Protocol and Dose Optimization in CT, Mammography, and Radiography in Latin America

Justification: Radiation dose monitoring for imaging tests is an important national and international concern, highlighted by the World Health Organization (WHO), the International Atomic Energy Agency (IAEA), the Brazilian College of Radiology (CBR). Radiation dose monitoring complies with quality programs and certifications of the CBR's Diagnostic Imaging Accreditation Program (PADI) and the Joint Commission International (JCI). Although most developed nations have established their national reference radiation dose values (DRL - dose reference level), unfortunately, Brazil and several other nations from Latin America do have established national or regional DRL. In 2019, the Brazilian Ministry of Health made changes to the ANVISA regulation (RDC 330), reinforcing the need for constant and active monitoring of patient dose by the institutional responsible party.

Objectives: To provide recommendations for protocol and radiation dose optimization in CT, mammography, and radiography exams. To determine the DRL based on clinical indication for the participating institution, as a sample of the national and regional DRL.

Methods: This project applies to hospitals or clinics in Latin America in outpatient, emergency, ICU, and inpatient sectors. It proposes the use of data collection through a virtual platform, via the DICOM protocol (Digital Imaging and Communications in Medicine) in CT, radiography equipment, and/or mammography and tomosynthesis for data collection. We propose retrospective and prospective analysis of cases from 2022 to 2023, stratified by age, gender, technical data, and clinical indication of the performed radiological exams (radiography, mammography, and CT) from the participating centers. We will obtain anonymized reports through the platform. The responsible parties from the participating centers will sign a confidentiality agreement and an acknowledgment form. Subsequently, We will make suggestions for realigning or optimizing protocols and educational actions for the healthcare professionals involved.

Expected results: Establishing a local estimate of the DRL (Dose Reference Level) and analytical reports from various locations in Latin America. We will suggest educational activities for the supervisors of the participating centers.

Keywords: Radiation dose, Computed Tomography, Mammography, Radiography, Information Technology Management.

INTRODUCTION

1.1 Concern of institutional bodies regarding the risks of ionizing radiation

The World Health Organization (WHO) has highlighted the risks of accumulated dose in patients from ionizing radiation exams, especially in children [1]. Governmental bodies in Brazil and the Brazilian College of Radiology (CBR) have encouraged radiological protection practices involving physicians, physicists, radiology technicians, engineers, and managers in patient care and technical preparation of professionals [2]. In the case of radiological exams that use ionizing radiation, such as CT and radiographic exams, there is a recommendation from the International Atomic Energy Agency (IAEA) to perform exams with the lowest possible dose strictly necessary for the patient's diagnosis, based on the clinical condition, and respecting the ALARA principle (As Low As Reasonably Achievable) [3,4]. CT and radiography exams represent approximately 50% of radiation dose in the medical field [1].

Local reference levels for radiation doses in radiodiagnosis are parameters used to avoid performing exams with excessive doses [5,6]. In Brazil and some countries in Latin America, approved national reference dose values have not yet been established by the responsible entities. The diversity of scenarios in a continental country contributes to the complexity of determining the Brazilian national DRL (Dose Reference Level) for different radiological modalities. It is recommended to determine both local and national DRL values [2].

Data collection for determining the DRL is also a challenge. An effective dose management strategy involves monitoring reference dosimetric quantities and technical parameters, which impact radiation dose [7]. In the case of CT, the recommended dosimetric quantities to be evaluated are DLP (Dose-Length Product, unit: mGy·cm) and CTDIvol (CT Dose Index volume, unit: mGy). Similarly, air kerma values at the patient's skin entrance can be used to monitor reference levels for radiography and mammography procedures. Reference values used to measure radiation dose in relation to patient weight, age, and gender can be assessed according to the criteria of the International Commission on Radiological Protection and the IAEA [6]. Organ dose has been an important parameter to monitor in order to prevent or minimize the cumulative effects of ionizing radiation exams and their risks to patients [1].

1.2 Diagnostic Reference Levels

The International Commission on Radiological Protection (ICRP) defines the concept of reference levels and recommends specific protocols with lower exposure factors for pediatric exams [13,14]. Establishing a dose reference level is not only about simply reducing dose, but also reducing radiation risk to the exposed individual, in this case, the patient, while maintaining image quality [15]. Furthermore, it is extremely important to train radiology professionals so that they can understand the equipment and ensure the best acquisition techniques, obtaining images with sufficient quality for medical diagnosis while minimizing the patient's dose, always considering the patient's physical characteristics and the region under analysis, as well as clinical needs [16,17]. Therefore, it is necessary to monitor the dose used in exams closely and have medical staff closely involved, also addressing indiscriminate requests and repetition of exams.

Some reference levels are indicated for dose indices in CT exams, including the European Guidelines on Quality Criteria for Computed Tomography, published in 2004. This guide represents a reference for good practices, providing a basis for radiological interpretation of images. Additionally, criteria for radiation dose in patients and reference values allow for quantitative analysis to identify inadequate techniques [18]. Another important reference for dose levels is the UK national levels (Doses from CT examinations in the UK), revised in 2011, which no longer includes single-slice equipment. UK levels are characterized by average values of the standard dose indices, CTDIvol and DLP, determined for patient samples. The report includes summaries of absorbed dose distributions and presents national doses for adult and pediatric exams based on statistical analysis of typical dose distributions [19]. Few national studies emphasize optimization in CT exams and their methodology [20].

Similarly to CT exams, the dose of mammography and radiography exams can be optimized while maintaining image quality [21-23].

