Impact of Allura Clarity Technology on Radiation Dose Exposure During Left Atrial Appendage Closure

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Summary

Background: To evaluate the impact of the Clarity IQ technology on reducing radiation risk in patients undergoing cardiac interventional radiology (IR) procedures.

Material/Methods: Phantom studies were performed with two angiographic systems, FD10 Allura Xper and FD10 Allura Clarity. In the study, we performed left atrial appendage closure. Dosimetric measurements were performed with thermoluminescent dosimeters (TLD) placed inside a CIRS anthropomorphic phantom. Radiation risk was estimated based on the TLD readings and expressed as the dose absorbed by particular organs. The Mann–Whitney U test was carried out to test for significance of differences in the absorbed radiation doses between the techniques.

Results: During left atrial appendage closure, the estimated dose absorbed by particular organs was lower in the case of the FD10 Allura Clarity system in comparison to the Allura Xper. In this procedure, dose reduction for particular organs ranged between 49–86%.

Conclusions: Application of the FD10 Allura Clarity system resulted in a significant dose reduction, thereby leading to a significant decrease in radiation risk for patients undergoing IR procedures.

MeSH Keywords: Radiation, Ionizing • Radiology, Interventional • Thermoluminescent Dosimetry

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Background

Interventional radiology (IR) is currently one of the fastest developing areas in the field of radiology. IR procedures are used in many areas of medicine both in adults and children. IR procedures can be used even in patients with contraindications to surgery. In addition, they allow observing vessel flow during interventions and are both faster and more cost-effective than conventional surgery. For these reasons, interventional radiology is used in neurosurgery, surgery of peripheral vessels, and most commonly in cardiac interventional procedures.

However, IRs are associated with a high radiation risk, which is a very important for patients and medical staff [1–23]. The diversity of performed procedures, differences in equipment, varying degrees of procedure difficulty, and differences in experience of operators influence the duration of IR procedures, and hence the range of radiation doses received by patients.

The importance of cardiac IR procedures and the applied radiation doses are summarized in issue 59 of the IAEA Report that mentions a typical average effective dose of 5.6 mSv for coronary angiography and 13 mSv for percutaneous cardiovascular interventions [24].

It is an undeniable fact that interventional procedures expose patients and medical staff to extremely high radiation doses. This may cause an increased risk of stochastic effects for both groups and results in the occurrence of deterministic effects in some patients (radiation-induced skin damage being most common) [25–27]. For this reason, radiation dose management in IRs is very important and should be used to minimize the risk of negative health effects for patients and reduce the risk of stochastic effects for medical staff.

The most important factor that affects radiation doses during IR procedures, except for operator experience and patient size, is the quality of equipment. All vendors

introduce new technological solutions to improve image quality and minimize radiation doses received by patients and personnel.

One of the novel angiographic systems is the Philips Allura Clarity witch the Clarity IQ technology. According to the producer, in the Clarity IQ technology, clinically fine-tuned parameters have been applied to the whole chain of image processing for each application. The technology allows filtering out greater amounts of radiation, uses shorter pulses and smaller focal spot sizes during IR procedures, and thus it reduces radiation doses [28].

This study aimed to compare the impact of the Allura Clarity and the Allura Xper technologies on reduction of radiation doses received by selected organs and parts of the body during left atrial appendage closure.

Material and Methods

Left atrial appendage closure was performed with two angiographic units – the FD10 Allura Xper and FD10 Allura Clarity, both manufactured by Phillips and installed in the Independent Public Provincial Hospital in Szczecin.

All steps of the procedure of left atrial appendage closure were identical in both angiographic units. Duration of particular steps of the procedures, C-arm angles, and number of DSA images are presented in Table 1.

The parameters used in both angiographic units under investigation were the following: protocol: left coronary artery, frame speed fluoroscopy: 15fr/sec, frame speed DSA: 6fr/sec, kV=80, exposure pre filter: 0.1 mm Cu + 1.00 mm Al; patient type: normal (70-90kg); fluoroscopy mode: low. For both angiographic systems, the total duration of fluoroscopy was 544 sec, and 36 DSA images were acquired. The differences in settings involved a fluoro pre filter and the mA(s) parameter, as they were built-in settings of the used systems (FD10 Allura Xper: fluoro pre filter – 0.9mm Cu + 1.00 mm Al, mA(s)=41; FD10 Allura Clarity: fluoro pre filter – 0.4 mm Cu + 1.00 mm Al, mA(s)=23).

