Journal of the American College of Cardiology
© 2006 by the American College of Cardiology Foundation
Published by Elsevier Inc.
Vol. 48, No. 7, 2006
ISSN 0735-1097/06/$32.00
doi:10.1016/j.jacc.2006.06.051

Variability in Fluoroscopic X-Ray Exposure in Contemporary Cardiac Catheterization Laboratories

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OBJECTIVES This study sought to assess fluoroscopic exposure rates in contemporary cardiac catheterization laboratories (CCL).

BACKGROUND Increasing attention is being focused on X-ray exposure during diagnostic and therapeutic cardiovascular procedures.

METHODS We measured fluoroscopic exposure rates (R/min) in 41 systems using a standardized methodology (National Electrical Manufacturers Association XR21 phantom). Measurements were obtained at 2 different phantom thicknesses to simulate varying patient body habitus.

RESULTS Fluoroscopic exposure rates under medium (median 3.0 R/min, interquartile range 1.4 R/min) and large (median 12.5 R/min, interquartile range 4.8 R/min) habitus conditions showed substantial variation. Fluoroscopic exposure was associated with simulated patient habitus, X-ray system type, vendor, and geographic region. Under medium habitus conditions, only 25% of systems operated within a zone of lower than average exposure rates and satisfactory image quality; this frequency diminished to 7% under large habitus conditions ($p < 0.001$).

CONCLUSIONS There is substantial variation (4- to 6-fold) in fluoroscopic exposure rates. This variation was not consistently associated with improved image quality. In the absence of a predictable benefit of higher (or lower) than average exposure rates, CCL quality improvement programs must minimize such potentially harmful variability in X-ray exposure. (J Am Coll Cardiol 2006;48:1361–4) © 2006 by the American College of Cardiology Foundation

The X-ray exposure levels in the cardiac catheterization laboratory (CCL) are consistently among the highest encountered in medical imaging (1). Although patient-, procedural- and operator-specific factors contribute to X-ray exposure in the CCL (2,3), the X-ray generating system itself plays a fundamental role in determining radiation exposure in the CCL (4). A general operating principle in all CCLs is to keep exposure to patients and staff as low as reasonably achievable (ALARA) to maintain optimal image quality (5).

Given the explosive growth in diagnostic and therapeutic cardiovascular procedures, image quality and radiation exposure are critical parameters that mandate periodic re-evaluation (6,7). To date, these efforts have been hampered by a lack of standardization of measurement conditions and the absence of an acceptable measurement tool. The purpose of the present study was to analyze fluoroscopic exposure in a sample of CCLs using a recently developed standardized technique.

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Manuscript received March 28, 2006; revised manuscript received May 25, 2006, accepted June 6, 2006.

METHODS

Twenty high-volume CCL facilities (41 individual X-ray systems) voluntarily requested a vendor-independent assessment of image quality. All testing was performed from May 2002 to September 2005 by a vendor-independent testing service (Clarte Imaging Solutions, Inc., Elk Grove, California). These 41 systems (25 with image intensifier detectors and 16 with flat panel detectors) were composed of equal numbers of academic- and community-based institutions across the U.S. The systems ranged in age from 2 to 18 years.

National Electrical Manufactures Association (NEMA) XR 21 phantom. The development of the NEMA fluoroscopic phantom and its implementation represent the conjoined efforts of multiple X-ray vendors, radiation physicists, and experienced clinicians (8,9). Consensus among the developers of the phantom allowed for thicknesses of 20 cm and 30 cm of Plexiglas to approximate the X-ray absorption characteristics of medium and heavy adult body habitus, respectively.

Examinations were performed by a trained, certified technologist not affiliated with the requesting institution in

Abbreviations and Acronyms

ALARA = as low as reasonably achievable
CCL = cardiac catheterization laboratory
IQR = interquartile range
lp = line pair
NEMA = National Electrical Manufacturers Association

accordance with the SCAI (Society for Cardiovascular Surgery and Interventions)/NEMA protocol (9). The outputs of the test determinations were entered into a confidential proprietary database. Vendor and facility identification remained anonymous.

