The Concordance of Physical Examination and Radiological Examination With Histopathological Findings In Breast Cancer Patients

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Abstract.

Breast cancer is a malignancy arising from the mammary glands and is the most common cancer found in women. The diagnosis of breast cancer is established using the triple assessment method, which involves physical examination, radiological assessment, and histopathological examination of the breast. This study aims to determine the concordance between physical and radiological examinations with histopathology, which serves as the gold standard. The study utilized an observational analytic cross-sectional design, gathering data from the medical records of breast cancer patients at Royal Prima General Hospital and Dr. Pirngadi General Hospital in Medan. Statistical testing using Chi-Square showed no significant concordance between physical examination and histopathological examination (p>0.05). The radiological examination, however, showed significant concordance but with a negative correlation, suggesting that a higher histopathological grade is associated with a lower BI-RADS level (r=-0.189; p=0.039). Radiological examination demonstrated better concordance with histopathology compared to the physical examination, but it still cannot replace the role of histopathology as the gold standard for breast cancer diagnosis.

Keywords: *Breast cancer; Triple assessment; Clinical Breast Examination and BI-RADS .*

I. INTRODUCTION

Breast cancer can be defined as a malignancy that occurs in the mammary glands, and it is the most frequently detected malignancy globally, with over 2 million new cases reported in 2020 [1]. The commonly followed procedure for establishing a diagnosis is the triple assessment, which includes an adequate anamnesis with findings from a physical examination, radiological evaluation via mammography and ultrasonography, and histopathology of the breast tissue. These three examinations, performed as a diagnostic pathway for breast cancer patients, collectively possess a sensitivity of 99% and an accuracy of 99%[2], [3]. Physical examination is an essential component required for breast cancer diagnosis. The cardinal physical finding in patients with breast cancer is typically the presence of a mass that is hard, irregular, immobile or fixed, and painless, which usually indicates malignancy [4]. Other physical findings may include skin thickening, *peau d'orange* (skin around the breast resembling an orange peel), unilateral nipple discharge, nipple inversion, bilateral asymmetrical breast size, and enlarged surrounding lymph nodes (usually axillary lymph nodes) [5].Mammography is a radiographic examination of the breast that uses low-energy X-rays to visualize the soft tissue and structure of the breast.

However, the mammography method has limitations, specifically the possibility of not comprehensively covering some parts of the breast tissue [6]. In contrast, ultrasonography provides information focused on the palpable area of protrusion, though this examination offers limited visualization of the malignant tissue[1]. Ultrasonography is a non-invasive, radiation-free examination that utilizes ultrasound waves to generate an image. With technological advancements, ultrasonography has evolved to incorporate automatic interpretation capabilities, compensating for its primary drawback of being operator-dependent [7]. Histopathological examination remains the gold standard for diagnosing breast cancer. However, this procedure is invasive, and not all patients with a palpable mass in or around the breast readily consent to it.The objective of this study is to determine the concordance between physical examination and radiological examination findings with the histopathological examination results in breast cancer patients at Royal Prima General Hospital and Dr. Pirngadi General Hospital in Medan. From the background presented above, the researchers are interested in observing the concordance between initial examinations—namely physical diagnostics and supporting examinations such as mammography and ultrasonography—with histopathological findings as the gold standard in breast cancer diagnosis.

II. METHODS

This study employed an observational (non-experimental) research design using a retrospective cross-sectional study method, which is descriptive and analytical. The study subjects were patients diagnosed with breast cancer via histopathological examination from 2020 to 2025 at Royal Prima General Hospital and Dr. Pirngadi General Hospital in Medan. The total sample size was 100 patients, selected using the simple random sampling technique. The sample size was determined using the Lemeshow formula. The sample criteria for inclusion included patients being female, having carcinoma type breast cancer, and the histopathological sample being derived from surgical tissue removal. The data collection method used secondary data, specifically the medical records of breast cancer patients who had undergone histopathological examination, along with the results of the physical and radiological examinations performed to establish the breast cancer diagnosis.

The histopathological examination was assessed using the WHO criteria, specifically the Nottingham grading system, which classifies the results into Grade 1 (well differentiated), Grade 2 (moderately differentiated), and Grade 3 (poorly differentiated/undifferentiated). The breast radiological examination was assessed using the BI-RADS (Breast Imaging-Reporting System) scale, which classifies results into five groups: BI-RADS 1 (Negative), BI-RADS 2 (Benign), BI-RADS 3 (Indeterminate/likely benign), BI-RADS 4 (Suspicious malignant), and BI-RADS 5 (Highly suspicious). Meanwhile, the physical examination was assessed based on the presence or absence of typical breast cancer findings, such as a mass, pain, discharge, nipple changes, immobility (immobile), lymphadenopathy, and peau d'orange.Data analysis was performed using IBM SPSS Statistics 27, by presenting the frequency of each variable and using the Chi-Square test as the primary statistical method.

