Complete internal audit of a mammography service in a reference institution for breast imaging[*]

Auditoria interna completa do serviço de mamografia em uma instituição de referência em imaginologia mamária

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Abstract   **Objective:** Undertaking of a complete audit of the service of mammography, as recommended by BI-RADS®, in a private reference institution for breast cancer diagnosis in the city of São Paulo, SP, Brazil, and comparison of results with those recommended by the literature.

Materials and Methods: Retrospective, analytical and cross-sectional study including 8,000 patients submitted to mammography in the period between April 2010 and March 2011, whose results were subjected to an internal audit. The patients were followed-up until December 2012.

Results: The radiological classification of 7,249 screening mammograms, according to BI-RADS, was the following: category 0 (1.43%), 1 (7.82%), 2 (80.76%), 3 (8.35%), 4 (1.46%), 5 (0.15%) and 6 (0.03%). The breast cancer detection ratio was 4.8 cases per 1,000 mammograms. Ductal carcinoma in situ was found in 22.8% of cases. Positive predictive values for categories 3, 4 and 5 were 1.3%, 41.3% and 100%, respectively. In the present study, the sensitivity of the method was 97.1% and specificity, 97.4%.

Conclusion: The complete internal audit of a service of mammography is essential to evaluate the quality of such service, which reflects on an early breast cancer detection and reduction of mortality rates.

Keywords: Breast cancer; Mammographic screening; BI-RADS; Audit of mammography service; Percutaneous biopsy; Positive predictive value.

Resumo   **Objetivo:** Realização de auditoria completa do serviço de mamografia de uma instituição privada, conforme preconizado pelo BI-RADS®, e comparação dos resultados obtidos com os recomendados pela literatura em serviço de referência em diagnóstico de câncer mamário na cidade de São Paulo.

Materiais e Métodos: Estudo retrospectivo, analítico e transversal contendo casuística de 8.000 pacientes que realizaram mamografias no período de abril de 2010 a março de 2011, submetidas à auditoria, com base no resultado de sua mamografia. Houve seguimento dessas pacientes até dezembro de 2012.

Resultados: De acordo com a categorização BI-RADS, a classificação radiológica das 7.249 mamografias de rastreamento, em relação ao número de casos, foi a seguinte: categorias 0 (1,43%), 1 (7,82%), 2 (80,76%), 3 (8,35%), 4 (1,46%), 5 (0,15%) e 6 (0,03%). Verificou-se taxa de detecção para câncer mamário de 4,8 casos para cada 1.000 exames realizados. O total de carcinoma ductal *in situ* foi 22,8%. Foram encontrados valores preditivos positivos para as categorias 3, 4 e 5 de 1,3%, 41,3% e 100%, respectivamente. A sensibilidade do método aferida foi 97,1% e a especificidade, 97,4%.

Conclusão: A auditoria interna completa do serviço de mamografia retrata a qualidade do serviço, e com isso contribui para a detecção precoce e diminuição da mortalidade relacionada ao câncer mamário.

Unitermos: Câncer de mama; Rastreamento mamográfico; BI-RADS; Auditoria em serviço de mamografia; Biópsia percutânea; Valor preditivo positivo.

INTRODUCTION

Breast cancer is the most frequent type of neoplasia affecting women worldwide, both in developed and developing countries. About 226,870 new cases with 39,510 deaths were reported in the United States of America in 2012[1]. In Brazil, according to Instituto Nacional de Câncer, 52,680

new cases of breast cancer were estimated in 2012, corresponding to an incidence of 52 cases per 100,000 women[2].

According to large observational studies, the breast cancer mortality rate has decreased in 31% due principally to the contribution from annual mammographic screening programs leading to early disease detection in a considerable number of cases[3–5].

The National Commission of Mammography of Colégio Brasileiro de Radiologia e Diagnóstico por Imagem (Brazilian College of Radiology and Imaging Diagnosis) recommends annual mammographic screening for all women in the age range from 40 to 69 years, and mammography on an individual basis after such an age range[6].

However, the mammographic screening started being followed by a high number of biopsies, and findings considered suspicious for malignancy may correspond to benign alterations. Thus, despite the high mammographic sensitivity and specificity, the positive predictive value (PPV) of biopsies reveals malignancy in only 15–40% of the procedures[7,8].

In order to ensure the early detection of breast cancer by mammography it is necessary that every diagnostic center has its activities carefully and systematically reviewed with the objective of verifying whether its results are in agreement with those reported in the literature[9–14].

Therefore, the medical audit is essential to evaluate a mammography center performance and, for such a purpose it is necessary to analyze PPVs for each category, rate of breast cancer detection, rate of recommendation for biopsy, rate of recall, amongst other parameters, to evaluate the effectiveness of each diagnostic center project[15].

The present study was aimed at undertaking a complete audit of a private institution mammography center, as recommended by BI-RADS®, as well as comparing the results from such an audit with those reported in the literature.

