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VERIDIC: VALIDATION AND ESTIMATION OF RADIATION SKIN DOSE IN INTERVENTIONAL CARDIOLOGY

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ABSTRACT

In interventional cardiology (IC), patients may be exposed to high doses to the skin resulting in tissue reactions (skin burns) following single or multiple procedures. To address this issue, online and offline software has been developed to estimate the maximum skin dose (MSD) to the patient from IC procedures. However, the capabilities and accuracy of such skin dose calculation (SDC) software to estimate MSD and 2D dose distributions markedly differ among vendors. Hence, this project focuses on the harmonisation of RDSR (radiation dose structured report) and on the validation of SDC software products in IC, which will optimise radiation protection of patients. The outcome of the project will include the standards for digital dose reporting, development of protocols for acceptance testing and Quality Control (QC) of SDC software and setting of diagnostic reference levels per clinical complexity, assessing the frequency of high-dose procedures as well as dose reduction strategies based on the multi-centric data collection. This paper focuses on the work performed to investigate performance of solid state dosimeters used in clinical environment.

1. Introduction

Fluoroscopically guided interventional procedures in interventional radiology (IR) and cardiology (IC) are techniques that have had increased use in the last decades. Although, they reduce most of the risks to patients, prolonged exposures due to complicated interventional procedures or use of inappropriate equipment may result in high doses to both patients and staff members, in particular, with potentially high radiation doses to the patient's skin. Numerous cases of radiation-induced deterministic tissue reactions following exposure in interventional procedures, such as erythema and hair loss, have been reported in the literature [1-3]. Recommendations for operators performing interventional procedures were published a few decades ago and the need for measuring patient dose was expressed [4]. Since then, a huge effort has been made to identify practical and easy-to-use methods to monitor and reduce patient skin doses in interventional procedures [2-3]. The steady increase in the number of IC procedures over the years has further strengthened that need.

2. Assessment of skin dose in interventional procedures

Until recently, measurements using passive dosimeters were the only way to assess patient's maximum skin dose (MSD) accurately. However, as these measurements are tedious and expensive to undertake, they could not be performed routinely at clinics and a more convenient means to estimate MSD was needed. Automated online and offline skin dose calculation (SDC) solutions have therefore been developed. Online software tools utilise live data streaming from the angiographic system to calculate skin doses directly during intervention, while offline solutions use data stored in the radiation dose structured report (RDSR) to compute skin exposure after the procedure. Currently, most vendors have implemented some form of skin dose calculations in their angiographic systems: from simple solutions only computing maximum cumulative air kerma doe specific angulations, values, to more advanced software solutions calculating a 2D distribution of the skin dose. Offline SDC software solutions have also been developed in research-based institutions or for commercial purposes, both as stand-alone products or integrated into the dose archiving and communication systems of the hospital. However, the capabilities and accuracy of such SDC software to estimate MSD and 2D dose distributions markedly differ among vendors; and the reporting of the MSD estimate and the related accuracy in the RDSR is neither systematic nor harmonised. In addition, there is currently no acceptance testing and quality control (QC) protocols of such systems.

3. VERIDIC project: accuracy of skin dose calculation software in interventional cardiology

Hence, the VERIDIC project (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology), funded under European Joint Programme for the Integration of Radiation Protection Research, H2020 (Grant agreement No 662287), focuses on the harmonisation of RDSR and on the validation of SDC software products in IC, which will optimise radiation protection of patients. The project involves 10 partners from 8 European countries. It started on the 1 February 2018 and will run for 2 years. The aims, methodology and some of the preliminary results of the VERIDIC project are presented

in this work. The project is divided in three work packages (WP), while specific aims of each WP can be summarized as:

- Standards for digital dose reporting: 1) A complete list of parameters necessary to calculate MSD and 2D dose distribution (tube voltage, filtration, beam orientation, table position, backscatter factor, table attenuation, air KERMA-to-skin dose conversion coefficient, etc.); 2) The recording (format and content) of MSD values and 2D dose distributions in the RDSR.
- Protocols for acceptance testing and QC of SDC software, including: 1) comprehensive calibration of field dosimeters to be used for software benchmarking, including estimation of associated uncertainty; 2) acceptance testing of online and offline software in simple irradiation conditions; 3) QC tests of the software in clinical settings reproducing complex cardiac procedures such as Chronic Total Occlusions (CTO).
- Interventional Diagnostic Reference Levels (DRL) and frequency of high-dose procedures as well as dose reduction strategies will be established thanks to a multi-centric data collection.

