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Clinical quality assurance in breast cancer screening and diagnosis: a warning regarding mammographic positioning

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ABSTRACT

Objective: This study aimed to evaluate the clinical image quality of mammograms performed in users of the Brazilian Unified Health System (SUS) referred to a tertiary hospital. **Methods:** A prospective study assessed mammograms from women referred to a specialist breast center in Goiânia, Goiás, Brazil, between May and October 2017. Scans performed in the preceding 6 months, either screening or diagnostic, were included in the study. Clinical quality was determined from 40 variables related to patient identification, technical performance, the equipment, radiological findings, reporting of results, and breast positioning. Scans performed in the public and private healthcare networks were compared regarding mammographic positioning. **Results:** Overall, 4,560 variables associated with the clinical quality of the images were evaluated in scans from 114 women with a mean age of 50.6 years. A total of 660 (14.47%) inadequacies were found, 443 (67.12%) of which were related to breast positioning. The most common errors were as follows: pectoral muscle could not be seen in 86.8% of scans in the craniocaudal view and inframammary angle could not be seen in 79.8% of scans in the mediolateral oblique view. Considering the breast-positioning criteria evaluated in the mediolateral oblique view, there was a greater risk of the breast not being centrally positioned with the nipple in profile (RR 4.66; 95%CI 1.05–20.62; p=0.02) and of nonvisualization of the retro-areolar area (RR 4.14; 95%CI 0.92–18.66; p=0.04) in the exams performed in the private compared to the public network. **Conclusion:** The clinical quality of the scans analyzed was found to be inadequate, with most of the nonconformities being related to breast positioning.

KEYWORDS: mammography; diagnostic imaging; mass screening; image enhancement; patient positioning.

INTRODUCTION

Quality assurance in mammography is essential if the high-contrast resolution required to adequately identify breast lesions is to be achieved[1,2]. Each component in the sequential formation of the image, from the quality of the equipment to the positioning of the patient, as well as the quality of reporting are of key importance. Therefore, to achieve the required quality standards, preestablished criteria have to be rigidly followed, ensuring that the professionals involved in obtaining the image are duly qualified and that the material and equipment used are adequate[1,2].

The quality of mammography is directly associated with the accuracy of the method. Sensitivity can be around 65% when the appropriate quality standards are lacking, whereas compliance with quality standards may increase diagnostic detection to around 85% of cases in women aged 50 years or older[3]. Nevertheless, despite initial efforts made to implement mammography quality assurance in Brazil[4-8], there is currently no effective nationwide assessment program in the country. With few clinical quality assurance programs having been implemented to date, there are few related Brazilian studies in the literature[9,10]. Conversely, technical quality control based on the use of specific tests to periodically evaluate equipment and processing has been common[8].

In the international scenario, the European Guidelines for Quality Assurance in Mammography Screening (EGQAMS)

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were drawn up in an effort to standardize protocols for the evaluation of mammograms and to reduce subjectivity in clinical quality control[11,12]. These guidelines establish rigid criteria insofar as the positioning of the patient and exposure to radiation are concerned, and they have been widely used in various population samples, both in Brazil and worldwide[10-12]. Nevertheless, in most of the Brazilian studies, the samples analyzed were restricted to screening mammograms[13], thus possibly constituting a selection bias in the mammography quality control process in this country.

The present study proposed to evaluate mammograms in the real-life setting of clinical practice, including patients with different indications for undergoing mammography. The objective of the study was to evaluate the clinical quality of mammograms performed on users of the Brazilian Unified Health System (SUS) referred to a tertiary hospital and to describe the distribution of inadequacies in the clinical evaluation of the images and in the mammography reports.

METHODS

This was a prospective, observational study conducted to evaluate mammograms from women referred for consultation at a specialist breast clinic in the city of Goiânia (GO), Brazil. The study was conducted with a convenience sample consisting of women receiving outpatient care, irrespective of any history of breast cancer or abnormalities detected at physical examination, and who had had a mammogram in the 6 months preceding their inclusion in the study. To minimize the possibility of selection bias, the women were approached in the waiting room of the referral center, just prior to their medical consultation.

Scans from patients with breast cancer who were undergoing neoadjuvant chemotherapy and those from patients who had previously been submitted to mastectomy of any type were excluded from the study. In addition, scans from women with conditions that could hamper the clinical evaluation of the scan, including acute inflammatory processes of the breast, were also excluded.

