Original Studies

Reporting of Radiation Exposure in Contemporary Interventional Cardiology Trials

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Objectives: To determine reporting of radiation exposure in contemporary interventional cardiology randomized trials published in leading journals. Background: Interventional cardiology procedures are a significant source of ionizing radiation, which can have detrimental effects on both patients and medical personnel. Methods: The EuroIntervention 2010 supplement served as a source of randomized trials in interventional cardiology published in scientific literature from 2000 to 2010. Results: Of all the trials in the supplement, 204 represented original research and were examined for reporting of radiation dose and fluoroscopy times. Only eight trials (3.92%) reported either radiation exposure or fluoroscopy time, covering 16,563 patients (4.55% of the total patient population of 363,727). All of these trials were published after 2006. The average fluoroscopy time reported in seven trials was 13.6 min and the mean radiation dose reported in three trials was 58.67 Gy cm². Conclusions: Radiation exposure is not consistently reported in contemporary interventional cardiology trials. Even when reporting occurs, trials may not report detailed data such as radiation dose, radiation exposure time, or fluoroscopy time. Although reporting of radiation exposure has not been a requirement in research studies, efforts by professional societies and regulatory authorities toward standardized reporting should aid clinicians in making a more informed decision on specific interventional procedures and devices. © 2012 Wiley-Liss, Inc.

Key words: ionizing radiation; interventional cardiology; radiation exposure

INTRODUCTION

The medical use of radiation is the largest and a growing man-made source of radiation exposure to patients, through diagnostic, interventional, and therapeutic procedures [1]. Deterministic effects of radiation occur if the radiation dose is substantial in one event, such as in an accident, and would result in a large number of cell death [1] and can result in skin injury or radiation burns to a patient. Cancer and hereditary effects could result from low levels that affect as few as one cell, thus with increasing doses of exposure or number of exposure events, the probability of these effects increases [1]. Ionizing radiation in the cardiac catheter laboratory is a potential source of these effects on a patient population.

Interventional cardiology procedures can result in patients being exposed to significant amounts of ionizing radiation [2–7], and ionizing radiation exposure has been linked to adverse outcomes, such as solid organ cancers including breast, thyroid, bone, and liver, and leukemia (except for chronic lymphocytic leukemia) [1,3]. With repeated imaging and interventional procedures, patients exposed to cumulative radiation exposure through a lifetime may have deleterious effects. Both interventional cardiology procedures and cardiac diagnostic imaging can result in radiation doses that vary widely among procedure and imaging techniques [3,4].

With differences in how much radiation a patient may be exposed to during a procedure or imaging modality, radiation exposure to patients who undergo...
multiple rounds of interventional cardiology can become significant over time. Exposure of health professionals to ionizing radiation has been discussed in previous studies [8,9]. At present time, the most common means to accurately assess the amount of radiation patients are exposed for each trial to report an exposure time or calculated dose of radiation received [10].

There are no contemporary standards or mandates on reporting of radiation dose in interventional cardiology trials. Structured reporting of radiation exposure has not been a requirement of interventional cardiology research studies. Importantly, recent trials have demonstrated that different vascular access approaches and different techniques may result in varying radiation doses and exposures [10–12]. The present review study was performed to determine whether standardization exists in radiation dose reporting among interventional cardiology trials published in leading scientific journals and to provide recommendations and establish a framework for future clinical trials.

METHODS

EuroIntervention is the official journal of EuroPCR and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). The 10th edition of the EuroIntervention supplement was selected as it represents a contemporary collection of leading clinical trials in interventional cardiology selected by experts in this field [13]. Articles in this supplement included randomized trials in interventional cardiology published in: New England Journal of Medicine, The Journal of the American Medical Association, Lancet, European Heart Journal, American Heart Journal, Circulation, American Journal of Cardiology, Annals Internal Medicine, and The Journal of the American College of Cardiology between 2000 and 2010, with only one trial published in 1996.

There were 254 articles included in the supplement. Since 28 articles were follow-up reports of previously published studies already included in the supplement, and 22 articles were not original research or clinical trials but rather meta-analyses of several randomized trials, those articles were excluded. For the final analyses, 204 published articles representing clinical trials or observational studies with original pools of 363,727 patients were selected. Categories of trials included in the supplement involved drug-eluting stents, percutaneous coronary intervention (PCI) for ST elevation myocardial infarction, revascularization strategy comparing PCI versus coronary artery bypass grafting, early invasive versus early conservative strategy for acute coronary syndromes, medical therapy versus PCI, stem cell therapy after PCI, prevention of thrombotic complications, PCI in diabetic patients, and PCI in bypass grafts. None of the trials examined the impact of radiation as a clinical endpoint.