The new regulation by the Ministry of Health in Brazil emphasizes the demonstration of monitoring and technical control in radiological exams and the responsibility of institutions and technical and legal authorities [24].

2 HYPOTHESIS

The hypothesis of this research is that data collection will provide assistance in determining local and regional DRLs in adult and pediatric patients, leading to improvements in radiological protection measures for patients and technical professionals.

3 OBJECTIVES

3.1 Main Objective

a. Collect data through a virtual platform to promote recommendations and educational actions for the management of radiation dose used in hospitals or clinics in Brazil and Latin America.

b. Determine the reference level (DRL) based on local clinical indications as a sample of the national and regional DRL.

3.2 Secondary Objectives

a. Perform data collection of technical parameters and radiation dose in radiology departments that conduct CT and/or radiography and/or mammography and/or tomosynthesis exams.

b. Establish local reference levels (DRLs) and compare them with values published in international literature.

c. Evaluate organ doses through radiological exams.

d. Prepare a report with optimization suggestions and educational recommendations.

e. Provide suggestions for improving the quality of care and patient safety.

4 MATERIALS AND METHODS

4.1 Project Design

International multicenter project, retrospective and prospective, observational, quantitative, with review and research in the database of participating centers' equipment using the DICOM protocol for the exams performed.

The project will be multicenter, initially submitted to the Research Ethics Committee (REC) of the School of Medical and Health Sciences at PUC/SP, which will review the first center, and after this approval, it will be submitted to other RECs. In the case of other Latin American countries,

this project will be submitted to the local committee with the inclusion of the organizers' names as authors.

Participating centers must meet the inclusion criteria described in section 4.3.1 to participate in the project.

After this stage, data will be collected through a virtual platform in an anonymized manner, following data protection laws and regulations for all participating institutions. Retrospective or prospective data will be collected after approval by the REC.

A comparative and statistical analysis will be conducted among the participating centers and international data. Technical data from radiological, mammographic, and CT exams will be reviewed, potentially providing information that enables suggestions for protocol adjustments and educational activities for the radiology technicians involved.

4.1.1 Study Data Collection

The project will be applied to hospitals or diagnostic imaging clinics that perform radiology and/or mammography and/or CT exams. All exams from the connected modalities will be sent to the virtual platform for subsequent analysis. The estimated minimum number of exams per month (including all modalities) in the participating centers will be 400 to 1000 exams.

The retrospective and prospective data will only be collected after the approval of each local Research Ethics Committee (CEP).

The following steps will be taken for implementation:

• Local team training

• Data collection

• Analysis of results.

Retrospective data will be collected from January 2022 to December 2023 for consecutive days.

The researchers have no conflicts of interest.

The following data from the platform will be collected:

a. Hospital information (name, location and type)

b. Patient's demographics (gender, weight, height, and age, BMI)

c. Types of radiological exams performed for each case and anatomical region.

d. Clinical indication

e. Equipment information (manufacturer, model and number of detectors)

4.1.2 Technical study data.

Description of technical data for CT exams related to radiation dose by the parameters below.

a. Technical parameters (pitch, gantry rotation time and exam start and end)

b. Number of scan phases and its type (non-contrast, arterial, venous, delay)

c. Radiation doses per scan phase (CTDIvol and DLP)

d. Reconstruction information (reconstruction technique employed and slice thickness)

4.1.3 Analysis of post-processing technical reports of imaging exams.

The following reports will be generated:

a. Study management, protocol, acquisition, cumulative dose per patient, and high dose level (alerts), amount of injected contrast.

b. Comparison of DRL with similar values published in national and international literature.

The review will be conducted by radiologists and a medical physicist, with statistical analysis and report preparation.

Descriptive analysis of the variables will be performed through frequency distributions with proportions of interest, graphs, and appropriate statistics calculation for quantitative variables.

4.2 Implementation of Activities

We will coordinate the activities of the project.

4.2.1 Periodic Meetings

Virtual or face-to-face meetings will be held for project development, involving supervisors from the participating centers and researchers.

4.2.2 Analysis of Results

A database will be constructed based on the collected data, with descriptive analysis of the variables through frequency distributions, proportions of interest, graphs, and appropriate statistics calculation for quantitative variables.

4.2.3 Recommendations

After analyzing the results, documents will be prepared with educational suggestions aiming to reduce radiation dose according to the recommendations of the Brazilian College of Radiology (CBR) and the International Atomic Energy Agency (IAEA).

4.3 Co-participating Research Centers

The institutions involved in the research will sign an authorization form for the project's implementation.

The responsible individuals from the participating centers involved in data collection will sign a confidentiality agreement for the data of each participating site.

The project will request a waiver of informed consent from patients, as the data will be anonymized in the digital platform and in the data registry of each equipment.

4.3.1 Inclusion Criteria

Any institution willing to provide complete data within different patients age group and clinical indication.

4.3.2 Exclusion Criteria

The exclusion criteria will include failure to complete and sign the data confidentiality agreement or failure to provide documentation ensuring data quality throughout the project.

4.5 Ethical Considerations

The project will be submitted to the Research Ethics Committee, which will evaluate the request from the coordinating center. In the other participating research centers, the project will only begin after approval from the corresponding RECs. A confidentiality agreement will be signed by the participating institutions. The data will be anonymized, and confidentiality will be ensured. The participants have no conflicts of interest. The project will seek a waiver for obtaining informed consent from patients due to the anonymized data collection via a digital platform using DICOM header information.