MATERIALS AND METHODS

The present retrospective, analytical and cross-sectional study, involving a team with at least ten years of experience in breast imaging, undertook an internal audit of the results of the mammography center at FEMME – Laboratório da Mulher, São Paulo, SP, Brazil.

The study sample included patients enrolled in a single health plan of which the authors' institution was the only reference in diagnostic breast imaging. All the patients were referred by their respective doctors.

In the period from April 2010 to March 2011, 8,000 mammography studies were performed in the mentioned center, under the coverage of a single health plan, 7,249 of such studies in asymptomatic women with mean age of 66 years (age range = 33 to 86 years) who were selected and submitted to audit based on their mammograms results.

The center has a Lorad Selenia full field digital mammography system, and the mammographic study includes the following steps: 1) completion of a standard form (includ-

ing identification, origin, etc.); 2) anamnesis based on the center's records; 3) clinical assessment of the breasts, whose results are also recorded on the form; 4) mammographic images acquisition according to the protocol, under the guidance of the assisting physician.

The mammographic report includes the following topics:

Part 1 – Clinical data: patient's age, indication for the study, and clinical examination of the breasts.

Part 2 – Mammographic report itself, with description of the breasts pattern and radiological findings.

Part 3 – Radiological impression and classification corresponding to diagnostic impression and respective classification according to the Consensus about Mammographic Reports Standardization[16] and BI-RADS[17,18].

Part 4 – Notes: further data, recommendations for mammography repetition for each case, as a function of the mammographic findings.

The follow-up of the diagnostic outcomes extend from September 2010 to December 2012, as the patients returned to the center to undergo new mammographic studies.

The following exclusion criteria were taken into consideration for the purposes of the present study: 1) mammograms of symptomatic patients (with signs and symptoms of breast disease); 2) mammographic studies covered by other health plans, since the follow-up of such cases was unfeasible.

RESULTS

Amongst the 8,000 mammographic studies selected in this study, 7,249 (90.6%) were performed in asymptomatic women, and 751 in symptomatic women (diagnostic mammography), the latter excluded from the study.

The radiological classification of the 7,249 screening mammography studies according to BI-RADS is shown on Table 1.

Amongst the 7,249 asymptomatic patients, 826 presented mammographic alterations and classified as BI-RADS categories 0, 3, 4 or 5. In this group, 558 (67.5%) patients were followed-up and 268 (32.5%) were missed in the follow-up.

The relationship observed between the patients' age range and the diagnosed cases of cancer can be seen on Table 2 where one can also observe that most of the patients (45.45%) were

Table 1—Distribution of mammographic cases according to BI-RADS categories.

BI-RADS category	Number of cases	%
0	104	1.43
1	567	7.82
2	5,854	80.76
3	605	8.35
4	106	1.46
5	11	0.15
6	2	0.03
Total	7,249	100

Table 2—Number of cancer cases detected per age range.

Age range (years)	Number of patients	Number of cancer cases	%
30 to 39	21	0	0
40 to 49	45	1	3.8
50 to 59	1,424	5	15.4
60 to 69	3,295	9	23.1
70 to 79	2,464	20	57.7
Total	7,249	35	100

included in the age range between 60 and 69 years, followed by 34% between 70 and 79 years, and 19.64% between 50 and 59 years.

Amongst the 165 biopsies performed for mammograms classified as BI-RADS categories 0, 3, 4 and 5, 35 patients presented malignant results at histopathological analysis, as follows: 1 case in category 0; 1 in category 3; 26 in category 4; and 7 in category 5. The PPVs of the percutaneous biopsies were calculated for each BI-RADS category of positive screening mammography, and the respective results are shown on Table 3.

Amongst the 35 cases which were positive for malignancy, 8 (22.8%) were ductal carcinomas in situ (DCIS), 24 (68.5%) invasive ductal carcinomas, and 3 (9%) invasive lobular carcinomas.

In the present study, the authors observed 221 positive screening mammograms (BI-RADS categories 0, 4 and 5, with 104, 106 and 11 cases, respectively), and 7,026 negative screening mammograms (BI-RADS categories 1, 2 and 3, with 567, 5,854 and 605 cases, respectively). Thirty-four cases of cancer were diagnosed by positive screening mammograms, while only one case was diagnosed to the present moment by negative screening mammography.

Table 3—Distribution of cases with percutaneous biopsy in agreement with BI-RADS classification and histopathological diagnosis of malignancy or benignity.

BI-RADS	Histopathological diagnosis					
	Benign		Malignant		Total	
	n	%	n	%	n	%
0	17	94.5	1	5.5	18	10.90
3	76	98.7	1	1.3	77	46.66
4	37	58.7	26	41.3	63	38.18
5	0	0	7	100	7	4.24
Total	130		35		165	100

BI-RADS 0: PPV 5.5%; BI-RADS 3: PPV 1.3%; BI-RADS 4: PPV 41.3%; BI-RADS 5: PPV 100%.

