

The Impact of Data Management on the Achievable Dose and Efficiency of Mammography and Radiography During the COVID-19 Era: A Facility-Based Cohort Study

Tarek Mohammed Hegazi*, Abdulaziz Mohammad AlSharydah , Iba Alfawaz, Afnan Fahad Al-Muhanna , Sarah Yousef Faisal

Diagnostic and Interventional Radiology Department, King Fahd Hospital of the University, Imam Abdulrahman Bin Faisal University, Al-Khobar City, Eastern Province, Saudi Arabia

*These authors contributed equally to this work

Correspondence: Tarek Mohammed Hegazi, Chairperson of the Radiology Department, King Fahd Hospital of the University, Imam Abdulrahman Bin Faisal University, Khobar City, Eastern Province, Saudi Arabia, Tel +966-0138966877 (EXT: 2007), Email tarek.hegazi@gmail.com

Purpose: To evaluate the impact of using computational data management resources and analytical software on radiation doses in mammography and radiography during the COVID-19 pandemic, develop departmental diagnostic reference levels (DRLs), and describe achievable doses (ADs) for mammography and radiography based on measured dose parameters.

Patients and Methods: This ambispective cohort study enrolled 795 and 12,115 patients who underwent mammography and radiography, respectively, at the King Fahd Hospital of the University, Al-Khobar City, Saudi Arabia between May 25 and November 4, 2021. Demographic data were acquired from patients' electronic medical charts. Data on mammographic and radiographic dose determinants were acquired from the data management software. Based on the time when the data management software was operational in the institute, the study was divided into the pre-implementation and post-implementation phases. Continuous and categorical variables were compared between the two phases using an unpaired *t*-test and the chi-square test.

Results: The median accumulated average glandular dose (AGD; a mammographic dose determinant) in the post-implementation phase was three-fold higher than that in the pre-implementation phase. The average mammographic exposure time in the post-implementation phase was 16.3 ms shorter than that in the pre-implementation phase. Furthermore, the median values of the dose area product ([DAP], a radiographic dose determinant) were 9.72 and 19.4 cGycm² in the pre-implementation and post-implementation phases, respectively.

Conclusion: Although the data management software used in this study helped reduce the radiation exposure time by 16.3 ms in mammography, its impact on the mean accumulated AGD was unfavorable. Similarly, radiographic exposure indices, including DAP, tube voltage, tube current, and exposure time, were not significantly different after the data management software was implemented. Close monitoring of patient radiation doses in mammography and radiography, and dose reduction will become possible if imaging facilities use DRLs and ADs via automated systems.

Keywords: average glandular dose, entrance skin dose, dose area product, radiograph, mammogram

Plain Language Summary

This comparative study aimed to establish the diagnostic reference levels (DRLs) and achievable doses (ADs) for adult and pediatric patients undergoing mammography and radiography at the Department of Radiology of the King Fahd Hospital of the University. Data on mammographic and radiographic examinations from all available devices were retrieved, and Siemen's TeamplayTM (a data management and analytical software) was used to develop practical DRLs of radiation. We used measured dose parameters and streamlined protocols to provide records of dose indicators utilized at the time of imaging, which were altered owing to the

coronavirus disease pandemic-related measures. Our results showed the impact of data management software on the establishment of DRLs and ADs. In mammography, it helped reduce the radiation exposure time by 16.3 ms; however, its impact on the mean accumulated AGD was unfavorable. In radiography, its impact did not differ favorably in terms of exposure indices, including DAP, tube voltage, tube current, and exposure time after implementing the data management software. Close monitoring of patient radiation doses in mammography and radiography and dose reduction will become possible if imaging facilities embrace the use of DRLs and ADs via automated systems.

Introduction

Radiology plays a crucial role in the management of several cancers, including cancers of the breasts, lungs, colon, rectum, and prostate. In Saudi Arabia, breast cancer accounts for 25% of all cancers among women, with approximately 8000 cases reported annually.¹ Thus, the Saudi Center for Evidence-based Health Care has recommended that women aged 40–49 and 50–69 years undergo mammographic screening every year and every 2 years, respectively.² Mammography is a reliable imaging technique; it reportedly helped to reduce the mortality rate by 30% among patients with breast cancer.³ However, studies have revealed that high radiation doses administered during mammography and radiography significantly increase the biological and cancer risks among patients with sensitive tissues.⁴

In 1996, the International Commission on Radiological Protection (ICRP) established diagnostic reference levels (DRLs) as benchmarks for identifying abnormally high radiation doses and optimizing radiation protection and image quality.^{5,6} Experts, advisory bodies, and regulatory agencies recommend the use of DRLs for radiological imaging.⁷

The ICRP emphasizes that DRLs are not intended for regulatory or commercial use, do not constitute dose limits, and are affected by variations in technology and clinical indications.⁷ DRLs are typically set to the 75th percentiles of the dose distribution values acquired from imaging studies conducted at large healthcare centers using a specific dosimetry protocol.⁸ There are major differences in DRLs established for multiple diagnostic modalities, both locally and nationally.^{8,9}

