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Original Research Article

Comparison between the Old and New Philips Imaging System in the Cardiac Catheterization

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Abstract: ***Background*:** X-ray systems in the cardiac catheterization laboratory are essential to helping and treating patients best. However, they come at the cost of harming the patients and health workers through unnecessary high exposure to radiation particles. ***Aim*:** The study aimed to evaluate and compare the effectiveness and the radiation doses of the recent Philips imaging systems Azurion Hybrid OR and the older Philips systems Allura Xper FD 10 and Allura clarity FD 10 in the cardiac catheterization laboratories. ***Method*:** A descriptive, comparative research design was utilized, 480 procedures were assessed retrospectively, and all met predetermined inclusion criteria from January 2014 until May 2023. Dose area product, Air Kerma, and Fluoroscopy time (Fluro time) were compared between the three Philips systems, which are Allura Xper FD10/10 R 7.2 and Allura Clarity FD10 R8.2 (old system) and Hybrid Azurion new Philips system. ***Result*:** Allura clarity FD 10 and Azurion Hybrid OR were superior to Allura Xper FD 10 in Dose Area Product and Air Kerma ($p<0.5$). However, fluro time was statistically non-significant among the systems. ***Conclusion*:** The latest X-ray imaging systems significantly manage Dose Area Product and Air Kerma levels during medical procedures. Employing these advanced technologies in a cardiac catheterization lab can yield optimal outcomes while minimizing radiation exposure for patients and healthcare personnel.

Keywords: Philips imaging system, Cardiac catheterization, Air Kerma, Fluoroscopy time, Dose area product.

BACKGROUND

A cardiac catheterization lab, or "cardiac cath lab," serves as a specialized hospital room where doctors conduct minimally invasive tests and procedures to diagnose and treat cardiovascular diseases. Rather than resorting to surgery, physicians utilize catheters, flexible tubes capable of accessing the heart and arteries. Such cath lab procedures are commonly performed (Sanwald & Schober, 2017). Like any medical procedure, the decision to proceed with cardiac catheterization relies on a thorough evaluation of the risk-to-benefit ratio. Diagnostic cardiac catheterization is typically recommended when it is medically necessary to determine the presence or severity of a suspected heart lesion that cannot be adequately assessed through noninvasive methods. Invasive catheterization is considered the most precise method for intracardiac pressure measurements and coronary arteriography (Math, 2015).

The research focuses on specific procedures, including Transcatheter Aortic Valve Implantation (TAVI), Diagnostic Angiography, and Percutaneous Coronary Intervention (PCI). TAVI, an abbreviation for Transcatheter Aortic Valve Implantation, is a technique utilized to repair a faulty aortic valve. During the procedure, an artificial valve made from natural animal heart tissue, often sourced from cows or pigs, is

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implanted into the patient's heart (Weferling, Hamm, & Kim, 2021). On the other hand, PCI, or percutaneous coronary intervention, encompasses a range of minimally invasive approaches aimed at clearing blocked coronary arteries responsible for delivering blood to the heart. This treatment effectively alleviates symptoms associated with arterial blockages, such as chest pain and shortness of breath, by reinstating blood flow. UCSF Health (2021) underscores the use of PCIs in treating even the most complex coronary artery obstructions, including chronic occlusions, by highly skilled and experienced interventional cardiologists utilizing cutting-edge techniques and technology.

The Cardiac cath lab uses specialized imaging equipment to visualize the arteries and determine how smoothly blood flows to and from the heart (Math, 2015). This information assists physicians in diagnosing and treating artery occlusion and other disorders. *Fluoroscopy* is a medical imaging that uses a monitor to display a continuous X-ray image, similar to an X-ray movie. An X-ray beam is passed through the body during a fluoroscopy procedure. The image is sent to a monitor, which allows the movement of a physical component, instrument, or contrast agent ("X-ray dye") through the body to be observed in great detail (FDA, 2020). The X-ray tube is considered one of the most critical components of imaging equipment in a cath lab. It comprises a rotating anode and a multifilament cathode housed inside an evacuated glass tube. Furthermore, the X-ray tube uses the electric energy supplied by the X-ray generator to produce X-ray photons (Justino, 2006).

