Evaluation of a Direct Ion Storage dosimeter efficiency to measure dose during interventional cardiology electrophysiology procedures

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ABSTRACT

Intracardiac electrophysiological invasive procedures guided by fluoroscopy aim to study the cardiac depolarization process. Depending on the complexity of the clinical case, both patients and professionals are subjected to radiation for a prolonged period. This work evaluated if a direct ions storage (DIS) dosimeter could measure occupational doses in different regions of the physician's body during these procedures. Doses were monitored close to the left eye (LE), right eye (RE), extremity (left ankle), and thorax, as well as the environmental dose, positioning the dosimeter in the center of the equipment gantry. These doses were evaluated in 31 procedures using one DIS dosimeter in each region. The Mann-Whitney U test demonstrated that the values obtained in the different regions represent different samples, while the Spearman test demonstrated that there is no evidence that there is a correlation between the data recorded in the different regions. DIS was effective in recording the doses in the LE region and the doses of dispersed radiation (Arc), with the values obtained: (3rd quartile / maximum): LE (0.07 / 0.20 mSv); Arc (0.38 / 1.53 mSv). DIS dosimeter wasn't able to measure dose in different regions of the physician's body, limiting its use as a complementary monitor in the control of occupational doses.

Keywords: dosimetry, direct ions storage, ionization chamber, Intracardiac electrophysiology, occupational dose.

1. INTRODUCTION

Personal dosimetry is used to measure the amount of occupational radiation dose an individual receives. These values are determined by considering acceptable risks of radiation exposure. Although a goal of zero is ideal, in a constant radiation environment, such as the cardiology sector in a hospital, radiation exposures are inevitable, and an alert system must be in place. For example, Souza et. al.[1] proposed and evaluated a system so these levels are calculated to be within a 50% safety margin of the maximum value. For example, since the whole-body effective dose is 20 mSv/year, an action limit of 10 mSv/year was instated. For a period of 12 months, 833.3 µSv per month was considered the maximum accepted value. If the number was higher during a certain month, an investigation must be performed resulting in adaptations, such as adding more shielding, changing internal protocols, and/or re-training of the staff.

In the medical field, hospitals are always in search for easy and effective alternatives to measure dose. Traditionally, badge, ring, and eye dosimeters are used. They are made of materials that need posterior processing to yield the monthly radiation exposure reading. The material is enclosed in small plastic badges and used for the determined period, usually one month. For example, thermoluminescent dosimeters (TLD) store the information on the amount radiation received. After the reading period, the badges are disassembled, and the TLDs are read through a heat process resulting in light emission. The system compares the light emitted with a pre-determined value (a calibration curve with light intensity x radiation dose).

Direct ion storage (DIS) dosimeters are being increasingly used in the hospital field, due to it easiness of reading. The new versions can transmit data in real time with reports being generated daily accessible by a cellphone application. Such devices vary in price and sensitivity but, as a constant, they are more expensive than TLD badges (just the device, not including reading is U$ 36.60 for TLD and U$ 110.00 for DIS [2]) and have a higher minimal detection range (3.81 cGy [3] for TLD and 0.01 mSv for DIS [4]). Before implementing DIS dosimetry, a study is necessary to evaluate if they are sensitive enough to measure the desired quantity.

Clinical electrophysiology, one of the important specialties of cardiology, uses advanced medical resources that enable the correct diagnosis of cardiac arrhythmias. This procedure has one of the highest therapeutic success rates in invasive cardiology [5].

Intracardiac electrophysiological studies (EPS) are invasive procedures that use electrode catheters (generally more than one), introduced by venous and arterial puncture, which, under fluoroscopic control, are positioned in different locations of the heart, with the aim of studying the process of cardiac depolarization. This assessment is performed during sinus rhythm or in the presence of arrhythmias induced with programmed stimulation and/or through various cardioactive drugs [5]. Depending on the complexity of the clinical case, patients and medical teams are subjected to high levels of radiation doses due to the routine use of fluoroscopy and/or cinefluorography for minutes or even hours. These doses must be constantly monitored and evaluated in order to optimize radiation protection [6-8].

