Reducing radiation exposure in an electrophysiology lab with introduction of newer fluoroscopic technology

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Abstract

The use of fluoroscopic devices exposes patients and operators to harmful effects of ionizing radiation in an electrophysiology (EP) lab. We sought to know if the newer fluoroscopic technology (Allura Clarity) installed in a hybrid EP helps to reduce prescribed radiation dose. We performed radiation dose analysis of 90 patients who underwent various procedures in the EP lab at a community teaching hospital after the introduction of newer fluoroscopic technology in June of 2016.Watchman device insertion, radiofrequency ablation procedures, permanent pacemaker (PPM)/implantable cardioverter defibrillator (ICD) placement and battery changes were included in the study to compare radiation exposure during different procedures performed commonly in an EP lab. In all cases of watchman device placement, radiofrequency ablation procedures, PPM/ICD placement and battery changes, there was a statistically significant difference (<0.05) in radiation dose exposure. Significant reduction in radiation exposure during various procedures performed in an EP lab was achieved with aid of newer fluoroscopic technology and better image detection technology.

Introduction

Many minimally invasive image-guided therapies have replaced highly invasive surgical procedures in the current healthcare scenario. Discharging patients on the same day as their procedure has become priority in number of surgical procedures in the United States. This trend is evident in various cardiology interventions as well mainly due to advent of catheter-based treatments instead of open vascular procedures.[1] Newer fluoroscopy techniques have helped to facilitate these complex catheter-based procedures. They have also helped to address issues of radiation exposure in both patient and medical staff in an EP/cardiac catheterization lab.

Materials and Methods

We performed radiation dose analysis of 90 patients who underwent various procedures in the EP lab at a community hospital before and after the introduction of newer fluoroscopic technology (Allura Clarity), in June of 2016.Watchman device insertion, ablation procedures and permanent pacemaker (PPM)/implantable cardioverter defibrillator (ICD) placement and battery changes were the procedures included in the study to compare radiation exposure during different procedures performed commonly in an EP lab. All of the patients had their procedure done between 04/2016 and 09/2016 in the EP lab at our hospital. This provided us an opportunity to compare radiation exposure 3 months prior to the installation of newer fluoroscopic technology (Allura Clarity) with 3 months after the installation. The statistical results have been presented as median with interquartile and total range. All the doses were expressed as cumulative air kerma (CAK). Non-parametric test was used to calculate P-value and it was considered significant if <0.05. To avoid inter-operator variability we collected data from patients of a single operator. As the radiation emission was not constant, the amount of radiation emitted per minute of the procedure time was not calculated and instead total average time has been presented.

Salient features of the new electrophysiology lab at our institution

In our newly made hybrid EP suite, novel-imaging technology (Allura Clarity) was utilized. Use of unique Clarity IQ software helped achieve excellent visibility at a low x-ray dose in patients of all sizes. We were encouraged to use Allura Clarity based on results of previously published studies which had shown 43% dose reduction in various EP procedures with aid of ClarityIQ technology compared to Allura Xper system.[2,3] In the new EP lab, transition from biplane to ceiling-mounted monoplane screens with a large detector was made. LED surgical lighting and three-dimensional visualization systems were installed for better procedural image quality and guidance. Image quality has been improved through the use of smaller spot sizes generated by flat emitters, shorter pulses, and automatic real-time motion compensation in subtraction imaging. Clarity IQ has been found to allow longer procedures to be performed with better image quality even in obese and high risk patient while the reduction in scattered radiation has been found to reduce radiation risk in EP/cardiac catheterization lab.[4] Flexible digital imaging pipeline for quicker processing of images, motion compensation feature to reduce image blurring on dynamic cardiac anatomy and spatial filtering to highlight structures and reduce the impact of background noise are some unique features that were not present in the conventional lab we had.

