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Feasibility of Fine-Needle Aspiration Biopsy and Rapid On-Site Evaluation for Immediate Triage in Breast Cancer Screening in Tanzania

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PURPOSE Clinical breast examination (CBE) is one of the most common methods used for early detection of breast cancer in low- and middle-income countries. CBE alone is limited by lack of specificity and may result in unnecessary diagnostic procedures. We evaluated the feasibility of integrating CBE, fine-needle aspiration biopsy (FNAB), and rapid on-site evaluation (ROSE) in triaging palpable breast masses for specialized cancer care.

MATERIALS AND METHODS An intensive breast cancer screening event was conducted at a national trade fair by a multidisciplinary team of care providers targeting a healthy population in Dar es Salaam, Tanzania. All adults age ≥ 18 years were invited to participate. CBE was performed by oncologists and/or pathologists. FNAB was performed by a pathologist on palpable masses that were then categorized as benign, indeterminate, or suspicious for malignancy or definitively malignant based on ROSE.

RESULTS A total of 208 individuals (207 females, one male; median age, 36 years; range, 18-68 years) were screened. Most (90.8%, 189 of 208) had normal findings, whereas 7.2% (15 of 208), 1% (2 of 208), and 1% (2 of 208) had a palpable mass, breast pain, and nipple discharge, respectively. Two participants had lesions too small for palpation-guided biopsy and clinically consistent with fibroadenomas; the participants were counseled, and observation was recommended. FNAB was performed on 13 breast masses, with 9 of 13 (69%) categorized as benign and 4 of 13 (31%) suspicious for malignancy. Final cytopathologic review of referred patients confirmed one case to be breast adenocarcinoma, one was suggestive of fibroadenoma, and two showed inflammations.

CONCLUSION Integration of CBE with ROSE and FNAB was feasible in a breast cancer screening program in Tanzania. In settings with constrained resources for cancer care, this may be an effective method for triaging patients with breast masses.

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INTRODUCTION

Low- and middle-income countries (LMICs) face a growing burden of cancer with healthcare systems that are inadequately prepared to meet this public health challenge. According to Tanzanian officials, there are approximately 42,000 new cancer patients per year nationwide.[1] Breast cancer is the second-leading cause of cancer-related mortality among women in Tanzania, with 63%-91% of women presenting with advanced (stage III or IV) disease.[2-6] Currently, in Tanzania, there is no national breast cancer screening program, and cancer care is concentrated in only a few zonal and national referral centers, which limits timely access for a majority of patients.[7] As a result, the overall 5-year survival rate for breast cancer is estimated to be < 45% in Tanzania, compared with > 90% in high-income countries.[7]

Breast cancer screening has been shown to significantly reduce cancer-related morbidity and mortality through earlier diagnosis.[8,9] However, cancer screening programs require organized health systems and intensive resources to deliver high-quality preventive and cancer care services, which many LMICs lack.[10,11] One of the priorities of the National Cancer Control Strategy set by the Tanzanian Ministry of Health is to increase breast cancer screening rates, and a set of comprehensive screening guidelines has been developed.[7,12,13]

Although the WHO recommends population-based screening mammography in well-resourced countries, screening mammography is generally not feasible in LMICs because of its high cost, the need for substantial infrastructure and trained healthcare providers, and increased demand on cancer care services.[14,15]

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CONTEXT

Key Objective

To determine feasibility of incorporating clinical breast examination (CBE), fine-needle aspiration biopsy (FNAB), and rapid on-site evaluation (ROSE) for immediate triage in breast cancer screening in a low-resource setting.

Knowledge Generated

This screening program was conducted by a multidisciplinary team of care providers targeting a healthy population attending a trade fair in Dar es Salaam, Tanzania. By performing CBE, FNAB, and ROSE, 19 individuals had abnormal CBE, of which four were suspicious for malignancy and referred for additional specialized care.

Relevance

Immediate triage using CBE, FNAB, and ROSE is feasible and may help to optimize and improve allocation of limited cancer care resources in low-resource settings.

Although clinical breast examination (CBE) has been demonstrated to be cost-effective and effective in down-staging breast cancer, CBE alone lacks specificity and may result in the detection of a large number of benign lesions and lead to unnecessary diagnostic procedures.[16-18] In LMICs, it is imperative that screening services refer only patients who truly need additional specialized diagnosis and cancer care to prevent overburdening already strained health systems.

Fine-needle aspiration biopsy (FNAB) is a minimally invasive and cost-effective tissue sampling method that has been successfully deployed in resource-constrained settings, which confers high accuracy in diagnosing palpable breast masses.[19,20] Rapid on-site evaluation (ROSE) allows for immediate assessment of FNAB samples for adequacy; when performed by a trained pathologist, a preliminary diagnosis can be rendered at the bedside, which allows for appropriate patient triage to optimize limited resources.[21] We aimed to evaluate the feasibility of integrating CBE, FNAB, and ROSE in an intensive breast screening program in Tanzania to improve triage of breast masses for specialized cancer diagnosis and care in Dar es Salaam, Tanzania.