There are multiple studies evaluating radiation-induced cataracts in cardiologists [9]. Cirac-Bjelac et. al. [10] found that the prevalence of posterior lens opacities among 52 interventional cardiologists was 53%, with corresponding relative risks of 2.6. Vano et. al. [11] found a 50% prevalence (58 physicians).

This paper has the goal to evaluate the possible implementation of a DIS dosimeter to measure dose in interventional cardiologists.

2. MATERIALS AND METHODS

2.1. Ethical Aspects

The study was submitted to the Research Ethics Committee of the Paulista School of Medicine, located at São Paulo Federal University (UNIFESP), and approved under number 102263/2015. Study participants were informed about the research and signed a Free and Informed Consent Term (FICT), in accordance with the requirements defined in National Health Council (CNS) Resolution 466/12 [12], which regulates research involving human beings in Brazil.

2.2. Location and materials

The study was carried out in the Hemodynamics and Invasive Cardiology Sector of the University Hospital of the Paulista School of Medicine, UNIFESP, located in the city of São Paulo.

The radiological equipment in which the data were collected is a KXO Angiographer – 100G from Toshiba Medical System, manufactured in 1992. It consists of a generator, an X-ray tube, and a flat detector with diameters of 30, 20, 16 and 12 cm, arranged in opposition in a C-shaped arc (gantry), which can rotate 360º around the patient. The operating voltage range of this equipment is 50-125 kV, and the maximum current is 1000 mA. The minimum total equivalent filtration is 3.5 mm Al for 70 kV. The equivalence is obtained by means of a Tantalum filter. The X-ray beam is activated by the physician through a pedal located next to the examination bed, and the image is viewed in real time through monitors inside the room. The equipment's quality control tests are carried out, according to the frequency established in the current national legislation [13] and to maintain good radiological protection practices.

Data regarding occupational doses obtained in different regions of the cardiologist's body (main operator) during the performance of 31 procedures were evaluated. The dose value was obtained and evaluated for each individual procedure. Inclusion criteria were patients aged 15 years or older with arrhythmia and indication for cardiac ablation. Gender, ethnicity, and biometric characteristics did not constitute exclusion criteria. The experience of the main operator was also not a criterion for excluding the sampled data.

The DIS dosimeter Instadose™, manufactured by Mirion Technologies, was used in this evaluation. The Instadose™ dosimeters were supplied by Konex - Indústria e Comércio Ltda, São Paulo, SP, Brazil, current representative of the manufacturer Mirion Technologies, California, USA. The device has a minimum reportable dose: 0.03 mSv; minimum detection limit: 0.01 mSv; measurable dose range: 0.03 mSv to 5 Sv; and energy response range: 5 keV – 6 MeV.

Outpatient elective procedures were selected, performed by six resident physicians (R2) working in rotation. The Instadose™ dosimeter was fixed in different regions of the body of the cardiologist responsible for conducting the procedure (main operator), as shown in Figure 1. At the end of each procedure, the dosimeters were removed from the physician's body for reading and recording of dose values.

Figure 1: *Instadose™ dosimeters positioned on the right (A) and left (B) sides of the region close to the eye lens, in the thorax (A - outside the lead apron) and in the region of the left ankle (C-extremity).*

In each procedure, one Instadose™ dosimeter was positioned in the central region of the gantry of the equipment (Arc) in order to monitor the scattered radiation in the environment, as shown in Figure 2.

Figure 2: *Instadose™ Dosimeter positioned in the central region of the gantry.*
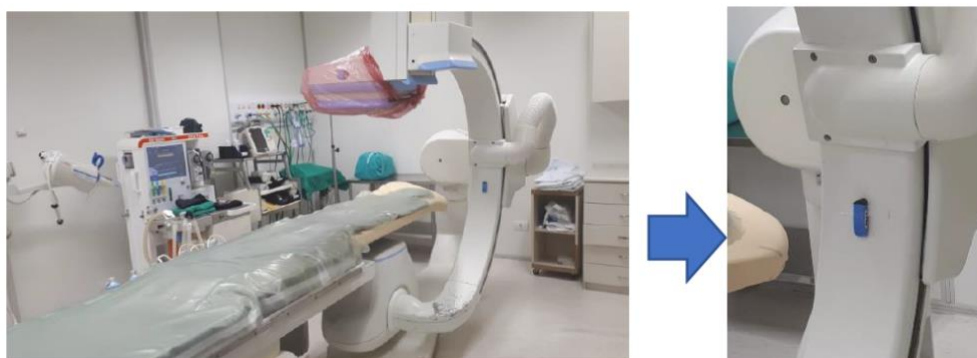
The protective devices used by physicians during the procedures were:

