Physica Medica 54 (2018) 42–48

Contents lists available at ScienceDirect

Physica Medica

journal homepage: www.elsevier.com/locate/ejmp

Original paper

Establishing the European diagnostic reference levels for interventional cardiology

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ARTICLE INFO

Keywords:
Diagnostic reference levels
Interventional cardiology

ABSTRACT

Interventional cardiac procedures may be associated with high patient doses and therefore require special attention to protect the patients from radiation injuries such as skin erythema, cardiovascular tissue reactions or radiation-induced cancer. In this study, patient exposure data is collected from 13 countries (37 clinics and nearly 50 interventional rooms) and for 10 different procedures. Dose data was collected from a total of 14,922 interventional cardiology procedures. Based on these data European diagnostic reference levels (DRL) for air kerma-area product are suggested for coronary angiography (CA, DRL = 35 Gy cm^2), percutaneous coronary intervention (PCI, 85 Gy cm^2), transcatheter aortic valve implantation (TAVI, 130 Gy cm^2), electrophysiological procedures (12 Gy cm^2) and pacemaker implantations. Pacemaker implantations were further divided into single-chamber (2.5 Gy cm^2) and dual chamber (3.5 Gy cm^2) procedures and implantations of cardiac resynchronization therapy pacemaker (18 Gy cm^2). Results show that relatively new techniques such as TAVI and treatment of chronic total occlusion (CTO) often produce relatively high doses, and thus emphasises the need for use of an optimization tool such as DRL to assist in reducing patient exposure. The generic DRL presented here facilitate comparison of patient exposure in interventional cardiology.

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https://doi.org/10.1016/j.ejmp.2018.09.012
Received 5 June 2018; Received in revised form 19 September 2018; Accepted 23 September 2018

1. Introduction

Interventional cardiac procedures can produce high patient doses and therefore require special attention to protect the patient from radiation injuries such as skin burns, cardiovascular tissue reactions or radiation-induced cancer [1]. In the early days of interventional radiology and cardiology the procedures and techniques were straightforward and the required fluoroscopy time was short. The introduction of more sophisticated catheters and stents in 1980's and 1990's led to more complex and time-consuming operations, thus increasing both patient and operator exposures [2]. Even though the use of fluoroscopy in medical procedures has a long and successful history, reported severe radiation-related injuries such as skin burns were relatively rare until 1990's. With technological advances, new techniques and procedures with potentially high-doses have been introduced recently, such as transcatheter aortic valve implantation (TAVI) and treatment of chronic total occlusions (CTO). At the same time, the technological advances such as reduced frame rates, virtual collimation, noise suppression etc. may compensate the potential increase in patient exposure.

One essential tool to promote optimization in interventional procedures is the diagnostic reference level (DRL). The use of DRLs is emphasized also in the new European Basic Safety Standard [3]. However, since the implementation of DRLs in interventional procedures varies significantly with the complexity and are only applicable to groups of patients, alert levels have been introduced to indicate doses that are high enough to cause tissue reactions such as skin effects on individual patients [4,5]. Alert levels typically use the online dose indicator (e.g. air kerma-area product P_{KA} or cumulative air kerma at patient entrance reference point C_K [6]) to estimate the peak skin dose to the patient.

Ideally, the DRLs should be set and regularly updated at a national or even at local (hospital) level. Then, each hospital performing the respective procedures should audit their patient doses to calculate their median values to ensure that they do not exceed the corresponding reference levels. However, some high-dose procedures are relatively new or done infrequently, hence setting local, national or regional DRLs is not always appropriate at the onset of operation. To provide basis for optimization, European DRLs in interventional cardiology (IC) have been suggested ten years ago in the SENTINEL project for some of the most common cardiac procedures [7]. Recently, in the European Union there have been several DRL studies in coronary angiography (CA) and percutaneous coronary intervention (PCI) [8–16], and also a few studies on pacemaker implantations (PI) and electrophysiological procedures (EF) [8,10,14,16]. However, for TAVI, pacemaker implantation and electrophysiological procedures the published DRLs remain scarce. One of the most recent examples is the Finnish national set of DRLs in cardiology [16]. If several national DRLs exist for a specific procedure, the simplest way of establishing a regional (i.e. group of countries) DRL is to use the national DRLs [17]. However, in the case of IC, the DRLs exist mostly for CA and PCI procedures and a separate survey is needed for other procedures. ICRP [17] suggests that the DRLs should be revised at regular intervals not exceeding 5 years.

In this work a study covering selected centers from 13 countries and 10 different cardiac procedures was conducted. The main goal of this study was to propose new European DRLs for selected common or recently introduced IC procedures. In addition to patient exposure parameters, some parameters related to patient physiology and execution of the procedure were also collected and were used to study the dependence of patient dose indicators on these parameters. The results of this study can be used to promote optimization in patient protection before national or local DRLs are set and also to provide a basis for comparison when these levels are being set.

2. Materials and methods

The data was collected from 12 European countries (Belgium (BE), Croatia (HR), Czech Republic (CZ), Finland (FI), France (FR), Greece (GR), Ireland (IE), Poland (PL), Serbia (RS), Spain (ES), Sweden (SE) and Switzerland (CH)) and Lebanon (LB). This included 37 clinics and nearly 50 interventional rooms. The IC procedures taken into consideration were coronary angiography (CA), percutaneous coronary intervention (PCI), pacemaker implantation (PI), electrophysiological procedures (EF) and transcatheter aortic valve implantations (TAVI). The chronic total occlusions (CTO) were considered separately for PCI, when the separation was reported by the hospital. Pacemaker implantations were further divided into single (SCH) and dual chamber (DCH) procedures and implantations of cardiac resynchronization therapy (CRT) pacemaker. Electrophysiological procedures were divided into atrioventricular nodal reentrant tachycardia (AVNRT), atrial flutter (FL) and atrial fibrillations (AF). The majority of the data was collected between years 2015 and 2017 using Excel data collection sheets, the rest being collected between 2011 and 2014 from hospital information systems. In total, data for 14,922 procedures were collected. The data were corrected for obvious errors (e.g. incorrect P_{KA} units) and then verified by medical physics experts from each participating hospital or institution.

The procedures and corresponding patient distributions are summarized in Table 1. Other collected parameters were

- Date of procedure
- Access route
- Classification of PCI procedures (elective PCI or CA followed by an ad hoc PCI)
- Number of images
- Fluoroscopy time (FT)
- Total exposure time (including both FT and cine time)
- Fluoroscopy air kerma area product (P_{KA})
- Total P_{KA}
- Cumulative air kerma at patient entrance reference point (C_K) [6]

The data were analyzed with R code, version 3.3.2 [18]. The DRLs were determined as a 75% level (third quartile) of the distribution of quantity under review (e.g. P_{KA} or C_K). To get European values, the median of the quantity under review for each country was calculated. The DRL was then calculated as the third quartile of these median values. Pearson and Spearman correlations were used to examine the

Table 1
Procedures for which the data were collected, number of procedures and characteristics of patient distributions. Data for PI was evenly distributed between SCH, DCH and CRT procedures.

Procedure	n	Mean age (y)	Sex	Mean mass (kg)	Mean height (cm)
CA	4319	67	F: 35%, M: 65%	81	171
PCI	6467	66	F: 25%, M: 75%	82	171
CTO	192	64	F: 13%, M: 87%	82	172
PI	1587	72	F: 33%, M: 67%	81	171
EF	1462	57	F: 36%, M: 64%	84	173
TAVI	895	82	F: 51%, M: 49%	74	164