MATERIALS AND METHODS

The Dar es Salaam International Trade Fair is an annual trade exhibition organized by the Tanzanian government, which showcases products and services from a wide range of industries. From June 28 to July 13, 2019, the Trade Fair was attended by more than 220,000 people, including the general public. Muhimbili University of Health and Allied Sciences (MUHAS), which is the premier public university training health professionals in Tanzania, participates in the fair annually and provides a range of basic health screening services.

A breast cancer screening program was announced during the opening ceremony, and all individuals age ≥ 18 years were invited to participate in the screening. The breast cancer screening program was hosted by a multidisciplinary team of pathologists, oncologists, oncology nurses, laboratory scientists, and clinical research coordinators from MUHAS and Ocean Road Cancer Institute. All participating pathologists were residents in the final quarter of training and had spent 18 months of their residency rotating through the fine-needle aspiration clinic at Muhimbili National Hospital (MNH). All participating oncologists had completed their training that included 6 months in the breast and cervical cancer screening unit at Ocean Road Cancer Institute. The equipment at the venue consisted of two examination beds, a table and microscope, and FNAB supplies.

During the screening, an oncology nurse or physician counseled participants about breast health, including the signs and symptoms of breast cancer and the importance of early diagnosis and treatment. A pathologist and/or oncologist then performed CBE, and whenever a palpable mass was detected, FNAB was offered. Those with normal CBE were advised on regular checkup. Patients with other abnormalities, such as breast pain or nipple discharge, or lesions that were considered too small for palpation-guided FNAB were counseled and referred for ultrasound at MNH.

For patients with masses detected by CBE, FNAB was performed by a pathologist according to MNH standard operating procedures. Three direct smear slides were prepared and fixed in 95% ethanol for at least 15 seconds. ROSE was performed by adding 1-2 drops of 0.5% toluidine blue and reviewed under the microscope. Preliminary diagnoses were categorized as benign, indeterminate, or suspicious for malignancy. Individuals with preliminary diagnoses of indeterminate or suspicious for malignancy were referred to MNH for further diagnostic workup, management, and follow-up. Deidentified data, including age, sex, CBE findings, and ROSE results, were transcribed onto case report forms from the clinical screening forms.

This report on the breast cancer screening program was approved by Institutional Review Boards under protocol numbers (DA.282/298/01) at MUHAS and (17-22963) at UCSF.

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RESULTS

A total of 208 people with the median age of 36 years (range, 18-68) participated in the screening, with 207 (99.5%) females and one (0.5%) male (Fig. 1). Nearly half of the participants were < 35 years old (n = 90, 45.2%) (Table 1). The majority (n = 189, 90.9%,) had no findings on CBE, whereas 9.1% (n = 19) had an abnormal CBE. Of the 19 participants with abnormal CBE, 15 (79%) were found to have breast masses, two (10.5%) had breast pain, and two (10.5%) had nonbloody nipple discharge.

Of the 15 patients with breast masses, two had lesions that were too small for palpation-guided FNAB. FNAB and ROSE were performed on 13 participants with breast masses, of whom 69.2% (9 of 13) were categorized as benign and 30.8% (4 of 13) were reported as suspicious for malignancy (Table 2). All four participants who had breast masses suspicious for malignancy based on ROSE were referred for additional care at MNH. The mean age of these women was 43.8 years (range, 34-54 years old), and the mean size of the masses was 4.8 cm (range, 3-6 cm), based on physical examination. The clinical characteristics of these four cases are summarized in Table 3. Final cytopathologic review confirmed one case (1 of 13, 7.7%) of adenocarcinoma, one was suggestive of fibrocystic change, and two showed inflammation (Fig. 2). The case initially diagnosed as adenocarcinoma by FNAB was confirmed to be invasive carcinoma based on the mastectomy specimen. The remaining three patients presented for follow-up care at MNH but, based on clinical reassessment and the final cytopathologic diagnosis, the women were counseled to monitor their breast lesions and did not require additional workup.