The X-ray exposure rate (R/min) was measured at a standardized position 25 mm in front of the entrance surface to the phantom using an ionization chamber dosimeter (model 2025, RadCal Corporation, Monrovia, California). Exposure rates were assessed with the X-ray system functioning under the usual working conditions for that laboratory (e.g., automatic brightness control, pulsed fluoroscopy, temporal and spatial filtering, etc). All determinations were performed in the 6- to 7-inch magnification mode for image intensifier systems or comparable degrees of magnification for flat detector systems.

Risk-benefit analysis. Fluoroscopic exposure rate (a measure of risk) and line pair (lp) resolution (lp/mm, a measure of image quality, or benefit) were plotted in the X-Y plane for each system. Using median exposure rate and a line pair resolution of 2.2 lp/mm (average value for this magnification mode) as cut points, the bivariate scattergram could be divided into discrete quadrants. Thus, under medium patient habitus simulation, Quadrant I includes those systems with exposure rates <3.0 R/min and spatial resolution >2.2 lp/mm. Quadrant II includes those systems with exposure rates >3.0 R/min and spatial resolution >2.2 lp/mm. Quadrant III includes those systems with exposure rates >3.0 R/min and spatial resolution <2.2 lp/mm. Quadrant IV includes those systems with exposure rates <3.0 R/min and spatial resolution <2.2 lp/mm.

Statistical analysis. Dosimetric data are summarized as medians and interquartile (25th to 75th) ranges (IQR). Exposure rates under medium versus large habitus conditions and flat panel versus image intensifier systems were compared with rank sum statistics. Analysis of variance was used to assess the influence of system age, type (image intensifier vs. flat panel), vendor, and geographic location on exposure rate. Contingency table analysis for matched pairs was used in the analysis of the proportion of facilities in each quadrant of the risk-benefit plane. All analyses were performed using Statview version 5.0 (SAS Institute Inc., Cary, North Carolina). A p value < 0.05 was considered statistically significant.

RESULTS

Fluoroscopic radiation exposure. Exposure rates under simulated medium habitus patient conditions ranged from <1 R/min to 6.5 R/min, with a median exposure of 3.0 R/min (IQR 1.4 R/min). Twenty-five percent of systems had fluoroscopic exposure rates >3.7 R/min, whereas 25% had exposure rates ≤2.3 R/min (Fig. 1A).

Exposure rates under simulated large habitus conditions ranged from 4.4 R/min to 16.1 R/min, with a median exposure of 12.5 R/min (IQR 4.8 R/min). These rates significantly exceeded those under medium habitus patient conditions ($p < 0.001$). Twenty-five percent of systems had fluoroscopic exposure rates >14.0 R/min under large habitus conditions (Fig. 1B).

Sources of variability in fluoroscopic exposure rate. Under medium habitus patient conditions, there was no association between fluoroscopic exposure rate and the type of detector or age of the system. There was a significant association between exposure rate and geographic locale ($p = 0.01$) and a non-statistically significant association between exposure rate and system vendor ($p = 0.14$).