The “as low as reasonably achievable” principle was introduced as a concept of radiation safety to regulate radiation exposure in patients. This concept was further emphasized during the coronavirus disease (COVID-19) pandemic, which introduced new challenges in diagnostic testing for healthcare practitioners and government representatives.¹⁰

An advisory group of the British National Radiation Protection Commission presented the achievable dose (AD) in 1999 to recognize the actual, more typical radiation doses administered in clinical practice.^{11,12} In 2018, the European Commission combined the existing national DRLs of 17 European countries and issued guidelines to establish diagnostic reference values for pediatric diagnostic imaging according to anatomical areas imaged. These were predominantly determined by age groups and partially by weight groups. Furthermore, in Saudi Arabia, a study investigated the dose levels for patients undergoing digital mammography and proposed a local DRL.¹³ However, no national DRLs based on patient dimensions or sizes are available.¹⁴

Local dose area product (DAP) values have not been widely investigated. A Saudi national study estimated that mean DAP values fall in the range of 2–244 cGycm². These values were strongly affected by the exposure time and applied mAs.¹⁵ A recent study conducted in the southern region of Saudi Arabia provided some input on the local mean glandular dose (MGD) parameter and revealed that MGD for mammography procedures were measured between 1.01±0.3 and 1.09±0.2 for cranial caudal (CC) and mediolateral oblique (MLO) projections, respectively.¹⁶

As mentioned previously, physicians and studies alike have raised concerns about radiation exposure during imaging. This has necessitated the implementation of dose-monitoring algorithms that analyze data from radiological examinations and support the benefits of medical imaging while minimizing patient exposure to unnecessary ionizing radiation. “Teamplay™”,¹⁷ a cloud-based data and performance management resource, generates a range of key performance indicators for use in radiology. Internal DRLs can be set in the system and compared with national reference levels. This system also enables comparison against a range of globally established DRLs considering data acquired from various data management and analytical software.^{17,18} The efficiency of this software for other modalities, such as mammography and radiography, will improve the contrasting aspects. However, this has not yet been established.

Therefore, we had the following aims in the present study: 1) to evaluate the impact of computational data management resources and analytical software on radiation doses in mammography and radiography in the COVID-19

ergonomics. 2) to develop DRLs, and 3) to describe ADs for mammography and radiography based on measured dose parameters.

Materials and Methods

All methods in this study were performed in accordance with STROBE guidelines and regulations of cohort studies.

Study Design, Setting, and Patients

This ambispective and comparative cohort study was performed at the Radiology Department of the King Fahd Hospital of the University (KFHU; Khobar city, Saudi Arabia) for 165 days (from May 25 to November 4, 2021) during the COVID-19 pandemic. This is one of the largest tertiary academic hospitals in Al-Khobar City, the Eastern Province of Saudi Arabia. Its Radiology Department has been operational since 1981.

On August 14, 2021, our department implemented the following rectifying strategies that were controlled using Teamplay™, Siemens Healthineers, Germany:¹⁷ (i) optimization of radiation doses and (ii) establishment of radiation dosage benchmarks for each scan type.

Irrespective of the manufacturer, all imaging devices at our institution (including those for magnetic resonance imaging, computed tomography (CT), single-photon emission computed tomography, interventional radiology, radiography, and mammography) were connected to the data management software and monitored remotely for smooth reporting of radiation exposure. The software, which is a Digital Imaging and Communications in Medicine (DICOM) node, accessed these modalities to retrieve relevant data.

The study was divided into two phases to determine the impact of the rectifying measures on ADs: A) the pre-implementation phase, which comprised patients imaged on or before August 14, 2021 (between May 25 and August 14, 2021 [81 days]), and B) post-implementation phase, which comprised patients imaged after August 14, 2021 (between August 15 and November 4, 2021 [81 days]).

Because data were retrieved by the data management software after radiation exposure during CT, a comparative ambispective design with a fixed interval (81 days before and after the implementation of the rectifying measures) was reasonable for studying the impact of the software on ADs.¹⁹ Furthermore, the design adopted for the current study was scientifically appropriate because it enabled appreciable gains in statistical power for vast cohorts, even in the absence of censoring,²⁰ and serves as a control strategy for potential recall bias in cohort studies.²¹

Retrospective retrieval and registration of prospective data using the software was performed before and after exposure to radiation in mammography and radiography. Comparative ambispective/ambidirectional design with a fixed interval has reasonable scientific merit for studying the impact of dose optimization across time.^{19,20}

Eligibility Criteria

The inclusion criterion was patients who underwent mammographic and radiographic examinations with commercially available mammography (model SDM-00001-3D, Hologic™; United States) and radiography (two models of DIGITAL DIAGNOS, Philips™ [Netherlands]; one model of SDR-OGCL60A, Samsung™ [South Korea]) scanners during the study period, respectively. Inclusion was irrespective of patients' nationalities, sexes, and age groups (children and adults). The exclusion criteria were missing demographic data, measurement data, and mammography- and radiography-related dose-estimation parameters. No patient fulfilled the exclusion criteria; thus, 12,910 patients (mammography: 795; radiography: 12,115) were included in the study.