4. Methodology of the VERIDIC project

WP1. Standards for digital dose reporting: SDC software solutions are analysed according to their calculation algorithms and their capabilities. In particular, the factors considered in the calculation of the MSD estimates (such as the backscatter, the table attenuation or the patient's body shape) and how they are reported by different manufacturers are investigated. The availability of the parameters mandatory for MSD estimate are evaluated within a sample of RSDR collected in the participating hospitals. Furthermore, recommendations for harmonisation of the MSD reporting among different systems will be formulated.

WP2. Protocols for acceptance testing and QC of SDC software: Most commonly used field dosimeters, Gafchromic films and thermoluminescent dosimeters (TLDs) and semiconductor dosemeters (multimeters), are characterised and calibrated for a wide range of conditions encountered in IC, leading to a precisely computed uncertainty. Protocols for acceptance and QC tests to be used by medical physicists in clinical practice will be developed. Those protocols will also enable the comparison of different SDC software. Tolerance levels and technical criteria for acceptance of SDC systems will be proposed. Techniques and existing equipment, such as phantoms and dosimeters, readily accessible to medical physicists in clinical environment will be favoured in the QC approach. The QC and acceptance protocols will be first tested on angiographic systems equipped with existing, online SDC software. The RDSR of these experiments will be extracted from the angiographic systems and input in available offline SDC software for skin dose calculations. Calculated results will be compared with reference measurements. Exposure parameters of high-dose procedures will be extracted from the RDSR collected in several European hospitals (see below). Those procedures will be repeated on a Rando-Alderson phantom and measured using TLDs and Gafchromic films. The results will be used for comparison of reference dose measurements with dose estimates using online and offline SDC in realistic clinical conditions.

WP 3. Interventional Reference Levels and dose reduction strategies: In at least 12 European hospitals, 19 angiographic units with RDSR/dose reports , the project partners

will collect at least 50 cardiac therapeutic procedures per centre with RDSR and clinical indications, in order to develop reference levels. Skin dose will be calculated on different SDC software solutions depending on the availability of RDSR. Statistical analysis will be performed to find correlation between clinical parameters (procedure as well as clinical parameters) and patient exposure on one side as well as technical parameters (from RDSR) and patient exposure on another side. Reference levels will be developed based on clinical complexity. Moreover, the frequency of high dose procedures will be assessed and recommendations for patient dose optimization will be derived.

5. Characterisation of the solid-state multimeters used in clinical practice

One of the tasks under *WP2. Protocols for acceptance testing and QC of SDC software* Task 2.1, is related to the calibration of field dosimeters and traceability to a national standard. Various examination techniques are employed in diagnostic radiology using tube voltages from approximately 20 kV to 150 kV. An accurate measurement of dose requires correct calibration of the instrumentation in radiation fields of known properties. In diagnostic radiology, the specification of radiation qualities is important as the response of all dosimeters depends, at least to a certain extent, on the spectral distribution of the X- rays employed. Ionization chambers have been the standard instruments used for diagnostic radiology dosimetry and quality assurance assessments for many years. Dosemeters based on semiconductor technology are now becoming widely available, and as the semiconductor detectors are smaller they are more convenient to use in many situations. Diagnostic dosemeters should be designed in compliance with IEC 61674 standard [5], which applies both to dosimeters equipped with ionization chambers and to semiconductor detectors. Traditionally, the main disadvantage of these devices has been their energy dependence of response which differs considerably from that of ionization chambers. Semiconductor diodes do not have the inherent relatively constant response with photon energy in the diagnostic X-ray range for measurement of air kerma that is a feature of ion chambers. Multiple semiconductor elements are incorporated into the semiconductor detector used for X-ray dosimetry. in order to make an assessment of radiation quality that is used to derive a dose compensation which is applied automatically. The angular dependence of measurements made using semiconductors is different from that of ionisation chambers. The commercial semiconducting detectors are mounted on lead backing plates, to attenuate radiation incident from the rear. This is required to ensure that the radiation incident on the detector elements represents that transmitted through filters at the front of the detector i.e.to ensure that the automatic energy compensation is applied correctly. As a result, it is the air kerma incident from the direction of the primary beam that is measured. Nevertheless, these types of detectors have found many applications in routine clinical measurements in hospitals. Most of them are capable of determining the air kerma, tube voltage, half value layer (HVL), and exposure time, as well as the output waveform from a single irradiation.

