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Performance of the Clinical Breast Examination Performed by Examiners with Visual Impairment to Detect Breast Nodules Compared to Ultrasonography

Desempeño en la Detección de Nódulos Mamarios del Examen Clínico de Seno Realizado por Examinadoras Invidentes Comparado con Ultrasonido

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Abstract

Introduction: Clinical examination of the breast is a simple method to detect nodules, which is useful to determine its nature, of low cost, non-invasive and of great value as a diagnostic tool when necessary. Traditionally, clinical examination is carried out by trained health personnel with a sensitivity of 54% and a specificity of 94%; it is unknown its usefulness compared to mammography, since the physical examination in patients without previous screening has not been evaluated.

Objective: to determine the performance of the clinical examination of tactile auxiliary examiners for detecting mammary nodules, compared with the ultra-sonography findings in the detection of mammary nodules.

Methods: a validation study of diagnostic tests was carried out with a random sample of 325 women from the San Juan de Dios Hospital, aged between 18 and 70 years, during a period of 2 months.

Results: The sensitivity was 64.8% (95% CI 57.5-71.0); specificity, 45.6% (95% CI 37.8-53.6); positive predictive value, 58.5% (95% CI 51.4-65.1); negative predictive value, 52.3% (95% CI 43.8-60.7). Proportion of false positives, 54.4% (95% CI 46.4-62.2); proportion of false negatives, 35.2% (95% CI 28.6-42.5).

Conclusion: The study showed that the clinical examination of the breast by trained personnel with visual impairment is a diagnostic test sensitive to the detection of mammary nodules; but it has little specificity. In addition, it is a complement to screening for mammary pathology, even though it does not replace the medical examination, nor the screening tests recommended by the clinical practice guidelines.

Resumen

Introducción: La examinación clínica es un método simple para la detección y determinar la naturaleza de nódulos, es de bajo costo, no invasivo y es una herramienta de gran valor diagnostica. Tradicionalmente, la examinación clínica es realizada por personal entrenado, presenta una sensibilidad del 54% y una especificidad del 94%. La utilidad es desconocida cuando se compara con la mamografía. No se ha evaluado la importancia del examen clínico en pacientes, sin un previo tamizaje.

Objetivo: Determinar el rendimiento de la examinación clínica táctil realizada por auxiliares de enfermería con discapacidad visual, comparada con la sonografía por ultrasonido para la detección de nódulos mamarios.

Métodos: Se realizó una validación de la prueba diagnóstica con personal entrenado con discapacidad visual, realizada con una muestra aleatoria de 325 mujeres en el Hospital San Juan de Dios, con edades entre 18-70 años, durante un periodo de 2 meses.

Resultados: La sensibilidad fue de 64.8% (IC 95% 57.5-71.0); especificidad 45.6% (IC 95% 37.8-53.6); valor predictivo positivo 58.5% (IC 95% 51.4-65.1); valor predictivo negativo 52.3% (IC 95% 43.8-60.7). Proporción de falsos positivos 54.4% (IC 95% 46.4-62.2); proporción de falsos negativos, 35.2% (IC 95% 28.6-42.5).

Conclusión: La examinación clinica de las mamas, realizada por personal entrenado con discapacidad visual es una prueba sensible a la detección de nódulos mamarios, pero presenta poca especificidad. Adicionalmente, es un complemento para la detección de la patología mamaria, aunque no reemplaza el examen médico, ni las pruebas de detección recomendadas por las guías de práctica clínica

Key Study Facts

Objective	To determine the performance of the clinical examination of tactile auxiliary examiners for detecting mammary nodules, compared with the ultra-sonography findings in the detection of mammary nodules
Study design	Observational descriptive study of diagnostic tests
Source of data	Primary source, patients at radiological center, in the San Juan de Dios Hospital
Population/Sample	A random sample of 325 women from the San Juan de Dios Hospital, aged between 18 and 70 years, during a period of 2 months
Statistical analysis	Sensitivity, specificity, positive predictive value, negative predictive value, diagnostics odds ratio
Main finding	Clinical examination of the breast by trained personnel with visual impairment is a diagnostic test sensitive to the detection of mammary nodules; but it has little specificity

Introduction

In Colombia, mortality, morbidity and the costs associated with breast cancer care are increasing; this is due to the problems generated by the low acceptability of screening, the low coverage of screening, inequity in access to mammography and the lack of policies aimed at performing a clinical breast examination (CBE) suitable for patients with breast signs and symptoms, which has led breast cancer being diagnosed in late stages (1,2).

The analysis of the Sub-directorate of Non-communicable Diseases (NCD) of the Ministry of Health and Social Protection reports an increase in breast cancer in the country. In Colombia, this disease is emerging as a public health problem due to the fact that because of it, 2,649 women die each year (2).

But specifically in terms of early detection, due to the scarcity of financial resources in the region, it makes us think that it will not be effective to implement organized population screening programs if the health system does not guarantee access to diagnostic confirmation, treatment and follow-up to all women who require it, regardless of their ability to pay, because otherwise it can become another mechanism of inequity in access to health services (3). It is needed the design of innovative screening programs based on educational and motivational strategies for women, which guarantee the development of healthy habits such as breast self-examination and the annual breast clinical examination (performed by well-trained personnel).