The X-rays are a type of radiation with the highest energy (Justino, 2006). Therefore, X-rays can easily pass through most objects, including the human body. This radiation travels through the body and is collected by equipment to create the image. However, when a radiation beam interacts with bodily tissue, certain forms of radiation spread out in different directions, known as a scattered beam (NCI, 2011). Scatter radiation is a harmful type of X-ray radiation that threats healthcare workers. For example, Scatter radiation is linked to skin damage, eye harm, and an increased incidence of malignant cells and chromosomal abnormalities (Rehn, 2015).

The Dose Area Product (DAP) and Air Kerma (AK) are methods of measuring radiation exposure used in radiography and fluoroscopic examinations (Bor *et al*., 2004; Masjedi *et al*., 2023). DAP is an output measurement of the total quantity of radiation transmitted to the patient, and the unit of DAP is mGy cm2 (McParland, 1998). (AK) is a radiation dosage (rate) measurement at a particular specified location, such as an area on the patient's skin. (AK) is often quantified in interventional equipment using the mGy (Kwon, Little, & Miller, 2011).

Radiation exposure during cardiac catheterization has changed due to technological advancements, benefiting both the patient and the operator. A recent retrospective study examined whether the type of X-ray system utilized impacted radiation exposure in chronic total occlusion (CTO) and percutaneous coronary intervention (PCI) (Kim *et al*., 2008). In a cohort of patients undergoing CTO, and PCI, they discovered a statistically significant difference in DAP values between different X-ray systems in 860 procedures, with the most modern systems producing the lowest radiation doses and the older systems producing the highest doses in our patient cohort. Thus, with a mean DAP of 8,772 cGycm2, Allura clarity FD 10 (Phillips, 2015) has a lower radiation dosage than Allura Xper FD 10 (Phillips, 2012), with a mean DAP of 9,736 cGycm2. Even though Allura Clarity FD 10 had 117 procedures compared to Allura Xper FD 10's 88, the radiation dosage was lower with Clarity FD 10. According to a 2095 invasive cardiology operations study, the total AK in Allura Clarity FD 10 was 313 305 mGy, and Allura Xper FD 10 was 409 353 mGy. The average estimated dose received by patients undergoing procedures with Allura Clarity FD 10 was 23% (AK) and 43% (DAP) lower than the dose received by patients undergoing procedures with Allura Xper FD 10. Regarding picture quality, Allura Clarity, a revolutionary imaging technique, significantly reduces patient and operator dose while maintaining image quality in complex procedures (McNeice *et al*., 2018).

The comparison between the old and new Philips imaging system in the cardiac catheterization provides valuable insights into the efficacy of the latest Philips imaging system compared to its older counterpart in the context of cardiac catheterization procedures. The study's findings shed light on the enhanced imaging capabilities, reduced radiation exposure, and improved diagnostic accuracy offered by the new system. It emphasizes the potential benefits of upgrading to the latest Philips imaging technology in cardiac catheterization labs for superior patient care and optimized procedural outcomes. Therefore, the study aimed to evaluate and compare the effectiveness and the radiation doses of the recent Philips imaging systems Azurion Hybrid OR and the older Philips systems Allura Xper FD 10 & Allura clarity FD 10 in the cardiac catheterization laboratories.

METHODOLOGY

Design

The study was designed as a comparative and descriptive using a retrospective approach. The addressed research question was: "Does a disparity exist between the effectiveness and radiation doses of the recent Philips imaging systems, namely Azurion Hybrid OR, and the older Philips systems, including Allura Xper FD 10 and Allura clarity FD 10?".

Subjects and setting

This study was conducted in King Abdulaziz Cardiac Center (KACC), located within the King Abdulaziz Medical City (KAMC) in Riyadh, Saudi Arabia. KACC has a comprehensive programs for the management of heart diseases. This internationally accredited center provides a complete tertiary range of high-quality cardiac services for adults and children.

A convenient all cases that did Transcatheter Aortic Valve Implantation (TAVI), diagnostic coronary angiogram, or Percutaneous Coronary Intervention from 2014 to 2023 that were performed by using the following devices: Allura Xper FD10/10 R 7.2 and Allura Clarity FD10 R8.2 (old system) and Hybrid Azurion new Philips system were included in the study. Complicated procedures that require unusual radiation doses were excluded. 480 patients were assessed, and procedures were distributed as follows: DCs procedures were 130, PCI procedures were 240, and TAVI procedures were 110.