Data Collection

Patients' charts were retrieved from the electronic medical record archival system at KFHU. Thereafter, the radiology department's database was reviewed using the Picture Archiving and Communication System, and data (readily available and computed using the data management software) were retrieved automatically. To ensure sufficient statistical power, the sample size was determined via a nonprobability simple sampling technique ($1 - \beta = 0.80$) using G*Power version 3.1.9.7 (RRID:SCR_013726, available at: <http://www.gpower.hhu.de/>).

The demographic characteristics that were analyzed included age, patient's size (accounted by patient's weight), and sex. Furthermore, mammographic and radiographic exposure indices and exposure time were also analyzed. For mammography, we adopted a combo-mode technique (two-dimensional and tomosynthesis) for screening and diagnostic protocols. The main dose-determinant parameters analyzed during mammography and used to define the DLR included the following: (i) entrance skin dose ([ESD], a typical entrance exposure to 4.2 cm breast thickness [unit: mGy]), (ii) average glandular dose (AGD; average absorbed dose to the glandular tissue of a uniformly compressed breast [excluding the skin; unit: mGy]).

The main dose-determinant parameters analyzed during radiography and used to define the DLR included the following: (i) DAP, a surrogate measure of the total amount of X-ray energy delivered to the patient (unit: cGycm²), (ii) ESD, a measure of the radiation dose absorbed by the skin as it reaches the patient (unit: cGy), (iii) tube voltage (kV), and (iv) tube current (mA).

Thereafter, these data were analyzed to assess the impact of the software management program on ADs to establish our departmental DRLs.

Statistical Analysis

All statistical analyses were performed using R v 3.6.3 Counts and Minitab version 17.0. Categorical variables (including sex, type of protocol, and body region) are expressed as percentages; continuous variables (including AGD, ESD, DAP, kV, and mA) are expressed as means (\pm standard deviations). Selective outcome reporting for categorical and continuous variables was analyzed by reporting the mean dichotomous and continuous data, respectively. Continuous and categorical variables were compared between the pre-implementation and post-implementation phases using an unpaired *t*-test and the chi-square test of independence, respectively. A linear regression analysis was performed to determine the factors associated with AGD, while a linear mixed-model analysis was performed to determine trends in the average exposure per person after the implementation of the data management software. A Kolmogorov–Smirnov test was used to examine data normality. $P < 0.05$ indicated statistical significance.

Ethical Approval

This study was performed in accordance with the 1975 Declaration of Helsinki (revised in 1983). The Institutional Review Board of Imam Abdulrahman Bin Faisal University granted ethical approval (IRB-2022-01-206) after considering the descriptive and ambispective nature of the study. Informed consent was obtained from each patient before imaging. The collected data were anonymized, analyzed, and reported solely in an aggregate form. No identifiable patient data (for example, the patients' images, faces, or names) were disclosed.

Results

Mammography Findings

The mammography data included 2897 mammographs from 795 patients (corresponding to an average of 3.6 images per patient). There were 448 and 347 patients in the pre-implementation and post-implementation phases, respectively. The analyses were performed with respect to the number of mammograms, rather than the number of patients. There were no significant differences in sex ($P = 0.89$) or age ($P = 0.47$) distribution between the two phases. In contrast, the mean accumulated AGD was significantly higher in the post-implementation phase than in the pre-implementation phase (15.6 vs 5.65 mGy; $P < 0.001$). The mean ESDs were 8.67 mGy and 9.20 mGy in the pre-implementation and post-implementation phases, respectively ($P=0.11$). The average AGD in the post-implementation phase was three-fold higher than that in the pre-implementation phase (Table 1).

Linear regression analysis of factors associated with AGD showed that age was negatively associated with the accumulated AGD per view. In contrast, the average accumulated AGD was 6.23 mGy higher in the post-implementation phase than in the pre-implementation phase (confidence interval [CI]: 5.44–7.02, $P < 0.001$; Table 2, Figure 1).

Analysis of the mammographic exposure time revealed that the mean post-exposure time in the post-implementation phase was 16.3 ms shorter than that in the pre-implementation phase (CI: 47.06–14.47, $P < 0.299$; Table 3).

Table 1 Descriptive Data of Patients Who Underwent Mammography Before and After the Implementation of the Data Management Software (N = 795)

	Pre-Implementation Phase (N = 448)	Post-Implementation Phase (N = 347)	P value
Sex			
Female	443 (98.9%)	345 (99.4%)	0.48
Male	5 (1.12%)	2 (0.58%)	0.37
Mean patient age \pm SD (years)	51.5 \pm 9.35	51.6 \pm 9.32	0.89
Mean patient weight \pm SD (kg)	80.0 \pm 29.1	126 \pm 46.0	0.38
Laterality			
Bilateral	277 (61.8%)	268 (81.0%)	<0.001
Left breast	71 (15.8%)	25 (7.55%)	
Right breast	100 (22.3%)	38 (11.5%)	

Abbreviations: N, number of patients; SD, standard deviation; %, percentage.