The dosemeters are routinely calibrated at the following standard radiation qualities (reference beam qualities according to IEC 61267): RQR 3 (50 kV) - RQR 5 (70 kV) - RQR 6 (80 kV) - RQR 8 (100kV) - RQR 9 (120 kV) which are not necessarily representative of the settings used clinically. The performance testing of X-ray equipment often requires the assessment of doses and dose rates for X-ray beams with

many different radiation qualities and in non-standard conditions. The combination of different energy and angular responses will influence detector performances in different X-ray fields, and could lead to significant differences in air kerma measurements. If different dosemeters are used for QC assessments, users must understand what is being recorded and how the measurements are influenced by the detector characteristics.

Table 1. Solid state dosemeters tested in different standard and non-standard beam qualities.

No	Manufacturer	Model	X-ray tube voltage or energy	Dose range	Dose rate range
1	RTI, Moldaln, Sweden	MPD, Barrcuda	35 – 155 kV	15 nGy – 1000 Gy	15 nGy/s – 450 mGy/s
2	RTI, Moldaln, Sweden	R100, Barrcuda	Not specified	2 nGy – 10 kGy	0.04 µGy/s – 160 mGy/s
3	RTI, Moldaln, Sweden	Black Piranha	50–150 kVp, 1–90 mm Al or 2 mm Cu	0.1 nGy–1500 Gy	1 nGy/s–320mGy/s
4	RaySafe, RTI, Moldaln, Sweden	Xi R/F Classic	35 – 160 kV/kVp (for up to 0.5 mm Cu or equivalent)	10 nGy – 9999 Gy	10 nGy/s – 1000 mGy/s

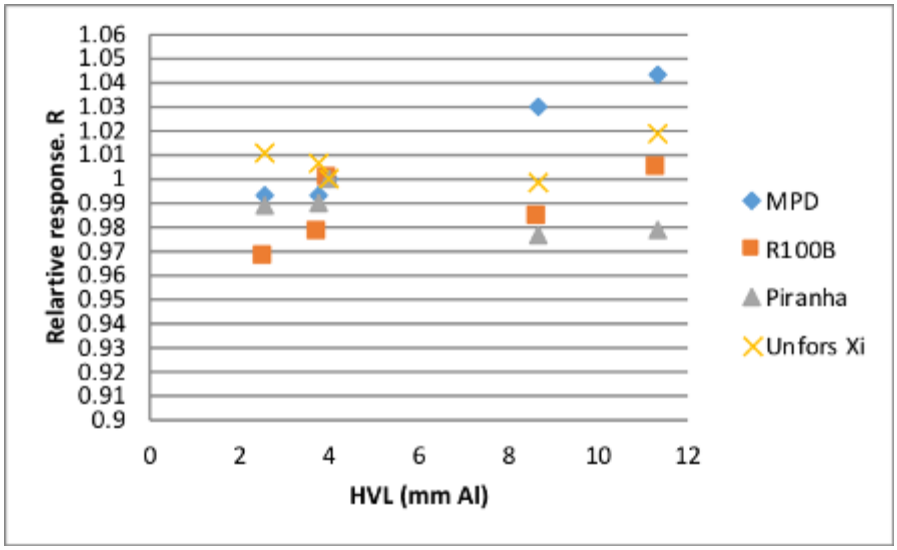

Figure 1. Energy response of four different solid -state dosimeters.

Therefore, the performance of four different semiconducor dosemeters/multimeters (Table 1) was investigated, both in standard and non-standard conditions. Tested parameters evaluated during characterisation of the solid-state dosemeters were: in air comparison, angular response, in air comparison for energy response and response linearity. The X –ray beams were generated using an X-ray unit Hopewell Design, with X-ray tube voltage (10-225) kV, whereas the dosimetry standard was an ionization chamber Exradin A3 with reference class electrometer Unidos (PTW, Germany).