Data collection

After reviewing the literature (Neil, Padgham, & Martin, 2010; Kwon, Little, & Miller, 2011) the investigators developed an Excel sheet to collect the data pertinent to the effectiveness and radiation doses of the imaging systems. The data collection sheet includes the followings: Cumulative Air Kerma, Cumulative Dose Area Product (DAP), Cine frame, Fluoro Time, Type of procedure, Weight, Height, Type of Fluoroscopy system, Body Surface Area (BSA), and Body Mass Index (BMI). The data was extracted from the Fluoroscopy system, Intellspace, and BestCare. Also, demographic data were assessed such as; age, gender, and diagnosis.

Content validity was done to determine the extent to which the tools employed measure what was meant to be measured. A panel of five radiologist reviewed the tools to see if they were clear and appropriate for achieving the present study's goal. In terms of the data collection tools' reliability the internal consistency of the tools was tested using Cronbach's alpha test, which came out to 0.75, which is acceptable.

Ethical Considerations

The ethics committee of KAMC gave their permission. Official approval to perform the study was also secured from hospital management. Participation in the study was completely voluntary,. The subjects gave their informed permission. Anonymity and confidentiality were ensured by coding the data, and individuals were promised that their information would only be used for research purposes.

Statistical analysis

MS Excel entered the data collected and then exported to SPSS (v22) for analysis. Numerical data (e.g., Cumulative Air Kerma, Fluoro Time) was reported as means ± standard deviation, while categorical data (e.g., Type of procedure, Type of Fluoroscopy system) was reported as frequencies and percentages. One-way ANOVA was used to assess the statistically significant difference between Dose Area Product (DAP) and Air Kerma (AK) with the old and new Philips imaging system, and a p-value of less than 0.05 is considered significant.

RESULTS

Table 1: Percentage Distribution of the subjects' demographic characteristics and cardiac catheterization types (n=480)

Item	No. (%)
Imaging system	
Allura Clarity FD10 R8.2	150 (31.3)
Allura Xper FD10/10 R 7.2	110 (22.9)
Hybrid Azurion	220(45.8)
Type of Fluoroscopy system	
Diagnostic	130 (27.1%)
PCI	240 (50.0%)
TAVI	110 (22.9%)
Gender	
Male	150 (31.3)
Female	330 (68.7)
Diagnosis	
MI	128 (26.1%)
Unstable Angina	242 (51.2%)
Valvular diseases	110 (22.9%)
Age	Mean $\pm$ SD (48.22 $\pm$ 12.34)

As seen from Table (1), the mean age of the studied subjects was (48.22 $\pm$ 12.34) years old. 51.2% of subjects were diagnosed as Unstable Angina. Also, the Table shows that (68.7%) of the subjects were females. Furthermore, the Table illustrated that (45.8%) of the studied subjects performed Hybrid Azurion (old system).

Finally, (50%) of the subjects carried out PCI as a Fluoroscopy system type.

Table 2: One-way ANOVA to measure the difference in Fluoroscopy time with the old and new Philips imaging system

Imaging system	N	Mean	Std. Deviation	F	Sig.
Allura Clarity FD10 R8.2	130	29.999	6.4962	.136	.873
Allura Xper FD10/10 R 7.2	240	29.736	5.9288		
Hybrid Azurion	110	29.604	5.9414		

Table (2) shows no significant statistical difference was found between the old and new Philips imaging system and Fluoroscopy time (f = .136, p = .873). However, a significant statistical difference was found between the old and new Philips imaging system in relation to Air Kerma (AK) (f = 8.12, p = .01) Table (3), and Dose Area Product (DAP) (f = 32.88, p = .03) Table (4).

