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Optimisation of patient doses and
image quality in diagnostic radiology



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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following papers, which are referred to by their Roman numerals:

- I Kepler, K.; Vladimirov, A. (2008). Optimisation strategies introduced for CR at health care centres in Estonia. *Radiation Protection Dosimetry*, 129(1–3), 127–131.
- II Kepler, K.; Vladimirov, A.; Servomaa, A. (2005). Interlaboratory comparison and accreditation in quality control testing of diagnostic X-ray equipment. *Radiation Protection Dosimetry*, 114(1–3), 198–200.
- III Zoetelief, J.; Schultz, F.W.; Kottou, S.; Gray, L.; O'Connor, U.; Salat, D.; Kepler, K.; Kaplanis, P.; Jankowski, J.; Schreiner, A.; Vassileva, J. (2008). Quality control measurements for fluoroscopy systems in eight countries participating in the SENTINEL EU coordination action. *Radiation Protection Dosimetry*, 129(1–3), 237–243.
- IV Padovani, R.; Trianni, A.; Bokou, C.; Bosmans, H.; Jankowski, J.; Kottou, S.; Kepler, K.; Malone, J.; Tsapaki, V.; Salat, D.; Vano, E.; Vassileva, J. (2008). Survey on performance assessment of cardiac angiography systems. *Radiation Protection Dosimetry*, 129(1–3), 108–111.
- V Vano, E.; Järvinen, H.; Kosunen, A.; Bly, R.; Malone, J.; Dowling, A.; Larkin, A.; Padovani, R.; Bosmans, H.; Dragusin, O.; Jaschke, W.; Torbica, P.; Back, C.; Schreiner, A.; Bokou, C.; Kottou, S.; Tsapaki, V.; Jankowski, J.; Papierz, S.; Domienik, J.; Werduch, A.; Nikodemova, D.; Salat, D.; Kepler, K.; Bor, M.D.; Vassileva, J.; Borisova, R.; Pellet, S.; and Corbett, R.H. (2008). Patient dose in interventional radiology: a European survey. *Radiation Protection Dosimetry*, 129(1–3), 39–45.
- VI Padovani, R.; Vano, E.; Trianni, A.; Bokou, C.; Bosmans, H.; Bor, D.; Jankowski, J.; Torbica, P.; Kepler, K.; Dowling, A.; Milu, C.; Tsapaki, V.; Salat, D.; Vassileva, J.; Faulkner, K. (2008). Reference levels at European level for cardiac interventional procedures. *Radiation Protection Dosimetry*, 129(1–3), 104–107.

Comment on participation

The author's research has been an essential part of all these publications. He was responsible in tests and measurements carried out in the Estonian health care centres and in the STUK laboratory for test setup, data collecting, analysing and reporting. In addition, the author's contribution to the articles I and II was planning, literature reviewing and writing. The contribution to publications II–VI was collecting technical and dosimetric data in Estonian health care centres, providing the data to the European SENTINEL coordinators, and participating in the teamwork of analysing and reporting the data.

ABBREVIATIONS

AEC	automatic exposure control
BMTK	Training Centre for Medical Physics and Biomedical Engineering
CA	coronary angiography
CCD	charge-coupled device
CD	cumulative dose
CEC	Commission of the European Communities
CNR	contrast-to-noise ratio
CR	computed radiography
DAP	dose area product
DDI	detector dose indicator
DICOM	Digital Imaging and Communications in Medicine (standard)
DQE	detective quantum efficiency
DRL	diagnostic reference level
EAL	European Co-operation for Accreditation of Laboratories
EP	electrophysiology
ESAK	entrance surface air kerma
FOM	figure of merit
FOV	field of view
FPD	flat panel (imaging) detector
FT	fluoroscopy time
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IDS	image detector system
IEC	International Electrotechnical Commission
II	image intensifier
ILC	interlaboratory comparison
IPEM	Institute of Physics and Engineering in Medicine (UK)
IR	interventional radiology
IRP	interventional reference point
ISO	International Organization for Standardization
KAP	kerma area product
MED	medical exposure directive (97/43/Euratom)
MPBE	Department of Medical Physics and Bioengineering of St James's Hospital, Dublin
MTF	modulation transfer function
NEQ	noise equivalent quanta
NPS	noise power spectrum
PACS	picture archiving and communication system
PMMA	polymethyl methacrylate
PTCA	percutaneous transluminal coronary angioplasty
QA	quality assurance

QC	quality control
RFCA	radiofrequency cardiac ablation
RIS	radiology information system
ROI	region of interest
SENTINEL	Safety and Efficacy for New Techniques and Imaging using New Equipment to Support European Legislation (EU coordination project)
SNR	signal-to-noise ratio
STUK	Finnish Radiation and Nuclear Safety Authority
TCDD	threshold contrast-detail detectability
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation

I. INTRODUCTION

I.1. Background

I.1.1. Patient dose surveys

Medical diagnostic radiation procedures make up the majority of the human exposure from artificial sources of ionising radiation [1, 2]. Now in some developed countries these doses can be compared with the average annual effective dose from background radiation [3, 1]. X-ray examinations are the most commonly used radiological examinations in medical diagnostics [2, 3, 4, 5]. In several European countries contribution of X-rays to average annual effective dose per caput has been estimated to be over 86 % of all diagnostic exposures, including nuclear medicine [6]. Among X-ray examinations in UK, angiographic and interventional procedures are responsible for 19% and radiographic and fluoroscopic procedures for 34% of the population dose, representing 93% of all X-ray examinations, while computed tomography represents 7% of all X-ray examinations and contributes 47% of the total population dose from medical X-ray examinations [4]. The annual per caput effective dose of 0.4 mSv from X-ray medical diagnostic exposures in UK [4, 6] in 2001 is low in comparison with other countries having similarly developed systems of health care (for comparison 1.7 mSv in Germany [6] in 2001 or 2.2 mSv in USA [5] in 2006).

The basis for low dose radiation protection has been based on the linear no-threshold (LNT) theory of radiation carcinogenesis [7, 8, 9]. In principle, the number of examinations with ionising radiation and the dose per image should be reduced as much as possible. To be able to keep doses as low as reasonably achievable (ALARA principle), a fundamental knowledge of the factors influencing patient doses is needed.

In 1997 the essentially voluntary system of patient dose management, introduced by the International Commission on Radiological Protection [7, 8] (the approach updated recently by ICRP publications 103 and 105 [9, 10]), and developed by IAEA [11], became mandatory in European Union [12]. By 1999 European diagnostic reference levels (DRLs), based on European dose surveys, were available in three sets of European guidelines on quality criteria: for radiographic examinations in adults and in children, for mammography and for computed tomography examinations [13, 14]. DRLs provide a broadly accepted tool to reduce the large variation in patient dose for the same type of X-ray examination, and to assist in the optimisation process [13, 15, 16]. For now initial patient dose surveys have been carried out in most of the EU member states, and quite often it is done in the framework of international collaboration (e.g. Nordic survey [17], EU coordinated research projects DIMOND [18] and SENTINEL, consortium comprising 22 members from 19 EU member states [19, 20], and IAEA coordinated research projects [21]). The present study was carried out mainly from 2003 to 2007, also participating in SENTINEL research activities.

Using DRLs for dose optimisation has been justified in regional and hospital level practice in many countries [22] and has steadily reduced the radiation burden of radiological investigations. For example, in UK the current reference doses are approximately 16% lower than the corresponding values in the previous review of 2000 [23], and are typically less than half the values of the original UK national reference doses that were derived from a survey in the mid-1980s. In the same time no clear evidence could be found for the use of digital imaging equipment having a significant effect on dose in UK [15], having a well established national quality system in radiology.

For 2008 under the framework of a multinational project DOSE DATAMED involving partners and institutes from ten European countries (UK, Switzerland, Germany, Sweden, Norway, Netherlands, France, Belgium, Denmark, Luxembourg) a guidance document for conducting national surveys of population exposure from medical radiology was developed [6]. The recommendations in this document are based on a comparative study on the methods and results of the most recent population dose surveys in each participating country.

It is widely recognized that some procedures in interventional radiology carry greater doses and radiation risks than many other radiological examinations [24, 25]. By a recent European study in 2006 the estimated average number of coronary angiograms is 5045 per million population, 1511 per million for PTCAs, 836 per million for stents and 918 per million for pacemaker insertions in the 29 countries studied [26]. A database on patient doses is a prerequisite for any formulation of national and European guidelines on the optimised use of radiographic and interventional procedures, including the setting of the reference levels.

An appropriate list of concepts and quantities for skin dosimetry in interventional radiology has been defined in ICRP Publication 85 [24]. Different methods to estimate the patient dose have been tested and compared [27, 28, 29, 30, 31]. ICRU report on patient dosimetry for X-rays used in medical imaging [32, 33] and IAEA guidance for dosimetry in X-ray diagnostics [34, 35, 36] have been published.

1.1.2. Advances in medical imaging technology

During recent decades conventional film–screen radiography, traditionally used for medical applications over the past century, has been replaced more and more by digital techniques. After the development of digital subtraction angiography the first application of digital image intensifier was introduced in the early 1980s. This method has been used for examinations of the gastrointestinal tract, myelography and arthrography [37].

In the middle of the 1980s storage phosphor technology (computed radiography) was introduced to medical radiological imaging [38, 39]. At first the difficult handling and the limited image quality has resulted in a delayed wide application, but after significant improvements, this method has replaced

in recent years film radiography and gives now an important contribution to imaging in projection radiography in most of European countries, including Estonia [40, 41, 42].

The further progress of radiation detection technology has made possible direct acquisition of the image information at the detector (flat panel detector technology) [43, 44]. After first being successfully tested in manufacturers' research laboratories, the new technology made the transition into clinical use in late 1990s, and in recent years successfully replacing the phosphor plate technology [45, 46].

New methods of digital radiography have facilitated operational conveniences, such as electronic archival, postprocessing, concurrent distribution and soft-copy viewing of the images, that were not feasible with analog, screen-film, systems [37, 45]. At the same time, it has introduced new challenges in the way the images are acquired and displayed. In particular, the concept of image quality has taken on new interpretations and meaning owing to some unique attributes of digital radiography. Nevertheless digital technologies have the potential to reduce patient doses, they also have the potential to significantly increase them [47]. Experience has shown that although many radiology departments have made the transition to digital equipment, patient doses have not gone down but have measurably increased [48, 49]. In digital radiography the grayscale appearance of an image (except for noise) is no longer limited by the applied radiographic technique (kVp and mAs). Lower doses would clearly result in some adverse impact on image quality with regard to noise, and probably would be noticed. However, if the doses drift upward, the overexposure will not be noticed because there will be no adverse effect on image quality [49]. The increase in dynamic range of the digital imaging system makes it more difficult to recognise overexposure or underexposure. Different possibilities of pre- and post-processing make the evaluation of image quality of digital techniques more complex compared with conventional film–screen radiography. As a result, the importance of dosimetry within the overall medical imaging strategy is increasing [50, 51, 47, 9, 10].

Another attribute of digital radiography systems is their varying sensitivity to X-ray energy. Most analog systems use a rare-earth phosphor screen with a K-edge peak sensitivity at about 58 keV. Current digital radiography systems use a variety of X-ray sensitive layers ranging from rare-earth phosphors to amorphous selenium, barium halide and CsI [52]. Most of these materials have spectral sensitivities that differ from analog film-screen systems suggesting that techniques considered 'optimum' for analog systems may no longer be considered optimum for digital systems.

The energy responses of digital radiography detectors are different from those of screen-film systems. To assure a consistent level of image quality at different tube potentials automatic exposure control (AEC) devices must be calibrated to be corresponding to the energy response of the image receptor used in the X-ray system. AEC calibration for digital radiography systems

requires an alternative parameter to optical density, which was used in film technology. Ideally it should be related to the quality of a digital image.

1.1.3. Quality assurance in diagnostic radiology

Special guidelines for digital radiography and interventional radiology are necessary to guarantee high image quality and to avoid overexposure and misdiagnosis. By the internationally accepted good practice in radiology these guidelines should be based on the quality criteria concept [13, 50]. The guidelines include usually criteria for the detectability of specific anatomic details, technical parameters for good radiographic technique and imaging performance, and reference dose values. Assessment of image quality by suitable phantoms and performance testing are prerequisites for quality assurance. For many years great efforts have been made by radiologists, medical physicists, radiographers, radiation protection experts, health authorities and national and international organisations to elaborate quality criteria for different radiographic techniques. Throughout the European Union a special quality and safety culture has been introduced [50]. The concept of safety culture, defined initially in the field of nuclear power plants by IAEA [53], has been developed also in medical radiology [54, 55]. Safety culture includes all the factors, including physical and human factors that influence patient and staff safety in medical use of radiation. In interventional procedures the staff operate near the patient and is exposed to a non-uniform radiation field due to patient-scattered radiation [56].

European directive on usage of medical exposures makes necessary the establishment of quality assurance programmes and criteria of acceptability for equipment and installations [12, 57, 58]. The quality assurance programmes include monitoring, evaluation and maintenance of the required characteristics of performance of equipment that can be defined, measured, and controlled. Practical consequences of these responsibilities are that acceptance testing must be carried out before the first use of the equipment for clinical purposes to ensure it complies with its performance specification and to provide reference values (benchmark) for future performance testing. Further performance testing must be undertaken on a regular basis, and after any major maintenance procedure. Necessary measures must be taken by the holder of the radiological installation to improve inadequate or defective features of the equipment. Competent national authorities must adopt specific criteria of acceptability for equipment in order to indicate when appropriate action is necessary, including, taking the equipment out of service. The holder of the radiological installation must implement appropriate quality assurance programmes including quality control measures [59, 58]. Inadequate quality control measures might cause low performance of the X-ray unit, high patient doses, low image quality and even wrong diagnosis. Principally, the quality assurance in radiology departments is teamwork of radiologists, who are responsible for accurate diagnosis based on good image quality, medical physicists (or biomedical engineers), who are responsible of compliant physical

performance of the equipment, and radiographers, who are responsible of using relevant examination techniques [59].

Continuous education and training in radiation protection are widely recognised as one of the basic components of optimisation programmes for medical exposures by all relevant international bodies. The International Commission on Radiological Protection (ICRP) [10], the World Health Organisation (WHO), the International Atomic Energy Agency (IAEA) [11] etc., along with several guidelines published by the European Commission (CEC) [60], recognise the importance of education and training in reducing patient doses while maintaining the desired level of quality in medical exposures. International coordinated recommendations for core curricula in radiation protection, regular multidisciplinary training, taking into account new developing technologies in medical radiology – these are some basic principles of such activities.

Recently the DIMOND and SENTINEL project partners have developed new strategies for optimisation and quality assurance for digital radiography in European health care institutions [61]. It includes consideration of diagnostic requirements of a given clinical situation, and also objectivation and standardisation of image quality, e.g. using contrast-detail test phantom, and constancy testing. In order to achieve appropriate justified image quality by optimising exposure parameters, it is essential in evaluation stage to use as much as possible the ‘normal mode’ of operation of X-ray equipment and image processing. Although the best way to evaluate the quality of medical imaging would be to measure clinical performance by quantitative methods, such as the receiver operating characteristics (ROC) analysis, the technical image quality is frequently measured using simple uniform phantoms and various test objects and is reported in terms of visibility limits, such as contrast-detail curves. Using physical test phantoms, automatic image quality quantification algorithms have been proposed and tested [62, 63, 64]. Although establishing the link between physical image quality measures and clinical usefulness has been sought for decades, the relationship between the results of physical measurements, phantom evaluations and clinical performance is not fully understood [65].

Quality assurance in radiology departments can be made by periodically reviewing the outcome of the X-ray examinations in terms of two fundamental parameters: the image quality and the patient dose. The former is observable every time an image is produced and is continuously assessed by radiographers and radiologists in the radiology department. This is naturally a rather subjective process, but a degree of standardisation and objectivity can be introduced by the use of test objects containing features of varying size and contrast. The performance checks that have been recommended on international and national level for radiography and fluoroscopy include measurements with such image quality test objects [58, 59]. The dose to the patient, however, is undetectable by the digital image and largely unknown unless it is regularly measured at certain intervals.

PCXMC is a computer program that has been developed at Finnish Radiation and Nuclear Safety Authority (STUK) for calculating organ doses

and the effective dose to patient in medical X-ray examinations [66, 67]. It uses the standard Monte Carlo technique, described previously in different applications for risk estimation. Effective dose is a measure of the radiation risk in X-ray examination and can be compared e.g. with the effective dose from background radiation [68]. The doses are calculated in 29 organs and tissues and the program calculates the effective dose with both the present tissue weighting factors of ICRP Publication 103 (2007) [9] and the old tissue weighting factors of ICRP Publication 60 (1991) [7]. The program incorporates adjustable-size paediatric and adult patient models and allows a free choice of the X-ray examination technique. Calculated organ doses can also be used in this program for the assessment of cancer risk resulting from the radiation exposure. The risk estimates are based on the models of the BEIR VII committee (BEIR 2006) [69].

1.1.4. Image quality evaluation methods and technical factors

In medical imaging it is necessary to define image quality with respect to what is needed to be detected in the image, i.e. as a task-based quantity [70]. Most commonly the evaluation of image quality is based on a subjective visual assessment, either from the images of actual patients or from those of dedicated test phantoms. Apart from it physical assessment covers objective components of medical image quality as contrast, spatial resolution (or sharpness) and noise [71]. Contrast is the difference in the image grayscale between closely adjacent regions on the image. Spatial resolution is a property that describes the ability of an imaging system to accurately depict objects in the two spatial dimension of the image. Noise interposes a random component into the image, and there are several sources of noise in an image (e.g. quantum noise, electronic noise, anatomic noise). There are also other quality related secondary features, e.g. image uniformity, image aspect ratio and artifacts, which can be usually evaluated by test phantom images as a part of quality control [65].

In principle, diagnostic performance can be measured using the receiver operating characteristic (ROC) methodology [72, 73], based on visual evaluation of actual patient images by the radiologists, but in practice this is too laborious for routine evaluation purposes. Clinical image quality criteria that are based on the visibility of normal anatomy, such as those published by the CEC [13], have been suggested for quality assurance use and imaging technique optimisation tasks. Both approaches are useful for many purposes, but it is difficult to see how either of them could be considered as a definite measurement that can be calibrated, repeated and compared with results obtained elsewhere.

The ambiguity caused by the variability in patients can be avoided by using test phantoms instead of patients, but there still remain two major problems with this kind of measurements: the clinical significance of the measurement results and subjectivity of the test [70]. A further possibility, especially useful for

constancy testing of digital imaging equipment, is to design software that evaluate the test images using suitable algorithms [62, 63, 64].