Data collection

An instrument based on the criteria described in the EGQAMS and the National Mammography Quality Program (PNQM) was constructed for the specific purpose of collecting data for this study[1,5,11]. The instrument was subdivided into image annotations regarding patient identification, technical performance, breast positioning, general observations on the image and equipment, and the mammography report of findings and additional comments. All the exams were analyzed by the same evaluator, with specific training in clinical quality control.

Image annotations included data on patient identification with the initials of the patient's name and registration number, the date of the exam, and the positional markers indicating either the craniocaudal (CC) or the mediolateral oblique (MLO) view. Regarding the technical performance, the scan was considered adequate if the image showed as much as possible of the lateral aspect of the breast, if there was effective compression of the breast, and if the position of the identification and other markers on the image were appropriate.

The items that were evaluated in relation to breast positioning, for both the CC and MLO views, were as follows: breast symmetry, image of the whole breast, position of the nipple, absence of obscuring skin folds, visualization of the pectoral muscle, demonstration of the inframammary angle, and visualization of the retro-areolar area. The position of the nipple was considered adequate when in profile, i.e., not projected onto the breast tissue, centralized in the CC view and parallel to the base of the film/detector in the MLO view[13]. The symmetry of the acquired images and whole breast inclusion were evaluated in each scan and classified as adequate or inadequate. The presence of skin folds obscuring the breasts or axillae in either view was considered a positioning error. The position of the pectoral muscle was considered adequate when visualized in the image in the CC view and when visualized down to nipple level in the MLO view[13]. Finally, visualization of the inframammary angle was evaluated in the MLO view.

General aspects of the image included adequate visualization of the skin, the vascular spaces, and Cooper's ligaments, when pertinent. Opacities and microcalcifications were classified as true or false lesions. The glandular component and the impact of this variable on the adequacy of the clinical evaluation of the scan were also evaluated. Reduced-scale images, irrespective of the percentage of this reduction, were considered inadequate.

The mammography report was analyzed regarding the appropriate description of the breast density pattern and mammography findings, the recommended management according to the Breast Imaging-Reporting and Data System (BI-RADS®)[14], and the identification of the examining physician. Additional comments evaluated included the effective reporting of breast implants, alterations that resulted in a need for additional images and artifacts[15], as well as the patient's history of any previous breast surgeries. Artifacts were classified as present or absent. Bearing in mind that some mammograms could have been performed at healthcare facilities not included in the SUS, evaluation took into account whether the scan had been performed within the public or private healthcare system.

Statistical Analysis

The data collected were included in a database using double data entry, tabulated, and then analyzed using the Microsoft Excel software program, version 2007 (Microsoft, Redmond, WA, USA). An exploratory analysis was performed using descriptive

statistics, with the calculation of means, absolute frequencies, and percentages. These data were presented to the team and are available for use in future projects, aimed at increasing the quality of mammography in the state of Goiás.

After the principal errors related to breast positioning had been identified, comparison was made as a function of the type of establishment in which the scan was performed (whether in the public or private healthcare network). The percentages (incidence) of each type of positioning error in both the CC and MLO views were measured and the relative risks (RR) between the types of establishment were then calculated for each type of error. The Pearson's χ^2 test and Fisher's exact test were used to verify statistical significance, considering a 95% confidence interval (CI). All the analyses were performed using the Stata software program, version 14.0 (Stata Corp., College Station, TX, USA).

Ethical Issues

This study is part of a line of research developed by the Brazilian Breast Research Network. The internal review board of the Hospital Universitário da Universidade Federal de Goiás approved the study protocol under reference CAAE 65644217.8.0000.5078. All the recommendations for good clinical practice were followed, as stipulated in Resolution 466/2012 of the Brazilian Ministry of Health's National Health Council and in the Helsinki Convention. All the women who agreed to participate in the study signed an informed consent form.

RESULTS

Overall, 4,560 items related to the quality of mammograms were evaluated, with 40 items being assessed in each scan. A total of 114 women with a mean age of 50.61±10.2 years (± standard deviation [SD]) were included in this study. Among them, 11 (9.64%) were under 40 years of age and were investigated for palpable lumps or monitored following a previous episode of breast cancer; 6 (5.26%) had breast implants; and 51 (44.73%) had undergone some type of breast surgery previously. Of the previous surgeries carried out, the most common was quadrantectomy associated with sentinel lymph node biopsy (n=24; 47.05%) (Table 1).

Evaluation of the healthcare system in which the scans were performed showed that 57 (50%) were carried out in the public healthcare system and 55 (48.25%) within the private healthcare network, while this information was missing in 2 (1.75%) cases. The distribution of the variables related to identification, the technique performed, and mammography reports is shown in Table 1, which also lists the general annotations on the scans.