The investigation was performed on a physical anthropomorphic CIRS phantom (representative for an adult male) [29]. The protocol for phantom exposure was based on careful observations of ten uneventful left atrial appendage closure procedures that were performed in adult patients with standard body sizes (the procedures were carried out in the Regional Specialist Hospital in Grudziadz). During the observed IR procedures, duration and current-voltage parameters in the used projections were recorded. The projection (i.e., position of the C-arm) was determined by the type of IR procedure; mean values were calculated in case of variations among procedures.

Dosimetric measurements for the CIRS phantom were performed using thermoluminescent dosimeters (TLD) of high sensitivity (MTS, LADIS Laboratory, Cracow, Poland) [30].

Volumes of organs inside the phantom corresponded to particular human organs, and their position was confirmed on CT of the CIRS phantom.

The doses absorbed by the particular organs or body parts were computed according the following formula:

$$D = (1/V)\sum_j (1/n) V_j \sum_i K_{ij}$$

where V_j – volume of the part of the organ contained in the phantom slice "j", V – total volume of the organ, K_{ij} – kerma read-out for TLD "i" placed in the slice "j". $\sum_i$ concerns the slices in which the organ was distributed.

Organ volumes were evaluated using the ImageJ software [31].

The K_{ij} values were read from the TLDs performed in the LADIS Laboratory according a standardized procedure.

The above formula was not used for the intestine, colon and the skeleton. All TLD readings were taken into consideration (in all slices), and the mean value was computed. The mean absorbed dose obtained in this way for the skeleton was then divided between the compact bone and red bone marrow, using the coefficient 1.1 and 1.6 for the compact bone and red bone marrow, respectively [32].

Table 1. Duration and C-arm angulation for the particular steps of left atrial appendage closure using the investigated angiographic units (FD10 Allura Xper and FD10 Allura Clarity).

Order of steps	Fluoroscopy/DSA	C-arm angle	Duration (sec)	Number of obtained images
1	Fluoroscopy	Rao 0° Cranial 0°	321	–
2	DSA	Rao 30° Cranial 20°	–	30
3	Fluoroscopy	Rao 30° Cranial 20°	79	–
4	DSA	Rao 30° Cranial 20°	–	6
5	Fluoroscopy	Rao 30° Cranial 20°	144	–

Table 2. Mean values of doses absorbed by particular areas of the CIRS phantom during left atrial appendage closure using the investigated angiographic units (FD10 Allura Xper and FD10 Allura Clarity).

Organ	Allura xper [mGy]	Allura clarity [mGy]
Red bone marrow	4.25	1.89
Colon	0.11	0.02
Lungs	8.44	4.33
Stomach	1.81	0.40
Gonads	0.00	0.00
Bladder	0.00	0.00
Liver	0.90	0.25
Thyroid	1.54	0.71
Compact bone	2.92	1.30
Brain	0.22	0.09
Eye lens	0.06	0.02
Heart	8.29	3.98
Intestine	0.12	0.02
Kidneys	1.29	0.18
Pancreas	0.52	0.12
Spleen	4.35	0.83

Based on the Shapiro-Wilk test, the data distribution was not normal; hence, to determine the level of significance, we used the nonparametric Mann-Whitney U test. The level of significance was determined for doses absorbed by 5 organs, i.e., lungs, heart, red bone marrow, thyroid (because these organs are located in the area of the primary beam and are most exposed to radiation), and colon (located outside the area of primary beam with the highest radiosensitivity, tissue weighting factor=0,12).
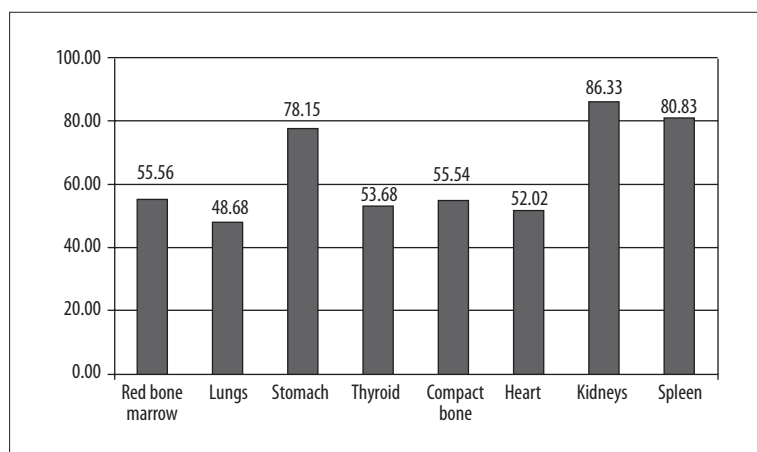
Results

The results of the performed measurements are presented in Table 2.

