Title of the study

« Reference dose levels during fluoroscopically guided procedures performed using mobile X-ray systems in operating rooms"

Approval numbers:
TPS 51076bis: CEREES (French Health Researches, Studies and Evaluations Expert Committee)
DR-2018-201: CNIL-FRANCE (the National Commission for Data Protection and Liberties)

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Protocol summary

This study is conducted by a working group of the French Society of Medical Physics (SFPM). Its main aim is to establish reference dose levels for the most common procedures performed in operating rooms using mobile x-ray systems, hence helping medical physicists and surgeons to evaluate their practice and optimize patient radiation protection.

This is a multi-centric prospective study involving 73 medical institutions of different categories (public university hospitals, clinics, cancer centers, etc.). It consists on progressively collecting anonymous data for 15 to 30 procedures from a list of 62 types of procedures, belonging to 7 surgery specialties (neurosurgery, orthopedic, digestive, urology, cardiology, vascular and multi-specialty). Collected data include patient BMI and information about the x-ray equipment, the procedure and the dosimetric parameters. Data collection doesn't require the access to the patient medical record and doesn't impact his medical care.

Proposed dose reference levels will be expressed in terms of KAP (Kerma-Area-Product), fluoroscopy time and air Kerma. Moreover, multiple statistical analyses will be done to investigate the impact of different variables on the procedure X-ray doses.

Context:

Reference dose levels, introduced by the International Commission on Radiological Protection (ICRP) in 1996, are intended to help professionals using medical imaging to evaluate their practice and optimize patient's doses.
European directive 2013/59/Euratom emphasizes the need to establish, use and regularly review reference levels for diagnostic and interventional procedures and to publish guidelines on this topic.
Furthermore, national reference levels were established for conventional radiology and CT exams. They are used as a tool for the optimization of medical practices. Besides, a working group of the French society of medical physicists (SFPM) has published in 2017 reference levels for interventional radiology procedures.
Although radiation protection is a big challenge encountered in operating rooms, few data are available in the literature regarding the use of mobile x-ray equipments.
In this context, the SFPM suggested the creation of a working group in 2017 to establish reference levels for the main procedures realized in the operating rooms using mobile x-ray systems. The aim of this working group is to help medical physicists and surgeons in evaluating their practice and optimizing patient radiation protection. The working group is composed of 5 medical physicists working in 5 different institutions in France.

Objectives

Main goal:
Establish dosimetric reference levels, in terms of KAP (Kerma-Area-Product)
Secondary goals:

- Reference levels in terms of fluoroscopy time and air kerma
- Analysis by the procedures details (impact of different techniques, instruments and materials, etc...)
- Assessing inter-site variability
- Correlation between KAP and BMI, fluoroscopy pulse rate and mode

- Ratio between fluoroscopy and radiography doses
- Effect of zoom and magnification on the dose
- Institution -type distribution of doses
- Impact of the surgical specialty on the doses delivered for some procedures.

Scope of the study

Surgical procedures: a total of 62 procedures (p=62) belonging to 7 different surgery specialties are involved in this study. Selected specialties are neurosurgery (p=12), orthopedic (p=15), digestive (p=6), urology (p=10), cardiology (p=6), vascular (p=11), multi-specialty (p=2). A brief summary of each procedure will be sent to the participating institution.

Study type and cohort: This is a multi-centric prospective study which consists on progressively collecting anonymous data for 15 to 30 procedures from a list of 62 procedures. This study is thus equivalent to a retrospective study. It doesn't require any access to patient medical records nor influence his medical care as the data are only provided by the x-ray system or the medical team.
In order to reach a good compromise between satisfactory statistical power and achievable database, 15 to 30 procedures per surgery type and per institution would be suitable for the study. This is consistent with the previous published studies and recommendations (ICRP, French legislation). Moreover, limiting the number of procedures to this range (15-30) will ensure enrollment of homogeneous cohorts between participating institutions.
73 health institutions of different categories (University hospital, clinic, cancer center, etc..) confirmed their participations to the study. Hence, the minimal number of procedure regardless of the procedure type would be 11490 and the maximal number would be 22980.

Inclusion criteria:
- Fluoroscopy guided procedures performed on adult patients (≥16 years old)
- Fluoroscopy guided procedures performed on mobile x-ray systems. Procedures performed outside of the operating rooms using mobile x-ray systems are included in this study
- Fluoroscopy guided procedures performed using mini C-arms or O-arms
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Exclusion criteria:
- Fluoroscopy guided procedures performed on pediatric patients (<16 years old)
- Fluoroscopy guided procedures performed on a fixed interventional radiology imaging system even if it was located in the operating theater.
- Medical procedures performed using both a mobile x-ray system and a fixed CT scanner
- Medical procedures performed using a mobile intra-operative CT scanner

Data collection

Data will be collected using a password-protected Excel spreadsheet. This excel file will be sent to all the participating institutions at the beginning of data collection. Every institution will send the excel file completed with anonymized data to the scientific responsible of the study through the secure email server of the APHP institution. Data collection period is set to 6 months.
Collected data have been organized into 4 categories:

- Data regarding the x-ray equipment and available on the quality controls (QC) reports : Year of construction, image detector type, size of the smaller field,

difference between the displayed and measured KAP for the smallest field, size of the biggest field, difference between the displayed and measured KAP for the biggest field, size of the largest filed adapted to the size of the phantom, difference between displayed and measured air kerma available in the last QC report, date of the last external QC previous to the procedure. Also, participating institution should precise whether if the x-ray equipment was connected to a Dose Archiving and a Communication system (DACS)

- Data regarding the patient (Optional) : Weight and height (provided from the equipment or given by the medical team)
- Data regarding the procedure: specialty, additional information about the procedure, size of the most used field for the concerned procedure. These data are provided by the medical team.
- Technical and dosimetric data available on the x-ray equipment : total KAP, Total air kerma, total number of image frames, fluoroscopy mode, fluoroscopy pulse rate, fluoroscopy time, dosimetric data specific to the O-arm equipment.

Outcomes:

The main goal of this study is to publish descriptive statistics (mean, standard deviation, median, 1st quartile, 3rd quartile) for each dosimetric data (KAP, fluoroscopy time, kerma, etc..) and for each category of surgery procedures. Results will be presented with a 95% confidence interval.

Moreover, correlation analysis between several variables as indicated previously in the goal section will be done. The differences between detector and equipment technologies will be also studied using appropriate statistical tests.

Study approval and patients consent

This study has received the approval of the French Health Researches, Studies and Evaluations Expert committee (CEREES-TPS 51076bis) on June 2018 and the National Commission for Data Protection and Liberties (CNIL-DR-2018-201) on august 2018. These national committees granted the study an exception from obtaining patients informed consent because it respected the following conditions:

- ✓ Anonymous data collection
- ✓ No codes are attributed to the patients
- ✓ No need and no possibility to access to the patient medical record
- ✓ No risk in identifying the patient afterwards
- ✓ The research could not practicably be carried out without the waiver of informed consent.

However, comprehensive and concise information regarding this study will be provided to patients in the form of collective display in the participating departments. This information leaflet mentions the purpose, risks and benefits of the study and informs the patients of the possibility of opposing the use of their data.