A total of 660 errors were found in the scans included in this study, corresponding to 14.47% of all the items analyzed. There were 443 errors related to breast positioning, which corresponded to 67.12% of all nonconformities, with a mean of 3.9 breast-positioning errors in each scan. The distribution of the number of positioning failures for each view (CC or MLO) is shown in Table 2.

All the scans were considered adequate with respect to the sharpness and contrast of the image, which are variables related to the equipment used. In contrast, noise and artifacts were found to be present in 5 (4.39%) and 23 (20.17%) scans, respectively. The scale of the images was reduced in 9 (7.89%), with a mean reduction of 20.7%. Following thorough examination of each image, 7 (6.14%) scans were found to have abnormalities that required additional images to be taken.

In relation to the findings of the mammography scans included in this study, evaluations were incomplete in 29 (25.9%) cases, i.e., BI-RADS® category 0. Regarding the results considered benign, 14 (12.5%) cases were classified as BI-RADS® category 1 and 48 (42.86%) as BI-RADS® category 2. For the other cases, there were 12 (10.71%) of category 3, 8 (7.14%) of category 4, and 1 (0.89%) of category 6. None of the 112 scans evaluated according to the BI-RADS® was classified as category 5.

With respect to the positioning criteria evaluated in the MLO view, the number of errors related to the requirement that the breast be centrally positioned with the nipple in profile (RR 4.66; 95%CI 1.05–20.62; p=0.02) and to the demonstration of the retro-areolar area (RR 4.14; 95%CI 0.92–18.66; p=0.04) tended to be greater in the scans performed in the private healthcare network compared to those performed in the public system. There were no other statistically significant differences between the two healthcare systems for any of the other variables related to breast positioning (Table 3).

DISCUSSION

The quality of mammography is directly related to the accuracy of this breast cancer diagnostic method[1,3,13]. Nevertheless, few studies have evaluated the clinical quality of mammograms in Brazil and those studies are limited to women participating in breast cancer screening programs[9,10]. Therefore, the relevance of the present study lies in the fact that clinical quality was assessed in a real-life clinical practice setting and that the study also included diagnostic mammograms and women with a prior history of breast cancer.

Identification markers are crucial in imaging exams in order to prevent reports from being switched and scans from being charged in duplicate. In this respect, although some isolated recommendations do exist[1,14], there is no established protocol governing identification procedures for mammograms and other imaging exams. In the present study, 25.4% of all scans were found to contain some form of identification error, particularly missing data on patient registration. In addition, the registration number printed on the mammogram image generally

Table 1. Factors taken into consideration in the evaluation of the quality of mammograms.

	Present		Absent	
	n	%	n	%
Identification				
Patient identification information	112	98.25	2	1.75
Organization identifier	112	98.25	2	1.75
Patient registration number	86	75.44	28	24.56
Date of the scan	113	99.12	1	0.88
Positional/anatomical markers (CC or MLO)	114	100.00	0	0.00
Performance of the scan				
The lateral aspect of the breast is clearly shown*	110	96.49	4	3.51
The position of the identification/other markers on the image was appropriate	113	99.12	1	0.88
Appropriate compression of the breasts	110	96.49	4	3.51
General observations regarding the image				
Reduced-scale image	9	7.89	105	92.11
Adequate visualization of the breast skin (no creases or folds)	112	98.25	2	1.75
Visualization of the vascular spaces through dense tissue	84	73.68	30	26.32
Visualization of Cooper ligaments	105	92.11	9	7.89
Do microcalcifications, when present, represent a true lesion?	34	85.00	6	15.00
Does opacity, when present, represent a true lesion?	37	88.10	5	11.90
Obscured breast glandular tissue	22	19.30	92	80.70
Mammography Report				
Adequate patient identification	112	98.25	2	1.75
Number of films**	60	53.57	52	46.43
Type of scan (public or private healthcare network)**	105	93.75	7	6.25
Report includes BI-RADS® classification**	111	99.11	1	0.89
Report includes mammography findings**	111	99.11	1	0.89
Report includes recommended management**	93	83.04	19	16.96
Identification of the examining physician	112	98.25	2	1.75

CC: craniocaudal; MLO: mediolateral oblique; BI-RADS®: breast imaging-reporting and data system. *The scans clearly show the medial border and as much as possible of the lateral aspect of both breasts. **n=112 due to missing data in two cases.

corresponds to the patient's registration at the radiology facility, which is not the same as her registration at the healthcare clinic; hence, it does not ensure that the patient is correctly identified during her medical consultation. In contrast, the majority of the scans analyzed in this study did contain the initials of the patient's name, the date on which the scan was performed, and positional and anatomical markers of the corresponding imaging views, thus ensuring that each participant in the study was correctly identified.