- Lead apron and thyroid protector with thicknesses equivalent to 0.50 mm of lead;
- Lead glasses with a thickness equivalent to 1.0 mm of lead.

2.3. Statistics

The Kolmogorov-Smirnov adherence test, the Sperman correlation test, the Mann-Whitney U test, and box-plot plots were used. All tests were performed manually in MS-Excel® spreadsheets.

The variables considered for the analysis were: dose in the dosimeter positioned in the center of the gantry, in the right (RE) and left eye (LE) regions, thoracic region (dosimeter over the lead apron), and in the ankle. The maximum error limit assumed for this study was $\alpha=0.05$.

3. RESULTS

Table 1 presents the characteristics of the patient sample in terms of gender and biometrics. Age prevalence was 46-65 years old; 61.3% and 38.7% were male and female, respectively; and most patients were overweight.

Table 1: Characteristics of the patient sample.

Age		
Years	Number of patients	
15-25	5	
26-35	0	
36-45	3	
46-55	8	
56-65	10	
66-75	3	
76-85	2	
Sex		
Classification	Number of patients	
Men	19	
Women	12	
Undeclared	none	
Body Mass Index - BMI		
BMI (kg/m^2)	Classification	Number of patients
<16	Severe underweight	0
16> BMI ≤18,5	Underweight	0
18,5> BMI ≤24,9	Normal	7
25> BMI ≤29,9	Overweight	16
30> BMI ≤34,9	Obesity 1	4
35> BMI ≤39,9	Obesity 2	2
BMI >40	Obesity 3 or morbid	2

Table 2 presents the values of examination time, voltage (kVp), and current (mA) recorded. It is possible to observe little variation in voltage and current and the automatic compensation between these operational factors. The values related to the time of exposure to X-rays during fluoroscopy vary according to the clinical situation of each patient and the complexity of the procedure.

Table 2: Values of kVp, mAs, and examination time.

Voltage (kVp)	Number of patients
80	23
70	7
60	1
Current (mA)	**Number of patients**
50-100	8
101-200	11
500-600	1
1001-2000	2
>2000	1
Exposure time (minutes)	**Number of patients**
1-30	7
31-60	10
61-100	8
100-200	4
>200	2

Table 3 presents the maximum, minimum, and median dose values recorded in the Instadose™ dosimeter, evaluated in the center of the gantry and in the left and right eyes, lower extremity (Ankle), as well as in the thoracic region. The values presented were calculated from the set of data, since each procedure was computed separately.

Table 3: Effective doses (mSv) recorded with Instadose™.

Patient	Voltage (kV)	Current (mA)	Exposure time (min)	Gantry's center	Right Eye	Left Eye	Ankle	Thorax
Minimum	60	30.3	9	0*	0	0	0	0
Maximum	80	2440	230	1.53	0.05	0.20	0.53	0.04
Median	80	152	58	0.1	0	0.05	0	0

* The 0 value means is below the detection level

The records of doses obtained in the lower extremity (ankle) were disregarded from the sample in the statistical analysis because they presented only one result different from zero or above the sensitivity threshold of the dosimeter. For this reason, doses in the lower extremities doesn't need to be investigated. Figure 3 shows the distribution of doses recorded in different regions of the main operator's body.