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Results

Radiation comparison during watchman insertion

Total 9 cases of watchman device placement were analyzed. Most common indication for watchman placement was: i) atrial fibrillation (AF) with recurrent gastrointestinal (GI) bleed with symptomatic anemia (5 cases); ii) AF with recurrent mechanical falls (2 cases); iii) AF with history of intracranial bleeding (2 cases). Out of total 9 cases, 6 Watchman procedures were performed in the new EP lab with a median radiation of 48.5 mGy (interquartile range: 174 mGy, total range: 19 to 252 mGy). Average fluoroscopic time for watchman insertion in new EP lab was 21.36 minutes. In comparison, the median radiation in 3 cases of Watchman done with the conventional fluoroscopic device was 871.4 mGy (interquartile range: 154.8, total range: 794 to 948.8) (P-value 0.01). Average fluoroscopic time for watchman in old EP lab was 23.4 minutes.

Radiation comparison during radiofrequency catheter ablation procedures

Thirty-five cases of all radiofrequency catheter ablation procedures were studied including those performed in old and new EP lab. Number of all ablation procedures done in conventional EP lab was 21. This included 10 cases of AF ablation with pulmonary vein isolation, 3 cases of AF ablation with re-isolation of pulmonary veins, 3 cases of supraventricular tachycardia (SVT) ablation, 3 cases of Atrial flutter ablation, 1 case of ventricular tachycardia (VT) ablation and 1 case of AF ablation with ICD interrogation. Number of all ablation procedures done in new EP lab was 14. Out of these, there were 3 cases of AF ablation with pulmonary vein isolation, 7 cases of AF ablation with re-isolation of pulmonary veins, 3 cases of VT ablation and 1 case of SVT ablation. Median radiation exposure for all ablation procedures in Old EP lab was 2003.7 m Gy (interquartile range: 1815.5, total range: 325 to 6681 mGy) while the median radiation exposure for all ablation procedures performed in new EP lab was 102 mGy (interquartile range: 58, total range: 30-548 mGy), P-value=0.00001 (Table 1). The wide variation in average VT and SVT ablation between old and new EP lab was contributed by difficulty in certain individual cases.

Atrial flutter ablation in old lab took 14.77 mins (average flouroscopic time). AF ablation with ICD interrogation in old lab took 47.5 mins (average fluoroscopic time). There were no similar procedures in new EP lab in our data collection to make a head-to-head comparison.

Radiation exposure during permanent pacemaker/implantable cardioverter defibrillator placement and battery changes

Total 46 cases of PPM/ICD placement and their battery changes were studied. Number of ICD generator change in old EP lab was 3 while in new EP lab was 5. New cases of dual chamber ICD pulse generator and leads placement were 2 apiece in old and new EP lab. There were 2 cases of new single chamber ICD pulse generator insertion in old EP lab while there was no new single chamber ICD pulse generator implanted in new EP lab during the study duration.

PPM generator change in old EP lab was done in 4 cases while it was done in 8 cases in new lab. 6 patients had their new dual chamber PPM placed in old *versus* 12 patients in new lab. There were 1 case each of new single chamber PPM placement and new dual chamber PPM placement and cardioversion in new lab but we did not have similar procedures in old lab.

The median radiation during PPM/ICD placement and battery changes in new lab was 4 mGy (interquartile range: 8.9, total range; 0.1-2208) while the median radiation in Old lab was 87.1 (interquartile range: 207.6, total range: 1-972), P-value=0.0001.

The average fluoroscopic time for new dual chamber ICD and new dual chamber PPM in old lab were 37.2 and 6.1 minutes respectively while those in new lab were 10.9 and 6.08 respectively.

Discussion

While fluoroscopy remains a valuable diagnostic tool, greater radiation exposure during medical imaging increases cancer risk.[5] Radiation disrupts DNA and enhances cellular breakdown via free radical injury. Although most radiation-induced damage in a human cell is rapidly repaired, any misrepair can lead to point mutations, chromosome translocations, and gene fusions that are linked to cancer induction.[6] The professional lifetime cancer risk is around 1 in 100 for the operators, and the recent reports have suggested that there is an excess risk of brain tumours among interventional cardiologists.[7] Radiation induced damage to human tissue can occur at any level of radiation exposure, but the likelihood increasing as the dose increases. Generally the duration between radiation exposure and cancer diagnosis is at least 5 years but it could be decades as well.[8] Radiation exposure is a concern for patients and medical staffs in an EP/cardiac catheterization lab too. With emergence of radiofrequency ablation as a potential treatment option for more complex arrhythmias including AF and VT, there has been a growth in number of such procedures performed worldwide.[9,10] ICD and PPM placement have been the standard of care for relevant indications for a long time now. Apart from this, placement of left atrial appendage closure devices (*e.g.*, Watchman) is becoming the standard of care in patients with atrial fibrillation who are not candi-