III. RESULT AND DISCUSSION

Research data on the distribution and the concordance of physical examination and radiologic findings with histopathological findings presented below by tables and bar diagram.

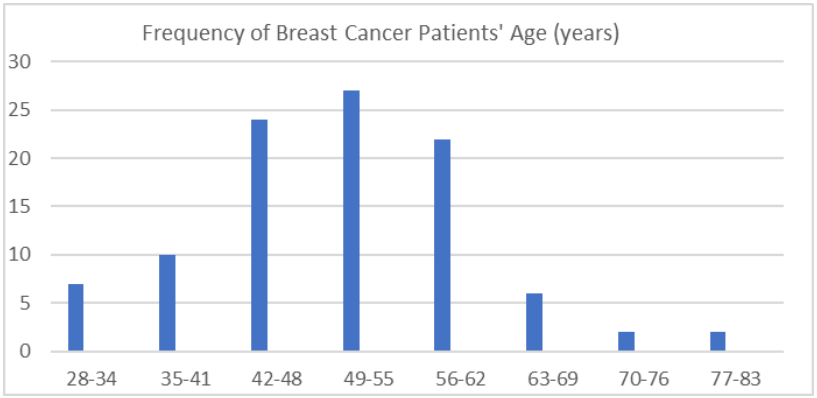

Fig 3.1. Frequency of breast cancer patients age (years)