CBE is necessary for the evaluation of patients with breast symptoms such as changes in skin, pain, discharge or inversion of the nipple; and especially in those who report the presence of nodules. In a primary clinical care study, 11% of women with breast nodules and 4% who reported other symptoms had breast cancer; it was notorious that 12% of women with cancer and palpable nodules had a normal mammogram of the immediately preceding year (4). Likewise, several studies on diagnostic mammograms report that the sensitivity of mammography in women with a breast tumor was 87.3%. This suggests that approximately 13% of clinically evident breast cancers may not be detected in mammographic projections (5). Palpable abnormalities are common and usually represent a benign finding; however, they may be the most common clinical presentation of breast cancer. The patient's age of presentation is considered when choosing between mammography and ultrasound as the initial imaging modality, with mammography being the initial modality for patients aged over 40 years, and ultrasound being preferred for patients aged under 30 years. For patients between the ages of 30 and 40 years, the American College of Radiology gives equal weight to any of the studies; however, breast cancer in younger women is associated with a more advanced stage and worse results (6).

In our country, the clinical practice guide for the early diagnosis of breast cancer has as a strong recommendation, the annual clinical examination of the breast in patients older than 40 years, associated with the screening mammography of two projections starting from 50 years to 69 years (6).

CBE is a low cost and easy access method, but it must be considered that the quality of this exam should be a fundamental pillar in order to improve its effectiveness; generally, the human conditions offer limitations for this procedure, so it is assumed that an increase in the acuity of the sense of touch can improve the sensitivity of palpation and thus the quality of the examination. Nowadays, it is known that the basis of development and learning of individuals with visual impairment, especially those with total blindness, is based on a system of perception, integration and assimilation of sensations through active touch, known as haptic perception.

A training program in CBE, known as Discovering Hands (7), was created in Germany. It was aimed at people with visual disabilities who are trained for nine months in aspects related to anatomy, physiology, physiopathology and the clinical examination of the breast. In the clinical examination, the breast is divided into zones by means of tapes located according to anatomical reference points; this allows orientation by coordinates, and the information is obtained from each level in Braille writing. This training program was implemented in the American continent for the first time in the city of Cali (Colombia), since September 2015; six women with visual disability were selected and trained in clinical breast examination.

Materials and methods

Methods

It was designed an observational descriptive study of diagnostic tests. The subjects underwent CBE by previously trained examiners with visual disabilities, and their findings were compared with ultrasonography findings.

For the calculation of the sample size, it was used the Epidat 4 tool, taking into account that when there are palpable lesions, CBE has a sensitivity of 54%, and ultrasonography of 99%. The prevalence of nodules in the breast was taken based on the statistics of the local hospital from the entire consultation for mammary symptoms, which was related in a 60% to the presence of nodules, with a 95% CI. In total, 325 subjects were evaluated.

Inclusion and exclusion criteria

The subjects who entered the study met the following criteria: female subjects; inhabitants of the city of Cali; belonging to the contributory, subsidized or special Colombian health regime (indigenous peoples; Afro-Colombian communities; displaced communities; and poor, non-affiliated persons); aged 18 years to 70 years; subjects who signed the informed consent. There were excluded subjects with: previous breast surgery; subjects who consulted for the presence of mammary nodules detected by self-examination; and male subjects, because of the low prevalence of the disease in this group.

The patients were explained clearly and in an understandable language what the study consisted of, and their personal data were collected. After that, if they agreed, the informed consent was signed. There were selected the subjects who met the inclusion criteria, and the CBE was carried out by the tactile auxiliary examiner after evaluation by a general physician.

The data obtained were recorded in a medical history format available to the research team. The findings of the clinical examination were recorded in a systematized format; and it was created a database to record and track the examined subjects. Each subject evaluated by the tactile auxiliary examiner underwent breast ultrasound at the SIRAD (servicios integrales de radiologia) radiological center, in the San Juan de Dios Hospital, by a radiologist trained in ultrasonography. It was used a TOSHIBA XARIO ™ 200 ultrasound scanner. A radiological report was generated with 3 copies: one for the subject, one for the study and another for the file. Bias control was made; and the results were analyzed for: validity index, predictive values and likelihood ratios, relative risk calculation correction and odds ratio calculation correction.

Results

There were 325 female subjects who met the inclusion criteria; they were evaluated by the auxiliary tactile examiners, and all of them underwent bilateral mammary ultrasonography. In the socio-demographic characterization of the population, it was observed that the highest percentage of women was in the age range of 41 to 70 years, with 239 subjects (73.5%); 18 subjects reported active smoking, as well as social alcohol consumption in 93 of the subjects. Regarding the health regime, 278 subjects belonged to the subsidized category; 44 subjects to the contributory one; and there were 3 poor, non-affiliated subjects; the other data can be in Table 1.

The results of the diagnostic test for the clinical breast examination performed by the auxiliary tactile examiners are show in Table 2, whereas result of test validity are shown in Table 3.