Table 2 Linear Regression Analysis of the Mammographic Exposure Indices, Namely the Maximum and Accumulated Average Glandular Doses

Predictors	AGD (mGy)		Accumulated AGD (mGy)	
	CI	P value	CI	P value
Patient age (years)	-0.03, -0.01	<0.001	-0.12, -0.05	<0.001
Laterality:				
Left side	-0.79, -0.29	<0.001	-0.63-2.09	0.29
Right side	-0.58, -0.10	0.005	-0.35-2.21	0.15
Time ^o (ms)	0.07-0.36	0.004	5.44-7.02	<0.001
R ² /R ² adjusted ^l	0.12/0.11		0.69/0.68	

Notes: ^oDifference in the exposure time between before and after the implementation of the data management software. ^lR²/R²adjusted coefficients represent the average change between before and after the implementation of the data management software.

Abbreviations: AGD, average glandular dose; accumulated AGD, lifetime accumulated glandular dose; CI, confidence interval.

In terms of quantitative efficiency, an overall increase in the number of mammographies by 159 mammogram images was observed during the post-implementation phase.

Radiography Findings

The radiographic data included 24,906 radiographs from 12,115 patients (corresponding to an average of 2.05 images per patient). The analyses were performed with respect to the number of radiographs, rather than the number of patients. There were 6779 (13,815 images) and 5336 (11,091 images) patients in the pre-implementation and post-implementation phases, respectively. There was no significant difference in sex distribution between the two phases. However, the age distribution differed significantly between the two phases ($P < 0.001$); adult predominance was observed in both phases (Table 4).

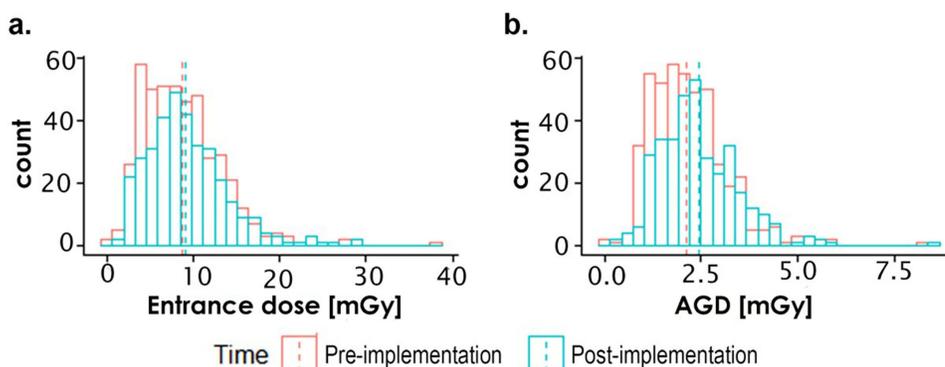


Figure 1 Overview of the efficacy of the data management software for exposure indices in mammography. (a) entrance dose and (b) average glandular dose*. *Bars represent the average exposure. Furthermore, bars from both time points are overlapped to illustrate the difference in exposure between the time points. **Abbreviations:** AGD, average glandular dose; mGy, milligray.

The median values of DAP were 9.72 and 19.4 cGycm² in the pre-implementation and post-implementation phases, respectively. Furthermore, the mean DAP was significantly lower in the pre-implementation phase than in the post-implementation phase (37.7 vs 80.5 cGycm²; P = 0.91).

Similarly, the tube voltage, tube current, and exposure time were lower in the pre-implementation phase than in the post-implementation phase (exposure energy: 6.99 vs 11.9 mA, exposure voltage: 80.0 vs 80.9 kV, and exposure time: 27.4 vs 42.1 ms; Table 5).

In terms of quantitative efficiency, an overall increase in the number of radiographs obtained from all body regions (other than the neck, chest, pelvis, and extremities) was observed during the post-implementation phase. A linear mixed-

Table 3 Mammographic Exposure Indices, Views, and Changes in the Exposure Time^o with the Use of the Data Management Software

	Pre-Implementation Phase (n = 1369)	Post-Implementation Phase (n = 1528)	P value
Mean exposure indices (± SD)			
AGD (mGy)	5.65 (4.01)	15.6 (10.1)	<0.001
ESD (mGy)	8.67 (4.54)	9.20 (4.67)	0.11
Median exposure indices [IQR]			
AGD (mGy)	1.99 [1.45; 2.65]	2.30 [1.67; 3.06]	<0.001
ESD (mGy)	8.18 [5.37; 11.1]	8.56 [6.06; 11.8]	0.12
Mammogram view			
Cranio-caudal view	754 (49.3%)	634 (46.3%)	<0.001
Mediolateral view	148 (9.69%)	52 (3.80%)	
Mediolateral oblique view	626 (41.0%)	683 (49.9%)	
Exposure time^o (ms)	Average estimated difference	CI	
	-16.30	-47.06–14.47	0.30

Note: ^oDifference in the exposure time between before and after the implementation of the data management software.

Abbreviations: n, number of images; SD, standard deviation; %, percentage; CI, confidence interval; AGD, average glandular dose; ESD, entrance skin dose; IQR, interquartile range.

