*.

Sepsis after Nephrostomy Tube Placement

A 56-year-old man with bladder cancer invading the right ureterovesicular junction and causing severe hydronephrosis undergoes elective placement of a nephrostomy tube as an outpatient. Preprocedural prophylactic antibiotic therapy with cefazolin is administered 1 hour before the procedure. During the percutaneous nephrostomy procedure, a diagnostic nephroureterogram is also obtained for more detailed evaluation of the distal ureteral obstruction. The urine sample obtained at the time of the nephrostomy is cloudy and is sent for Gram stain and culture. Approximately 4 hours after the procedure, fever develops (100.6°F), accompanied by chills. Gram stain demonstrates abundant Gram-negative bacteria. The patient is admitted, and broad-spectrum intravenous antibiotic agents are administered, which are later tailored according to the laboratory culture and sensitivity results. Defervescence is observed, and the patient is discharged home 48 hours later with an appropriate oral antibiotic regimen.

Inferior Vena Cava Filter Retrieval

A 46-year-old healthy woman presents with 2 days of acute left leg swelling. Ultrasonography reveals an iliofemoral DVT. Results of a complete blood count are normal, and the International Normalized Ratio is 0.9. There are no contraindications to thrombolysis. Catheter-directed thrombolysis is initiated after prophylactic inferior vena cava (IVC) filter placement. After 48 hours of thrombolysis, the DVT resolves in the femoral and iliac veins. May–Thurner compression of the left common iliac vein is diagnosed on completion venography, and a 14-mm × 60-mm self-expanding stent is placed, with good angiographic results. The patient is discharged by the medical team with a prescription for warfarin, with no follow-up instructions or appointments with interventional radiology regarding filter retrieval. She presents 24 months later describing right lower-back pain. A CT angiogram shows that multiple struts of the IVC filter have penetrated the IVC and extend beyond the lumen. One of the wire struts has penetrated the aorta and another has penetrated the psoas muscle. The filter is successfully removed percutaneously, but the patient experiences worsening pain following removal. Another CT scan is obtained, which shows a small retroperitoneal hematoma surrounding the IVC where the filter had been located. She is admitted for observation, but is discharged the following day because she has experienced significant improvement in her pain. No further treatment is necessary.

Hemobilia after Percutaneous Biliary Drainage

A 47-year-old man with known pancreatic cancer and a previous Whipple procedure presents with biliary ductal dilation and jaundice. The patient is afebrile and, other than an elevated bilirubin level, the preprocedural laboratory data are normal. The patient undergoes successful placement of an internal/external biliary drainage catheter from a right-sided percutaneous transhepatic approach. After an overnight admission, the patient is discharged with the drain in place and connected to a drainage bag. Over the next several days, he has persistent daily passage of a large number of clots into the drainage bag, and returns after 1 week for injection of the drainage catheter, which shows satisfactory drainage into the bowel and no obvious abnormality. He returns home with the drain in place, but continues to experience daily passage of clots for a further 1 week. He returns to the hospital, where he undergoes hepatic angiography, which demonstrates an 8-mm-diameter pseudoaneurysm immediately adjacent to the drainage catheter. The pseudoaneurysm arises from a branch of the right hepatic artery, which is successfully treated with transcatheter coil embolization, with resultant cessation of hemobilia.

Bronchial Artery Embolization

A 25-year-old woman with cystic fibrosis experiences massive hemoptysis and is referred for bronchial artery embolization. Bronchoscopy before angiography shows hemorrhage emanating from the lower lobe of her right lung. A right bronchial artery embolization is performed, which also includes embolization of the right T6–T9 intercostal arteries. Four hours after the procedure, she is found to have bilateral lower-extremity paraplegia with bowel and bladder incontinence. A retrospective review of the intraprocedural angiograms shows opacification of a spinal artery arising from the right T7 intercostal artery. She is transferred to a rehabilitation facility, where she recovers bowel and bladder function, but her lower-extremity paraplegia never improves.

Foreign Body

The tip of a 0.018-inch micropuncture guide wire is sheared off during an attempted jugular puncture in a fairly healthy 56-year-old patient classified as ASA status 2. The guide-wire fragment cannot easily be removed, so it is left in the soft tissues of the neck. The patient is discharged home with no further intervention or medication. The patient returns 3 days later to the emergency department with an infected hematoma at the puncture site. The guide-wire fragment and hematoma are evacuated surgically. Hypotension and bradycardia develop during surgery, requiring intubation. A stroke causing left-sided hemiparesis is noted after the patient is extubated.

Cardiac Arrest

A hemodialysis-dependent patient with longstanding chronic kidney disease presents for image-guided placement of a new tunneled hemodialysis catheter. The previously placed catheter had been removed 2 days earlier because of catheter-related infection, and the patient had last undergone dialysis just before catheter removal. Before starting the catheter placement, blood is sent for complete blood count, coagulation parameters, and serum potassium measurement. However, because all of these laboratory values had been acceptable during the most recent dialysis, it is elected to start the procedure before the results are available. Moderate sedation is provided. During introduction of the hemodialysis catheter, sudden cardiac arrest occurred, which is successfully treated through activation of the code team. The serum potassium level is subsequently found to be 7.2 mEq/L.

Repeat Biopsy

A biopsy of enlarged cervical lymph nodes is performed under general anesthesia in a 10-year-old child. Samples are obtained by using a 20-gauge Chiba needle and a 20-gauge cutting needle. Cytopathology is present at the time of biopsy. Samples are also submitted for bacteriologic culture, but these samples are subsequently lost. A second biopsy is therefore required, and this eventually is positive for a fungal infection.

Survey Links

Example of survey links for the case scenario "Tunneled Hemodialysis Catheter Placement" are as follows: Existing classification (*https://www.surveymonkey.com/r/CZ33JFC*); new classification (*https://www.surveymonkey.com/r/C5KLV9Q*).