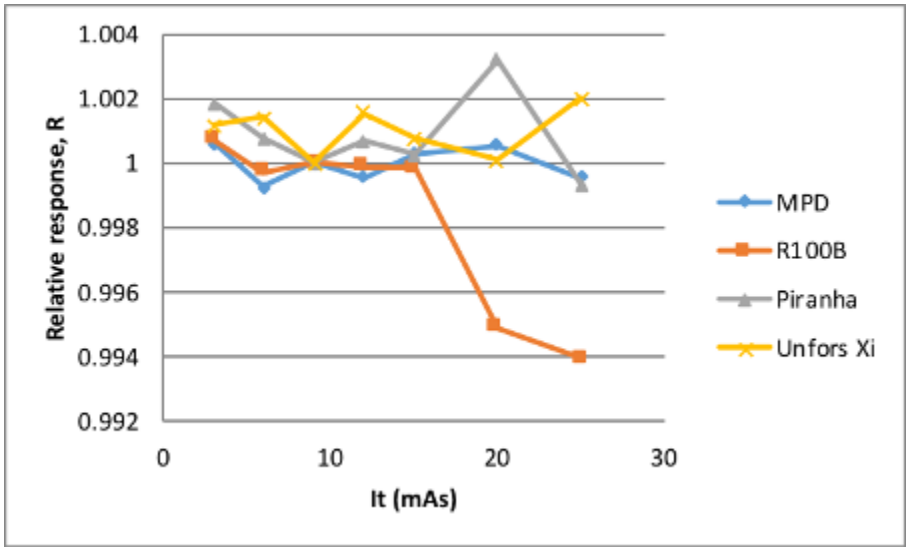

Figure 2. Linearity of four different solid -state dosimeters.

Preliminary results are presented in Figures 1-3, indicating consistent performance.

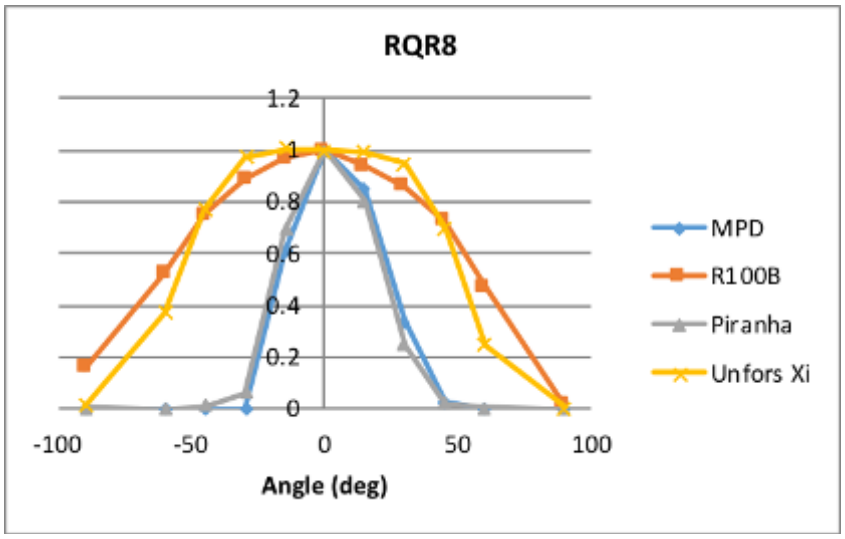

Figure 3. Angular response of four different solid -state dosimeters.

6. Acknowledgement

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VERIDIC: VALIDACIJA I PROCENA DOZE NA POVRŠINI KOŽE ZAPACIJENTE U INTERVENTNOJ KARDIOLOGIJI

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SADRŽAJ

Interventne procedure u radiologiji i kardiologiji povezani sus a visokim dozama za kožu pacijenta i potencijalnim radijacionim povredama kože. Različita metodologije i rešenja razvijene us za procenu maksimalne doze za kožu, čija se svojsvta, uključujući i tačnost značajno razlikuju. U radu su prokazani ciljevi, metode i preminiran a rešenja projekta VERIDIC usmerenoj na validaciju zaličitih ofline i online softvera za procenu doze za kožu pacijenta u intervenatnoj kardiologiji.