STANDARDS OF PRACTICE

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.