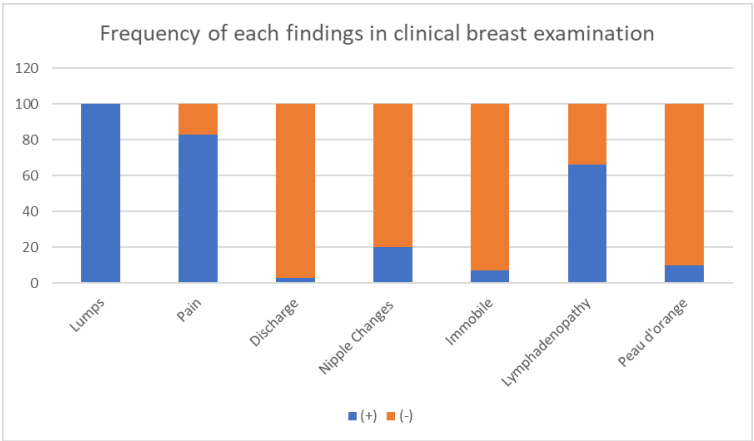

Fig 3.2. Frequency of each findings in clinical breast examination

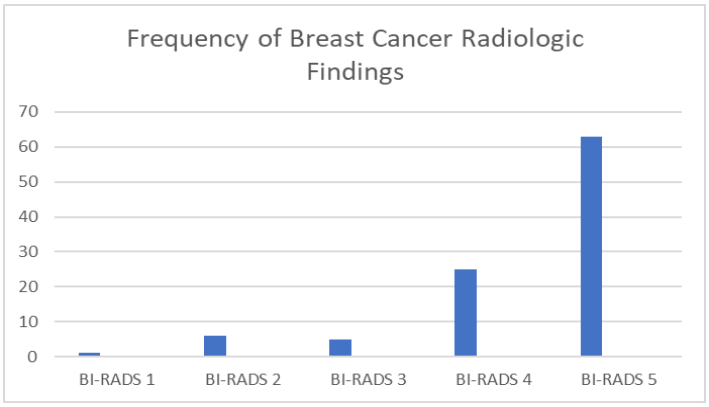

Fig 3.3. Frequency of breast cancer radiologic findings

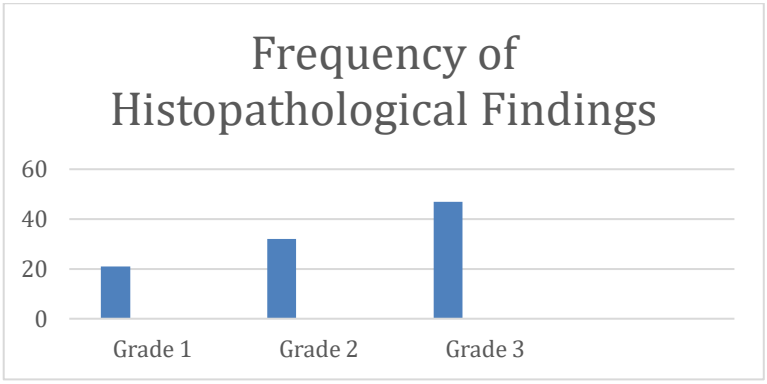

Fig 3.4. Frequency of histopathological findings

The visual results of frequency in each research variables can be seen in Fig 3.1, Fig 3.2, Fig 3.3, Fig 3.4. With total of 100 samples, Fig 3.1 show the age distribution that is grouped by Sturgess formula. The highest frequency shown in perimenopausal age (49-55 years) (n=27). Based on Fig 3.2 , all patients reported a lumps in the breast (100%) , with 83% of them experiencing pain in the area of the mass and 7% of the mass findings being immobile. Abnormal discharge from the breast was found in 3% of breast cancer cases. Nipple changes were observed in 20% of breast cancer cases. Enlarged lymph nodes (lymphadenopathy) were found in the majority of breast cancer cases (66%). Meanwhile, the skin around the breast resembling an orange peel (peau d'orange) was only found in 10% of cases. Based on Fig 3.3 that shows radiological findings from USG and mammography of breast cancer patients show that the highest frequency is BI-RADS 5 (n=63). Based on Fig 3.4, grade 3 is the highest frequency (n=47).

		Histopathological Results (%)			Total	p-value
Clinical Breast Examination Results		Grade 1	Grade 2	Grade 3		
Lumps	(+)	21 (21)	32 (32)	47 (47)	100 (100)	-
	(-)	0 (0)	0 (0)	0 (0)	0 (0)	
Pain	(+)	17 (20,4)	23 (27,7)	43 (51,8)	83 (100)	0,072
	(-)	4 (23,5)	9 (52,9)	4 (23,5)	17 (100)	
Discharge	(+)	1 (33,3)	0 (0)	2 (66,6)	3 (100)	0,306
	(-)	20 (20,6)	32 (32,9)	45 (46,3)	97 (100)	
Nipple Changes	(+)	7 (35)	7 (35)	6 (30)	20 (100)	0,139
	(-)	14 (17,5)	25 (31,2)	41 (51,2)	80 (100)	
Immobile	(+)	1 (14,2)	3 (42,8)	3 (42,8)	7 (100)	0,794
	(-)	20 (21,5)	29 (31,1)	44 (47,3)	93(100)	
Lymphadenopathy	(+)	15 (22,7)	22 (33,3)	29 (43,9)	66 (100)	0,680
	(-)	6 (17,6)	10 (29,4)	18 (52,9)	34 (100)	
Peau d'orange	(+)	2 (20)	4 (40)	4 (40)	10 (100)	0,846
	(-)	19 (21,1)	28 (31,1)	43 (47,7)	90 (100)	
Total		21 (21)	32 (32)	47 (47)	100 (100)	

Table 3.1. The concordance results of clinical breast examination and histopathological findings

		Histopathological Findings, *n (%)*			Total	*p-value*	*r*
		Grade 1	Grade 2	Grade 3			
Radiological findings	BI-RADS 1	0 (0)	1 (100)	0 (0)	1 (100)	0.039*	-0.189
	BI-RADS 2	1(16,6)	4 (66,6)	1 (16,6)	6 (100)		
	BI-RADS 3	0 (0)	0 (0)	5 (100)	5 (100)		
	BI-RADS 4	2 (8)	7 (28)	16 (64)	25 (100)		
	BI-RADS 5	18 (28,5)	20 (31,7)	25 (39,6)	63 (100)		
Total		21 (21)	32 (32)	47 (47)	100 (100)		

Table 3.2. The concordance results of radiological findings and histopathological findings.

