VERIDIC: Validation and Estimation of Radiation skIn Dose in Interventional Cardiology

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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. As the number and complexity of IC procedures have been steadily growing, online and offline software has been developed to estimate the maximum skin dose (MSD) to the patient during (or after) 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. Besides, the reporting of the MSD estimate in the Radiation Dose Structured Report (RDSR) is neither systematic nor harmonised.
The VERIDIC (Validation and Estimation of Radiation skIn Dose in Interventional Cardiology) project aimed to contribute to RDSR harmonisation, to develop Acceptance and quality control (QC) testing protocols for the accuracy of SDC software in IC and to foster patient dose reduction.To achieve these objectives, the project was divided into three Work Packages (WPs).

Within WP1, a complete list of parameters necessary to calculate the MSD and the 2D-skin-dose distribution was established. A review of the software products enabling calculation of the MSD was performed from literature and contacts with the manufacturers and developers. 18 software products were considered; for 13 of those sufficient data was obtained to perform the review. In addition, the availability of the parameters mandatory for MSD estimate was evaluated within the RDSR from the four manufacturers of angiographic units. Recommendations for harmonisation of the RDSR were formulated.

Within WP2, Acceptance and QC testing protocols for the accuracy of SDC software in interventional cardiology were developed. The Acceptance protocol is composed of 13 fundamental irradiation set-ups and 3 clinical procedures, intended to represent more realistic conditions. The QC protocol is based upon the Acceptance protocol and is made of 8 fundamental irradiation set-ups. Measurements were performed following the acceptance protocol on a GE Innova IGS 540, a Philips Allura Xper, a Siemens Artis Zee biplane and a Toshiba Infinix CF-i biplane. QC dosimeters (type multimeter), thermoluminescence dosimeters and gafchromic films were used for the measurements, after calibration using four new reference beams dedicated to IC applications and traceable to dedicated primary

standards. Skin dose estimates were performed with up to 8 SDC software products (CareMonitor, Dose Tracking System, Dose, DoseMap, em.dose, OpenSkin, Radiation Dose Monitor, Skin Dose Map and SkinCare,) depending on the system compatibility.
The MSDs estimated by most SDC software products were within ±40% of the measurements during the fundamental irradiations and the clinical procedures. However, about half of the software products could not provide MSD estimates for lateral irradiations because a flat phantom was used. Among the remaining software products, accuracy of the MSD estimate for lateral irradiations was quite variable and could be very poor. Most SDC software produced maps representing acceptably the dimensions, the shape and the relative position of the MSD region, although some software could miss the MSD region when situated at the thin intersection of multiple fields. In addition, few software could handle wedge filters, which caused inaccurate dimensions and shape of the MSD region if not addressed. SDC software solutions can produce acceptable results and may account for fine technical details of the procedure; however, the determination of the patient body contour and position remains challenging. This can dramatically degrade the software accuracy particularly for lateral irradiations and irradiations that are not centred on patient back.

Within WP3, data were collected for procedures with high dose potential in 13 hospitals from 8 European countries, including more than 20 angiography units. 534 percutaneous coronary interventions (PCI), 219 PCI for chronic total occlusions (CTO) and 209 transcatheter aortic valve implantation (TAVI) procedures were collected. Univariate and multivariate statistical analysis of data samples was performed on the air kerma at the reference point ($K_{a,r}$) , the kerma-area product (P_{KA}) and MSD. The main aim was to compare different databases per type of procedure (PCI, CTO, TAVI) and to determine and quantify the effect of common clinical factors having an influence on the $K_{a,r}$, the P_{KA} and the MSD. Moreover, reference levels were determined for each type of procedures. Two models were also suggested to calculate the MSD: an a priori model based on clinical factors allowing the interventional cardiologist to have a raw MSD estimate at the start of the procedure and an a posteriori model based on limited clinical and technical factors used during the procedure.

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