In addition to visual evaluation methods there are several objective measures that can be used to achieve more precise and universal results. The concepts from statistical decision theory [74, 72, 75] include the ideal observer's signal-to-noise ratio (SNR), the related quantities noise equivalent quanta (NEQ) [76] and detective quantum efficiency (DQE) [77] and their constituents: modulation transfer function (MTF) [78], noise power spectrum (Wiener spectrum, NPS) [79] and large-area signal transfer factor (K). Also it is obvious that certain visual and physical tests are necessary if the medical image is presented on LCD or CRT display [72, 80, 81, 82]. Below, only the assessment of the image data stage in digital imaging is considered. The display stage can be designed and calibrated so that a human observer can perceive the image information optimally.

The factor K , image sharpness (MTF) and image noise (NPS) can be combined to define the quantity NEQ [72, 74]:

$$\text{NEQ}(f_x, f_y) = \frac{K^2 \cdot \text{MTF}^2(f_x, f_y)}{\text{NPS}(f_x, f_y)}, \quad (1.1)$$

which can be interpreted to express the quantum fluence that the image is "worth" at various spatial frequencies (f_x, f_y) [70, 74]. NEQ can be related with the actual fluence at the image receptor (Q). This results in the descriptor DQE by the following

$$\text{DQE}(f_x, f_y) = \frac{\text{NEQ}(f_x, f_y)}{Q}, \quad (1.2)$$

which expresses the efficiency with which the imaging system uses the information carried by the quanta impinging on it. DQE does not refer to the patient dose and neither NEQ nor DQE take into account all factors that influence the detectability of the actual object detail, such as the energy dependence of the radiation contrast [70]. These image quality descriptors are therefore not always sufficient, e.g. when the imaging conditions are being optimised. They are intended for the intrinsic performance evaluation of only one component of the imaging system: the image detector [70, 52]. Their limitations include lack of consideration for signal-specific and background specific spectral changes, the use of incident exposure as an estimate for dose/risk, the neglect of anatomical noise, and the neglect of supra-detector system elements and processes such as grid and scattered radiation. In addition, the DQE is often measured at specific tube voltages and filtrations for more standard comparison between various detectors. X-ray energy (spectral quality) or filtration is rarely studied as an independent variable in medical radiology [52].

If the noise in the image is normally distributed and signal independent, and the imaging system is linear and shift-invariant, the best possible observer can detect a detail object (having frequency components $\Delta S(f_x, f_y)$) with the SNR [72, 74]:

$$\text{SNR}^2 = \iint \frac{K^2 \cdot \text{MTF}^2(f_x, f_y) \cdot |\Delta S(f_x, f_y)|^2}{\text{NPS}(f_x, f_y)} df_x df_y. \quad (1.3)$$

This SNR specifies the ideal observer's detection performance of the given detail completely. The ideal observer's SNR is the proper quantity to use when the task-dependent image quality is considered; it takes into account all factors of importance, including the subject contrast. If it is required to relate image quality to the patient dose, it is suggested to evaluate the dose efficiency by calculating the quotient SNR^2/D , where D is the patient dose. The quantity D can be chosen from a variety of dose quantities (e.g. entrance skin dose or effective dose) according to the optimisation strategy chosen [65, 70]. The imaging parameters which result to the maximum SNR^2/D are the most efficient parameters for the detection task considered, and the optimisation is concluded by deciding on the image quality level (or dose level) required. This final result is then a figure of merit (FOM) identifying the optimal imaging conditions, in the physical sense of image formation.

It is well known that it is more difficult to detect details against radiographic backgrounds of patients than against the uniform backgrounds of homogeneous phantoms. It is frequently found [83, 65] that detectability is not limited by system noise, but often by normal anatomic structure. Therefore, because image performance does not appear to be system noise-limited in many diagnostic tasks, it is often concluded that there may be notably room for dose reduction in diagnostic radiology (e.g., [84]). For certain imaging tasks, it might be possible to define a FOM that also captures an element of anatomical noise [52]. For example, in chest radiography, the pattern created by the overlay of the projected ribs has a significant impact on the detectability of lung nodules. Using an optimum technique could minimise the bone contrast in relation to soft tissue or lesion contrast. Therefore, the ratio of lesion-to-bone contrast may serve as a secondary FOM in imaging tasks in which bone contrast has an unfavourable effect on target detectability.

There are several practical approaches that can be used to optimise X-ray imaging techniques in clinical environment [61, 65, 52, 85]. Primarily, it is done by calibrating automatic exposure control (AEC) curves keeping constant detector dose indicator (DDI), using signal-to-noise ratio (SNR), contrast-to-noise ratio (CNR) or pixel value [86, 87]. The next step is to find the technique factors where SNR^2/D (SNR squared related to dose) or other figure of merit (FOM) is maximum for the detail type of interest [52, 88].

Threshold contrast-detail detectability (TCDD or $H_T(A)$) is an image performance parameter that utilises human observers or image analysing software

to assess the entire imaging system [89, 59]. In this test the lowest visible contrast is measured and reported for a range of detail sizes and contrasts [89, 90, 91]. The test result can be considered combining the system's sharpness, contrast transfer and noise properties. Also in contrast-detail testing the measurement depends on the dose (radiographic imaging) or dose rate (fluoroscopic imaging) [89].

The contrast-to-noise ratio (CNR) is a descriptor for the pixel value difference between a test object (typically a thin aluminium disk) and its neighbourhood is measured and compared to the pixel value standard deviation in the background [92]. CNR is equal to the concept of signal-difference-to-noise ratio (SdNR) [52]. Such measurements are useful for constancy testing and may also be used for optimising the radiation quality in a given X-ray system [65, 52, 92].

Test phantom performance data have been collected and used for the optimisation in a number of X-ray departments [85, 91, 92]. However, some authors (e.g. Månsson et al [84]) criticise the use of contrast-detail phantoms and other test methods that are based on homogeneous patient-simulating phantoms for optimisation studies, and suggest that their use should be limited to constancy checks. They argue that use of such methods is not relevant to the clinical tasks in diagnostic radiology, where lesion detectability is frequently much more limited by anatomical background than by system noise; therefore, optimisation studies need be done with actual patient images or with high-quality anthropomorphic phantoms. They still mention that this approach enables one to reduce radiation doses in cases where the diagnosis is not quantum-limited.

Busch and Faulkner [61] reach the similar conclusion that the optimisation must be finally based on clinical studies, whereas test phantom imaging is useful for quality control and standardisation purposes. Although such data are not directly related to clinical requirements, they should be useful to verify typical and/or acceptable X-ray system performance, much in analogy with the approach using diagnostic reference doses [85].

AEC devices of diagnostic X-ray systems are designed to enable images to be recorded for patients of varying thickness, for different regions of the body, and with different tube potentials using exposures close to the optimum. This is achieved through automatic termination of exposures at preset air kerma levels at the dose detector. Conventional X-ray systems using film radiography are adjusted to give similar optical densities, but the variation in sensitivity of digital detectors with photon energy is significantly different from that of screen-film phosphors [93]. Calibrating AEC devices for the kV-dependence of digital systems therefore requires the use of alternative parameters, ideally linked to the quality of the image. Digital radiography systems have much broader dynamic ranges than film-screen systems [38, 39].

Maintaining a constant DDI is recommended as the method of choice for setting up AECs for digital radiography by Doyle and Martin [93]. The relative sensitivity of the CR system at different tube potentials was measured by using

pixel value, DDI and SNR. All these image performance indicators demonstrate a similar trend within $\pm 2\%$ and should therefore have equal validity in determining the correct tube potential compensation curve.

The manufacturers of digital imaging systems use a variety of DDIs related to the exposure response of the imaging plate phosphor. The DDI values are calculated from analysis of the histogram of image pixel values over an appropriate region of interest. Images with a similar value for the DDI should have a consistent level of image quality at different tube potentials [86, 93]. Different manufacturers measure the response of the system to a given exposure value using different beam qualities and report the response using indices which have different dependences on exposure. The lack of uniform calibration protocols among different manufacturers makes the definition of the acceptable exposure ranges from the CR response (exposure index) values complicated [86].

1.1.5. Use of medical diagnostic exposures in Estonia

Systematic data collection of patient doses is not nationally regulated yet (in spring 2009) in Estonia. Patient doses have been studied sporadically since 1999 with the further goal of collecting data for estimating preliminary reference doses in some typical examinations in paediatric and adult radiology [94, 95, 96, 97, 98]. The available data are not enough for estimating the overall population dose from medical diagnostic examinations and for comparing the results with the data published by UNSCEAR and DOSE DATAMED [2, 6].

In 2004 in Estonia the mean frequency of X-ray examinations was about 750 per 1000 population [99] that is close to that of UK [4, 3]. Statistics collected by the Estonian National Institute of Health Development shows that the number of X-ray examinations has grown steadily year-by-year in Estonia [42]. In April 2008 there were 18 computed tomography systems, 72 radiography and 34 fluoroscopy systems (including the angiography systems used in interventional radiology) for clinical use. There were 33 employees charged by the responsibilities of medical physicists in the hospitals, but only 12 of them have higher qualification in medical physics (or biomedical engineering) [42].

Continuous education and training in radiation safety and new techniques has been regularly arranged by professional societies of radiographers, radiologists and medical physicists, but is still dependent on the overall status of the quality management systems in radiology departments [20]. Dose-quality management should be a component of medical physics and biomedical engineering master studies curricula in Tartu University and Tallinn Technical University [100].

In Estonia there is no legal regulation for establishment of the patient dose assessment and optimisation system in radiology departments yet. A regulation of the Ministry of Social Affairs for use of radiation in medical radiology, following all requirements of Medical Exposure Directive (MED) [12],

including management of the system of diagnostic reference levels, is due since 2004 [42].

Although the requirements for quality assurance (including quality control of X-ray equipment) have not been stated by the Estonian regulations yet, elements of good international practice in radiology (image quality and dose management) has been started to introduce in several hospitals [20]. It has been supported by the performance tests provided by hospital physicists or by the independent testing laboratories, as Testing Centre of the University of Tartu.

1.2. The aims of the thesis

The main aim of the thesis was to develop and introduce new strategies in dose-quality optimisation, quality control of radiographic equipment and patient dosimetry in X-ray diagnostic radiology with emphasis on needs in Estonian hospitals, and to participate in the European clinical dosimetry surveys for estimating reference levels in typical interventional procedures.

The detailed goals of the conducted studies were:

- to carry out pilot study of physical measurements for the dose-quality optimisation, evaluating the performance of an automatic exposure control (AEC) at different sensitivities when used with a computed radiography (CR) system;
- to investigate image quality, using threshold contrast-detail detectability (TCDD) and signal-to-noise ratio squared related to dose (SNR^2/D) at different sensitivities and tube potential values, and to compare the image performance of the same type of CR systems in different health centres;
- to propose optimum speed modes and optimal settings to be used in the radiographic examination programmes in the clinical environment based on the image evaluation data;
- to investigate and compare performance characteristics and test methodology of digital fluoroscopic and cardiac angiography systems in various health centres in Europe, including Estonia;
- to investigate patient doses for most frequent interventional radiology and cardiology procedures in various health centres in Europe, including Estonia, and to estimate these in the context of the European diagnostic reference levels;
- to participate in European coordination activities that will provide valuable contribution in introducing suitable methods for estimating reference doses and optimisation dose/image quality in radiological departments.

2. METHODOLOGY

2.1. Optimisation of computed radiography systems

Majority of measurements was carried out on the X-ray unit Diagnost 93 (Philips Medical Systems, Eindhoven, The Netherlands, 1997), and also for comparison in three other health-care centres equipped with Duo-Diagnost (Philips Medical Systems, 1999), UD150LR11 (Shimadzu Corporation, Kyoto, Japan, 1998) and Siregraph CF (Siemens Medical Solutions, Erlangen, Germany, 2000). For image readout, the same type of CR system FCR Capsula XL (Fujifilm Corporation, Tokyo, Japan) with IP Cassette Type CC (Fujifilm Corporation) was used in all departments.

Exposures relating to the use of different parameters for the optimisation were made by using standard polymethyl methacrylate (PMMA) phantoms (University of Tartu, Tartu, Estonia) with total thickness of 15 cm ($6 \times 2,5$ cm). The CDRAD 2.0 PMMA phantom (Artinis Medical Systems, Zetten, The Netherlands) was placed in the middle between the standard PMMA phantoms (to give more realistic scatter conditions in the same position as in the patient). All tested AEC systems had been previously set up for typical film–screen speed classes (100, 200 and 400). The image plates were read out in AUTO mode, which is used in case of chest examinations. In this mode, sensitivity and latitude of the reader are automatically adjusted. In order to estimate the entrance surface dose D , tube radiation output was measured at different tube potentials, by using an X-ray multimeter Barracuda (RTI Electronics, Mölndal, Sweden). The measured output curve of the X-ray tube SRO 33100 (Philips Medical Systems, Eindhoven, The Netherlands, 1997) of the X-ray system Diagnost 93 is given in Figure 2.1.

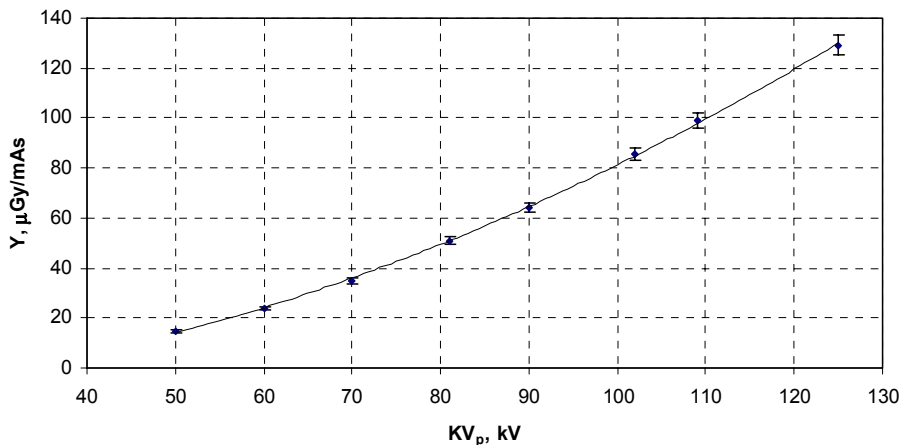


Figure 2.1. Radiation output Y versus tube potential KV_p of the X-ray tube, measured at a distance of 100 cm from the focal spot (large focus of 1.3 mm, $HVL = 3.76$ mm Al @ 81 kV, values of Y are given with standard uncertainty bars and second order regression line).

SNR from images of PMMA with CDRAD was measured and calculated by using DICOM image processing software ImageJ version 1.37 (National Institutes of Health, Bethesda, USA) [101]. The SNR was defined as the mean pixel value μ , calculated by formula

$$\mu = \frac{1}{N} \sum_{i=0}^{N-1} x_i, \quad (2.1)$$

where the signal is contained in x_0 through x_{N-1} , taken from regions of interest (ROI) of 1 cm^2 drawn at the centre of each image, divided by the standard deviation σ , calculated by formula

$$\sigma = \sqrt{\frac{1}{N-1} \sum_{i=0}^{N-1} (x_i - \mu)^2}. \quad (2.2)$$

ROI of 1 cm^2 was drawn in the central area of the image of PMMA with CDRAD where the CDRAD phantom had full thickness (i.e. 16 cm PMMA in total).

The contrast of detail is defined as:

$$C = \frac{|I - I_D|}{I}, \quad (2.3)$$

where I is the primary transmission through the full phantom thickness of 160 mm and I_D is primary transmission through the contrasting detail of the CDRAD phantom and the PMMA phantom of 150 mm.

To estimate the detail contrast, the transmitted air kerma (the phantom output) was calculated for the particular CDRAD detail with the PMMA phantom at different tube potentials by using relevant tube data (tungsten target, anode angle 12° , ripple of the generator voltage 5 %) and spectral data derived from IPEM Report 78 [102]. A X-ray spectrum calculated for 80 kV is given in Figure 2.2.

The CDRAD phantom was used to measure the lowest contrast detectable (C_T) as a function of detail size. All CDRAD images were evaluated (including finding contrast-detail curves) with CDRAD Analyzer software v1.1 (Artinis Medical Systems, Zetten, The Netherlands) [103]. The pattern of the CDRAD 2.0 phantom and the radiographic DICOM image of the phantom (at 60 kV, 15 cm PMMA) are given in Figure 2.3.

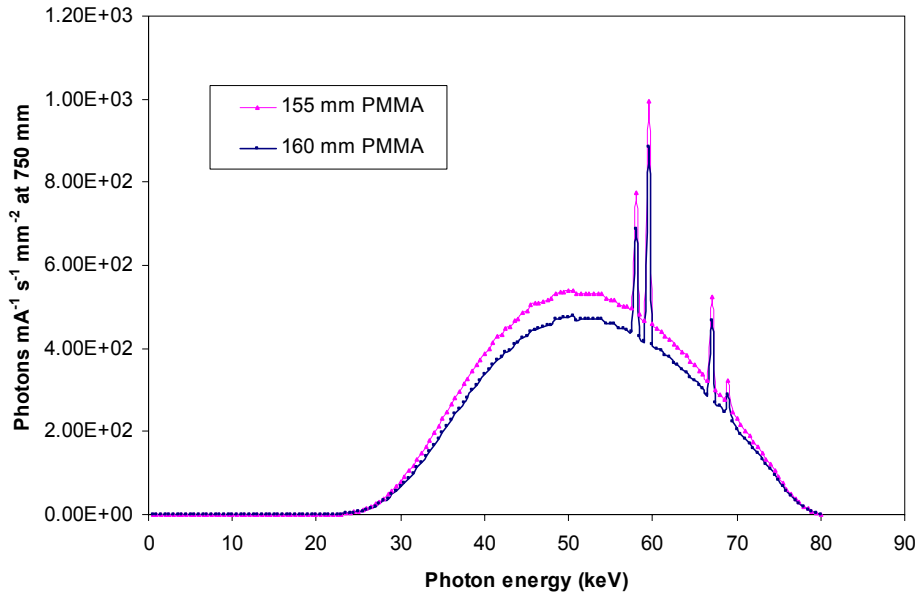


Figure 2.2. Calculated X-ray photon spectrum for 155 mm and 160 mm of PMMA (tube voltage 80 kV, ripple 5 %, total filtration 4.4 mm Al, anode angle 12°, target material W).