RESULTS

Of the 204 studies, eight reported radiation exposure to patients. These studies either reported fluoroscopy time or calculated the amount of radiation patients were exposed during the study. This represented 3.92% of the studies examined. The eight studies that reported fluoroscopy time or radiation exposure included 16,563 patients, representing 4.55% of all patients included in the 204 trials. The characteristics of the eight trials which reported radiation exposure or fluoroscopy time are summarized in Table I.

The eight trials that reported patient radiation dose exposure or fluoroscopy times were published in five of the nine journals the EuroIntervention supplement covered. The journals American Heart Journal, American Journal of Cardiology, The Lancet, and Annals Internal Medicine were the four journals that did not have any research trial that reported radiation exposure data. The publication dates of these eight trials were all after October 31, 2006.

There were seven trials that reported fluoroscopy time [14–20] with an average of 13.59 min among all trials (range, 3.5–86.67). Average fluoroscopy times for each patient group in these trials are summarized in Fig. 1. There were three trials that reported a calculated radiation dose [14,19,21] with a mean dose of 58.67 Gy cm² (range, 10.1–117.2). Average doses for each patient group in these trials are summarized in Fig. 2. Only two studies reported both indicators—fluoroscopy time and radiation dose [14,19].

DISCUSSION

Our study demonstrates that in our sample of 204 randomized trials published from 1996 to 2010, only a small percentage (3.92% of the studies) had some form of radiation exposure reported. As a result, only 16,563 (4.55%) of 363,727 patients had a documented amount of radiation they had been exposed to through interventional cardiology procedures and cardiac imaging techniques. There was no standard form of reporting, since some of the data were presented as radiation dose, radiation exposure time, or fluoroscopy time. All trials that reported radiation dosing or fluoroscopy time were published in 2006 and later, which suggests increased recognition and appropriately directed reporting efforts. Nonetheless, with such a small percentage of trials reporting radiation dose, such trends inadequately address patient safety using ionizing radiation. These
TABLE I. Interventional Cardiology Trials Reporting Radiation Dose or Fluoroscopy Time

<table>
<thead>
<tr>
<th>Authors</th>
<th>Publication year</th>
<th>Journal</th>
<th>Patient size</th>
<th>Reporting dose or time of radiation exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galloe et al. [14]</td>
<td>2008</td>
<td><em>JAMA</em></td>
<td>2,098</td>
<td>Radiation dose: 60 (range, 33–103 Gy/cm²) for Sirolimus-eluting stent; 61 (range, 35–106 Gy/cm²) for Paclitaxel-eluting stent; Radiation exposure time: 6.5 (range, 3.5–10.8 min) for Sirolimus-eluting stent; 6.5 (range, 3.7–12.1 min) for Paclitaxel-eluting stent</td>
</tr>
<tr>
<td>Jensen et al. [15]</td>
<td>2007</td>
<td><em>JACC</em></td>
<td>12,395</td>
<td>Fluoroscopy time: 7.3 (range 4.2–12.4 min) for bare metal stents; 8.2 (range 5.0–14.1 min) for drug-eluting stents</td>
</tr>
<tr>
<td>Sviolaas et al. [16]</td>
<td>2008</td>
<td><em>NEJM</em></td>
<td>1,071</td>
<td>Fluoroscopy time: 7 min (interquartile range, 4.5–9.5 min)</td>
</tr>
<tr>
<td>Brilakis et al. [17]</td>
<td>2009</td>
<td><em>JACC</em></td>
<td>80</td>
<td>Fluoroscopy time: 20 ± 9 min for bare metal stent; 21 ± 11 min for Paclitaxel-eluting stent</td>
</tr>
<tr>
<td>Steigen et al. [18]</td>
<td>2006</td>
<td><em>Circulation</em></td>
<td>413</td>
<td>Fluoroscopy time: 15 ± 9 min for main vessel stenting only; 21 ± 10 min for main vessel and side branch</td>
</tr>
<tr>
<td>Ferenc et al. [19]</td>
<td>2008</td>
<td><em>European Heart Journal</em></td>
<td>202</td>
<td>Fluoroscopy time: 13 ± 7 min provisional t-stenting; 15 ± 9 min routine t-stenting; Radiation exposure: 41.2 ± 23.2 Gy/cm² for provisional t-stenting; 47.7 ± 37.6 Gy/cm² for routine t-stenting</td>
</tr>
<tr>
<td>Lee et al. [20]</td>
<td>2006</td>
<td><em>European Heart Journal</em></td>
<td>62</td>
<td>Median fluoroscopy time: 1,166 sec (319–5200 sec) for adenosine group; 1,402 sec (530–4420 sec) for standard group</td>
</tr>
<tr>
<td>Hoole et al. [21]</td>
<td>2009</td>
<td><em>Circulation</em></td>
<td>242</td>
<td>Radiation dose: 69.4 (SD, 41.9 Gy/cm²) for control group; 72.7 (44.5 Gy/cm²) for remote ischemic preconditioning group</td>
</tr>
</tbody>
</table>


**Fig. 1.** Interventional cardiology trials reporting fluoroscopy time. Seven trials reported fluoroscopy time by control group and experimental group, and values were reported in minutes. Shown here are average times reported by each trial, with average times ranging from 6.5 to 23.4 min.