Table 4 Descriptive Data of Patients Who Underwent Radiography Before and After the Implementation of the Data Management Software

	Pre-Implementation Phase (N = 6779)	Post-Implementation Phase (N = 5336)	P value
Sex			
Female	3498 (51.6%)	2753 (51.6%)	1.00
Male	3280 (48.4%)	2583 (48.4%)	1.00
Mean patient age \pm SD (years)	35.4 \pm 20.2	39.3 \pm 18.9	<0.001
Adults	5330 (79.2%)	4829 (91.1%)	
Children	1396 (20.8%)	470 (8.87%)	
Mean weight \pm SD (kg)	52.4 \pm 32.3	62.6 \pm 31.8	<0.001
Mean patient weight \pm SD (kg)	80.0 \pm 29.1	126 \pm 46.0	0.38

Abbreviations: N, the total number of patients; SD, standard deviation; %, percentage.

Table 5 Radiography Exposure Indices and Changes in Exposure Time with the Use of the Data Management Software

Exposure Indices	Pre-Implementation Phase (n = 13,815)		Post-Implementation Phase (n = 11,091)		P value
	Mean (\pm SD)	Median [IQR]	Mean (\pm SD)	Median [IQR]	
DAP (cGycm ²)	37.7 (101)	9.72 [5.28; 22.9]	80.5 (172)	19.4 [8.20; 68.1]	0.91
Exposure voltage (kV)	80.0 (29.1)	66.0 [60.0; 125]	80.9 (27.7)	67.0 [60.0; 125]	0.79
Exposure energy (mA)	6.99 (15.8)	2.90 [1.90; 4.90]	11.9 (24.0)	3.60 [2.30; 10.1]	0.76
Exposure time (ms)	27.4 (69.6)	7.00 [3.00; 13.0]	42.1 (85.1)	10.0 [4.00; 33.0]	0.67

Abbreviations: n, number of images; SD, standard deviation; IQR, interquartile range; DAP, dose area product.

model analysis on DAP revealed that the average exposure per person in the post-implementation phase was 0.17 points higher than that in the pre-implementation phase (CI: 0.14–0.20; $P < 0.001$; Table 6 and Table 7, Figure 2).

Discussion

The primary concern during the pandemic was limiting patient contact by shortening the examination time. Accordingly, most radiology department protocols were revised to optimize exposure and shorten examination time, including mammography, which can be achieved by obtaining direct three-dimensional (3D) mammograms for both screening and diagnostic cases, instead of limiting 3D for diagnostic cases. Using the 3D technique for screening will reduce callback for supplementary views and hence, decrease patient hospital visits.

This study has shown that the data monitoring system reduced the overall radiation tube exposure time in mammography by 16.3 ms. The reduced post-implementation exposure time suggests that data management improved the efficiency of mammographic procedures during the pandemic (May 25 to November 4, 2021). In addition, the average AGDs were 1.99 and 2.30 mGy in the pre-implementation and post-implementation phases, respectively (Table 3, Figure 1); denoting a higher accumulated AGD in the post-implementation phase. This is higher than the previously registered national value from Saudi Arabia of 1.1 mGy.²² However, both values were lower than the 3.0 mGy benchmark set by the International Atomic Energy Agency.²³ Hence, data management facilitated the maintenance of patient dosimetry, acquisition of medical imaging data, and exploration of ADs and DRLs in mammography.²³

The increased average AGD may be attributed to the racial differences in mammographic breast densities, as denser breasts are prone to absorb more radiation; this should be considered a contributing factor in image quality, imaging

Table 6 Quantitative Changes in the Number of Radiographs and Exposure Voltage and Time with the Use of the Data Management Software (by Body Region Radiographed)

Radiographed Area	Pre-Implementation Phase (n = 13,815)	Post-Implementation Phase (n = 11,091)	P value	Exposure Voltage (kV)					Exposure Time (ms)				
				N1	N2	M1	M2	P	N1	N2	M1	M2	P
Chest	2864 (20.7%)	2146 (19.3%)	0.007	2864	2146	123.27	123.08	0.60	2864	2146	6.79	11.33	<0.001
Extremity	9782 (70.8%)	7080 (63.8%)	<0.001	9782	7080	60.54	61.41	<0.001	9782	7080	25.04	36.86	<0.001
L-Spine	514 (3.72%)	524 (4.72%)	<0.001	514	524	84.66	86.24	<0.001	514	524	69.19	145.44	<0.001
Pelvis	197 (1.43%)	170 (1.53%)	0.521	197	170	76.94	79.54	<0.001	197	170	59.05	62.55	0.70
T-Spine	29 (0.21%)	122 (1.10%)	<0.001	29	122	81.83	77.81	0.01	29	122	159.55	128.02	0.27
Abdomen	183 (1.32%)	447 (4.03%)	<0.001	183	447	73.70	75.30	<0.001	183	447	176.74	87.53	0.00
C-Spine	106 (0.77%)	321 (2.89%)	<0.001	106	321	69.90	70.13	0.57	106	321	123.27	103.73	0.05
Skull	0 (0.00%)	71 (0.64%)	<0.001	2	4	96.50	86.50	0.43	2	4	288.50	75.00	0.31
Head	15 (0.11%)	66 (0.60%)	<0.001	15	66	73.33	70.38	0.01	15	66	86.93	49.48	0.14
Whole Body	48 (0.35%)	52 (0.47%)	0.160	48	52	83.25	84.12	0.53	48	52	170.79	141.42	0.25
Spine	36 (0.26%)	51 (0.46%)	0.011	36	51	82.89	83.02	0.90	36	51	121.36	142.43	0.26
Neck	11 (0.08%)	9 (0.08%)	1.000	11	9	59.27	60.00	0.56	11	9	156.36	191.67	0.62

Notes: Analysis was performed using an unpaired t-test; P indicates the P value for the unpaired t-test. Only protocols used more than twice in both time periods were included.