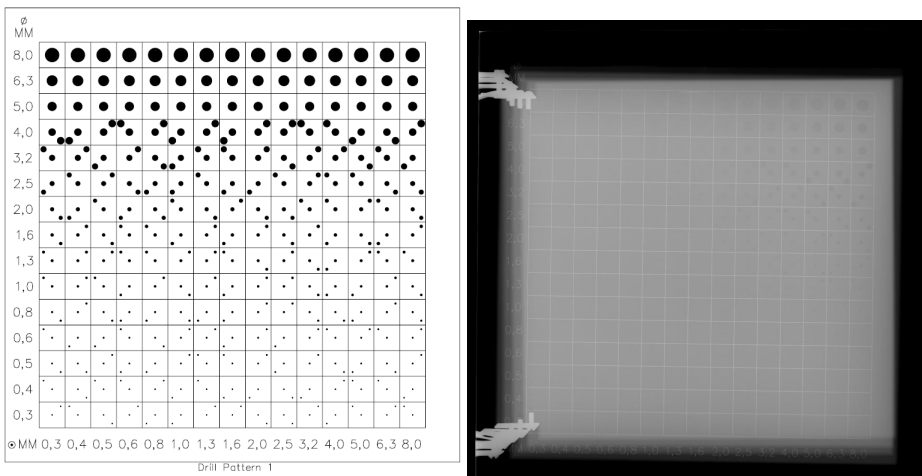


Figure 2.3. Pattern of the CDRAD 2.0 phantom and radiographic DICOM image of the CDRAD with 15 cm standard PMMA phantom.

The lowest contrast detectable (the threshold contrast level) was determined by the computer analysis. Using the Student t-test with Welch correction the program determines if the contrast-detail combination in a certain square is positively seen [103]. The same Alpha level of significance (Alpha=1e-008) was selected for all evaluations. The contrast detail score diagram and the contrast detail curve of the evaluated CDRAD phantom DICOM image acquired at 60 kV with 15 cm PMMA are shown in Figure 2.4.

The data were presented graphically as the TCDD index $H_T(A)$ against the square root of detail area A (in mm) by the formula [89]

$$H_T(A) = \frac{1}{C_T \cdot \sqrt{A}}, \quad (2.4)$$

where C_T is the detected threshold contrast.

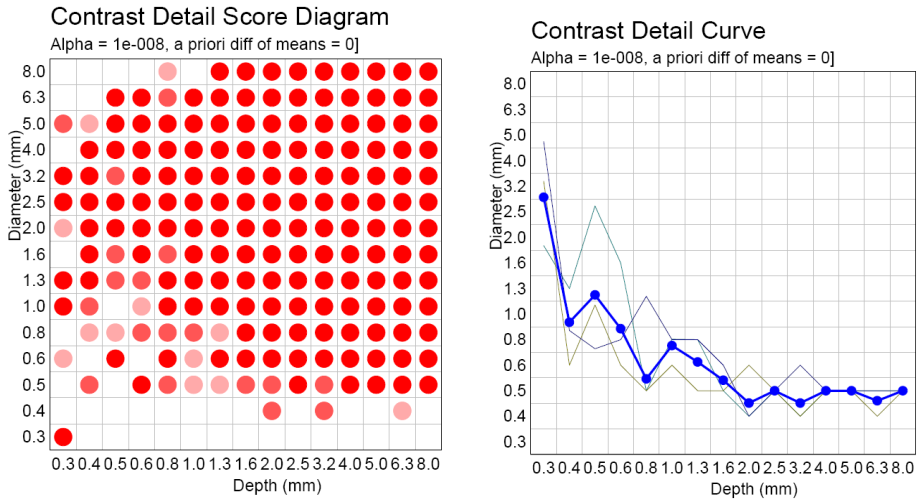


Figure 2.4. Contrast detail score diagram (left) and contrast detail curve (right) of the evaluated CDRAD phantom DICOM image acquired at 60 kV with 15 cm PMMA.

2.2. Interlaboratory comparison tests

According to good practice in quality assurance of radiology, and as stated by several international and national requirements and guidelines, quality control (QC) tests of X-ray equipment should be carried out regularly in all radiology departments [58, 59]. Medical physics experts should oversee and take responsibility for carrying out the performance testing and for expressing the results and uncertainties of the physical measurements and tests and so on. The acceptance and performance requirements for X-ray equipment have been described in several international standards and guidelines [104, 57, 58].

Directive 97/43/Euratom has set specific requirements for the availability of medical physics experts in radiology departments [12].

There is an approach for providing a QC service for diagnostic X-ray equipment from outside the hospital, when the hospital orders the testing service from an independent dedicated laboratory. This is obligatory if the hospital does not employ any qualified medical physicists. In many cases, this practice will be more cost-effective for the hospitals, as there is no need to purchase their own test equipment.

In Estonia, such a scheme has been followed since 1997. It was initiated as a quality audit of medical equipment in Estonian hospitals. A specialised survey was ordered by the Ministry of Social Affairs and was carried out by the Training Centre for Medical Physics and Biomedical Engineering (BMTK) of the University of Tartu (UT).

At present the BMTK centre has almost twelve years' experience of providing a QC service in the majority of the diagnostic X-ray departments of Estonian hospitals and has a QC database of more than 190 units. The testing methodology has been adopted from the IEC and other relevant standards [104, 57, 59].

The Testing Centre of UT (in collaboration with the BMTK) was firstly accredited in this methodology in 2003. Besides the implementation of the quality management system, participation in proficiency testing and inter-laboratory comparison (ILC) was one of the prerequisites for the accreditation, as is established also by the international standard ISO/IEC 17025 [105, 106]. The European Co-operation for Accreditation of Laboratories (EAL) has issued guidelines on how to use proficiency testing and ILC as a tool for accreditation in testing [107, 108]. The standard states that information on uncertainty is needed in test reports where it is relevant to the validity or application of the test results, when the uncertainty affects compliance with a specification limit. The ILC is considered to be an important tool for comparing and evaluating the measurement uncertainties reported by laboratories and for proving the equivalence of test results, on both national and international levels. It is insisted that the primary aim of proficiency testing has a significant educational element. Proficiency testing also enables laboratories to monitor their tests over time.

In this study, elements of EAL proficiency testing and ILC schemes have been adapted. The testing was carried out on an X-ray unit Valmet BR1001 in the Radiation and Nuclear Safety Authority (STUK) laboratory in Helsinki and included tests of STUK (lab1, in the role of reference laboratory) and UT (lab2) for estimating reproducibility of X-ray tube voltage and dose rate, accuracy of X-ray tube voltage and accuracy of exposure time. The measurement process was judged by calculating the parameter E_n normalised with respect to the stated uncertainties.

Equipment

The tests and measurements were carried out using a high voltage unit Dynalyser II (Machlett) and a radiation monitor Model 9015 (Radcal) by lab1, and a dosimetric system TRIAD Model 10500AM (Keithley) with dosimeter and kVp meter by lab2.

Methods and data reporting

In this ILC, the methods of lab1 and lab2 for testing and quality control of diagnostic X-ray equipment were used. These methods have been adopted from the relevant IEC standards.

The X-ray equipment was operated in fluoroscopy mode to get the more complicated shape (higher ripple) of the high voltage and dose waveforms (and therefore of their X-ray spectra and energy dependence).

Combined standard uncertainty in measurements of a quantity X (dose rate, peak voltage (kVp) and exposure time) was calculated by the formula

$$u_c(X) = \sqrt{u_A(X)^2 + u_B(X)^2} \quad (2.5)$$

where u_A is the component of uncertainty arising from a random effect (e.g. reproducibility of dosimeters and reproducibility of X-ray output) and u_B is the component of uncertainty arising from a systematic effect (e.g. accuracy of the dosimeter).

$u_A(X)$ is expressed as an experimental standard deviation $s(\bar{X})$ of the mean value X in a series of n repeated readings X_i and is given by

$$u_A(X) = s(\bar{X}) = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n(n-1)}} \quad (2.6)$$

When estimating u_B , a rectangular probability distribution is assumed. If $\Delta(X)$ is the intrinsic error (semi-range of variation) of the instrument, the type B standard uncertainty is given by

$$u_B(X) = \frac{\Delta(X)}{\sqrt{3}} \quad (2.7)$$

Relative accuracy for dosimeter and kVp meter are $\pm 2\%$ and for the exposure time measurements $\pm 1\%$.

The expanded uncertainty with a coverage factor of $k = 2$ (corresponding to a confidence level of $\sim 95\%$) in the measurement of quantity X is calculated as

$$U(X) = k \cdot u_c(X). \quad (2.8)$$

A common method of judging the quality of a measurement result (ILC performance) is by calculating the deviation E_n normalised with respect to the stated uncertainty, that is

$$E_n = \frac{|X_{\text{lab1}} - X_{\text{lab2}}|}{\sqrt{(U_{\text{lab1}}^2 + U_{\text{lab2}}^2)}}, \quad (2.9)$$

where X_{lab1} is the measurement result of the reference laboratory lab1 (STUK), U_{lab1} is the expanded (with coverage factor $k = 2$) uncertainty of X_{lab1} as given in the report. X_{lab2} is the measurement result of lab2 (UT), U_{lab2} is the uncertainty of X_{lab2} .

E_n numbers are used in measurement comparison schemes to compare a laboratory's result with that obtained in a reference laboratory. Usually, when E_n value exceeds the critical value of unity ($E_n > 1$), it is necessary to check the estimation (calculation) of the measurement uncertainty or to check the measurement process. Absolute values of E_n less than unity ($E_n < 1$) should be obtained for the ILC measurement process to be acceptable [107].

2.3. Quality control measurements of digital fluoroscopy systems

Quality control (QC) is becoming increasingly important in relation to the introduction of digital medical imaging systems using X rays. It was, therefore, decided to organise and perform a trial on image quality and physical measurements. The SENTINEL toolkit for QC measurements of fluoroscopy systems containing equipment and instructions for their use in the assessment of dose and image quality circulated among participants in the trial. Eight SENTINEL partners participated in the trial on image quality and physical measurements of digital fluoroscopy systems in 2006. The protocols of the Department of Medical Physics and Bioengineering (MPBE) in Dublin were considered as starting point for QC of conventional X-ray systems since they were complete for that purpose and were based on IPEM 77 [109] and IPEM 32 [110]. Protocols that appeared in 2005 [59] were not available at the time. The used protocols include measurements on X-ray tube and generator, automatic exposure control, patient dose and image quality.

In addition, monitors were to be checked using a software tool, MoniQA [111], made available by the University of Leuven, Belgium.

The SENTINEL toolkit (Table 2.1) containing equipment and instructions for their use circulated among seven participants (Table 2.2). The Leeds test objects were provided by partner 2 (Department of MPBE, Dublin, Ireland), the instruments by SENTINEL partner 8 (Division de la Radioprotection, Luxembourg) and the shielding materials and the protective case by partner 10 (Delft University of Technology, Delft, the Netherlands).

Table 2.1. Contents of the SENTINEL toolkit for the trial on QC of fluoroscopy units.

Leeds test objects (S/N 28)
0.5 mm copper filtration (15 × 15 cm)
1 mm copper filtration (15 × 15 cm)
1.5 mm copper filtration (15 × 15 cm)
SW4 grey scale test object
FSG4 matrix/field size test object
Hüttner line pair resolution phantom type 18
SSM4 710 mm woven mesh test object
LCD4 noise test object
TCD4 contrast detail test object
VS4 edge test object
Manual
BNC cable + three connectors
Instruments
Unfors Instruments kVp meter, Type 9001, S/N 91728
Unfors Instruments Mult-O-Meter, Type 731L, S/N 125534
+ Prova 15 AC/DC mA Current Probe (clamp), no. 02200480
+ Pen detector holder
Manual for Mult-O-Meter + Addendum
Manual for Test-O-Meter
Radcal Corporation Radiation Monitor Controller, Model 2026C, S/N 260276
Radcal Corporation Electrometer/Ion Chamber, Model 20 × 6–60, S/N 21860
Serial connector cable
Certificate of calibration (John Perry Radiation Metrology Laboratory, job no. 7168)
Instructions for use
Shielding material
4 mm lead filtration (13 × 10 cm); weight 600 g
Documents/Quality assurance protocols
MPBE QC, Fluoroscopy System
MPBE quality assurance, general X-ray system (for background information only)
Reference to website to download MoniQA software

The participants and the fluoroscopy systems (image intensifier (II) and TV system (TV) or charge-coupled device (CCD), or flat panel imaging detectors (FPDs)) for which the trial was performed are shown in Table 2.2. The participants had the toolkit available for measurements for 1 week. Unfortunately only one participant was able to perform the monitor tests with MoniQA. It appeared that the suppliers of the monitors are apparently hesitant to install other software than their own. By using MoniQA it can be discovered if the monitors do not comply with the DICOM standard and the DICOM recalibration is needed [82].

Table 2.2. Overview of the measurements made by the partners using the SENTINEL toolkit.

Partner	Fluoroscopy protocol	Imaging system	Monitor tests
2, Ireland	Siemens Multistar	II + CCD	No
	Philips Easy Diagnost	II + TV	No
8, Luxembourg	Siemens Axiom Artis	FPD	No
11, Greece	Philips Integris V3000	II + CCD	Yes
12, Poland	GE Innova 2000	FPD	To be performed
13, Cyprus	Mecall Superix 180 N	II + CCD	No
14, Slovakia	Siemens Artis dFC	FPD	No
	Chirana Chiraskop 2000	II + CCD	No
15, Estonia	Toshiba KXO-60G	II + CCD	No
19, Bulgaria	Siemens Axiom Iconos MD	II + CCD	No

2.4. Performance assessment of cardiac angiography systems

The number of fluoroscopically guided interventional cardiology procedures increased more and more rapidly in the last decade together with their complexity. The main reason is that, with interventional cardiology, even more patients can often be cured without the use of surgery and their stay in hospital is limited.

Advances in imaging technology have facilitated the development of increasingly complex radiological interventional cardiology equipment [112, 113]. Consequently, there is a need for definitive equipment requirements [114, 115, 116, 117].

The aim of this study was to assess the performances of different cardiac angiographic systems and reference levels for relevant performance parameters. This study was performed in cardiac centres participating in European SENTINEL Project.

Dosimetry data (typical entrance air kerma rate in fluoroscopy and imaging mode), image quality evaluation parameters (low and high contrast resolutions) and DAP meter calibration factors were collected from 13 centres. The delivered questionnaire included also instructions on the agreed methodology to be followed for measurements.

The list of angiographic units included in the survey is reported in Table 2.3 and comprises six systems with flat panel imaging detectors (FPDs) and six with image intensifier chains (II). Estonian partner is presented by the unit number 4. The table reports also the year of installation. Tests included measurement of air kerma dose rates in fluoroscopy and digital acquisition modes and a subjective assessment of image quality using the Leeds test object TOR 18FG. Dose rates were measured under automatic exposure control in fluoroscopy and digital acquisition modes by measuring the entrance surface air kerma rate when a phantom of 20 cm PMMA thickness simulates a patient attenuation, and the field of view (FOV) on the detector has been set at 22 cm or

nearest with a focus-entrance phantom distance of ~65 cm and the image detector positioned at 5 cm from the exit phantom surface.

With the purpose to use the DAP meter calibration factor to correct collected patient KAP values, the calibration procedure is performed taking into account the attenuation determined by the patient table and mattress. The calibration has been performed at 60–80–100 kV X-ray qualities with an ion chamber on the axis of the X-ray beam placed at minimum 10 cm away from the patient table and the image detector to avoid scatter. The different X-ray qualities are reached inserting in the X-ray beam, between the ion chamber and the image detector, attenuating material (copper and/or aluminium) simulating the patient attenuation and driving both high voltage and added filtration to typical clinical conditions.

Surface area is calculated from field dimensions measured with a radio-opaque ruler or an equivalent method. DAP meter calibration factor is assumed as the mean value of the calibration factor measured for the three X-ray qualities.

Table 2.3. Cardiac angiographic systems included in the SENTINEL survey.

Unit no.	Manufacturer	Model	Imaging detector	Year of installation
1	Siemens	Axiom Artis dBc	FPD	2005
2	Siemens	Axiom Artis dBc	FPD	2005
3	Siemens	Bicor Top	II	1995
4	Siemens	Multistar T.O.P.	II	1995
5	Philips	Allura F9	FPD	2002
6	Philips	Allura 9	II	2002
7	Philips	Integris 5000H	II	1998
8	GE	Innova 2000	FPD	2002
9	Philips	Integris 3000	II	1994
10	Siemens	Axiom Artis	FPD	2003
11	Philips	Integris CV9	II	2003
12	Siemens	Axiom Artis	FPD	2004
13	Philips	Integris 5000H	II	2002

2.5. Patient dosimetry in non-cardiac interventional radiology

In the study V, non-cardiac interventional procedures in the sample of hospitals in 13 European partner countries were evaluated. There were two purposes for it-to review the current interventional practices and the basic characteristics and performance of interventional X-ray equipment used, and to collect samples of patient doses, both in diagnostic and therapeutic X-ray-image-guided common interventional procedures, in order to compare these with previously described practices [118, 119, 120, 121, 23, 122, 123, 124, 125] and to assess the possibilities of setting reference levels.

In total, data for 20 procedures for about 1300 patients were collected, including for 2 procedures (lower limb arteriography, peripheral therapeutic procedures) for 81 patients from Estonia.

The study has mainly been conducted through a questionnaire distributed to all partners. The tabulated forms for the collection of data requested the following information:

- Country data (population, number of X-ray systems used primarily for IR, annual number of diagnostic X-ray procedures and annual number of IR procedures)
- Data on X-ray systems and their dosimetric characteristics (manufacturer, type, date of the latest quality control, typical entrance dose rate and dose per image, calibration of dose area product or DAP meter);
- Procedures selected (name of the procedure, annual number);
- Patient doses (for each selected procedure): patient data (identification, gender, age, weight, height), total DAP and DAP for fluoroscopy, cumulative dose, fluoroscopy time, number of series and total number of images, complexity of procedure, calibration factors for DAP and cumulative dose.

For patient dose collection, data on four selected common IR procedures, two diagnostics IR and two therapeutic IR procedures, were requested for at least 10 patients per procedure. The IR procedures to be included were characterised as fluoroscopy guided procedures of catheter insertion. Lower-limb arteriography and hepatic chemoembolisation were requested to be included if possible. It was assumed that, generally, the partners could provide data for a minimum of two rooms in a selected hospital of the partner's country.

2.6. Estimating reference levels in cardiac interventional radiology

In the study VI, a European survey was conducted by the SENTINEL consortium to investigate doses in selected interventional cardiac procedures and to establish updated reference levels.

The radiation dose depends on a number of factors, including patient size, equipment, technique and type of examination. Large variation in patient dose, for the same type of X-ray examination, has been demonstrated in several studies [119, 126, 127, 128, 129]. These variations are almost due to different complexities of the procedures, equipment performance, procedure protocols and patient body size. Reference levels (RLs) provide a framework to reduce this variability and assist in the optimisation process [130, 118, 15].

Cardiac procedures were divided into three main groups:

- 1) coronary angiography (CA);
- 2) percutaneous transluminal coronary angioplasty (PTCA);

3) electrophysiology (EP) procedures, including diagnostic electrophysiology, pacemaker implantation, defibrillator implantation and radiofrequency cardiac ablation (RFCA).

The survey involved nine European partners and near 2000 procedures were examined (Table 2.4).