Table 4—Mammography performance indicators (sensitivity and specificity).

Therefore, the present study recorded 34 true positive (TP) results, 187 false positive (FP) results, 7,025 true negative (TN) results, and 1 false negative (FN) result (Table 4).

With such indicators, the authors could establish the calculations for sensitivity and specificity by means of the following equations: sensitivity = TP (TP + FN) and specificity = TN (TN + FP). Thus, sensitivity was 97.1%, and specificity, 97.4%.

In the present study, the rate of recall related to the number of cases requiring further investigation (BI-RADS category 0) was 1.43%.

All the results observed in the present study and considered of interest for the purposes of the audit, are shown on Table 5[18–20].

Table 5—Results clinically significant for the complete audit of the mammography center.

Item	Results
1. Total number of screening mammograms	7,249
2. Rate of recall	104 (1.43%)
3. Total number of cases classified as BI-RADS 4	106 (1.46%)
4. Total number of cases classified as BI-RADS 5	11 (0.15%)
5. Total number of cases classified as BI-RADS 4 and 5 submitted to percutaneous biopsy	70
5a. Number of such cases found to be benign	36 (51.4%)
5b. Number of such cases found to be malignant (PPV)	34 (48.6%)
6. Total number of cases of tumors in situ	8 (22.8%)
7. Total number of cases of invasive ductal/invasive lobular tumors	27 (77.2%)
8. Number of cases of cancer per 1,000 mammograms	4.8
9. Sensitivity	97.1%
10. Specificity	97.4%

DISCUSSION

The Brazilian radiological literature has recently been concerned with the role played by imaging methods in the improvement of breast diseases diagnosis[21–31].

The detection of breast cancer at its earliest phases is the most effective measure in the management of the disease[32,33]. The mammography's contribution to such an early detection is dependent on appropriate mammographic equipment utilized in the context of a quality program and under the supervision of a responsible physician[34]. Additionally, it is imprescindible that the clinical team is trained and experienced in breast imaging, and that the mammography studies are performed and supervised according to the best imaging techniques[35].

		Biopsy results	
		Positive (malignancy demonstrated by biopsy within one year)	Negative (benignity in biopsy study or no cancer detected within one year)
Screening mammography	Positive mammography (categories 0, 4, 5)	34 (TP)	187 (FP)
	Negative mammography (categories 1, 2, 3)	1 (FN)	7,025 (TN)

The women's age range may affect the disease prevalence[13]. In the present study, mammography was performed in women in the age range between 33 and 86 years, and cancer was found in 35 of them. Breast cancer was detected in 4.8 per 1,000 patients, within the expected average range according BI-RADS, i.e., 2 to 10 cases per 1,000 mammograms[19,20,32].

The rate of recall represented by the number of women called or with indication for further investigation[36] corresponded to 104 (1.43%) patients, a number that is much inferior to the recommended standards (5% to 10%)[14]. Such a fact is due to the acquisition of supplementary mammographic images at the moment of the routine mammography, as the physician evaluates the images before releasing the patient.

In the present study, the PPV based on percutaneous biopsy (TP results/number of biopsies in categories 4 and 5) was 48.6%, superior to the expected range according to the literature (15% to 40%)[14,37–42]. Remarkably, category 3 presented a PPV of 1.3%, reproducing the values reported by Sickles et al.[37]. Table 6 compares the study results with those expected by relevant studies in the literature and correlates the data with the distribution of cases according to the BI-RADS classification.

Table 6—Distribution of cases according BI-RADS classification and predictive value for malignancy as compared with data in the literature[14,37–42].

BI-RADS	Distribution of cases according to BI-RADS classification	Observed PPV	Expected PPV
0	104 (1.43%)	5.5%	< 10%
1	567 (7.82%)	0	0
2	5,854 (80.76%)	0	0
3	605 (8.35%)	1.3%	< 2%
4	106 (1.46%)	41.3%	< 30%
5	11 (0.15%)	100%	95%
6	2 (0.03%)	–	100%
Total	7,249 (100%)		

In the present study, the sensitivity was 97.1% because until the end of the patients follow-up, in December 2012, only one case of cancer (BI-RADS category 3) was found. Such a result is superior to the one reported by Sickles et al.[37] (93.1%) and by Baines et al.[38] (69%), but reproduces the recommendations by Basset et al.[14] (> 85%). The specificity observed in the present study was 97.4% and studies in the literature recommend results > 90%[14,37,38,42]. The authors attribute such results to the experience of the medical team (minimum 10-year training in breast imaging) and also to the quality of the mammography services provided by the center.

CONCLUSION

The complete internal audit of the mammography center is essential and depicts the quality of the service. The authors believe that the present study results reproduce the best results reported by international publications, ensuring the correct classification according BI-RADS categories, as well as the performance of appropriate percutaneous biopsies, thus contributing for the early breast cancer detection and reduction of the mortality associated with the disease.

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