Evaluation of Fluoroscopic Cases Qualifying as Potential Fluoroscopic Sentinel Events

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Rationale and Objectives: To address the risk of radiation injury during interventional procedures, the Joint Commission has defined prolonged fluoroscopy resulting in a cumulative skin dose of 15 Gy or more to a single field as a reviewable sentinel event. The goal of this work is to present a system for identifying potential fluoroscopic sentinel events (FSE) and describing common case characteristics.

Materials and Methods: Criteria based on fluoroscopic time (FT) > 150 minutes and reference air kerma (RAK) > 6 Gy were used to identify potential sentinel events. Case information including procedure type, number of procedures, and radiation dose parameters was recorded. Peak skin dose (PSD) was calculated by a medical physicist. Values were compared between procedure types and the relationship between FT, RAK, and PSD was evaluated.

Results: Between 2008 and 2011, 183 events exceeding the investigation criteria were identified in three interventional categories: cardiology (54%), neuroradiology (31%), and vascular (16%). The average number of procedures/patient was 1.7 ± 0.1, with the majority (59.6%) having undergone only one procedure. Most cases could be identified using the RAK criterion alone (96.7%). Based on the PSD/RAK ratio, a threshold RAK of 7.5 Gy would effectively identify all cases that would exceed 15 Gy in PSD.

Conclusion: Radiation delivered during interventional cases can place patients at risk of cutaneous radiation injury and potential sentinel events. Using appropriate thresholds to determine which cases require detailed investigation allows efficient utilization of department resources for identifying sentinel events.

Key Words: Sentinel event; radiation overdose; fluoroscopic time; reference air kerma; peak skin dose.

As interventional procedures in surgery, cardiology, and radiology have become more prevalent, the risk of radiation-related injuries has become a substantial concern. Prolonged use of radiation during fluoroscopically guided interventional (FGI) procedures can subject patients to a large dose and place them at risk for radiation injury (1). Effects of high doses of radiation to the skin can range from mild transient erythema to severe necrosis requiring surgical intervention (2).

To facilitate awareness of radiation overexposure and drive process improvements to enhance patient safety, in 2005 the Joint Commission created a reviewable sentinel event that applied to fluoroscopic procedures. The fluoroscopic sentinel event (FSE) was defined as prolonged fluoroscopy resulting in a cumulative skin dose of 15 Gy or more to a single field. According to guidance from the Joint Commission, this dose may be accumulated either during a single procedure or multiple procedures over 6 months to a year (3). When a sentinel event occurs, a root cause analysis must be performed to address underlying systems issues that can improve patient safety.

Although a number of publications have addressed which fluoroscopic procedures are likely to result in a high peak skin dose (PSD) (4,5), little published information has directly addressed FSEs. Initial publications in the area have focused on guidance for monitoring sentinel events, including setting criteria for identifying potential cases (6–10). This article describes a system for identifying and investigating high radiation exposure cases. Additionally, it provides a retrospective review of high-dose cases identified using this system, providing insight into common characteristics of potential FSEs. These findings provide a framework for identifying potential FSEs based on dose indicators available during the procedure.

MATERIALS AND METHODS

Systematically Monitoring for Potential Sentinel Events

To properly identify sentinel events, a system must be used to identify potential high-dose cases. Although the Joint Commission does not explicitly indicate that fluoroscopic cases must be maintained in a database (3), accurate recording of cases is necessary to identify potential sentinel events. The

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goal of an identification mechanism is to identify all cases that may have surpassed the 15-Gy limit. To achieve this high sensitivity, investigations should be triggered by stricter threshold criteria. Using previously published information as a guide (7–9), criteria of 6 Gy of reference air kerma (RAK) and 150 minutes of fluoroscopic time (FT) total over a 6-month period were established. When these criteria were exceeded, a peak skin dose (PSD) calculation was performed by a medical physicist. According to Joint Commission guidelines, if cumulative PSD exceeds 15 Gy, a root cause analysis is necessary. A schematic summarizing this process for identifying potential FSEs is shown in Figure 1.

Data Collection

Data were collected at a large public hospital, a university hospital, and a specialty neurologic hospital. All cases that exceeded the identification criteria between 2008 and July 2011 were recorded in a database of high-dose cases. Recorded information included the following: department in which the procedure was performed; type of procedure performed; whether the case had been identified based on FT, RAK, or both; FT and RAK for all procedures performed; and total number of procedures on each patient. In some cases, not all information was available. Specific circumstances of the cases were qualitatively assessed through review of the electronic medical record regarding the procedure.