Information, such as fluoroscopy time (FT), number of frames, air kerma-area product (KAP) and, when available, the cumulative dose (CD) to interventional reference point (IRP), were provided.

The accuracy of dose values provided has been submitted to a dosimetry intercomparison [131, 132].

Table 2.4. Cardiac interventional procedures in the sample of patient dose survey.

Procedure	No. of patients
Coronary angiography (CA)	672
Percutaneous transluminal coronary angioplasty (PTCA)	662
Electrophysiology diagnostic procedure	112
Pacemaker implantation	51
Radiofrequency cardiac ablation	337

3. RESULTS AND DISCUSSION

3.1. Optimisation of computed radiography systems (Study I)

The aim of this work was to evaluate the performance of an automatic exposure control (AEC) at different sensitivities when used with the Fujifilm CR system in different hospitals. Image quality, using threshold contrast-detail detectability (TCDD) and signal-to-noise ratio squared related to dose (SNR^2/D), was also investigated for different sensitivities and tube potential values for this combination. SNR was used as an image performance indicator at different speed modes. At the same time, entrance dose for receptor was estimated.

Figure 3.1 shows the phantom output dose at and indicates that the AEC was pre-calibrated for film–screen combination in different speed modes. All the sensitivity curves have higher preset AEC values at lower kV in order to compensate lower film/screen response at this energy range.

Figure 3.2 shows that SNR has also a slight trend for decreasing towards the higher tube potentials. The non-monotonic behaviour of the curves in Figure 3.2 could be due to slightly different algorithms automatically applied in CR pre-processing of the CDRAD images. For phosphor plate usage, dose could be reduced at low voltages keeping SNR on the same level. For speed 400, the dose could be remained at low tube voltages, but for higher voltages could be slightly increased.

Figure 3.3 gives the dependence normalised to phantom (patient) entrance dose D . It shows no difference for the FOM at low potential (60 kV) between the selected speed modes or the phantom entrance doses. The SNR^2/D coefficient in Figure 3.3 shows that in order to increase the FOM and reduce patient dose the higher tube potential technique would be more preferable for the detail type of interest. At low tube potential, the difference in the sensitivity curves is not remarkable, though the FOM remains practically the same for different entrance doses. At the same time, the $H_T(A)$ curves for different speed modes at different tube voltages in Figures 3.4 and 3.5 reveal higher contrast-detail detectability for lower voltages.

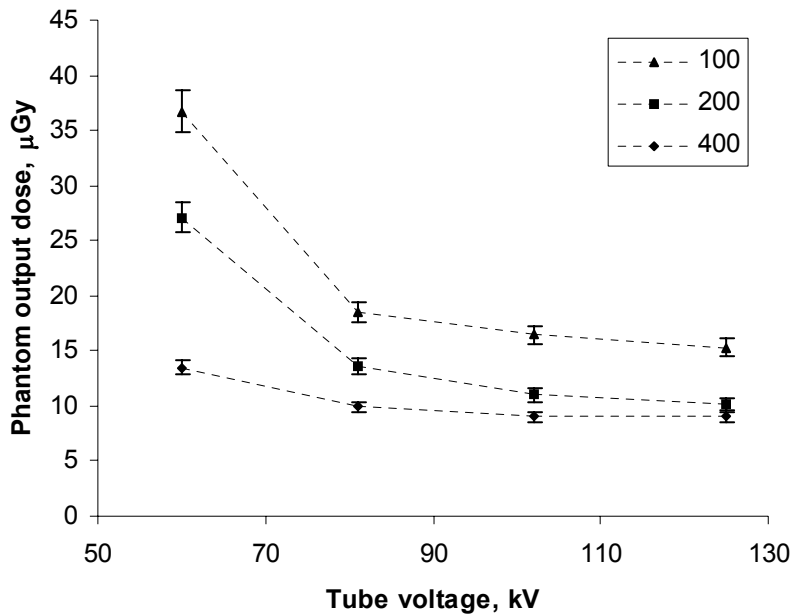


Figure 3.1. The phantom (15 cm PMMA + CDRAD) output dose at different speed modes of 100, 200 and 400.

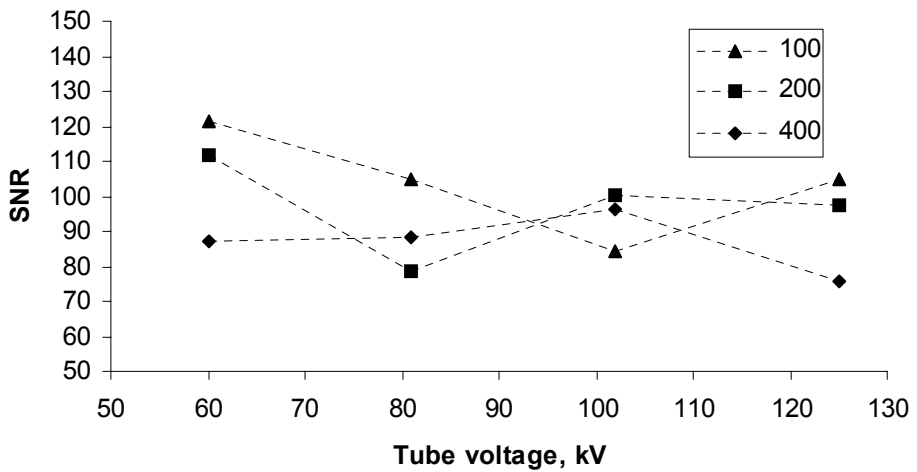


Figure 3.2. Comparison of SNR using different speed modes of 100, 200 and 400 (15 cm PMMA + CDRAD).

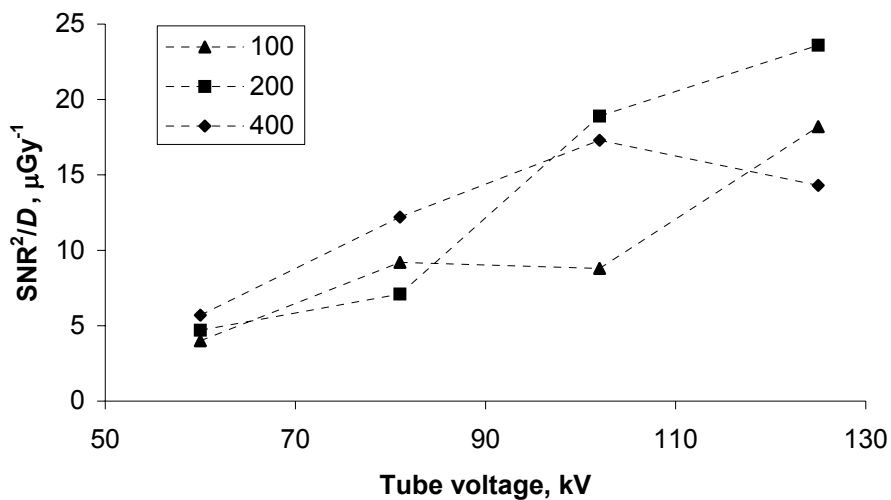


Figure 3.3. Comparison of SNR^2/D using different speed modes 100, 200 and 400 (15 cm PMMA + CDRAD).

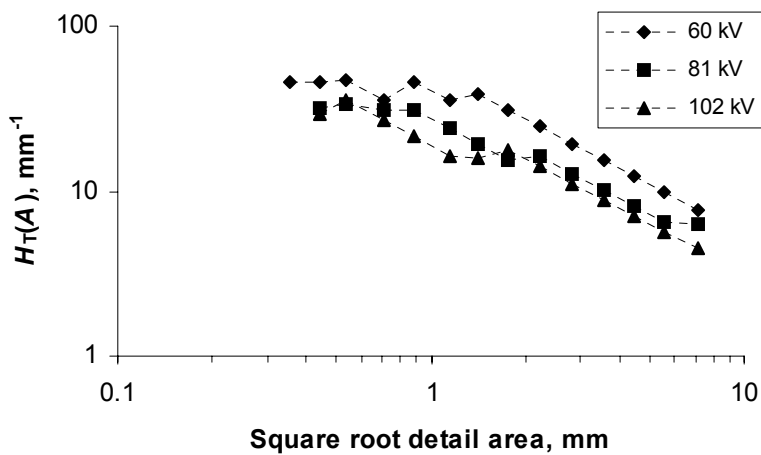


Figure 3.4. Comparison of the threshold contrast-detail index at different voltages by using speed mode of 400 (15 cm PMMA + CDRAD).

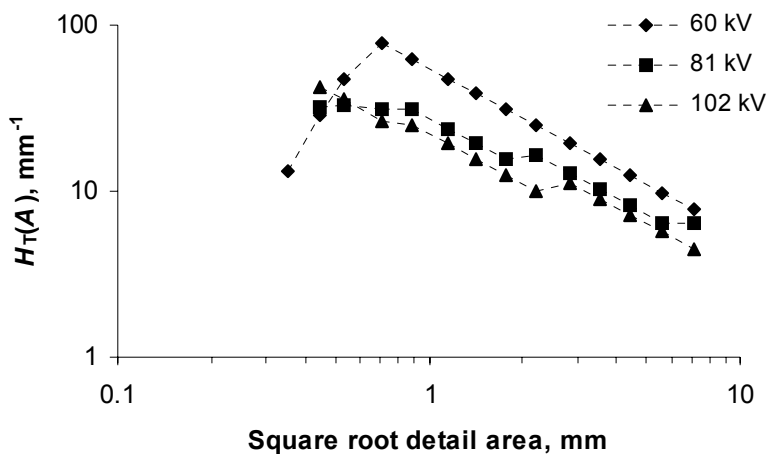


Figure 3.5. Comparison of the threshold contrast-detail index at different voltages by using speed mode 100 (15 cm PMMA + CDRAD).

Comparison of $H_T(A)$ index dependences for different speed modes at tube potentials of 81 and 125 kV are given in Figures 3.6 and 3.7. Figure 3.8 gives the distributions of the threshold contrast-detail index for the four health centres using the same type of CR system.

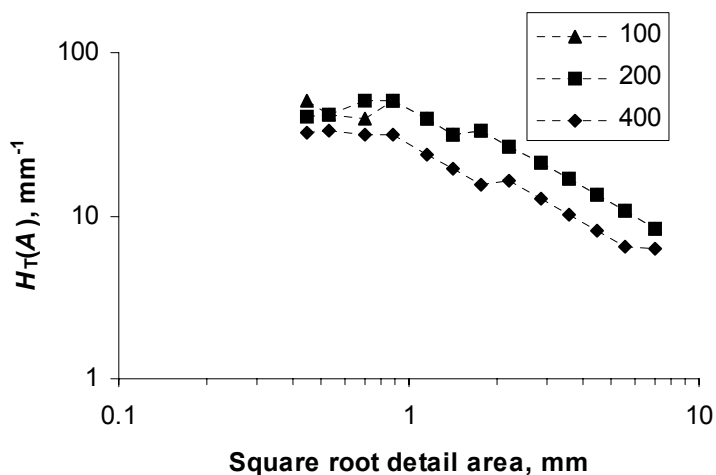


Figure 3.6. Comparison of the threshold contrast-detail index at different speed modes at 81 kV (15 cm PMMA + CDRAD).

By comparison of $H_T(A)$ index dependences for different speed modes in Figures 3.6 and 3.7, it could be found that at the high tube potential range difference between low and higher AEC speed modes does not give any advantage in terms of contrast detail. To reduce dose, the higher speed mode

(400) would be optimum in this range. At the same time, by measuring SNR, the lowest speed mode (100) would provide less noise (Figure 3.2), but difference in SNR^2/D in different speed modes is more remarkable at higher tube potential than at lower tube potentials (Figure 3.3). Optimum between these two image performance indicators should be found, taking into account the clinical criteria as well. The main strategy could include the following steps: calibrating AEC curves keeping constant DDI, using SNR, CNR or pixel value. The next step is to find the technique factors where SNR^2/D and TCDD as image performance parameters have been optimally balanced.

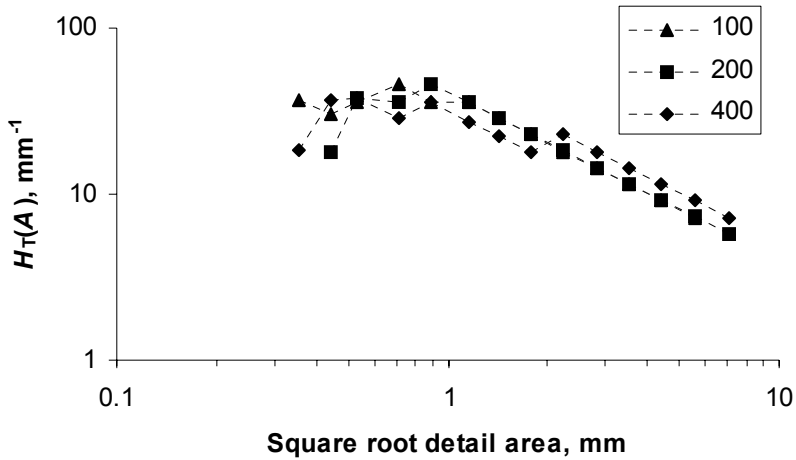


Figure 3.7. Comparison of the threshold contrast-detail index at different speed modes at 125 kV (15 cm PMMA + CDRAD).

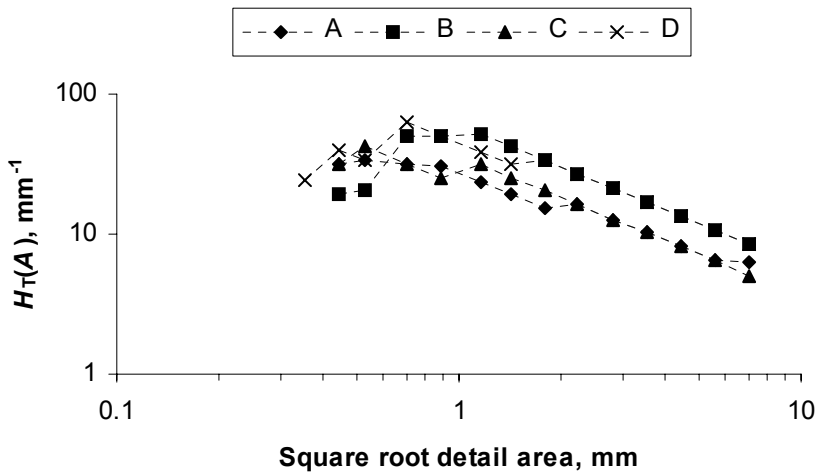


Figure 3.8. Comparison of threshold contrast-detail index in different hospitals using the same type of CR system (15 cm PMMA + CDRAD, 81 kV, speed mode 400).

As the same type of CR scanners (with the same type of software and image pre-processing but different AEC settings with the detector entrance doses in the centres A, B, C and D as 8.5, 4.8, 8.4 and 4.8 mGy, respectively) was used in all these centres, the similar trend for all performance curves in this figure is remarkable. The uncertainty in measurements of the smaller details in CDRAD is higher than for the larger details.

Using only homogeneous phantoms gives physical–technical evaluation but more realistic approach with conditions closer to clinical is needed. In this work, CDRAD and PMMA homogeneous phantoms were used together, but using these more complex phantoms can cause fluctuations in CR pre-processing.

For different organ programmes, it was needed to choose optimum quality class or speed mode. Based on the image evaluation data, optimum speed modes for the organ programme settings have been proposed in Table 3.1. The suggested speed modes are slightly different from the X-ray unit default settings, but almost the same as that recommended in DIMOND III Final Report [45].

Table 3.1. Optimisation of organ programmes.

Organ programme	Tube voltage, kV	Default speed mode	Suggested speed mode	Quality class by Busch [45]
Chest PA	125	100	200	M
Chest LAT	125	100	200	M
Abdomen	81	400	400	M, L
Skull + maxilla	70	200	200	M, H
Head LAT	66	200	400	M
Neck	66	200	400	M, H
Shoulder	63	200	400	M
Thoracic spine	73	400	400	M
Thoracic spine LAT	81	400	400	M
Lumbar spine	77	400	200	M
Lumbar spine LAT	96	400	400	M
Pelvis/hip	70	400	400	M

3.2. Interlaboratory comparison tests (Study II)

The interlaboratory comparison (ILC) tests between the Radiation and Nuclear Safety Authority in Helsinki (STUK) and the Testing Centre of the University of Tartu (UT) for estimating reproducibility of tube voltage and dose rate, accuracy of the voltage and accuracy of exposure time were carried out on a diagnostic X-ray unit in the STUK laboratory in Helsinki. The measurement

performance was judged by calculating deviation E_n normalised with respect to the stated uncertainties.

The ILC results for dose rate, high voltage peak (KV_p) and exposure time are given in Figures 3.9 to 3.11 (lab1 – STUK, lab2 – UT).

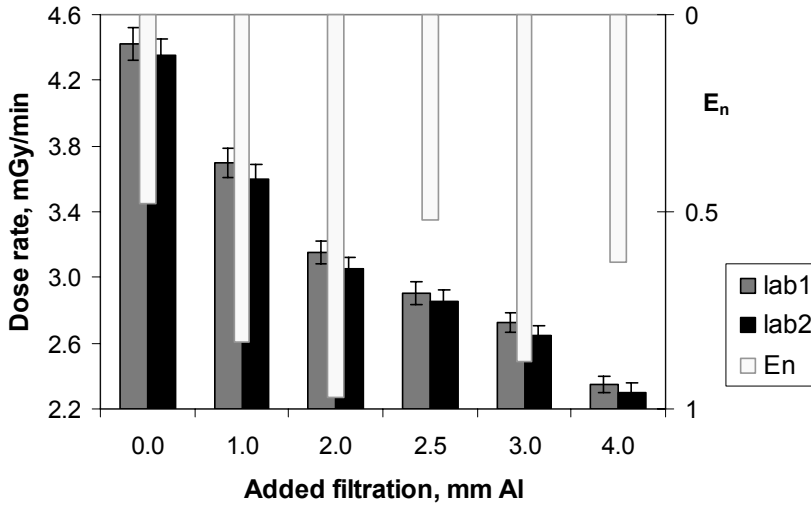


Figure 3.9. Comparison of dose rate measurements, E_n score.