Validaty test

The sensitivity was 64.8% (95% CI 57.5-71.0); specificity, 45.6% (95% CI 37.8-53.6); positive predictive value, 58.5%. (95% CI 51.4-65.1); negative predictive value, 52.3% (95% CI 43.8-60.7). Proportion of false positives, 54.4% (95% CI 46.4-62.2); proportion of false negatives, 35.2% (95% CI 28.6-42.5).

Discussion

With the design of new clinical practice guidelines proposed by developed countries, which have sophisticated infrastructure and technological capacity, the importance of the clinical examination of the breast in the diagnosis of mammary pathology has been minimized. For this reason, the Ministry of Health has for some years standardized clinical practice guidelines (8) to our environment, considering that the clinical examination of the breast continues to be a useful tool for the detection of mammary nodules, which in turn affects the early detection of breast cancer. This study demonstrates the importance of CBE for mammary nodule detection with an innovative technique, easily accessible to the population and performed by personnel with visual disabilities who have been previously trained.

There are several theories supporting that visual impairment of people in general, and in particular Braille readers, could lead to the improvement of tactile acuity in terms of the sense of touch, which is known as tactile experience hypothesis. Alternatively, the absence of vision itself could improve tactile acuity, which is also known as the visual deprivation hypothesis. When participants with vision undergo intensive training in a tactile task, their performance in that task improves in the trained finger, and to a lesser degree in the adjacent and contralateral fingers (9,10).

In addition, it was observed greater sensitivity of the test performed by the tactile auxiliary examiners, when it was combined with medical clinical examination, and confirmed with imaging or biopsy. As appropriate in this work, the clinical examination was tested in conditions of difficulty that included patients with nodules that have not been clinically found by the patients themselves, or previously by medical personnel; the findings had acceptable levels of sensitivity and specificity for the exercise of this diagnostic activity as a complement to standardized early detection activities. Currently, scientific evidence is still scarce, and additional studies with a larger population are recommended (11).

It is noteworthy that this is a great opportunity for labor inclusion for auxiliary tactile examiners, who with the support of governmental entities and the private sector managed to start working; and who perform this task, at present, with a high level of satisfaction, according to what the users have expressed.

Conclusions

This study demonstrated that the clinical examination of the breast by trained personnel with visual impairment is a diagnostic test sensitive to the detection of breast nodules, but it is not specific; it can be recommended as a diagnostic test in patients, but must be subject to a confirmatory test, either by mammography or another imaging test showing a higher sensitivity.

The exam performed by the auxiliary touch examiners has a good performance and it is within the sensitivity parameters of trained

Table 1. Socio-demographic characterization

Variable		No	%
Age (years)	18-40	86	26.5
	41-70	239	73.5
Civil status	Single	136	41.8
	Married/free unión	51	15.7
	Divorced	25	7.7
	Widow	16	4.9
Education level	None	10	3-1
	Primary	249	76.6
	Secondary	33	10.2
	Technical	19	5.8
	Undergraduated	14	4.3
Occupation	Employee	108	33.2
	Independent worker	27	8.3
	Housekeeper	179	55.1
	Student	8	2.5
	Unemployed	1	0.3
	Retired	2	0.6

Table 2. Relationship of Clinical Breast Exam vs. Findings in Ultrasonography

	Mammary nodules by ultrasonography		
Clinical breast exam	**Present**	**Absent**	**Totals**
Positive	114	62	176
Negativa	81	68	149
Totals	192	130	325

medical personnel (S 40-69% E 86-99%). The specificity remains low for this test; however, when evaluating this clinical test as a diagnostic test, we found that it is an exam that aims to detect nodules in the breast, but not to be a confirmatory test.
Although both false positives and false negatives are important in this test, they do not create a risk for patients, since there will always be performed the confirmatory test that is currently in rule, according to the recommendations of the clinical practice guidelines.

The clinical examination performed by the tactile auxiliary examiners becomes a complement to screening for mammary pathology, but it does not replace the medical examination or the screening tests recommended by the clinical practice guidelines. It was observed that in the Guidelines of Clinical Recommendations, in developed countries, the self-examination of the breast is not recommended, as well as in the national guidelines. However, it is a good point of clinical practice as a strategy of awareness and self-knowledge.

Conflict of interest
The authors declare no conflict of interest.

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Table 3. Results of test validity

Test			**a**	
Sensitivity	64.8	57.5	71.4	
Specificity	45.6	37.8	53.6	
Positive predictive value	58.5	51.4	65.1	
Negative predictive value	52.3	43.8	60.7	
Proportion of false positives	54.4	46.4	62.2	
Proportion of false negatives	35.2	28.6	42.5	
Accuracy	56.0	50.6	61.3	
Diagnostic Odds ratio	1.54	0.99	2.41	
Youden´s J index	0.10			
LR (+)	1.19	0.99	1.43	Taylor
		0.84	1.20	Miettien
LR (-)	0.77	0.60	0.99	Taylor
		0.77	1.30	Miettien
Pretest probability (Prevalence)	54.2			

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