(*) ($p < 0,05$) = there are significant differences

The research data were analyzed using Chi Square by using the Pearson Chi Square significancy score as primary statistical score and Likelihood Ratio significancy score as alternative statistical score. The results that show concordance between clinical breast examination and radiological findings to the tissue histopathology shown in Table 3.1 and Table 3.2. The statistical test results concerning the physical examination and the histopathological examination showed no significant relationship between the two, while the statistical test between the radiological examination and the histopathological examination indicated a significant, yet inverse relationship. This negative correlation denotes a weak association, as the coefficient value is close to zero. These findings mean that a higher histopathological grade is associated with a lower BI-RADS level.This study utilized 100 medical record data points from breast cancer patients at Royal Prima General Hospital and Dr. Pirngadi General Hospital in Medan, with all subjects being female. The highest frequency of patients was found in the 49–55 age group (27 patients), followed by the 42–48 age group (24% of patients). Epidemiologically, this result is consistent with global findings confirming that women during their reproductive years (15–49 years) are most at risk for breast malignancy [8]. The peak incidence of breast cancer occurs in the 45–49 age group. Furthermore, this risk continues to increase with advancing age. This pattern indicates that breast malignancy tends to emerge around the age approaching menopause.Breast malignancy is a multifactorial event. The age of menopause and a history of hormonal exposure in women play a crucial role in the development of abnormal cells in the breast. The average age of menopause for Indonesian women is within the 48–51 year range, which supports the observed shift in the age of breast cancer incidence [9].

Other contributing factors include screening delays, a lack of knowledge about the disease, and limited health facilities. Patients in Indonesia often neglect small palpable masses, considering them to be benign lesions that will disappear on their own. This situation is exacerbated by the lack of mammography access in peripheral areas [10]. These diverse factors support the observed shift in the age characteristics of breast cancer patients. A similar phenomenon was also found in a study of breast cancer patients at RS Ibnu Sina Makassar, which stated that the highest number of breast cancer sufferers was in the 46–55 age group (34.9%), confirming that the incidence increases, especially when women are approaching menopause[11].The physical examination of 100 breast cancer patients revealed various findings. Breast lumps were found in all patients (100%), reinforcing findings from a qualitative study in Indonesia that women tend not to seek healthcare if a palpable mass has not yet reached a significant size [10]. Breast pain was experienced by 83% of the patients. The high incidence of pain in advanced-stage cancer is influenced by tumor size, which exerts pressure on surrounding tissue, causing damage, local inflammation, and the stimulation of peripheral nociceptive fibers, ultimately leading to neuropathic pain [12]. Lymphadenopathy (enlarged lymph nodes) was detected in 66% of cases, a figure similar to the incidence of lymphadenopathy in breast cancer regardless of its molecular subtype. This enlargement is a mechanism of cancer metastasis, where abnormal tissue triggers inflammation and the infiltration of T and B cells, resulting in lymphoid tissue hyperplasia[13].

Other physical findings such as nipple changes, immobility (*immobile*), discharge, and *peau d'orange* were not dominant findings in this study, although these signs are nonetheless considered highly suggestive of malignancy [14]. The results of the breast radiological examinations (USG and mammography) among 100 patients diagnosed with breast cancer showed the highest frequency in the BI-RADS 5 group (63%), with a total of 88% of radiological results being dominated by the BI-RADS 4 and 5 groups. This

indicates a very high suggestion of malignancy within this study sample. A noticeable difference was found compared to another study on breast cancer screening methods in women in Turkey, which reported the highest frequency in the BI-RADS 2 group [15]. This difference arises because the current study used a sample of patients who already presented with breast cancer symptoms, such as a painful lump, for diagnostic purposes, rather than for screening. Nonetheless, a study comparing the accuracy of ultrasonography (USG) with the histopathology standard found that the BI-RADS 3 group had the most cases (47%), which aligns with other studies [16], [17]. The variability and potential inconsistency in BI-RADS interpretation results can be attributed to several factors, including the differences in USG machine brands used across various health facilities, differences in competency and subjectivity among examiners, and variations in resolution between ultrasonogram machines, which may lead to potential errors in BI-RADS assessment in breast mass cases [18].

Histopathological examination is the gold standard for diagnosing breast cancer. The findings from this study of 100 patients showed that the case distribution was dominated by Grade 3 (47%), followed by Grade 2 (32%), and the remaining Grade 1 (21%). This Grade 3-dominated distribution aligns with findings from a study at RSUD M. Yunus Bengkulu, although it differs significantly from research conducted at RS Madiun, where the majority was Grade 1 (58.7%) [19].The variation in the *grading* distribution can be influenced by several factors. One key factor is the tumor stage (classified based on the TNM system). Larger tumors tend to have a high *grade* due to a fast growth rate, characterized by increased mitotic activity, cell pleomorphism, and reduced cellular differentiation. Studies show a positive association between tumor stage and histopathological *grading*, despite significant variability in results [20].Furthermore, differences in histopathological *grading* can also be caused by the results of breast tissue immunohistochemistry (IHC). Molecular classifications such as Luminal A tend to have a lower *grade* because they are characterized by positive hormonal receptors (Estrogen Receptor and Progesterone Receptor), making them responsive to hormonal therapy and leading to a better prognosis. Conversely, IHC results such as Triple Negative and HER-2 generally have a worse prognosis and require chemotherapy because of the absence of hormonal receptor expression in the breast tissue [20], [21].Physical examination is the simplest method for diagnosing breast cancer and can be performed without requiring special instruments. However, the study results show that there is no significant concordance between the findings of the physical examination and the histopathological *grading*. This is supported by screening performance studies reporting that the sensitivity and specificity of physical examination for detecting breast malignancy are only 15.0% and 84.8%, respectively[22].