Calculating Patient PSD

PSD estimates were performed by a medical physicist. The RAK meter accuracy on each fluoroscopy unit was verified at least annually using a calibrated dosimetry system. For each identified case, PSD was estimated based on information stored in DICOM image tags, structured reports, and procedure notes. RAK attributed to each angiographic run was either taken directly from system data or was calculated from technique factors, beam filtration, and measurements of radiation output. Although the total RAK associated with the fluoroscopy was known, the details of its delivery were not. The RAK attributed to the fluoroscopy was distributed proportionately between the known angiographic runs. Using this combined fluoroscopic and angiographic RAK, air kerma maps corresponding to the surface of a patient lying on the table pad were calculated using customized software written in IDL (Excelis Visual Information Systems, Boulder, CO) that corrected for inverse square law distance-scaling, beam collimation, and tube angulation. Backscatter factor, air-to-tissue dose conversion, and table/pad attenuation corrections were applied to the air kerma map to estimate PSD.

Group Comparison and Statistical Analysis

Initial inspection of cases determined that they could be grouped into cardiology, neuroradiology, and vascular interventional categories. Case characteristics were compared between groups

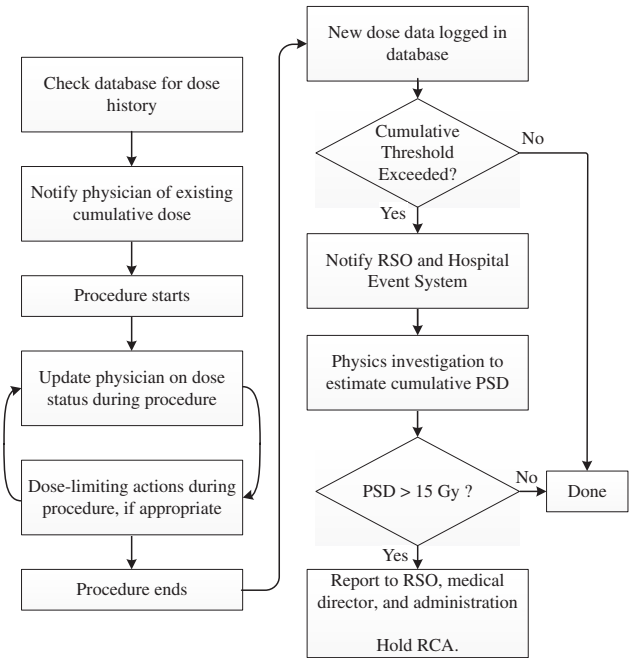

Figure 1. Schematic describing the system implemented for tracking and identifying potential sentinel events. RCA, root cause analysis; RSO, radiation safety officer.

using a *t*-test with a level of significance, α, of 0.05. Bonferroni correction was used whenever multiple comparisons were necessary. Mean values and 95% confidence intervals were obtained. The relationship between FT, RAK, and PSD was further evaluated using PSD/FT and PSD/RAK ratios after segregation by procedure category. If either cumulative FT or RAK values were not available for a patient, the case was excluded only from that specific portion of the analysis.

RESULTS

Number and Type of Cases Identified

In the period included in the study, 183 high radiation dose cases qualifying as potential sentinel events were identified. Complete data for all cases were present in 81.4% of recorded cases, with one or more FT or RAK measurements missing from the remainder of cases (13.1% and 5.5%, respectively). The average total FT and RAK were 105 $\pm$ 40 minutes and 8.9 $\pm$ 1.2 Gy. The average physicist-calculated PSD was 8.6 $\pm$ 1.5 Gy.

Cases fell into three primary categories: cardiologic, neuroradiologic, and vascular interventional, which are detailed in Table 1. The most common subgroup was cardiac angioplasty and stenting, which constituted 44.8% of all cases. These cases were frequently the most complex cardiac procedures, which involved occlusion or severe stenosis of a single vessel, multivessel disease, or unexpected events in the interventional suite. Neuroradiology cases, including embolization of cerebral aneurysms, arteriovenous malformations, carotid-cavernous fistulas, and other arteriovenous fistulas also constituted a large number of