Abbreviations: N1, number of data points in the pre-implementation phase; N2, number of data points in the post-implementation phase; M1, average exposure in the pre-implementation phase; M2, average exposure in the post-implementation phase.

Table 7 Quantitative Changes in the Number of Radiographs and Tube Current Exposure and DAP with the Use of the Data Management Software (by Body Region Radiographed)

Radiograph Type	Pre-Implementation Phase (n = 13,815)	Post-Implementation Phase (n = 11,091)	P value	Tube Current (mA)					DAP (cGycm ²)				
				N1	N2	M1	M2	P	N1	N2	M1	M2	P
Chest	2864 (20.7%)	2146 (19.3%)	0.007	2864	2146	2.23	3.81	<0.001	2864	2146	15.34	29.30	<0.001
Extremity	9782 (70.8%)	7080 (63.8%)	<0.001	9782	7080	5.53	7.40	<0.001	9782	7080	18.08	30.73	<0.001
L-Spine	514 (3.72%)	524 (4.72%)	<0.001	514	524	35.48	65.58	<0.001	514	524	177.57	371.02	<0.001
Pelvis	197 (1.43%)	170 (1.53%)	0.52	197	170	12.00	17.39	0.01	197	170	87.62	174.01	<0.001
T-Spine	29 (0.21%)	122 (1.10%)	<0.001	29	122	52.60	51.62	0.92	29	122	209.96	254.37	0.30
Abdomen	183 (1.32%)	447 (4.03%)	<0.001	183	447	51.35	37.01	<0.001	183	447	289.49	271.01	0.46
C-Spine	106 (0.77%)	321 (2.89%)	<0.001	106	321	25.46	21.41	0.04	106	321	46.00	49.17	0.47
Skull	0 (0.00%)	71 (0.64%)	<0.001	2	4	129.80	23.95	0.28	2	4	507.90	212.65	0.18
Head	15 (0.11%)	66 (0.60%)	<0.001	15	66	17.47	14.73	0.57	15	66	54.87	63.78	0.46
Whole Body	48 (0.35%)	52 (0.47%)	0.16	48	52	56.08	46.33	0.27	48	52	245.83	263.11	0.71
Spine	36 (0.26%)	51 (0.46%)	0.011	36	51	40.54	45.54	0.45	36	51	167.38	184.95	0.60
Neck	11 (0.08%)	9 (0.08%)	1.000	11	9	28.85	38.33	0.49	11	9	61.17	56.63	0.89

Notes: The analysis was performed using an unpaired t-test; P indicates the P value for an unpaired t-test. Only protocols used more than twice in both time periods were included.

Abbreviations: DAP, dose area product; N1, number of data points in the pre-implementation phase; N2, number of data points in the post-implementation phase; M1, average exposure in the pre-implementation phase; M2, average exposure in the post-implementation phase.