The percentage reductions of the organ-absorbed doses, using the system Allura Clarity in comparison to Allura Xper, for the organs most exposed to radiation, are presented in Figure 1.

Statistical analyses demonstrated significant differences in the doses measured for lungs, heart, thyroid, and colon, but not for red bone marrow (red bone marrow is distributed not only in the area of the primary beam but also in the whole trunk area). The level of significance (p-value) determined for doses absorbed by selected organs was: for lungs, p-value=0.000003; for heart, p-value=0.001; for thyroid, p-value=0.0015; for colon, p-value=0.00007; for red bone marrow p-value=0.1.

Discussion

The aim of the study was to evaluate the impact of a novel technology, Allura Clarity, on radiation doses absorbed by particular organs during left atrial appendage closure in comparison to its predecessor, Allura Xper.

According to the manufacturer, the Allura Clarity system with the Clarity IQ technology is associated with significantly reduced radiation doses to the patient and medical staff due to a number of technical solutions used in this system, as compared with the previous technology. These include solutions that improve image quality, such as motion compensation, image enhancement, and realtime noise reduction. But more importantly, anatomy-specific optimization of the full acquisition chain is used in the system (grid switch, beam filtering, pulse width, spot size, detector and image processing), which results in dose reduction [28].

Owing to the use of an anthropomorphic phantom, our study allowed to assess the impact of the Allura Clarity technology on radiation doses without a potential influence of other factors. The used anthropomorphic phantom was representative for an adult patient, and its application reduced the influence of factors other than technical

Figure 1. Percentage dose reduction of organ-absorbed doses using the FD10 Allura Clarity system in comparison to the FD 10 Allura Xper, for organs exposed to radiation doses above 1 mGy.

characteristic of the X-ray system, patient size, the degree of procedural difficulty, or experience of medical staff.

The results indicate a significant dose reduction for the Allura Clarity in comparison to the Allura Xper. The average reduction of absorbed doses in particular organs ranged between 49–86%. Extremely significant dose reductions with the Allura Clarity system were obtained for the organs closest to the center of the X-ray beam, like the heart (4.31 mGy) and lungs (4.11 mGy).

Earlier publications on the Allura Clarity system are in agreement with the obtained results, as they showed a reduction of patient exposure to ionizing radiation with the Allura Clarity system in comparison to the Allura Xper. In IR electrophysiology procedures in adult patients, a 43% reduction of the dose area product (DAP) was seen [33,34], and in congenital heart diseases, the observed DAP decrease was in the range of 56–71% [35].

Our study brings new dosimetric information to the field of interventional radiology. Previous studies were usually based on retrospective and indirect analyses of radiation doses, as calculated by the built-in software of the tested system. Such data provide information only on the surface dose measurement (surface air kerma, dose area product). Our phantom experiments were based on direct measurements and demonstrate the exposure of specific body organs during a cardiac interventional procedure.

A limitation of our experiments is the lack of simultaneous evaluation of image quality for the used angiographic systems. However, in previous publications, there was no deterioration of image quality despite dose reduction that was obtained with the Allura Clarity system [36,37].

It should be noted that the difference in the absorbed radiation doses between the two studied systems was not significant in the case of red bone marrow (p=0.1). This can be due to the fact that red bone marrow is distributed throughout the entire phantom and not only in the region of the primary beam. Therefore, the calculated mean radiation doses for red bone marrow also involved areas that received almost no radiation.

Conclusions

Based on the obtained results, a significant radiation dose reduction is associated with the use of the Allura Clarity system in comparison to the Allura Xper. The dose reduction observed in the investigated organs ranged between 49–86%.

This high radiation dose reduction is extremely important for patients, especially for those undergoing cardiac procedures, as these procedures are most common in the field of interventional radiology. Moreover, this is also important for medical staff for whom cardiac procedures comprise the largest part of occupational exposure.

In conclusion, the application of the novel Allura Clarity technology significantly reduces the radiation dose for patients undergoing IR procedures, thus considerably reducing the radiation risk for medical staff.

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