Nonconformities related to breast positioning are the most common type of error found in mammograms[13]. Nevertheless, despite the heterogeneity of the sample in the present study, the percentage of errors found was almost twice that reported in a previous study conducted with 5,000 scans performed for breast cancer screening in the state of São Paulo, Brazil[10].

In the sample included in the present study, the pectoral muscle was visible in the CC view in only 13% of scans, a rate that is lower than the recommended rate of 30%.[1,5] In the MLO view, the inframammary angle could not be seen in 79.8% of scans. These facts together reflect breast-positioning issues in both views. Nevertheless, continued education and constant training of the radiology technicians is believed to reduce these errors and improve the final quality of mammograms[13].

Regarding correct criteria insofar as breast positioning is concerned, the factors for which the percentages of accuracy were greatest were the absence of obscuring skin folds in the breast and axillae in 84.21% of the CC and 80.70% of the MLO views. This rate of accuracy is lower than that reported in a previous study conducted at the Barretos Cancer Hospital in which accuracy rates of 97.2% and 95.4%, respectively, were found regarding

Table 2. Distribution of positioning failures in each incidence of mammography.

	Conformities		Nonconformities	
	n	%	n	%
Craniocaudal view				
Symmetrical radiography	91	79.82	23	20.18
Exams favoring a quadrant	89	78.07	25	21.93
Nipple in profile	95	83.33	19	16.67
Nipple centered	95	83.33	19	16.67
Skin folds	96	84.21	18	15.79
Presence of the pectoral muscle	15	13.16	99	86.84
Visualization of the retro-mammary fat	109	95.61	5	4.39
Adequate sampling of the medial and lateral portions	113	99.12	1	0.88
Mediolateral oblique view				
Symmetrical radiography	85	74.56	29	25.44
Nipple in profile	91	79.82	23	20.18
Nipple centered	103	90.35	11	9.65
Skin folds	92	80.70	22	19.30
Visualization of the retro-mammary fat	103	90.35	11	9.65
Visualization of pectoralis major muscle at or below the nipple	79	69.30	35	30.70
Anterior border of convex pectoral muscle	102	89.47	12	10.53
Inframammary angle	23	20.18	91	79.82

Table 3. Distribution of positioning failures between mammograms performed in the private and public network*.

	Private network (n=55)		Public network (n=57)		RR	95% CI		p-value
	Failures (n)	Failures (%)	Failures (n)	Failures (%)		LL	UL	
Craniocaudal view								
Symmetrical radiography	14	25.45	8	14.04	1.81	0.82	3.97	0.12
Exams favoring a quadrant	13	23.64	12	21.05	1.12	0.56	2.24	0.74
Nipple in profile	11	20.00	7	12.28	1.62	0.68	3.89	0.26
Nipple centered	12	21.82	7	12.28	1.77	0.75	4.17	0.17
Skin folds	8	14.55	10	17.54	0.82	0.35	1.94	0.66
Presence of the pectoral muscle	48	87.27	49	85.96	1.01	0.87	1.17	0.83
Visualization of the retro-mammary fat	3	5.45	1	1.75	3.1	0.33	28.99	0.29
Adequate sampling of the medial and lateral portions	1	1.82	0	0.00	.....**	.....	.....	.....
Mediolateral oblique view								
Symmetrical radiography	17	30.91	12	21.05	1.46	0.77	2.78	0.23
Nipple in profile	16	29.09	7	12.28	1.95	0.87	4.33	0.08
Nipple centered	9	16.36	2	3.51	4.66	1.05	20.62	0.02
Skin folds	13	23.64	9	15.79	1.49	0.69	3.21	0.29
Visualization of the retro-mammary fat	8	14.55	2	3.51	4.14	0.92	18.66	0.04
Visualization of pectoralis major muscle at or below the nipple	20	36.36	15	26.32	1.38	0.79	2.41	0.25
Anterior border of convex pectoral muscle	6	10.91	6	10.53	1.03	0.35	3.01	0.94
Inframammary angle	14	25.45	9	15.79	1.61	0.76	3.41	0.20

RR: relative risk; 95%CI: 95% confidence interval; LL: lower limit; UL: upper limit. *n=112 due to missing data in two cases; **the relative risk could not be calculated because there were no failures in the public network.

the absence of skin folds[10,13]. Nevertheless, since the present study population included breast cancer survivors, scars from previous surgeries and sequelae resulting from radiotherapy could have increased the occurrence of obscuring skin folds, asymmetries, and other breast-positioning errors.