These data indicate that breast physical examination is not able to directly determine the nature of a mass (benign or malignant), let alone predict the degree of cellular differentiation of the breast tissue.The accuracy of the breast physical examination itself is variable and tends to be low, as the level of accuracy is highly influenced by the skill and ability of the examiner. Nevertheless, this effectiveness can be improved. When physical examination is combined with mammography, both yield significantly higher sensitivity and specificity. This combination is important because physical examination can assess invasive cancer and large breast masses, while mammography provides more accurate details regarding the size, shape, margins, architecture, and characteristics of the tumor [14].In the context of a single examination for early breast cancer detection, some studies suggest that physical breast examination indirectly has effectiveness almost equivalent to mammography when performed correctly. Furthermore, physical examination is the best option for low-to-middle-income countries because it offers the advantage of cost-effectiveness, making it highly suitable for developing countries. Although it cannot replace breast radiology, the combination of regular physical breast examination along with public education regarding breast cancer has a strong potential to increase early detection, reduce the prevalence of advanced-stage cases, and requires lower costs [23].The radiological examination serves as a continuation of suspicious physical findings before proceeding to invasive procedures, such as mastectomy, within the triple diagnostic approach for breast cancer. The results of this study indicate a significant relationship or concordance, albeit an inverse one. Other studies demonstrate that ultrasonography (USG) performs well and has high accuracy (sensitivity 83.9%, specificity 95.5%, PPV 88.7%, NPV 93.4%) in differentiating between benign and malignant lesions.

USG is also considered an appropriate and more affordable option when histopathological examination is not feasible [17]. Further research also reports a high concordance and low discordance between radiological and histopathological examinations in distinguishing benign and malignant breast tumors [16]. Therefore, radiological examination can accurately determine the nature of a breast lesion, which explains the significance value in this study (p-value = 0.039).The inverse (negative) concordance observed in this study is attributed to differences in USG machine resolution across various hospitals, as this was a multi-center study, potentially leading to inconsistent BI-RADS results in breast radiological examinations. Variations in USG machine models and brands can affect image quality, resolution, and contrast of breast masses, thereby influencing BI-RADS interpretation, including margins, shape, and echo-pattern [18]. Additionally, differences in BI-RADS interpretation can also be caused by other confounding factors, such as the type of USG system used—automated breast ultrasound (ABUS) versus handheld ultrasound (HHUS). Research has confirmed that ABUS tends to yield lower BI-RADS values compared to HHUS for small lesions in the breast, while still maintaining the suspicion of malignancy [24]. This perspective is further supported by the current study's findings, where the majority of the sample (88%) received BI-RADS 4–5 interpretations (highly suggestive of malignancy), and a low correlation coefficient (r=-0.189) indicates a weak, inverse relationship between radiological and histopathological results. Radiological examination is susceptible to operator bias or interobserver variability. The use of imaging methods as a diagnostic modality is limited to differentiating benign and malignant lesions, but it cannot accurately assess a lesion down to the cellular level as provided by histopathological examination [7].

IV. CONCLUSION

The characteristics of breast cancer patients in this study show the highest frequency in the 49–55 age group (27%), which is a high-risk perimenopausal age group. Although physical examination findings were dominant for masses (100%), pain (83%), and lymphadenopathy (66%), there was no statistically significant relationship between the physical examination and histopathology *grading* (p>0.05). Conversely, the radiological examination (BI-RADS 4–5 in 88% of cases) demonstrated a significant relationship with histopathology (p=0.039), despite having an inverse correlation (r=-0.189) due to machine and operator variability[7]. The majority of histopathology results were Grade 3 (47%), indicating a diagnosis at an advanced stage. Overall, the radiological examination showed a better level of concordance compared to the physical examination regarding histopathological results, but it still cannot replace histopathology as the *gold standard* for diagnosis.

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