Figure 1. View of the newer fluoroscopic devices and better monitors in the electrophysiology lab at Easton Hospital.

Table 1. Radiation comparison during various procedures performed in New and Old electrophysiology lab.

	Median radiation (mGy)	Interquartile range	Total range	P-value
Watchman insertion				
New Lab	48.5	174	19-252	0.01
Old Lab	154.8	154.8	794-948.8	
Ablation procedures				
New Lab	102	58	30-548	0.0001
Old Lab	2003.7	1815.5	325-6681	
PPM/ICD placement and battery change				
New Lab	4	8.9	0.1-2208	0.0001
Old Lab	87.1	207.6	1-972	

dates for conventional anticoagulation therapies.[11] Thus, it is prudent to embrace newer fluoroscopic techniques to effectively reduce chances of adverse effects of ionizing radiation in an EP lab including skin injury, radiation-induced malignancy and genetic effects.[12] Technical aspects of the x-ray system can be changed in conventional X ray equipment also in order to reduce radiation dose but the reduced dose rate is associated with decreased image quality due to the reduced frame rate. Physicians have to compromise with their desire to achieve excellent image quality in order to maintain lower radiation dose.[13] This compromise is smaller with the new systems that have improved image quality and even for older systems, the human eye adapts very well and after a while, the operators do not generally suffer from the difference in image quality. There have been various changes in an EP lab geared up to address issues of reduction in radiation dose, enhancement in image quality and improvement in procedural image guidance. These features have made various EP procedures swifter and thus have helped to decrease radiation dose significantly. There has been a transition from biplane to ceiling-mounted monoplane intervention labs with a large detector. LED surgical lighting and three-dimensional visualization systems can provide better procedural image quality and guidance. Changes in detectors are evident as well. Currently, dedicated cardiac catheterization labs use smaller detectors in the range of 8- to 10-inch diagonal to allow C-arm angulations. This provides different views of the anatomy. Some companies have added a new 16-bit digital detector on their platform, which offers higher contrast. Real-time dose feedback about the cumulative amount of x-ray dose received after each procedure is utilized at various institutions. Archiving, reporting, and analyzing radiation data has helped healthcare facilities prevent long-term radiation exposure. At our hospital, by incorporating newer fluoroscopic technology (ClarityIQ) with better x-ray tube and more sensitive detectors, the cardiologist have been able to adjust the frame rates to reduce the dosage. Frame rates have been considerably low for the same image quality that conversely reduces radiation. The new software and its algorithm used to decipher information during procedures have made the major difference. Significant reduction in prescribed radiation dose was observed uniformly among patients undergoing various procedures with the aid of new fluoroscopic technology. Advances in software and fusion of the CT images with the creation of live 3-D fluoroscopic images have helped to achieve excellent visibility at a low dose in patients of all sizes. We use Cardiac Ultrasound for guidance and placement of devices like Watchman, PPM and ICD. Other notable ancillary features include G-tube gravity device, which allows physicians to have radiation protection without having to wear heavy lead aprons during a long procedure and an easily movable C-arm which provides more space to work for a multidisciplinary team (Figure 1).

Conclusions

The newer fluoroscopy devices improve the safety of both the patient and medical staff by significantly reducing radiation dose for all kinds of procedures done in an EP lab. These procedures can be performed relatively quickly as demonstrated by decreased fluoroscopy time. The operator with addition of newer devices reported greater degree of procedural ease. This was a subjective finding.

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