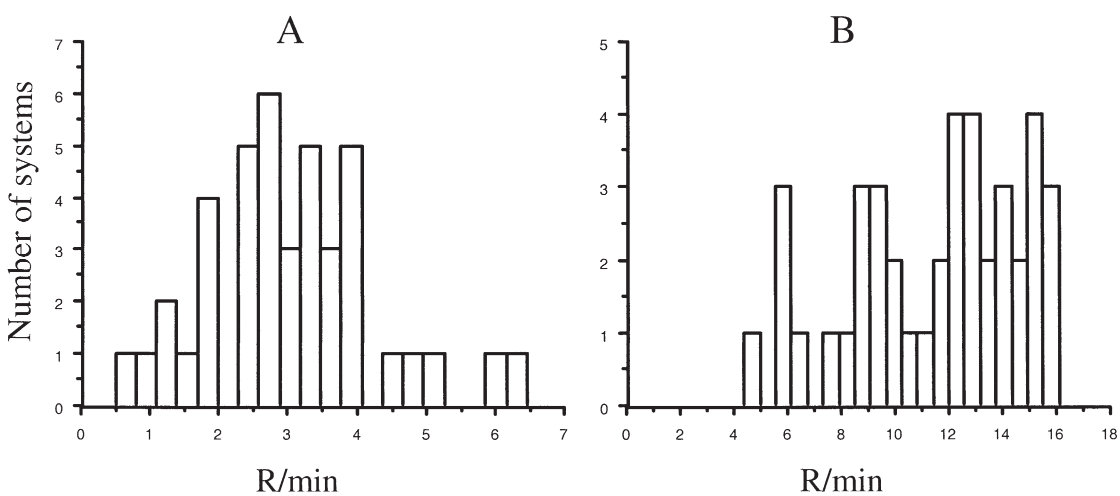

Figure 1. **(A)** Histogram of fluoroscopic exposure rates (R/min) under simulated medium habitus patient conditions (20-cm Plexiglas). **(B)** Histogram of fluoroscopic exposure rates (R/min) under simulated large habitus patient conditions (30-cm Plexiglas).

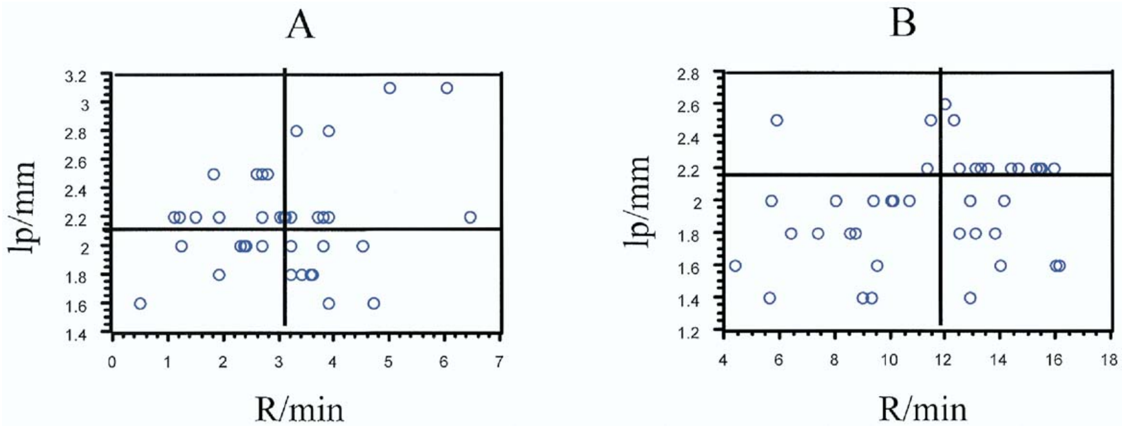

Figure 2. **(A)** The relationship between exposure rate (R/min) and spatial resolution (line pair [lp]/mm) under simulated medium patient habitus conditions. The **dark vertical and horizontal lines** define the median and average exposure rate and spatial resolution, respectively. The X-ray systems in Quadrant III are exposing patients to excessive radiation with inferior image quality, whereas systems in Quadrant I are obtaining improved image quality at lesser exposures. **(B)** The relationship between exposure rate and spatial resolution under simulated large patient habitus conditions. To facilitate comparison with Figure 2A, the dark vertical line defines the median exposure rate under these latter conditions, and the dark horizontal line corresponds to an average spatial resolution of 2.2 lp/mm. The risk-benefit ratio is altered compared with that in Figure 2A, with more X-ray systems operating at higher exposures and inferior image quality.