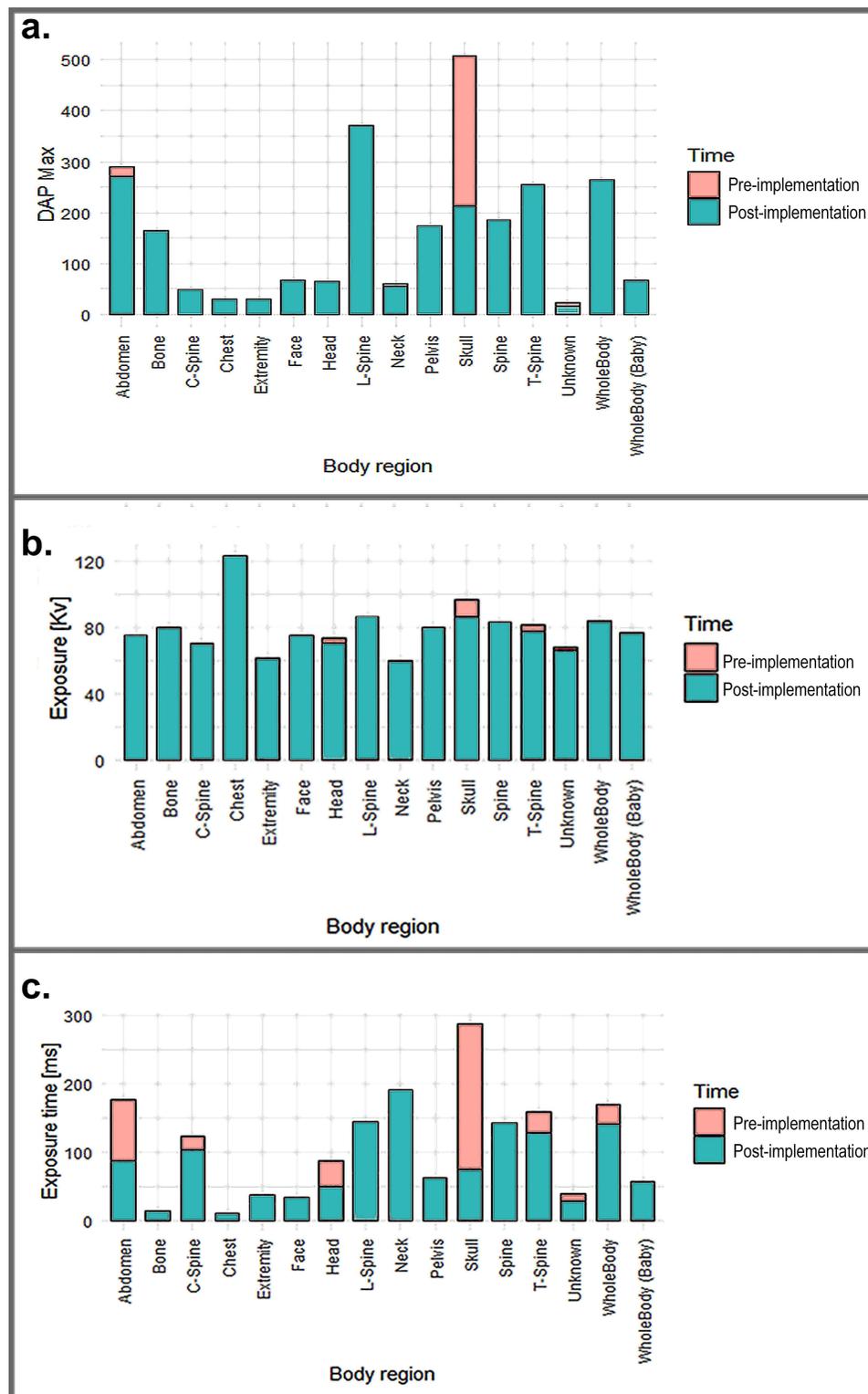


Figure 2 Overview of the efficacy of the data management software for exposure indices in radiography. (a) DAP^o_MAX, (b) tube current exposure voltage^l, and (c) exposure time (ms); in both study phases*. *Maximum Dose area product (DAP) stratified by time and body region. ^lStratified by time and body region. *Bars represent the average exposure. Furthermore, bars from both time points are overlapped to illustrate the difference in exposure between the time points.

technique [2D/tomosynthesis vs direct Combo 3D], and radiographic system used during protocol alterations. Our estimates reflected the radiation doses required for glandular tissues in the Asian Arab race, which are denser than those of some other ethnicities.²⁴ However, a recent study by Østerås et al in Norway revealed that the AGD values

(reported directly from the DICOM metadata) were 1.74 and 2.10 mGy for digital mammography and digital breast tomosynthesis, respectively.²⁵ Using a similar mammography system as in our study, Kawaguchi²⁶ obtained an average AGD of 1.6 Gy; however, this value was slightly lower than the AGD value obtained in our study (Table 3).²²

In the aforementioned Norwegian study,²⁵ variations in AGD values can be partially explained by the recent trend toward using a higher ESD exposure with an expected increase in AGD.²⁶ Nonetheless, Warren et al,²⁷ Hauge et al,²⁸ and Baeck et al²⁹ have reported AGD values of 0.01, 8.2, and 3.6 mGy, respectively. These studies show previously averaged DRLs, for current counterfactual comparison. Our study findings help address the scope for future research from a recent study conducted in Saudi Arabia, which investigated the dose levels during digital mammography and proposed the implementation of local DRLs to reduce radiation-related cancer risks.³⁰

Our study revealed that the number of radiographic scans performed for the thoracic spine, abdomen, cervical spine, bones, head, and face increased significantly after implementing the software-based dose regulation. However, this number decreased significantly for the chest and extremities during the post-implementation phase. Moreover, when categorizing our results according to the examined body parts, only the chest, extremities, and spine had a significantly higher dose exposure indices in the post-implementation phase than in the pre-implementation phase. Furthermore, the average exposure per person increased by 0.17 points in the post-implementation phase.

The COVID-19 pandemic has undoubtedly jeopardized health systems worldwide. This has resulted in a reduction in the number of non-urgent procedures performed, such as mammographic and radiographic screening for cancer and other diagnostic imaging services.^{10,31} It has been postulated that a pandemic-related decline in screening and diagnostic imaging reduces the number of breast cancer cases diagnosed.³² For instance, many patients at risk would slip under the radar as sub diagnosed cancer sufferers, and only be diagnosed at fairly advanced stages, resulting in a poor prognosis.