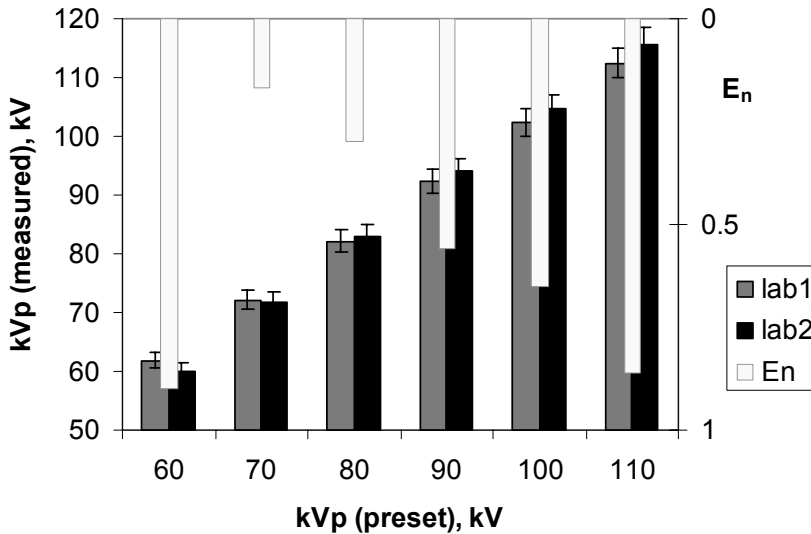


Figure 3.10. Comparison of high voltage peak (KV_p) measurements, E_n score.

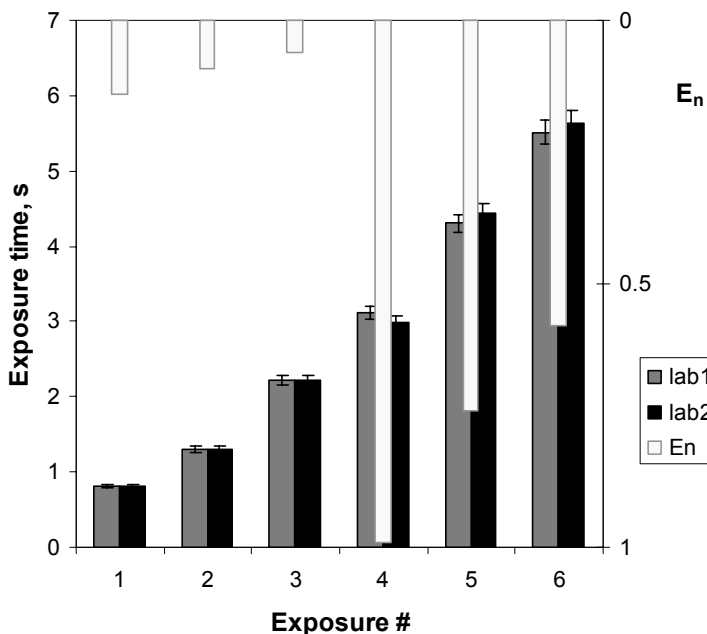


Figure 3.11. Comparison of exposure time measurements, E_n score.

Error bars in the figures express graphically the expanded uncertainty at the confidence level of 95% ($k=2$). E_n score describes the consistency of both results.

3.3. Quality control measurements of digital fluoroscopy systems (Study III)

The SENTINEL toolkit for QC measurements of fluoroscopy systems containing equipment and instructions for their use in the assessment of dose and image quality circulated among eight participants (Estonian partner indicated by 15) in the trial on image quality and physical measurements.

Various tests were performed by the participants according to the protocol MPBE QC of fluoroscopy system using the equipment and instructions provided with the toolkit. In this section, it is indicated whether the participants provided descriptions and performed tests. In addition, problems experienced by the participants were noted and/or improvements suggested for (sections) of the protocol.

System details

The section in the protocol on system details was completed to various extents by the participants (Table 3.2). It is proposed to add options ‘under couch tube’ and ‘flat panel detector’ to the table in the protocol.

Test equipment (instruments) could be presented in the table given in the protocol as options. This latter provision would make completion easier. Maybe participants presumed that the equipment was known since, generally, the toolkit was used.

Table 3.2. System details provided by the participants.

Partner	2 ^a	2 ^b	8	11	12	13	14 ^a	14 ^b	15	19
Equipment										
Manufacturer	y	y	y	y	y	y	y	y	y	y
Make/Model	y	y	y	y	y	y	y	y	y	y
Serial number	n	n	n	y	n	y	n	y	y	n
Screening Tube	n	y	n	y	n	n	n	y	n	y
Over couch Tube	n	n/a	n	n	–	n	n	y	y	n
Under couch Tube	–	–	y	–	y	–	–	–	–	–
Image intensifier	n	y	–	n	y	n	–	y	y	n
Flat panel detector	–	–	y	y	y	–	y	–	–	–
Nominal Rating	n	y	n	y	y	n/y	n	n	y	y
Nominal Filtration	n	y	y	y	y	n	n	n	y	n
Installation Date	n	y	y	y	y	n	y	y	y	y
Instruments										
Ionisation chamber	–	y ^c	–	–	–	–	y	y	y ^c	y ^d
Multimeter	–	y ^e	–	–	y ^e	–	y/y ^f	y/y ^f	y ^e /y ^g	–
Oscilloscope	–	–	–	–	y ^j	–	–	–	y ^j	–
Tube voltage meter	–	–	–	–	–	–	y	y	–	–
Leeds test objects	–	y ^h	–	–	–	–	y ^h	y ^h	–	y ⁱ

^{a,b}Denote separate units by the same partner.

^cRadcal 60 cc ionisation chamber.

^dPTW Unidos E, 112 cc.

^eUnfors Mult-O-Meter.

^fXi Unfors Mult-O-Meter.

^gBarracuda MPD.

^hTest objects from MPBE.

ⁱOwn Leeds test objects.

^jTektronics TDS 3012 or TDS 360.

Responses: y = yes, n = no.

Tube and generator performance

How far tube and generator measurements were performed is shown in Table 3.3. It appeared that various QC measurements concerning tube and generator performance are not easily performed for modern equipment. Since tube and generator performance of modern equipment is usually much better than for older equipment, the protocol could be restricted to ‘tube output varying

potential' and to 'tube output consistency'. The specification of performance should be given explicitly in the protocol, which was not shown by any participant. It is recommended to include a way to indicate if a test is passed/failed and what are the consequences of failure. This latter recommendation holds also true for other parts of the protocol. The linearity tests by varying tube current at fixed tube voltage and varying tube potential at fixed tube current were carried out only by two participants, including 14 and 15.

Table 3.3. Tube and generator performance.

Partner	2 ^a	2 ^b	8	11	12	13	14 ^a	14 ^b	15	19
Tube output										
Constant current	n	1p ^c	y	n	^d	^e	^f	y	y ^g	e,f
varying potential										
Constant potential	n	^h	–	n	y	n	y	y	y ^g	n
varying current										
Tube output consistency	n	y	y	n	y	y	y	y	y	y
Tube potential										
Varying tube current at	n	^h	n	n	n	n	^f	y	y	n
fixed tube voltage										
Varying tube potential	n	1p ^c	n	n	n	n	^f	y	y	n
at fixed tube current										
Specification of	n	n	n	n	n	n	n	n	n	n
performance										

^{a,b}Denote separate units by the same partner.

^c1p means at one tube potential.

^dAlternative for AEC system, where tube voltage is varied and tube current varies automatically (table needs adaptation).

^eCurrent cannot be stabilised.

^fNo manual control.

^gMeasured with two instruments.

^hNot available.

Responses: y = yes, n = no.

Automatic exposure control

The execution of tests of the automatic exposure control of the fluoroscopy systems by the participants is given in Table 3.4. In the protocol, the terminology should be adapted to digital equipment, e.g. the term 'image intensifier (II)' has to be replaced by 'image detector system (IDS)'. More extended tables in the protocol for IDS and patient incident air kerma will be useful. Performance criteria, if given in the protocol, are not applied by the participants to evaluate the results. The copper filter prescribed for the measurements can cause problems for FPD systems.

Leeds test objects

The performance of tests on image quality using the Leeds test objects in the trial is given in Table 3.5. The Leeds test objects referred to in the protocol (GS2, N3, TO10, M1, MS1, MS3, MS4) are apparently replaced by a new series of phantoms (SW4, LCD4, TCD4, FSG4, SSM4). A statement should be added to the protocol that the latter series of phantoms can also be applied. For flat-panel detector systems, the shape of the test objects should be rectangular instead of circular in cross-section, since this does better fit the shape of the image detector. In some cases, phantoms with circular cross-sections cannot be used since they do not cover the whole detector field. As a consequence of this, parts of the FPD will be overexposed.

Table 3.4. Automatic exposure control.

Partner	2 ^a	2 ^b	8	11	12	13	14 ^a	14 ^b	15	19
II entrance dose rate	y ^d	y ^d	y ^c	n	n	n	n	n	y ^d	y ^d
According to specification of performance				n	–	n	–	–		
II entrance air kerma rate for 7 cm x 7 cm field	n	n	n	n	n	y	n	n	y	y
At each level of operation (push button control or maximum and minimum)	y	y	–	y	y	y	n	n	y	y ^f
At clinical settings	y	y	–	–	y ^h	–	y ^f	y	n	n
At magnification settings	y	y ^g	–	y	y ^h	y	n	y	n	y
II entrance dose rate										
Pulsed fluoroscopy	y	y	y	n	y	y	y	n	n	y
Digital acquisition	–	y	–	–	–	–	–	–	–	–
Patient entrance dose rates	–	y	y	y	y	y	n	y	–	–
Maximum dose rate patient can receive	–	n	n	n	y	y	y	n	y	y
Pulsed mode and magnification settings	y	y ⁱ	y	y	n	y	y	n	n	y
Digital acquisition	–	y	n	n	n	n	n	n	n	n
Specification of performance	n	n	n	n	n	n	n	n	n	n

^{a,b}Denote separate units by the same partner.

^cFlat panel detector, only pulsed mode.

^dYes, but not concluded.

^eDetector entrance dose rates do only fulfil entrance dose rate requirement for fluoroscopy LD and ND and 6p/s.

^fValues appear very high.

^gAlready in previous measurements.

^hFor pulsed mode.

ⁱAdaptation of table needed.

Responses: y = yes, n = no.

The video voltage output test appeared difficult to perform: only two participants, including participant 15, were able to do the QC measurement with this test object. The reason could be that the measurement is too invasive for some modern systems. It is, therefore, proposed by the group to skip this test from the protocol for modern (digital) systems.

There are no specifications of performance for the grey scale test in the protocol. In the summary of the tests of system 2^a (Table 3.6), requirements for the grey scale test are given. The test seems not very selective as all X-ray systems included in the trial do comply with the criteria in Table 3.6.

The low contrast (noise) test object performance criteria as specified for old systems are commonly complied with by the participants' X-ray systems. The low contrast (noise) test object performance criteria as specified for new systems are not complied with by the tested equipment. This is surprising since most of the X-ray systems of the participants are relatively new.

None of the X-ray systems of the participants are capable of complying with the performance criteria for the contrast-detail test object. It seems that the criteria are too strict. The field coverage test object seems too small. Instructions for scoring S-distortion and pincushion distortion should be added to the protocol. The radiation field should be smaller than the imaged field. This means that the criterion as formulated in the protocol should be inverted.

Table 3.5. Leeds test objects.

Partner	2 ^a	2 ^b	8	11	12	13	14 ^a	14 ^b	15	19
Video voltage output	n	n/a	n	n	y	n	n	n	y ^c	n
Specification of performance	n	n/a	–	–	y ^c	–	–	–	y ^d	–
Grey scale test										
Number of steps visible	10	10	y	y	y	10	10	10	y	10
Black and white discs visible	y	y	y	y	y	y	2	y	y	y
Monitor adjustment	n	n	n	n	n	n	y	y	n	n
Specification of performance	y	–	–	–	–	–	–	–	–	–
Low contrast (noise) test object										
No. discs visible (full field)	11	10.5	9	10	11	11	9	10	10	15
No. discs visible (mag. 1)	11	12	10	10	11	12	9	11	n	14
No. discs visible (mag. 2)	11	12	10	10	11	12	9	11	n	14
Other kerma rates	n	–	y	–	n	n	y	y	y	n
Specification of performance	y ^c	y ^c	n ^d	n ^c	n ^c	n ^c	n ^d	n ^c	n ^c	n ^c
New systems	n ^d	y ^d	n ^d	n ^d	n ^d	n ^c	n ^d	n ^d	–	n ^c
Contrast-detail test object										
Test performed?	y	y	n	y	y	y	y	y	y	y
Plot detection index values	y	y	n	n	n	n	n	n	n	n

Partner	2 ^a	2 ^b	8	11	12	13	14 ^a	14 ^b	15	19
Specification of performance	y ^d	n ^d	n ^d	n ^d	n ^d	n ^d	n ^d	n ^d	n ^d	n ^d
Field coverage test object										
Full field	y	y	y	n	y	y	y	y	y	y
Magn. 1	y	y	y	y	y	y	y	y	n	y
Magn. 2	y	y	y	y	y	y	y	y	n	y
S-distortion	y	y	y	n	y	n	y	y	y	y
Pincushion distortion	y	y	y	n	y	y	n	n	y	y
Specification of performance	n	n	y	n	y	n	n	n	y	y
Radiation field/image field	y	y	y	n	y	n	n	n	y	y
Specification of performance	y	y ^c	y	n	y	n	n	n	y	n
Inverse	y	–	–	–	–	–	–	–	–	–
Limiting resolution test object										
Full field	y	y	–	–	y	–	–	–	y	y
Magn. 1	y	y	–	–	y	–	–	–	n	y
Magn. 2	y	y	–	–	y	–	–	–	n	y
Full field digital	y	y	–	–	–	–	–	–	–	–
Magn. 1 digital	y	y	–	–	–	–	–	–	–	–
Magn. 2 digital	y	y	–	–	–	–	–	–	–	–
Full field pulsed	–	n	y	y	–	y	y	y		y
Magn. 1 pulsed	–	n	y	y	–	y	y	y		y
Magn. 2 pulsed	–	n	y	y	–	y	y	y		y
Specification of performance	–	y ^c	y	y ^c	y ^c	y ^c	y ^c	y ^c	y ^c	y ^c
Specification of perform. digital	–	y ^c	–	–	–	–	–	–	–	–
Uniformity of focus test objects	–	^c	–	–	–	–	–	–	–	–
MS1	y	n	y	y	n	n	n	n	y	y
MS3	y	n	y	y	n	n	n	n	n	y
MS4	y	y	y	y	n	n	n	n	n	y
Specification of performance	y	–	–	–	–	–	–	–	–	–

^{a,b}Denote separate units by the same partner.

^cFulfilled but not indicated.

^dNot fulfilled but not indicated.

Responses: y = yes, n = no.

Table 3.6. A summary of the measurements on image quality for fluoroscopy system 2^a using the Leeds test objects.

Test object	Requirement	Type of test	Test result
Grey-scale test object (GS2)	All 10 grey steps, black and white discs visible	Baseline	Satisfactory
Low contrast test object (N3)	FF: 0.033 M1: 0.033 M2: 0.033 M3: 0.030	< 0.04	Pass, similar to previous inspection
Contrast detail test object (TO10)	Graph	Baseline	Satisfactory, similar to previous inspection
Field coverage test object:	FF: 0.80 M1: 0.89 M2: 0.88 M3: 0.93	0.85 – 1.0	Partial pass, similar to previous inspection
Limiting resolution test object (Hüttner):	FF: 1.25 lp/mm M1: 1.70 lp/mm M2: 2.00 lp/mm M3: 2.80 lp/mm	FF: ≥ 0.7 lp/mm M1: ≥ 0.9 lp/mm M2: ≥ 1.0 lp/mm M3: ≥ 1.25 lp/mm	Pass, similar to previous inspection
Uniformity of focus (Mesh test objects: MS1, MS3, MS4):	MS1: Visible throughout MS3: Visible throughout MS4: Not visible	Baseline	Satisfactory
Equipment condition			Satisfactory

Note: It should be noted that some of the requirements given in the table are different from those in the protocol, i.e. for GS2 here a requirement is given; for N3 here only the requirement for old equipment is shown; for TO10 the graph does not fulfil the nominal values, although the results here are better than for the other units; for the field coverage test object the requirement is here as expected, i.e. one at maximum; here the requirements for the limiting resolution are less strict than in the protocol; for uniformity of focus here requirements are given, but not in the protocol.

3.4. Performance assessment of cardiac angiography systems (Study IV)

This study shows the performances of different cardiac angiographic systems (Estonian partner is presented by the unit number 4). A questionnaire was sent to centres participating in SENTINEL Project to collect dose data (typical entrance dose rate in fluoroscopy and imaging mode), image quality evaluations (low and high contrast resolutions) and DAP meter calibration factors.

Entrance surface air kerma rates

The majority of the tested systems have a wide range of user selectable dose options, including a range of pulsed fluoroscopy modes, digital acquisition frame rates and automatic insertion of spectral filters. The pulsed fluoroscopy mode most frequently used on the equipment tested is 12.5 or 15 pulses per second (pps) and the acquisition modality 12.5 or 15 images per second. Figure 3.12 shows entrance surface air kerma rate for different fluoroscopy modes available in each system.

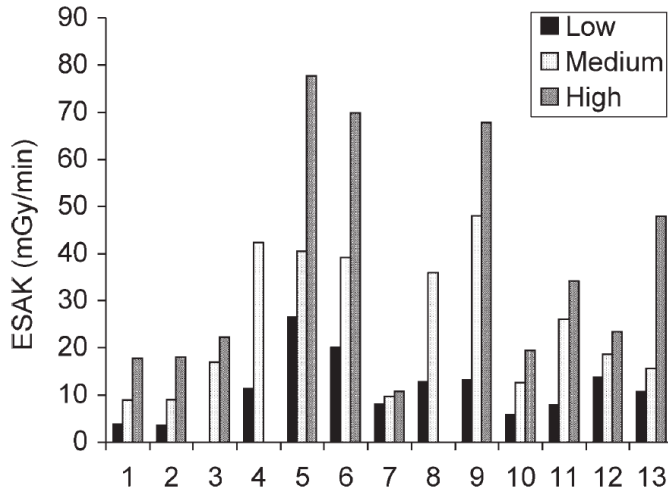


Figure 3.12. Entrance surface air kerma rate in fluoroscopy at the entrance surface of a phantom of 20 cm of PMMA and a FOV of about 22 cm for 13 cardiac angiographic systems.

The air kerma entrance rates range from 3.6 to 26.5 mGy/min in low fluoroscopy mode, from 8.8 to 48 mGy/min in medium fluoroscopy mode (respectively 11.3 and 42.3 mGy/min for unit 4) and from 10.7 to 77.7 mGy/min in high fluoroscopy mode. Air kerma entrance rate does not seem to be strictly manufacturer dependent. For the majority of the systems tested, the patient entrance dose rate varies between 5 and 20 mGy/min for low and medium modes. The two systems presenting the highest dose rates are installed in the same centre.

For comparison, by the CEC acceptability criteria [57] for the fluoroscopic equipment the maximum dose rate including backscatter at the skin of the patient or at the surface of some form of patient substitute (e.g. 25 cm PMMA phantom) on the side facing the X-ray tube should not exceed 100 mGy/min.