The distribution of the breast-positioning errors found in the MLO view showed that the quality of the scans performed in the public healthcare network was better than that of the scans carried out in the private healthcare network. However, no statistically significant differences were found between the two healthcare networks for any of the variables evaluated in the CC view. Moreover, on the one hand, the majority of the scans performed in the public healthcare network and included in the present study were carried out in a university hospital that is currently in the initial stages of implementing internal quality control. In contrast, the scans performed in the private network originated from various different radiology units with varying standards of quality control. Therefore, despite the absence of statistically significant differences, it is notable that almost all the different types of error were more prevalent in the private network, except for the occurrence of obscuring skin folds.

In relation to the general observations on the image, attention is drawn to the occurrence of reduced scale in 9 (7.89%) scans, which may compromise the evaluation of the images and their comparison with previous ones. Nevertheless, despite the 16 (14.04%) cases of artifacts and 22 (19.30%) cases of obscured breast glandular tissue, among other nonconformities, only 7 of the patients included in the study had to repeat the scan. In other cases, when selective compression or magnification was required, the patients already had the additional images when they arrived for consultation, since the radiologist had already requested them. An observational study, in which 5,000 mammograms were performed using screen-film mammography, computed radiography, and full-field digital mammography, found that 11% of the errors detected were related to the mammography used, with a predominance of the screen-film mammography machines[13]. Therefore, the gradual replacement of screen-film machines for full-field digital ones, that has been occurring over recent years, may contribute toward reducing the nonconformities associated with the mammography machine used.

Mammography reports are the interface between the radiologist and the attending physician and, therefore, must also meet preestablished quality criteria[4]. In the present study, cases were common in which information on the clinical indication for performing the exam and/or the number of films or images produced had been omitted from the mammography report. Nevertheless, these data can be acquired at the time of the medical consultation and such errors do not generally hamper the diagnostic investigation. In contrast, 19 (16.96%) of the reports failed to include the recommended management. In clinical practice, this type of error can delay the diagnosis of a clinically suspicious breast lesion and the patient's subsequent referral to an oncology center, indirectly contributing to a need for more radical treatment and reduced overall survival[16,17].

The BI-RADS® classification, developed by the American College of Radiology, standardizes mammography, ultrasonography, and magnetic resonance imaging of the breasts and allows the potential malignancy of the respective radiological findings to be predicted and the exams and services performed to be audited[14]. In the present study, 99.11% of the mammography reports analyzed contained the respective BI-RADS® classification, reflecting the extent to which this methodology has been consolidated in the description of mammography findings. In contrast, the predominance of scans considered inconclusive or abnormal is explained by the fact that the sample analyzed consists of patients attending a tertiary hospital that is a regional reference for the diagnosis of breast cancer.

The limitations of the present study include the small number of scans examined in relation to the number of medical consultations made during the same period. This could be explained by the centralized process of recruitment and image evaluation, the objective of which was to increase control over the study and reduce the possibility of a selection bias and of interobserver variations. Nevertheless, the patients were included in the study over a 6-month period, which minimizes the possibility of a time bias in the quality of the scans.

CONCLUSION

The quality of the mammograms analyzed was found to be inadequate, with a predominance of nonconformities related to breast positioning. This is probably typical of what happens in most such facilities around the country. However, continued education and constant training for radiology technicians should reduce breast-positioning errors and improve the overall quality of mammograms.

AUTHORS' CONTRIBUTION

LRS: Conceptualization, Investigation, Methodology, Validation, Visualization, Writing – original draft. RMSR: Conceptualization, Investigation, Methodology, Project Administration, Supervision, Validation, Visualization, Writing – review & editing. VCJQ: Conceptualization, Investigation, Methodology, Validation, Visualization, Writing – original draft. ÉCA: Data curation, Formal Analysis, Investigation, Validation, Writing – original draft. RSC: Data curation, Investigation, Visualization, Writing – review & editing. DCNR: Data curation, Investigation, Visualization, Writing – review & editing. LSC: Data curation, Investigation, Visualization, Writing – review & editing. RFJ: Conceptualization, Investigation, Methodology, Project Administration, Supervision, Validation, Visualization, Writing – review & editing.

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