The exposure time, distance, and shielding are the major radiation protection principles for reducing radiation exposure. In medical imaging, national DRLs and ADs guide physicians in managing radiation doses while maintaining good imaging quality. DRLs identify unusually high radiation doses for common diagnostic radiographic procedures, whereas ADs are used alongside DRLs to optimize the dose and quality. In other words, ADs are used to compare, rather than set the maximum or minimum dose limits.³² Kanal et al³³ reported that the implementation of DRLs and ADs is most effective if the facility has a system to automatically monitor patient dose indices so that aggregate results can be evaluated.³³

Although several studies have evaluated strategies to reduce radiation exposure during mammography and radiography, there are concerns regarding the delivered dose in daily practice. Moreover, it is mandatory to adopt patient dose-estimation techniques for minimizing the probability of malignant tumor induction.³⁰ Currently, there are no national DRLs considering patient dimensions or sizes.^{13,23}

It is necessary to use a systematic process and assess DRLs using medical imaging. Radiologists must support and participate in dose regulation efforts by adhering to data management software. This will address the critical proposition of radiology departments to maintain lower doses and reduce patient exposure.³⁴ Considering the impact of the COVID-19 pandemic, hospitals must provide radiologists with advanced software and monitoring systems that assist them and minimize their growing workload by replacing inaccurate manually acquired data, thereby reducing the time required for image analysis. This will also improve the reliability of results, reduce associated costs, and limit radiation exposure.³⁵

This controlled ambispective study also revealed that the implementation of a data management software had no significant impact on the DAP, produced tube current, exposure voltage, or exposure time. Although this implementation may increase the quantitative efficiency of the obtained radiographs, further evidence is required in support of this. The data management software did not lower the average exposure per person; however, it increased the mean accumulated AGD in mammographic imaging. Thus, implementing a data monitoring system has a greater impact on the AD and efficiency of mammography than those of radiography.

Limitations and Strengths

We believe that our study makes a significant contribution to the literature because dose-monitoring algorithms are required for analyzing radiological imaging data and minimizing the exposure of patients to unnecessary ionizing radiations. The study design enables appreciable gains in statistical power for vast cohorts, even in the absence of censoring.²⁰

Nevertheless, the study was limited by its retrospective phase, which was dependent on the documentation of medical charts; this may have introduced substantial observer bias. Furthermore, the system only computed the body mass index and did not account for the exact weight (kg), which may occasionally be required as an indicator of patient size. Therefore, the tube current was not adapted to the body weight. Although beyond the scope of discussion in the current study, the data management software used in our study could not calculate organ dosage (unlike some other dose management systems). Moreover, this study was limited to one mammography and three radiography scanners. This study also did not assess the image quality; it focused merely on calculating the impact of the data management software on the radiation doses, and the effect of close monitoring.

Scope for Future Research

Further research is warranted to address the need for a systematic process for the assessment of mammographic and radiographic DRLs in medical imaging. Moreover, further studies are required to validate the impact of data management software on the elimination of the risk of manual errors, improvement in the reliability of results, and reduction in related costs. With advancements in technology, radiologists would be able to adjust the radiation dose and exposure time for patients in the future, thereby reducing the risk of induced carcinogenesis. Therefore, radiologists and other concerned medical professionals must conduct further research and establish DRLs in Saudi Arabia for mammographic and radiographic examinations so that the risk of malignancy due to high radiation exposure can be reduced to the lowest level possible.

Conclusion

The COVID-19 pandemic jeopardized the healthcare system worldwide, including radiology facilities; however, it opened the horizons for adopting new protocols for monitoring radiation exposure. Although the data management software used in this study helped reduce the radiation exposure time by 16.3 ms in mammography, its impact on the mean accumulated AGD was unfavorable. Similarly, radiographic exposure indices, including DAP, tube voltage, tube current, and exposure time, did not differ favorably after implementing the data management software. This is likely attributed to the enhancement of image quality during protocol alterations. Nevertheless, the quantitative efficiency of the obtained radiographs was increased. Close monitoring of patient radiation doses in mammography and radiography and dose reduction will become possible if imaging facilities embrace the use of DRLs and ADs via automated systems.

Abbreviations

ICRP, International Commission on Radiological Protection; DRL, diagnostic reference levels; COVID-19, coronavirus disease; AGD, average glandular dose; AD, achievable dose; KFHU, King Fahd Hospital of the University; MGD, mean glandular dose; DAP, dose area product; SD, standard deviation; IQR, interquartile range; CI, confidence interval; ESD, entrance skin dose; 3D, three-dimensional.

Data Sharing Statement

All data generated and/or analyzed are included within the manuscript itself.

Ethics Approval and Informed Consent

This study was performed in accordance with the 1975 Declaration of Helsinki (revised in 1983). The Institutional Review Board of Imam Abdulrahman Bin Faisal University granted ethical approval for this study to be conducted at KFHU (IRB-2022-01-206) after considering the descriptive and ambispective nature of the study. The collected data were anonymized, analyzed, and reported solely in an aggregate form. No identifiable patient data (such as their images, faces, or names) were disclosed in the manuscript.

Consent for Publication

Consent for the publication of the manuscript and related patient information has been obtained from the Radiology Department of the King Fahd Hospital of the University (affiliated to the Imam Abdulrahman Bin Faisal University).

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Disclosure

The authors report no conflicts of interest in this work.

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