Exposure rates under large habitus conditions were greater for flat panel detectors than for traditional image intensifiers (median values 13.8 and 9.5, respectively; $p < 0.001$). Under large habitus conditions, there was a non-statistically significant association between the system age ($p = 0.17$) and geographic locale ($p = 0.08$) and a significant association with vendor ($p = 0.02$).

Risk-benefit considerations and ALARA. Under medium habitus conditions, there were 10 systems (25%) with satisfactory image quality obtained at low exposure rates (Quadrant I) (Fig. 2A). In contrast, there were 9 systems (22%) with poor image quality obtained at higher exposure rates (Quadrant III) (Fig. 2A). The remaining systems were distributed between those with superior image quality, albeit at higher exposure rates (Quadrant II, n = 10) or those with inferior image quality and below average exposure rates (Quadrant IV, n = 7).

This risk-benefit analysis is dramatically affected under large habitus patient conditions (Fig. 2B). The number of optimal systems (Quadrant I) decreased to 3 (compared with Fig. 2A), whereas the number of suboptimal systems (Quadrant III) remained at 10. There, are, however, more systems in Quadrants II and IV reflecting conditions of either satisfactory image quality at higher exposure rates or poor image quality at lower exposure rates ($p < 0.\ 01$ for comparison with medium habitus). Overall, the fraction of systems in Quadrant II and III (exposure in excess of need) represents a frequency of deviation from the ALARA principle of 46% under medium habitus patient conditions and 59% under large habitus patient conditions ($p = 0.01$).

DISCUSSION

There was significant variation in fluoroscopic exposure rates among 41 contemporary CCL systems tested under unbiased, standardized conditions. Such variability, in addition to being of concern with respect to quality improvement processes (10), resulted in frequent departures from the ALARA principle. At identical levels of spatial resolution, fluoroscopic exposure rates varied over 6-fold under medium patient habitus conditions. Moreover, exposure rates were significantly higher under large habitus conditions.

A prior survey of exposure rates among 62 independent fluoroscopic systems also noted substantial variation of exposure rates under identical measurement conditions (11). No similar multifacility studies have been performed in CCLs, in large part because of a lack of agreement concerning standardization of the data collection process. The virtue of the NEMA phantom lies in its industry acceptance, its standardized application, and the ability to load the X-ray system (simulate changes in body habitus) to provide clinically meaningful data. This also serves to explain the frequency of exposure rates greater than the federal regulatory limit of 10 R/min (12). The latter is assessed with the measurement probe in free air at a fixed geometry. The NEMA standard measures phantom (patient) entrance exposure at a standardized position in front of the phantom and accounts for higher readings than those measured in free air (backscatter from the phantom now contributes to the total exposure). This is consistent with the higher exposure rates noted with the 30-cm phantom because the latter results in greater backscatter.

Interpretation of X-ray exposure data must be undertaken with an awareness of the many factors that determine overall radiation exposure during fluoroscopic procedures. Among these factors are patient habitus, operator technique, procedural complexity (13–15), and the X-ray system itself (16). In a study of this limited nature we could not identify, or quantify, the many system-specific sources of variation in exposure rates. Among the latter are details regarding system calibration, pattern of use, preventive maintenance schedules, and so on. Differences in frame, or pulse, rates will result in different exposure rates when expressed in R/min. However, our findings and conclusions remained unchanged when the exposure data were analyzed on a per frame/pulse basis. Differences in kVp and mA, not controlled for under these "real-life" conditions, likely reflect vendor-specific system calibrations and vendor-specific beam filtration techniques. Thus, it is not surprising that vendor and geographic locale were associated with exposure (the latter can be viewed as a surrogate for vendor service).

Finally, these data suggest that in contemporary CCLs there are frequent deviations from the ALARA principle—a fundamental tenet of radiation safety—that has direct implications for patient and personnel exposure (17). Given the increasing concern regarding patient exposures during diagnostic and interventional fluoroscopic procedures (3,13,18), these data support renewed attention to overall system performance, including exposure rates, as part of ongoing quality improvement efforts in CCLs.

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