Figure 3: *Box-Plot graph of the distribution of doses recorded in the operators' eye and thorax regions*
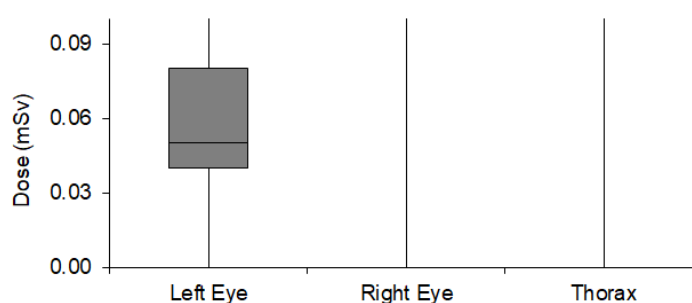
The Kolmogorov-Smirnov adherence test indicated that all research data are non-parametric. The null hypothesis for the test is to verify that the data adhere to a normal distribution ($p > 0.05$). The values obtained are shown in table 4.

Table 4: Results of the adherence test for the variables of interest in the study

Position	p-value
Gantry	0.0024
RE	9.35E-09
LE	0.0041
Thorax	1.641E-06

All p-values obtained are below the maximum error level. It is observed that there is no adherence between the observed and the expected distribution, thus, all variables are treated as non-parametric.

The final analysis consists of verifying if there is a correlation between the variables studied and if the registered doses have similar characteristics. The appropriate test for correlation is the

Spearman test, which evaluates the ranked positions of each analyzed variable. The result found is that there is no evidence that there is a correlation between the values measured in the different regions evaluated (gantry, left/right eye, and thorax). Table 5 presents the result of the p values for the tested combinations.

Table 5: p-values for the analyzed combinations using Spearman test.

Combination	p-value
Gantry x LE	0.15
Gantry x RE	0.20
Gantry x Thorax	0.28
Thorax x RE	0.40
Thorax x LE	> 0.50

Equivalent to T-student test, the Mann-Whitney U test is suitable for non-parametric data with 2 independent samples, with a single variable, and ordered data. The result found for all combinations of the variables studied was that they all have different characteristics from each other, that is, the samples differ from each other. Therefore, there is evidence that there are significant differences in occupational doses, as shown in table 6.

Table 6: p-values for the different combinations evaluated using Mann-Whitney U test.

Combination	p-value
Gantry x LE	0.000091
Gantry x RE	6.4E-10
Gantry x Thorax	8.2E-9
Thorax x RE	0.000021
Thorax x LE	8.2E-9

All results obtained for the comparison statistical tests were considered, including dose values below the sensitivity threshold of the Instadose™ dosimeter.

The result of the measurements in the different regions of the body are presented as the third quartile value and the maximum value in table 7, all with evidence that they are different measurements between the analyzed groups.

Table 7: Dose values in mSv of the 3rd quartile and maximum obtained for the different regions analyzed

Local	3º quartile (mSv)	Maximum (mSv)
Gantry	0.38	1.53
RE	0.00	0.05
LE	0.07	0.20
Thorax	0.00	0.40

DIS was effective in recording the doses in the LE region and the doses of dispersed radiation (Gantry), with the values obtained: (3rd quartile / maximum): LE (0.07 / 0.20 mSv); Arc (0.38 / 1.53 mSv). In the other regions, DIS was effective to confirm that doses were below the threshold for detection. It was not possible to compare occupational doses between different regions of the physician's body, limiting its use as a complementary monitor in the control of occupational doses.

4. DISCUSSION

At the time of the fluoroscopy-guided cardiac electrophysiology procedure, the patient receives most of the dose in the irradiated target region (skin and heart), while the main operator receives scattered or secondary radiation, from different directions, in the thorax, face/ skull and extremities. In these cardiac ablation procedures, unlike catheterization and angioplasty, the same region of the patient's thorax is continuously exposed to radiation, with no significant changes in the beam's incidence angle, which can result in high doses on the patient's skin and in tissue reactions in the exposed region. Hence the importance of optimizing procedures both for patients and for the control of occupational doses.