In Figure 3.13, the entrance surface air kerma per image is shown for all imaging acquisition modes available and for the same geometry and FOV used for fluoroscopy measurements. The entrance surface air kerma per image ranges from 32.9 to 192 μ Gy per image in the low cine mode and from 77.8 to 316 μ Gy per image in the normal acquisition mode (respectively 34.0 and 79.3 μ Gy per image for unit 4).

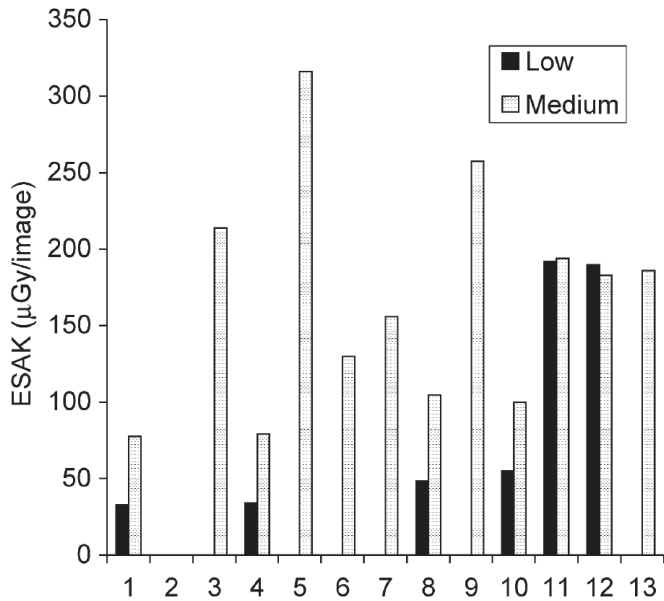


Figure 3.13. Entrance surface air kerma in image acquisition modes (cine modes) at the entrance surface of a phantom of 20 cm of PMMA and a FOV of about 22 cm.

Image quality

Image quality was assessed by imaging the Leeds test objects TOR 18FG. Threshold contrast for fluoroscopy modes is shown in Figure 3.14. For all the systems, the threshold contrast varies between 2.5 and 4 %. Only unit no. 3 has a threshold contrast quite lower (2.3 %).

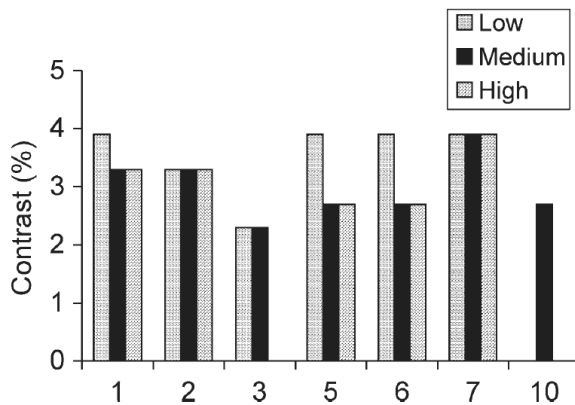


Figure 3.14. Threshold contrast in fluoroscopy for the Leeds TOR 18FG test phantom inserted in the central plane of the 20 cm PMMA phantom, FOV of about 22 cm.

In general, an improvement in image quality is not apparent for the systems operating at higher dose levels: this is particularly important for systems exhibiting the highest entrance doses. Results on the evaluation of limiting spatial resolution of high contrast details of FG18 test phantom are shown in Figure 3.15. All analysed systems have limiting spatial resolution 1.25 lp mm^{-1} . Only system 3 has a resolution lower than 1.25 lp mm^{-1} .

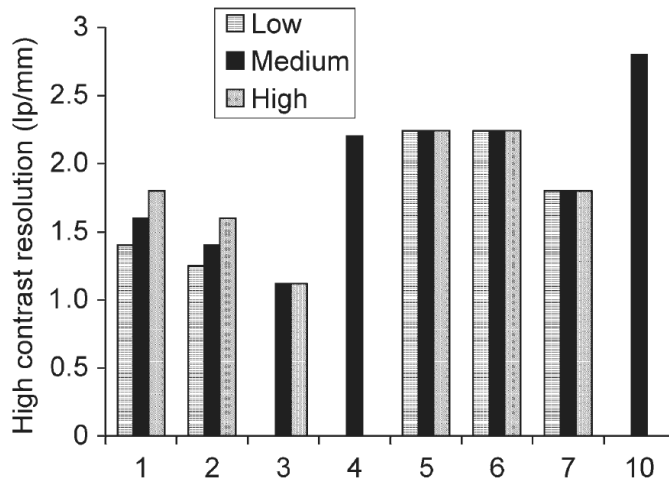


Figure 3.15. Limiting spatial resolution in fluoroscopy for the Leeds 18FG test phantom inserted in the central plane of the 20 cm PMMA phantom, FOV of about 22 cm.

For comparison, by the CEC acceptability criteria [57] for the fluoroscopic equipment the resolution of the image intensifier TV chain combination should be at least 0.8 line pair per mm at a field size of 30–35 cm determined from the use of a specified test object (e.g. Hüttner type 18 resolution grating or Leeds test object). For field sizes of 23–25 cm and 15–18 cm these values are 1.0 and 1.4 lp/mm respectively. In a spot image, the resolution should be at least 2.0 lp/mm. The contrast threshold under automatic operation estimated from the TV monitor image should be 4% or less.

Kerma area product meter calibration

The calibration factors evaluated in the survey are reported in Table 3.7. A large variation, $KAP_{\text{real}}/KAP_{\text{displayed}}$ from 0.68 to 1.05, in DAP meter calibration and/or in the attenuation properties of patient tables and mattresses is recognised and cannot be neglected when patient doses are reported or compared between centres.

As an outcome of this study, a preliminary set of reference levels for the ESAK quantity is proposed in Table 3.8.

Table 3.7. DAP meter calibration factors for the angiographic units included in the survey.

Unit	DAP meter calibration factor
1	0.880
3	0.890
4	0.714
5	0.841
8	0.789
10	0.683
12	1.049
13	0.844

Table 3.8. Reference levels proposed for interventional cardiology equipment.

Imaging mode	Entrance surface air kerma rate
Fluoroscopy, low dose rate	13 mGy/min
Image acquisition	100 μ Gy per frame

3.5. Patient dose in interventional radiology: an European survey (Study V)

Patient doses for a few common fluoroscopy-guided procedures in interventional radiology (IR) (excluding cardiology) were collected from a few radiological departments in 13 European countries, including Estonia (mentioned as partner 15). The major aim was to evaluate patient doses for the basis of the reference levels. In total, data for 20 procedures for about 1300 patients were collected (including data for 2 procedures for 81 patients from Estonia).

Number of IR equipment and procedures

The number of X-ray equipment (systems) dedicated to IR procedures and the annual numbers of diagnostic and therapeutic IR procedures, all data given per number of population, are shown for a few partners in Figures 3.16 and 3.17.

The number of IR systems seems to be between 1 and 5 per one million of inhabitants. The annual number of all IR procedures (non-cardiac) varies from 3500 to 9300 per one million of inhabitants. A majority of the IR procedures seem to be diagnostic.

These figures should be considered only illustrative, as the sample of countries is small and there is an inherent large uncertainty of consistent classification of IR procedures and of the dedication of X-ray equipment to IR procedures.

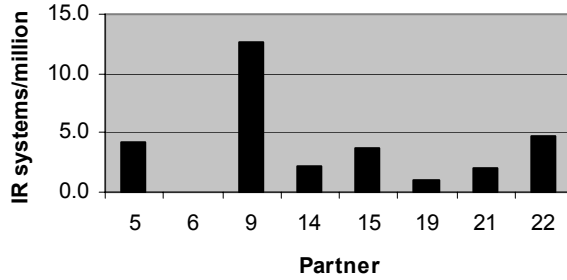


Figure 3.16. Number of IR systems per number of population.

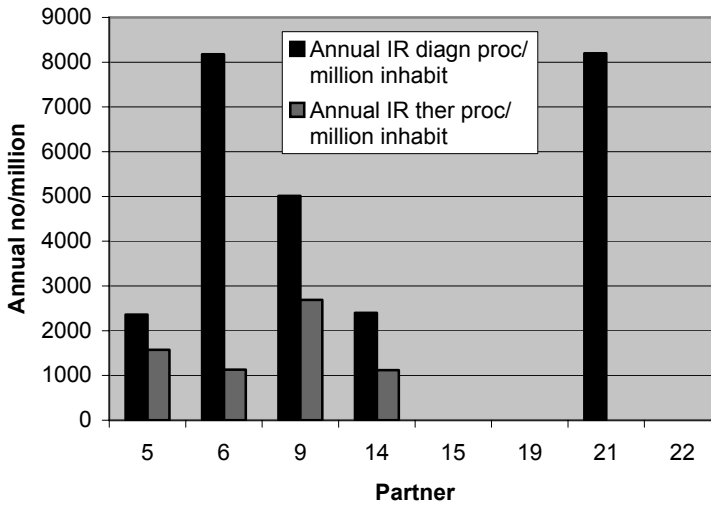


Figure 3.17. Annual numbers of IR procedures per number of population.

Technical and dosimetric data on IR equipment

Types of IR equipment

Altogether, 28 different types of X-ray equipment from five different manufacturers (General Electric, Philips, Shimadzu, Siemens and Toshiba) were used in this study. About half of the equipment has been installed before 2000, half in the last 6 y.

For patient protection, all systems were provided by the DAP meter, at least occasionally. The cumulative dose indicator was reported only for 3 out of the 28 units. The dose reduction system was reported for 10 out of the 28 units, including pulsed fluoro mode, selection of frame rates and factors to vary dose (seven units), added filtration (five units) and one special system (Siemens C.A.R.E system).

Accordingly, except for the DAP meter, the provisions and practices for patient protection seem to vary much.

The acquired images were available in DICOM format on compact discs for 21 out of the 28 units. The date of the latest quality control testing was reported for 19 out of the 28 units, the date being less than 4-y old in all cases.

Calibration of DAP meters

The calibration of the DAP meter was reported for 15 out of 28 units. The latest calibration was less than 2-y old for all units where it was specified. The calibration factors varied from 0.37 to 1.41 with a mean of 0.83 for 15 units (Figure 3.18). The results indicate that without taking the calibration factor into consideration, the DAP values indicated will overestimate the true DAP on the average by about 20%. The patient dose (DAP values) presented in this report are corrected for DAP calibration.

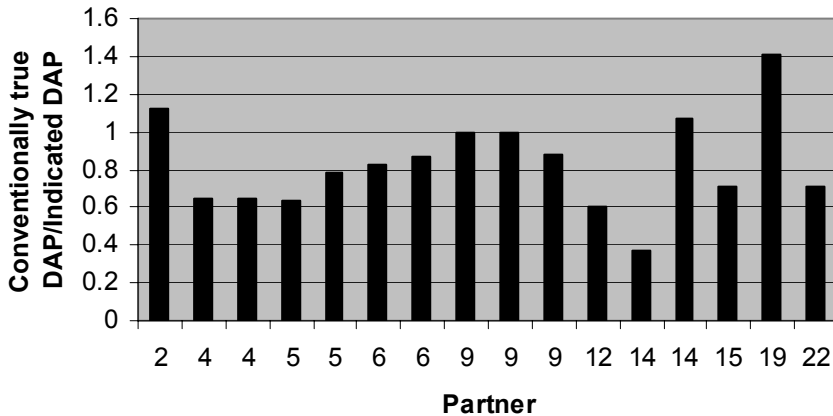


Figure 3.18. DAP calibration factors for 16 different units from 11 countries.

Entrance dose and dose rate

The entrance dose rate reported for the three fluoro modes – low, medium and high – is summarised in Figure 3.19. The entrance dose rate varies by a factor of 6–14 within a given dose rate setting (fluoro mode). Most of the values in medium or high mode agree reasonably well with the average values from 20 to 42 mGy min⁻¹ reported for IR equipment in different IR procedures by Aroua et al. [118].

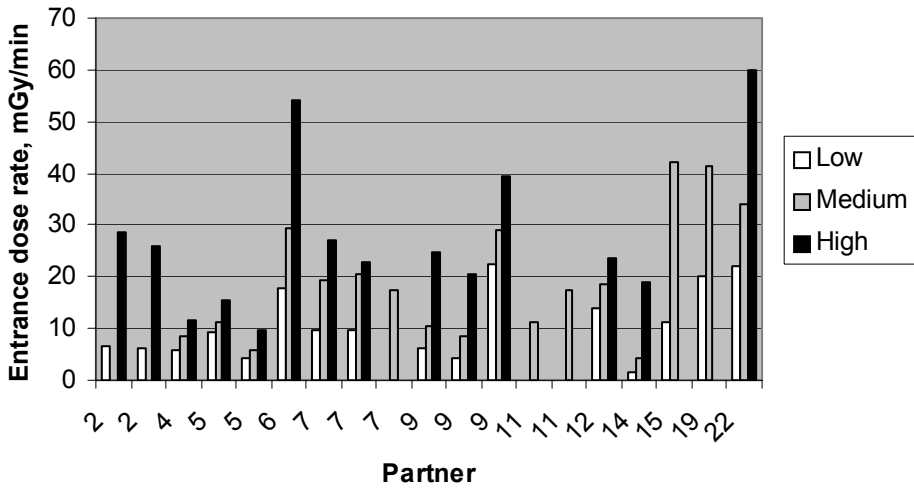


Figure 3.19. Entrance dose rate in different fluoroscopy modes (low, medium and high) for the IR units considered in this study.

The entrance dose per image reported for two image acquisition modes, low and normal, is summarised in Figure 3.20. The entrance dose varies by a factor of 100 at maximum, which refers to the large margin in optimisation strategies. Again, most of the values in the normal mode agree reasonably well with the average values from 1.6 to 6.0 mGy per frame reported for IR equipment in different IR procedures by Aroua et al. [118]

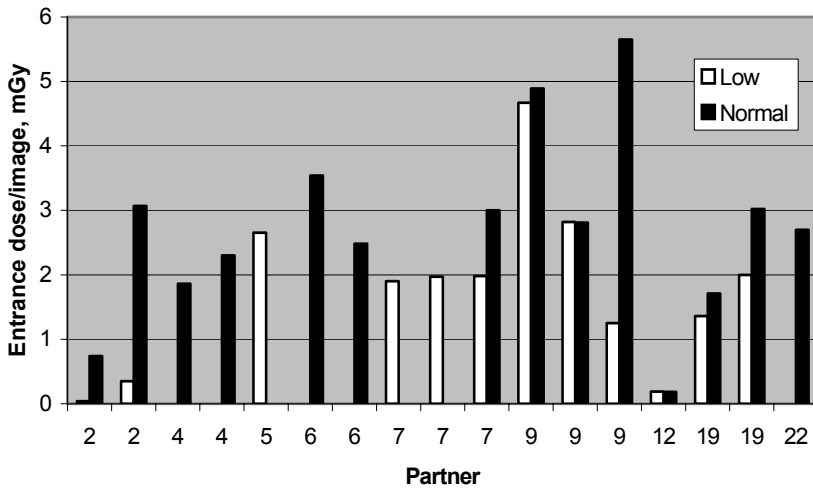


Figure 3.20. Entrance dose in different image acquisition modes (low and normal) for the IR units considered in this study.

Patient doses

IR procedures selected

The four most common interventional procedures selected by each partner (two of them diagnostic IR procedures and two therapeutic IR procedures) were different. In total, the patient dose data for 20 different IR procedures were reported. The number of patients varied between 2 and 434 for these procedures. In total, data for 1343 patients were accepted for consideration.

There was no exact consistency of the terms for the different IR procedures, but the partners used different names for practically the same procedures.

For two diagnostic and two therapeutic IR procedures, a reasonable number of patients were received from at least five partners. Further, one diagnostic and one therapeutic procedure had a reasonable number of patients, for which comparative data from other studies were also available.

These procedures were as follows and were considered in more detail.

- lower limb angiography (434 patients, 12 partners);
- carotid angiography (112 patients, eight partners);
- cerebral arteriography (72 patients, three partners);
- hepatic embolisation (149 patients, eight partners);
- peripheral therapeutic procedures (142 patients, five partners);
- nephrostomy (49 patients, two partners).

Patient dose values

The summary of the third quartile values calculated from all data in this study are shown in Tables 3.9 to 3.11, for total DAP, fluoroscopy time and number of frames (images), respectively. For comparison, a few other published data have been collected in the tables. To get an impression on the significance of the data, the sample size (number of patients) is shown in parentheses whenever given in the publications.

As an example of detailed data, Figure 3.21 illustrates the differences of the mean and median values of total DAP between the partners for lower-limb angiography, and Figure 3.22 illustrates the same for fluoroscopy time. The differences between partners (hospitals) for both DAP and fluoroscopy time are about 5-fold at maximum. At a given hospital, the variation of DAP from patient to patient is also very high, and the standard deviation from 20 to 130%.

There is a poor correlation between the total DAP value and the fluoroscopy time as shown in Figure 3.23. High values of total DAP can be obtained with relatively small fluoroscopy time, suggesting considerable differences in the field size or other parameters of the practices. It has been shown [123, 124] that the DAP for fluoroscopy usually is from about one third to half of the total DAP (from two-thirds to half for radiography), and the high variation of relative amount of fluoroscopy with regard to radiography may also explain the poor correlation in Figure 3.23. The variations of entrance dose rate in two or three different dose rate modes of the IR equipment can explain part of the differences.

Table 3.10. Fluoroscopy time (FT), in minutes, third quartile values.

IR procedure	This work	Aroua et al.[118]	Hart et al.[23]	McParland [123]
Cerebral angiography	12 (72)	15 (91)		14.2 (28)
Carotid angiography	11.2 (112)			14.0 (11)
Lower-limb angiography	3.8 (434)	8 (94)	5.1 (5866)	12.5 (15)
Hepatic embolisation	24.3 (149)	30 (70)		
Nephrostomy	15 (18)		8.9 (273)	10.5 (35)
Peripheral	15.1 (142)			

Table 3.11. Number of frames, third quartile values.

IR procedure	This work	Aroua et al.[118]
Cerebral angiography	550 (72)	480 (91)
Carotid angiography	297 (112)	
Lower-limb angiography	285 (434)	150 (94)
Hepatic embolisation	85 (149)	160 (70)
Peripheral	166 (142)	

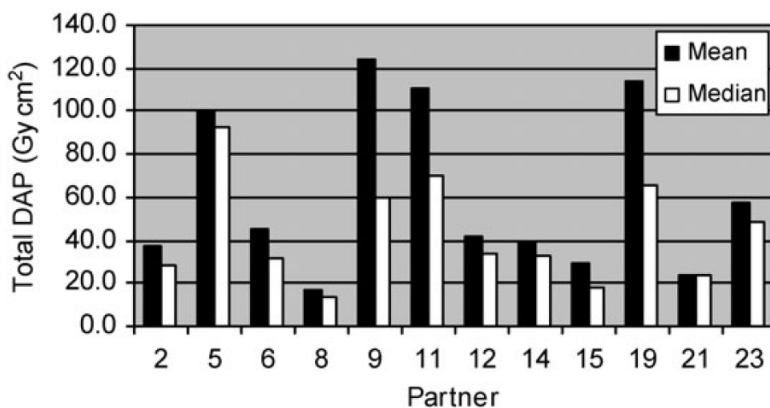


Figure 3.21. Mean and median values of total DAP for lower limb angiography.