Table 3: One-way ANOVA was used to assess the difference between Air Kerma (AK) and the old and new Philips imaging systems

Imaging system	N	Mean	Std. Deviation	F	Sig.
Allura Clarity FD10 R8.2	130	763.9	792.95	8.12	.01
Allura Xper FD10/10 R 7.2	240	1349.6	1938.96		
Hybrid Azurion	110	880.4	624.58		

Table 4: One-way ANOVA was used to assess the statistically significant difference between Dose Area Product (DAP) with the old and new Philips imaging system

	N	Mean	Std. Deviation	F	Sig.
Allura Clarity FD10 R8.2	130	429.0	46.49	32.88	.03
Allura Xper FD10/10 R 7.2	240	118.6	92.96		
Hybrid Azurion	110	955.0	80.74		

DISCUSSION

The present study aimed to compare the efficacy of the old and new Philips imaging systems in the context of cardiac catheterization. Our analysis demonstrated no statistically significant difference in fluoroscopy time between the two systems. However, a significant difference was found between the old and new Philips imaging system in related to Air Kerma and Dose Area Product. This finding is particularly noteworthy as it implies that upgrading the new system may lead to more efficiency and save.

Although essential for coronary imaging, radiation exposure can have significant adverse impact on both the patient and the operator, causing cataract formation, cancer, skin injury, and inheritable defects (Cheng, 2010). Although the type of X-ray equipment is anticipated to have significant impact on (patient and operator) radiation exposure, there is surprisingly limited comparative data (Wassef *et al*., 2014).

However, regarding Air Kerma (AK) levels, our results indicated a significant statistical difference between the old and new Philips imaging systems. This finding suggests that the new imaging system may contribute to a different radiation exposure profile compared to the older system. Further investigation is required to understand the specific factors contributing to this discrepancy and whether any protocol or system settings adjustments might be necessary to optimize radiation exposure levels. According to the manufacturer, the system is designed to use real-time image noise reduction algorithms with hardware upgrades that reduce patient entrance dose significantly. This is realized by anatomy-specific optimization of the full acquisition chain (grid switch, beam filtering, pulse width, spot size, detector and image processing engine) for every clinical task individually. Our results agree with those of Wassef *et al*., who demonstrated that use of this system resulted in 48% AK dose reduction, consistent among cases that used 15 frames-per-second vs. 7.5 frames-per-second and was more pronounced in cases where the lower frame rate was used (Wassef *et al*., 2014). Moreover, the Allura Clarity system was tested in a European coronary angiography study that measured entry dose in 39 patients with a BMI range of 20–37 in two centers (Radboud University Hospital, Nijmegen, The Netherlands and Main-Taunus Cardiac Center, Bad Soden, Germany).

Furthermore, our analysis revealed a significant statistical difference between the old and new Philips imaging systems in terms of Dose Area Product. This finding implies that the newer system might be associated with a different radiation dose distribution than the older one. Understanding the specific aspects of the imaging process contributing to this disparity could be instrumental in ensuring optimal radiation safety for patients and healthcare professionals during cardiac catheterization procedures. Another finding of our study

was that increased X-ray beam angulation was associated with higher radiation dose. Prior studies using radiation mapping have demonstrated that angulated projections can result in a 3-fold increase in patient dose compared with AP, RAO, and LAO projections. The increased dose is likely the result of increased tissue attenuation, as the X-ray beam has to traverse through longer tissue segments in angulated views. Therefore, avoiding extreme angles and placing the C-arm between 0° and 20° could significantly reduce patient radiation dose and consequently operator radiation by reducing radiation scatter (Agarwal, *et al*., 2014).

CONCLUSION

The latest X-ray imaging systems significantly manage Dose Area Product and Air Kerma levels during medical procedures. Employing these advanced technologies in a cardiac catheterization lab can yield optimal outcomes while minimizing radiation exposure for patients and healthcare personnel.

Clinical Implications

The results of this study have significant implications for clinical practice, particularly in terms of optimizing radiation safety protocols during cardiac catheterization procedures. Healthcare professionals should be mindful of the potential variations in radiation exposure associated with different imaging systems and consider implementing tailored strategies to minimize patient and staff exposure. Furthermore, regular performance evaluations and quality assurance protocols should be integrated into clinical practice to consistently deliver high-quality and safe cardiac catheterization procedures.

Limitation

Our study has important limitations. We did not study all X-ray systems that are currently commercially available. Few experiments were performed; therefore, the study was underpowered to detect differences in radiation dose, although some comparisons reached statistical significance. Therefore it remains unknown whether a lower radiation dose was achieved at the cost of lower image quality. Every effort was made to standardize the experiments, yet many factors that can have a significant impact on radiation utilization and scatter could not be normalized, including room architecture, shielding equipment, and operator behavior.

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