**Fig. 2.** Interventional cardiology trials reporting radiation exposure. Three trials reported radiation exposure by control group and experimental group, and values were reported in Gy cm². Shown here are average doses reported by each trial, with these average doses ranging from 41.2 to 72.7 Gy cm².
findings illustrate a concerning lack of conformity in standardized ionizing radiation reporting in clinical literature and lack of consistency among clinical trials that expose patients to radiation.

The adverse effects of use of ionizing radiation in the health care field have not gone unnoticed. Exposure to radiation is receiving increasing attention as an important potential risk of all interventional procedures; however, it is under-reported for several reasons, including confusion and lack of standardization on which is the best measure to report. The major public media have become aware of the consequences of these procedures when not tightly regulated, with one example being the article “The Radiation Boom” published in The New York Times on July 31, 2010. Legislative bodies and science organizations have become started paying special attention to this issue and have recognized that uncontrolled use may result in adverse patient outcomes. The State of California recently introduced legislation in response to excessive radiation exposure to patients. This law mandates radiation exposure doses be recorded on patient records and for procedures utilizing ionizing radiation. Similarly, the National Institutes of Health (NIH) have also mandated that radiation-producing scanners employed at NIH clinics record radiation doses patients are exposed to and document it into an electronic medical record [22]. Although such initiatives are needed, a limitation of this mandate is that it only affects vendors of NIH clinics [22].

The Society of Cardiovascular Angiography and Interventions (SCAI) endorses that complex PCI and electrophysiology procedures have increased the average procedural radiation dose [23]. Recommendations from the SCAI acknowledge the increase of radiation exposure to patients and offer a practical approach to assist cardiac catheterization laboratories in establishing a radiation safety program [23]. From clinician and investigator standpoint, failure to limit and record this information in a consistent fashion may not offer optimal medical care.

Conformity in reporting of radiation used during interventional cardiology trials would assist clinicians in two main categories: weighing the risks and benefits of a procedure among the available options, and reducing patient and operator exposure to radiation. Interventional cardiology trials frequently compare different techniques, which may result in different radiation exposure, such as vascular access site comparison [11] or different bifurcation stenting strategies [12]. Present lack of a consistent form of reporting along with lack of widely accepted standards may be detrimental to patients as radiation exposure is expected to increase with more complex cardiology procedures being performed. We propose including radiation dose as a clinical outcome and examining radiation dose differences between various interventional devices and techniques as a clinical endpoint. To reliably track the amount of radiation during cardiology procedures, development of a standardized reporting system for clinical trials would help clinicians make a more informed decision on procedure choice and minimize patient radiation exposure. Inclusion of standardized radiation exposure reporting in leading journals and the peer review process would facilitate inclusion of this information in future research publications.

Published studies have used fluoroscopy time, dose area product and air kerma as measures of procedure-related radiation exposure. Fluoroscopy time may not accurately describe the radiation delivered as some procedures may use less cineangiography that results in higher overall dose. Dose area product measurements are dependent on operators’ use of coning. Hence, some authors have advocated use of air kerma [10]. Similarly, the relationship of patients’ weight, gender, and age on resulting radiation exposure is not included in the published literature.

This study has several limitations. We used the Euro-Intervention supplement, because it included interventional cardiology randomized trials published in the last 10 years in high-impact factor journals, with clinically most relevant studies reporting principal developments in interventional cardiology. The trials included in the supplement, though, cannot be considered to be all-inclusive or exhaustive of all trials published during this period. These trials serve to represent an example of what interventional cardiology research was performed during the last 10 years. Despite this, these publications were important enough to be singled out in this supplement and selected for inclusion by experts in interventional cardiology, representing the most significant interventional cardiology trials of the last decade.

In summary, ionizing radiation exposure is under-recorded among interventional cardiology trials. Legislation to record radiation exposure to patients has recently been introduced [22], while contemporary published research studies do not consistently report radiation exposure or report without a standardized system. Organizations such as the SCAI recognize the increase of radiation exposure to patients in the cardiac catheter laboratory [23]. Conformity in radiation dose reporting would allow clinicians to better evaluate the merit of one procedure over another by considering the radiation involved.

REFERENCES