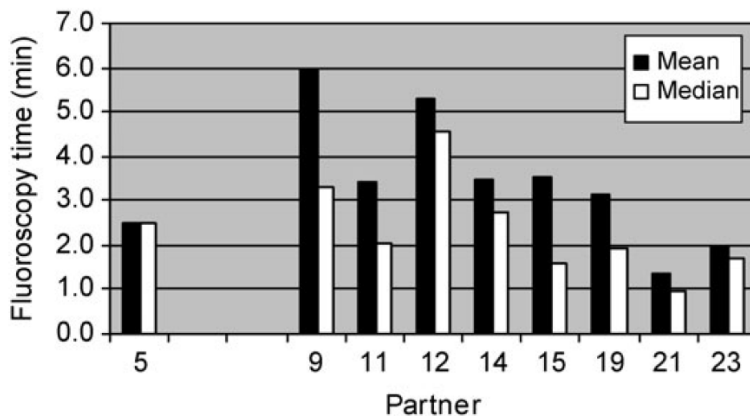


Figure 3.22. Mean and median values of fluoroscopy time for lower limb angiography.

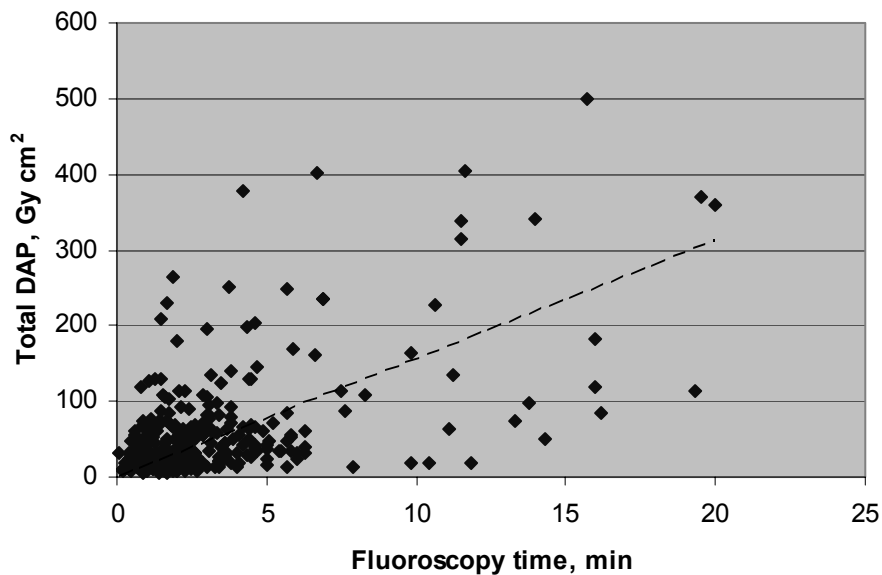


Figure 3.23. Correlation between the total DAP and the fluoroscopy time (mean values) for lower limb angiography.

The histogram for the DAP values is shown in Figure 3.24. The distribution is skewed or characterised by an asymmetric shape: a main peak, a tail and a few extreme values. The histogram is typical of what is expected for examinations involving fluoroscopy.

The third quartile values calculated from all results in this study are compared with other published values in Tables 3.9 to 3.11 and in Figure 3.25, for DAP, fluoroscopy time and number of frames.

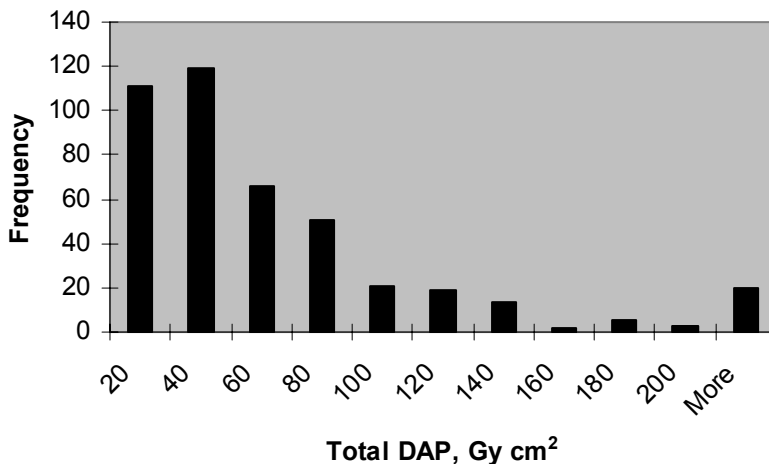


Figure 3.24. Histogram of total DAP values based on data from all partners for lower limb angiography.

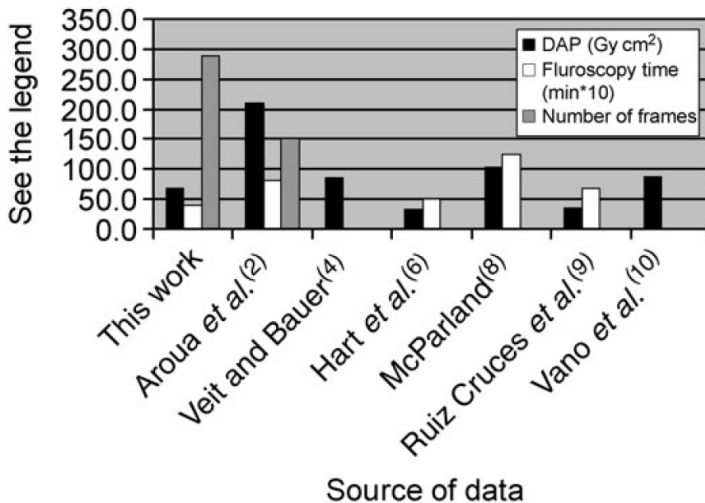


Figure 3.25. Comparison of the third quartile values obtained in this study with other published values, for lower limb angiography.

Except for the results of Aroua et al.[118], the values obtained in this study agree with other results within about a factor of 3.

For carotid angiography, the differences between the partners (hospitals) for total DAP values were more than 10-fold at maximum, and for fluoroscopy time, about 4-fold. For hepatic chemoembolisation, the differences between the partners for both DAP and fluoroscopy were about 6-fold at maximum. For peripheral therapeutic procedures, the differences between partners for total DAP were over 10-fold, and for fluoroscopy, about 2-fold at maximum.

Reference levels

One of the aims of this study was to obtain insight in the patient dose level in interventional diagnostic and therapeutic procedures, in order to propose the reference levels. The term ‘reference level’ is used here instead of ‘diagnostic reference level (DRL)’, because not only diagnostic but also therapeutic interventional procedures are discussed.

Reference levels can be set for total DAP, fluoroscopy time and the number of frames and are intended to be a simple indication of abnormally high values. They act as a trigger to identify those practices in most urgent need of investigation and corrective action, if they cannot be clinically justified.

Preliminary reference levels for a few IR procedures, where a reasonable amount of data from a number of partners in this study was obtained (including data for lower-limb angiography from the Estonian partner), and also comparative data from other publications were available, are proposed in Table 3.12. These reference levels should be considered very cautiously and only as the first approximation when better values based on a large number of local or national data are not available. They should trigger particular attention to the procedures but might not indicate a proper triggering level for remedial actions applicable to the local conditions of patient doses. This is because of the high variations (up to 10-fold) between the third quartile values from different partners as shown earlier.

The use of reference levels in IR procedures is challenging also because of the high individual variability of the procedures within the same type of procedure. Generally, data from a large number (>50) of patients should be collected and the mean value calculated for comparison with the reference level. The mean values of total DAP, fluoroscopy time and number of frames measured by the Estonian partner for lower-limb angiography procedures were, respectively, 29 Gy·cm², 3.5 min and 134 frames, which are all below the reference values.

For more reliable setting of reference levels, the definitions and grouping of the procedures should be improved and considerably more data for any given procedure should be collected. When the data come from a number of hospitals, ideally the same number of procedures should be obtained from each partner. The main reasons for high (many-fold) observed differences between the data from different partners should be carefully investigated before they are accepted for calculation of reference levels. This is done to avoid biasing of the results by very abnormal or even erroneous values, representing, that is, very old equipment or some clear shortcoming of practices. For grouping of the IR proce-

dures, the procedures which are reasonably similar from point of view of patient dose values should be identified and classified with appropriate terms.

Table 3.12. Preliminary reference levels for a few IR procedures based on the results of this study.

IR procedure	Reference level		
	Total DAP, Gy cm ²	Fluoroscopy time, min	Number of frames
<i>Diagnostic procedures</i>			
Cerebral angiography	120	15	500
Carotid angiography	120	12	300
Lower-limb angiography	100	5	300
<i>Therapeutic procedures</i>			
Hepatic embolisation	150	30	100
Nephrostomy	20	15	
Peripheral therapeutic procedures	40	15	200

3.6. Reference levels at European level for cardiac interventional procedures (Study VI)

The SENTINEL consortium has coordinated a survey in nine European centres, collecting information on near 2000 procedures, and a new set of DRLs for coronary angiography and angioplasty and diagnostic electrophysiology has been assessed for air kerma-area product, effective dose, cumulative dose at interventional reference point, fluoroscopy time and cine frames. Because equipment performance and set-up are the factors contributing to patient dose variability, entrance surface air kerma for fluoroscopy and image frame, have also been proposed in the set of DRLs.

Coronary angiography procedures

Examined dose or dose analogue data exhibit a large variability. In Figures 3.26 and 3.27, mean and median values of FT and KAP, respectively, are reported for CA procedures.

The examinations have been pooled, and the frequency distribution of FT, number of frames and KAP have been derived together with the associated DRLs. DRLs have been assessed as the rounded values of the 75th percentile of distributions.

Figures 3.28 and 3.29 report the histograms of FT and KAP values, respectively, for all CA procedures evaluated in this study.

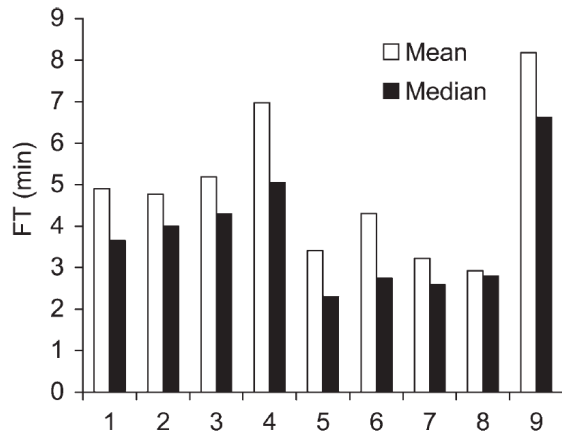


Figure 3.26. Fluoroscopy time of CA procedures in the nine participating centres.

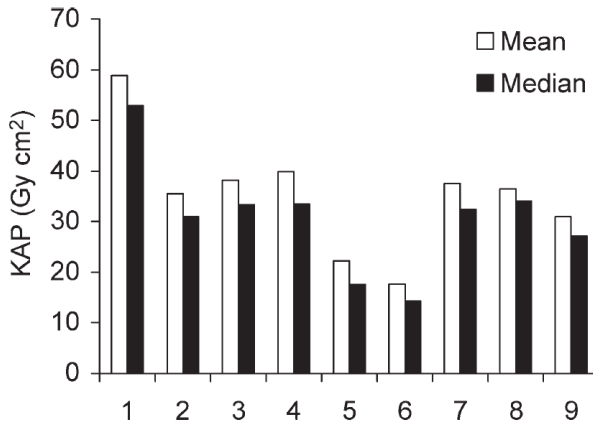


Figure 3.27. Air KAP of CA procedures in the participating centres.

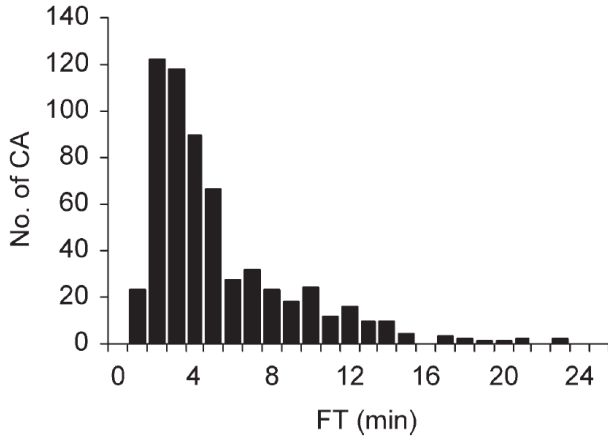


Figure 3.28. Frequency distribution of FT for CA procedures.

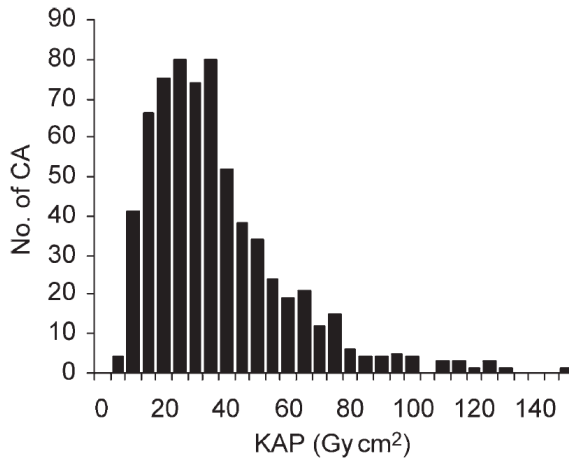


Figure 3.29. Frequency distribution of air KAP for CA procedures.

PTCA procedures

In Figures 3.30 and 3.31, histograms of FT and KAP, respectively, for PTCA procedures are reported.

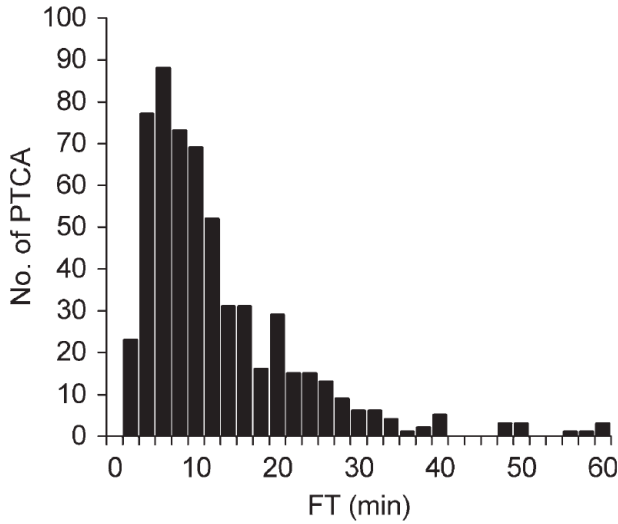


Figure 3.30. Frequency distribution of FT for PTCA procedures in participating cardiac centres.

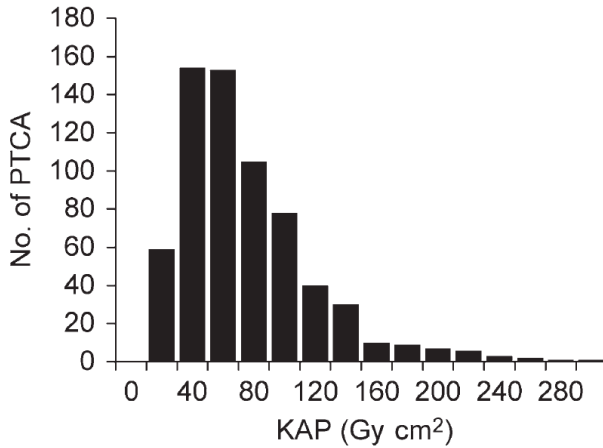


Figure 3.31. Frequency distribution of air KAP for PTCA procedures in participating cardiac centres.

Electrophysiology procedures

Frequency distribution histograms approximate a log-normal shape in all cases. This result represents the effects of differences between patient sizes and procedure protocols, as well as technical differences between equipment.

Reasons arise from a variety of RFCAs performed to treat different arrhythmias: atrial fibrillation, atrial flutter, nodal tachycardia, ventricular tachycardia and Wolff-Parkinson-White syndrome.

Important differences in procedure protocols provide different mean FT and KAP values.

In Figure 3.32, the frequency distribution of FT for RFCA procedures is reported and it is possible to recognise the distribution does not have a lognormal shape.

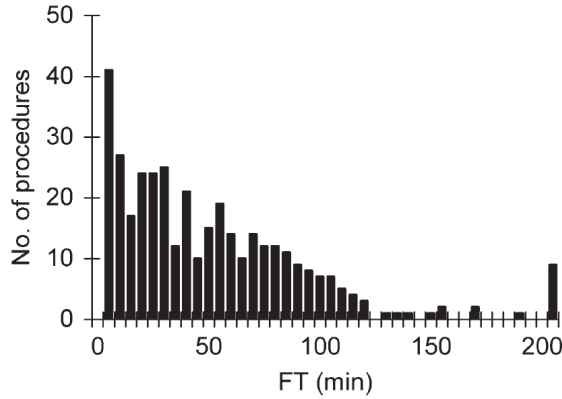


Figure 3.32. Frequency distribution of FT for electrophysiological procedures.

Figures 3.33 and 3.34 report the data from an electrophysiology laboratory (Udine Hospital, Italy), where the information on type of RFCA have been collected.

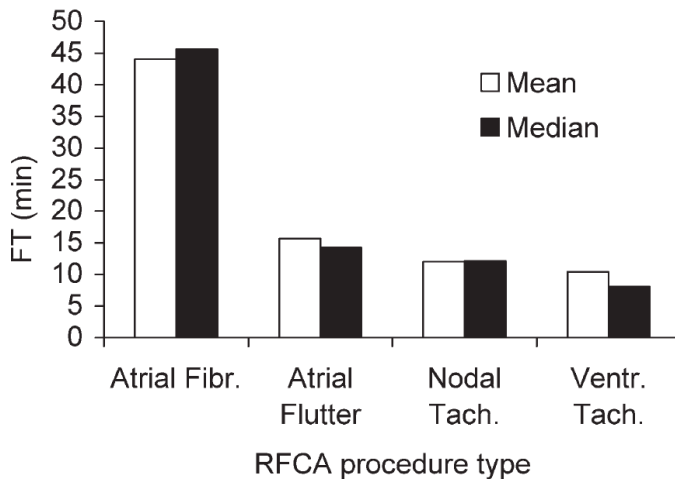


Figure 3.33. FT of different types of RFCA procedures.