Estimating an average value of occupational effective dose for the physician, in general, is difficult due to the many conditions involved, from the variable beam geometry, biometric and clinical characteristics of the patient, variability of the techniques selected in view of the complexity of the pathology, and even the skill/experience of the physician. There is also the dose impact related to detector size, characteristics, and quality settings. All these variables suggest the importance of a robust sample for dose assessment. In the present study, even with a small sample, it was possible to verify statistically differences between the values obtained in the evaluated

regions of the physician's body, even in the face of dose values per procedure very close to the sensitivity threshold of the dosimeter. These low doses are attributed to operating conditions, mainly to the maintenance of X-ray beam selection at a rate of 7.5 pulses/s. During the procedures, there was also a minimal variation in the angle of incidence of the beam, which contributed to a low fraction of scattered radiation in the patient.

Every dosimetric system must be evaluated before being adopted within the hospital routine. To function as a dosimeter it must have at least one physical property that is a function of the dosimetric quantity measured and this property can be easily calibrated from standard sources [14]. In addition, to be considered effective, the dosimetric system must meet 3 requirements:

- Maintain a dose-response curve with a slope angle high enough to distinguish between different dose values (linearity);
- Do not lose data between exposure and reading;
- Be stable under the conditions of use.

Instadose^{TM} is a DIS type dosimeter based on the combination of an ionization chamber and an electronic charge storage element. As the charges move in the meter, an electric current is created, keeping the proportionality with the incident amount of radiation. This current value is stored and converted to a dose value by a software that has the information from the calibration curve [4]. To be efficient, DIS dosimeters need to receive enough radiation so that the ions and electrons formed do not recombine and electrons can be collected. It is possible that under the conditions of the data sample with values equal or close to zero, there was a charge recombination and no detection of the electric current. This explains recordings below the dosimeter sensitivity threshold.

Due to all the variables, it is very difficult to compare the dose received by cardiologists, but as a rule of thumb in angioplasty procedures doctors receive about 2-3 times more radiation dose than in electrophysiology [15, 16]. A study performed with this same dosimetric system by Moreira [17] compared dose results for Coronary Angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA) using Instadose^{TM} and thermoluminescent (TLD100) dosimeters. The author reports the difficulty of recording low dose values with the Instadose^{TM} (close to the detection threshold), which corroborates the results obtained in this present research.

The estimation of occupational doses is also relevant for the purpose of optimizing procedures. In Brazil, occupational monitoring is mostly performed using thermoluminescent (TLD) or optically stimulated (OSL) dosimeters, using monitors positioned in the thoracic region, over the lead apron. As it is a passive dosimeter, there is a delay of at least 2 months for the professional to become aware of their monthly doses, which makes it very difficult to associate situations of care practice with the doses received. In addition, only doses received in the core region are routinely monitored. Some studies show that not all professionals routinely use the individual dosimeter or have doubts about its position [18]. That is why studies that evaluate the implementation of direct reading dosimeters, as complementary dosimetry, are important for radiological protection as they can fulfill an educational role in clinical practice, in addition to being able to contribute to the optimization of radiological protection.

5. CONCLUSION

Based on the data sample from fluoroscopy-guided electrophysiology (FES) procedures, this study concluded that the occupational dose values per procedure are less than or equal to the sensitivity threshold of the Instadose^{TM} dosimeter, except for values obtained in the left eye region. Occupational doses obtained in the left eye region were (3rd quartile / maximum value) 0.07 / 0.20 mSv.

With the data recorded by the Instadose^{TM} dosimeter, it was not possible to compare the occupational doses monitored between the different regions of the physician's body.

The doses recorded with the dosimeter positioned in the center of the gantry (3rd quartile / maximum value) were 0.38 / 1.53 mSv are statistically different from the occupational dose values recorded in the left eye region (p= 0.000091). Statistical analysis showed that there is no correlation between these values (p = 0.15).

The Instadose^{TM} presented a limited performance in the complementary monitoring of occupational doses in FES, due to its sensitivity threshold. In future work, we intend to evaluate other dosimetric systems, if Instadose^{TM} can be use in monthly evaluation (if the information is

correctly preserved and stacked) and evaluate the influence of the X-ray tube position in the operators' received dose (such what was done for CT by Knott et. al. [19]).

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