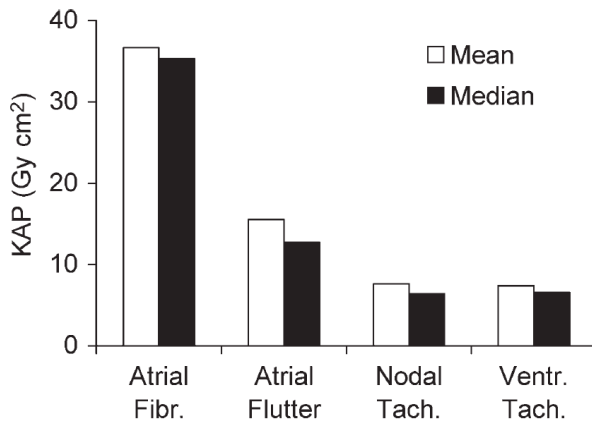


Figure 3.34. KAP of different types of RFCA procedures.

It is possible to recognise that the treatment for atrial fibrillation is the procedure that requires the highest FT (median value of 45 min) and, consequently, the highest KAP (median value of 35 Gy cm²) values.

The data of electrophysiology collected in the Udine Hospital imply the impossibility to pool all RFCA data together.

In contrast, the data available for each single procedure are insufficient to treat them separately.

Consequently, from this survey, it is not possible to assess RLs (DRLs) for RFCA procedures.

Reference levels

In Table 3.13, RLs, assessed as the rounded value of the 75th percentile of distributions, are reported for KAP, effective dose (defined as $E = 0.18 \times \text{KAP}$), CD at IRP, FT, and number of cine images. The mean values of KAP, E , FT and number of cine images measured by the Estonian partner for a sample (7) of PTCA procedures were, respectively, 50 Gy cm², 9 mSv, 8.3 min and 883 images, which are all below the reference values.

Because equipment performance and set-up by the maintenance service are also important factors contributing to patient dose variability, entrance surface air kerma for fluoroscopy and image acquisition, measured at the entrance of a 20 cm PMMA phantom, are also introduced in the set of proposed RLs.

The RLs proposed for coronary angiography and angioplasty are lower when compared with those assessed in 2004 by the DIMOND group (CA: KAP = 57 Gy cm²; PTCA: KAP = 94 Gy cm²) [130]. The main difference derives from the lower number of cine images that had influenced the KAP.

Regarding the introduction of the CD at IRP in the set of RLs, it is necessary to better evaluate the impact of this quantity in the optimisation process of patient exposure.

Table 3.13. SENTINEL reference levels for interventional cardiac procedures.

Dose or dose analogue	Procedures		
	CA	PTCA	EP
KAP (Gy cm ²)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	–
FT (min)	6.5	15.5	21
Number of cine images	700	1000	–
Entrance surface air kerma rate	Fluoroscopy, low dose rate mode: 13 mGy/min Image acquisition mode: 0.10 mGy per frame		

4. CONCLUSIONS

4.1. General

The concept of diagnostic reference doses for optimisation of radiation doses and image quality in medical radiology has been broadly implemented in European countries, but not regulated in Estonia by the legal acts yet, although special requirements on it have been established in the EC directive on medical exposures. This study has introduced new optimisation strategies for digital radiography and fluoroscopy and compared it in several health care centres. The performance checks have been regularly carried out in most of the radiological departments on X-ray systems periodically, but also interlaboratory comparisons of the testing laboratories should be done to follow the international standards and good practice as concluded from this study. The results of the coordinated international surveys carried out in the European SENTINEL project have shown the comparable performance indicators and patient dose distribution of the radiological practice of the participating countries. Reference levels for interventional radiology in Europe can be set as primary guidance levels in each EC member state, including Estonia.

Digital systems are characterized by their flexibility as the dose can be reduced at the expense of image quality and vice versa. The imaging parameters need to be individually optimised according to the best performance of a system. Digital techniques increasingly offer options for dose reduction. At the same time there is a risk to accidentally substantially increase patient dose due to the lack of visual dose control. Therefore, the implementation of quality-dose indicators and dose monitoring is mandatory for digital radiography. The use of image quality classes according to the dose requirements of given clinical indications are a further step towards modern radiation protection and safety culture.

In Estonia practical guidance on how radiology departments could compare their own performance with national and international practice is needed for implementation of their own quality management systems. It could be based on the experimental results and practical suggestions from the present study. Also, regulation concerning recommendations for periodic patient dose measurements and the coordinated system for establishment diagnostic reference levels has to be brought into force in national level, could be based on the European good practice in quality assurance in radiology, revealed in this study.

4.2. Optimisation of computed radiography systems

The estimation of image performance parameters has shown that in order to increase the figure of merit SNR^2/D and reduce patient dose the higher tube potential technique would be more preferable for the detail type of interest, but by comparison of contrast- detail detectability $H_T(A)$ curves for different speed

modes, it could be concluded that at the high tube potential range difference between low and higher AEC speed modes does not give any advantage in terms of contrast detail.

For optimisation of clinical settings, it is reasonable to find out experimentally the optimum tube potential to keep balance between noise and contrast- detail detectability. Final optimisation could be done only by using anthropomorphic phantom and clinical evaluation.

Based on the image evaluation data, optimum speed modes for the organ programme settings have been given in Table 3.1.

The same type of CR scanners (with the same type of software for digital image acquisition and pre-processing) in different health centres were compared and the similar trend for all performance curves is remarkable, but as different AEC settings with different detector entrance doses were preset, the performance comparison of the systems must be carried out with caution.

4.3. Interlaboratory comparison tests

Proficiency testing and interlaboratory comparison could be reliable tools for estimating competence levels and physical measurement capabilities of independent testing laboratories providing X-ray quality control service to hospitals. It may be needed also for the hospital medical physics departments, carrying out quality control tests with their own equipment and methodology.

The estimated ILC-scores E_n for all tests were less than unity and thus, according to the common ILC criteria, the testing performance of UT can be considered as acceptable and the results of both laboratories are quite comparable. This also shows that the stated levels of uncertainties in measurements are realistic.

4.4. Quality control measurements of digital fluoroscopy systems

The adapted MPBE protocol, tested in eight European countries, including Estonia, appeared to be useful for quality control of new digital fluoroscopy systems. It appears, however, that not all tests are useful or applicable for modern systems, e.g. concerning II-systems. The wording in some parts of the protocol needs to be adapted to the availability of digital systems. Performance requirements for some of the tests are not explicitly given and need to be added. The present protocol of most of the participants, including Estonian protocol, needs the addition of a section, or an addition to each section, to state compliance with the requirements. It is recommended to include a way to indicate if a test is passed/failed and what are the consequences of failure. The

circular cross sections of the Leeds Test Objects need adaptation for new rectangular FPD systems.

The low contrast (noise) test object performance criteria as specified for old systems are commonly complied with by the participants' X-ray systems. The low contrast (noise) test object performance criteria as specified for new systems are not complied with by the participants' equipment. This is surprising since most of the X-ray systems of the participants are relatively new.

None of the X-ray systems of the participants are capable of complying with the performance criteria for the contrast-detail test object. It seems that the criteria are too strict. The field coverage test object seems too small. Instructions for scoring S-distortion and pincushion distortion should be added to the protocol. The radiation field should be smaller than the imaged field. This means that the criterion as formulated in the protocol should be inverted.

The limiting resolution test object seems to be easy to use. The specification of performance is not always given by the participants.

Only one participant was able to perform the monitor test using the MoniQA software. This is due to the fact that assistance is apparently required from the suppliers of the X-ray systems. This problem needs to be solved to apply MoniQA tests in practice.

4.5. Performance assessment of cardiac angiography systems

The survey on the cardiac angiographic units in a sample of European centres demonstrates a large variability in entrance dose rates for both, fluoroscopy and image acquisition modes, image quality performance and DAP meter calibration.

As an outcome of this study, a preliminary set of reference levels for the ESAK rate quantity is proposed for different examination modes in Table 3.8. For the cardiac angiographic unit tested in Estonia the measured values were below the reference levels, showing enough compliance with the exposure criteria.

The reference levels can be adopted by centres and maintenance engineers to set up cardiac equipment at an acceptable dose performance level and by standardisation bodies as an input to introduce proper standards. SENTINEL consortium is finally recommending a European action directed to harmonise the level of performances of angiographic systems used in the daily cardiac practice.

4.6. Patient dose in interventional radiology: a European survey

There are high variations in the number of IR equipment and the number of IR procedures per population in different European countries. For IR equipment, the variation in entrance dose rate can vary by a factor of more than 10 within a given dose rate setting. For patient dose estimation with DAP values, the DAP values indicated can overestimate the true DAP on the average by 20% unless the calibration factor of the DAP meter is taken into consideration.

The patient dose data collected in this study, that is, total DAP, fluoroscopy time and number of frames, for a number of diagnostic and therapeutic IR procedures, indicated many-fold variations between the mean and median values obtained from several partners. At a given hospital, the variation of total DAP from patient to patient was also very high (standard deviation 20–130%). There were very large variations and no clear correlation between the total DAP and the entrance dose rate, or between the total DAP and the fluoroscopy time, indicating that there are a number of parameters of the procedures affecting the dose differences.

Because of the limited number of patients, preliminary reference levels have been proposed only for a few procedures, where a reasonable amount of patients from several partners was available and where also comparisons with other published data could be made. These levels should be used very cautiously as the first approximation until reference levels based on significant amount of national or local data are available. The mean values of total DAP, fluoroscopy time and number of frames for lower-limb angiography procedures calculated by the Estonian data were all below the preliminary reference values.

There is a clear need to improve the optimisation of IR procedures. Further, for setting the reference levels, the definitions of procedures and their proper grouping with regard to the patient doses should be developed, whereby the different complexities of the procedures should also be considered.

By the high variations in calibration factors it can be concluded, that it is important to calibrate dose monitors regularly to avoid too high uncertainties in estimating patient doses.

4.7. Reference levels at European level for cardiac interventional procedures

The SENTINEL survey performed on interventional cardiology in a sample of European centres demonstrates the presence of a large variability in the entrance surface air kerma rates for both fluoroscopy and image acquisition modes. For the first time, reference levels for these quantities are proposed to be used in the process of optimisation of patient exposure.

The SENTINEL reference levels assessed also include the effective dose, calculated from the KAP reference value, and the CD at the IRP, quantity today displayed in the interventional room by the new equipment.

The reference levels estimated in the European surveys can be adapted as preliminary reference levels for interventional radiology departments in Estonia.

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SUMMARY

Medical diagnostic radiation procedures make up the majority of the human exposure from artificial sources of ionising radiation. In several European countries contribution of X-rays to average annual effective dose per caput has been estimated about 90 % of all diagnostic exposures, including nuclear medicine. Diagnostic reference levels provide a broadly accepted tool to reduce the large variation in patient dose for the same type of X-ray examination in different radiology departments, and to assist in the optimisation process. A database on patient doses is a prerequisite for any formulation of national and European guidelines on the optimised use of radiographic and interventional procedures, including the setting of the reference levels. In Estonia systematic data collection of patient doses for establishment and application of reference doses is not nationally regulated yet. New digital technologies in medical radiology have the potential to reduce patient doses, but they also have the potential to significantly increase them without loss in image quality as shown by clinical surveys. Quality assurance in radiology departments can be made by periodically reviewing the outcome and optimising of the X-ray examinations in terms of two fundamental parameters: the image quality and the patient dose.

The main purpose of this thesis was to introduce and develop new methods in dose and image quality optimisation, quality control of radiographic and fluoroscopic equipment and patient dosimetry in X-ray diagnostic radiology with emphasis on needs in Estonian hospitals, and to participate in the European clinical dosimetry surveys for estimating reference levels in typical interventional procedures.

The work was carried out as a pilot study of physical approach for the dose and image quality optimisation, evaluating the performance of an automatic exposure control at different sensitivity settings when used with a computed radiography system. The tests were designed to investigate image quality, using threshold contrast-detail detectability (TCDD) and signal-to-noise ratio squared related to dose (SNR^2/D) at different sensitivities and X-ray tube potential values, and to compare the image performance of the same type of computed radiography systems in different hospitals. The optimum speed modes and optimal settings to be used in the radiography examination programmes were proposed based on the image evaluation data. In cooperation with other European partners under the SENTINEL consortium performance characteristics of digital fluoroscopic and cardiac angiography systems were investigated and compared in seven European countries, also reference levels for some typical interventional radiology procedures were estimated.

This study introduces interlaboratory tests for quality control of X-ray equipment that are needed for comparability and accreditation of test laboratories. The results of the coordinated international surveys carried out by the SENTINEL research partners has given comparison data on performance indicators and patient dose distribution of the radiological practice of the participating countries. For example, the survey performed on interventional

cardiology in a sample of European centres demonstrates the presence of a large variability in the entrance surface air kerma (ESAK) rates for both fluoroscopy (more than 7 times) and image acquisition (more than 5 times) modes. For the first time, reference levels for these quantities are proposed to be used in the process of optimisation of patient exposure. The mean values of total dose area product, fluoroscopy time and number of frames for a sample of lower-limb angiography procedures calculated by the Estonian data were all below the estimated reference values.

The results and conclusions of this work present valuable information for further research, development of national legislation on use of medical exposures (e.g. criteria for acceptability of X-ray equipment, specification of standard procedures and good practice in diagnostic radiology), for developing guidelines for quality assurance programs of radiology departments, quality control protocols of medical physics departments, teamwork between clinical medical physicists and radiologists and radiographers, and for improvement of radiation safety of patients and radiological personnel.

SUMMARY IN ESTONIAN

Patsiendi kiirgusdoosi ja pildi kvaliteedi optimeerimine diagnostilises radioloogias

Suurima osa kõigi kasutuselolevate tehisallikate ioniseeriva kiirguse doosidest annavad meditsiinidiagnostilised kiiritusprotseduurid. Paljudes Euroopa maades on röntgenkiirgusest tingitud ligi 90 protsenti kõikide radiodiagnostiliste uurin-gute (sh nuklearmeditsiin) efektiivdoosist. Diagnostiliste referentsväärtuste kasutamine on aluseks üldtunnustatud meetodile erinevates radioloogiaosakon-dades samatüübiliste röntgenuurin-gute patsiendidooside vaheliste suurte erine-vuste vähendamisel ja optimeerimisel. Patsiendidooside andmebaasid on alu-seks radioloogiliste protseduuride optimaalse rakendamise siseriiklike ja Euroo-pa juhendite koostamisel, samuti referentsväärtuste kindlaksmääramisel. Eestis puudub senini süstemaatiline patsiendidoosi registreerimise riiklikult regulee-ritud süsteem, kuigi see on nõutav Euroopa direktiividega. Uued digitaaltehno-loogiad meditsiiniradioloogias võimaldavad patsiendidoosi vähendada. Nagu näitavad arvukad kliinilised uuringud, võib patsiendidoos piisavate ohjemeet-mete puudumisel siiski üsna märkimisväärselt ka kasvada, kusjuures digitaal-radioloogias ei avaldu doosi kasv alati pildi kvaliteedi langemises. Kva-liteeditagamise aluseks radioloogiaosakondades on röntgenuurin-gute väljundi järjepidev kontroll ja kahe olulise suuruse – pildi kvaliteedi ja patsiendidoosi – optimeerimine.

Käesoleva doktoriväitekirja eesmärgiks oli kasutusele võtta ja arendada uusi meetodeid patsiendidoosi ja pildi kvaliteedi optimeerimisel, röntgenülesvõtte- ja läbivalgustusaparatuuri kvaliteedikontrollil ja patsiendidosimeetrias, lähtudes Eesti haiglate vajadustest, ning ühtlasi võtta osa Euroopa kliinilise dosimeetria uuringutest menetlusradioloogia referentsväärtuste hindamisel.

Uurimistöö teostati füüsikalise lähenemisviisi pilootturinguna doosi ja pildi kvaliteedi optimeerimisel, hinnates röntgenseadme automaatekspositsioonisüs-teemi toimivust erinevates tundlikkusrežiimides koos kasutatava kompuuter-radiograafia süsteemiga. Katsetes mõõdeti pildi kvaliteedi parameetritena lävikontrastsus-teravust (TCDD) ja signaal-müra-suhte ruudu ning doosi suhet (SNR^2/D) röntgenseadme erinevate tundlikkuste ja röntgentoru pingete korral, võrreldes tulemusi sama tüüpi kompuuterradiograafia süsteemide vahel. Pildi evalveerimistulemuste põhjal soovitati kasutada optimaalseid tundlikkusrežiime ja talitusparameetreid. Koostöös SENTINEL konsortsiumi teiste Euroopa partneritega uuriti ja võrreldi digitaalfluoroskoopia ja kardioangiograafia süsteemide toimimishäitajaid seitsme riigi haiglates, samuti hinnati referentsväärtusi mõnedes tüüpilistes menetlusradioloogia protseduurides.

Käesolev töö tutvustab laboritevahelisi võrdluskatseid röntgenseadmete kvaliteedikontrollil tulemuste võrreldavuse ja laborite akrediteerimistingimuste tagamiseks. SENTINEL koostööpartnerite koordineeritud uuringutest saadi võrdlusandmeid osalevate maade radioloogilises praktikas kasutatavate sead-

mete toimimisenäitajate ja patsiendidooside jaotuse kohta. Näiteks, menetlusradioloogias läbi viidud uuringud näitavad suuri erinevusi uuringus osalenud keskuste vahel sisendõhukerma (ESAK) kiiruses nii läbivalgustusrežiimi (üle 7 korra) kui ka pildihõiverežiimi (üle 5 korra) korral. Esmakordselt on eelnimetatud suurusi soovitatud kasutada patsiendidoosi optimeerimisel muude referentsväärtuste hulgas. Alajäseme angiograafia protseduuride valimi kohta arvatud summaarse doos-pindala, läbivalgustuskestuse ja kogutud kujutiste arvu keskvväärtused olid Eesti andmete põhjal hinnangulistest referentsväärtustest madalamal.

Käesoleva töö tulemused ja järeldused annavad väärtuslikku informatsiooni edasisteks uuringuteks, riiklike õigusaktide koostamiseks meditsiini kiirituse kasutamisel (nt röntgenseadmete vastavuskriteeriumid, standardprotseduuride spetsifikaat ja hea tava diagnostilises radioloogias), radioloogiaosakondade kvaliteeditagamise programmide arendamiseks, haigla meditsiinifüüsikute ja radioloogide ning radioloogiatehnikute koostöö arendamiseks, ning patsientide ja radioloogiapersonali ohutuse parendamiseks.

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PUBLICATIONS

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1. **Andrus Ausmees.** XUV-induced electron emission and electron-phonon interaction in alkali halides. Tartu, 1991.
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