TABLE 1. Demographic Characteristics of Screening Participants

Age Group	Frequency (N)	Percentage (%)
18-34	90	45.2
35-39	34	16.3
40-49	53	25.5
≥ 50	27	13.0
Total	208	100.0

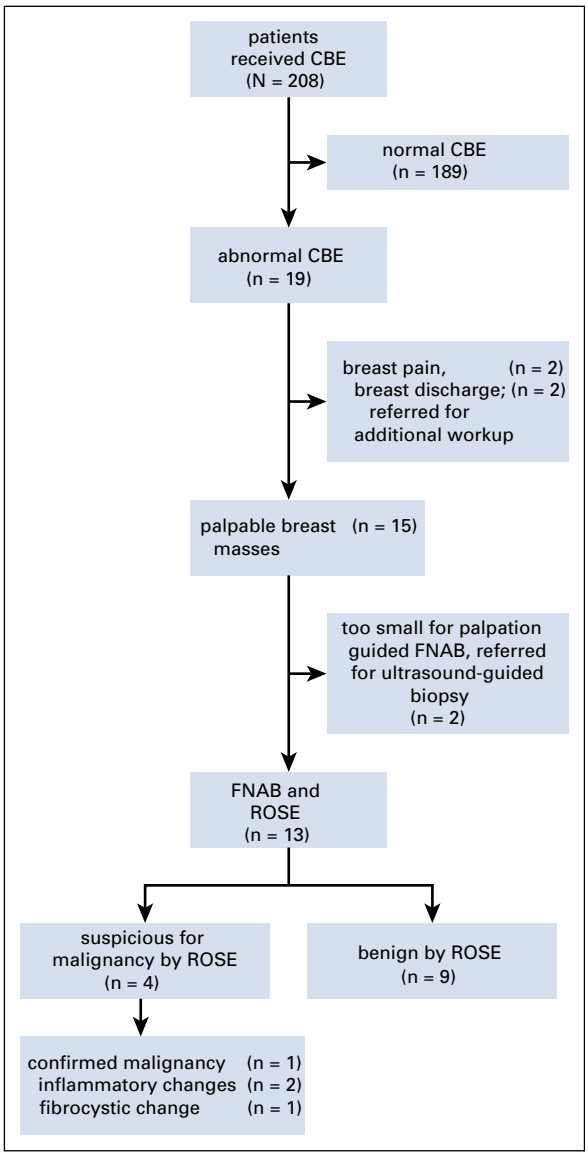


FIG. 1. Schematic diagram showing the flow of participants in the screening program. CBE, clinical breast examination; FNAB, fine-needle aspiration biopsy; ROSE, rapid on-site evaluation.

DISCUSSION

The goal of breast cancer screening in limited-resource settings is to detect breast cancers earlier, as measured by cancer stage at diagnosis; current international guidelines recommend CBE as a preferred approach.[14,15] However, controversy surrounds the efficacy of breast self-examination and CBE for population-based screening program, since a large randomized controlled trial in Russia showed increased biopsies but no improvement in breast cancer-related mortality.[16] Moreover, financial and health system barriers in LMICs preclude effective implementation of consensus guidelines for breast cancer screening, often because of unavailability of equipment and insufficient workforce.[22,23] Thus, there is an opportunity to evaluate innovative screening models that are resource appropriate in LMICs, such as Tanzania.

FNAB is a well-established diagnostic modality that has been shown to be highly accurate when performed by a trained operator, with a sensitivity of 92.7% and a specificity of 94.8%,[20] and the addition of ROSE ensures adequate cellularity and allows for on-site interpretation, which, in turn, has the potential to reduce unnecessary diagnostic workup in patients with benign masses.[21] Our group has also previously demonstrated that intensive workshops can be effective in developing skills essential for high-quality FNAB.[24]

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TABLE 2. Clinical Breast Examination and Rapid On-Site Evaluation Findings For All Screening Participants

CBE and FNAB Status	CBE Finding	ROSE	Number (n)
Abnormal CBE; FNAB performed	Breast mass	Suspicious for malignancy	4
		Benign breast tissue	1
		Fibroadenoma	8
Abnormal CBE; FNAB not performed	Breast mass, too small for aspiration	NA	2
	Breast pain	NA	2
	Breast discharge	NA	2
Normal CBE; FNAB not performed	None	NA	189
Total			208

Abbreviations: CBE, clinical breast examination; FNAB, fine-needle aspiration biopsy; NA, not applicable; ROSE, rapid on-site evaluation.

The current pilot study demonstrates the feasibility of combining CBE, FNAB, and ROSE to expedite patient triage for breast cancer care. During this pilot program, 19 of 208 screened individuals had an abnormal CBE. Of these 19, only four required a referral for additional specialized care based on clinical, FNAB, and ROSE results. Of the 15 who did not require additional specialized cancer care, nine received benign diagnoses at the time of biopsy performed during the screening. An additional six patients were referred for further imaging and diagnostic workup, of which two had lesions too small for palpation-guided FNAB and four had breast pain or discharge. This demonstrates the effectiveness of a screening program using CBE, FNAB, and ROSE to optimize resources, limiting referrals only to those requiring specialized care.

In other settings, such as Peru, CBE and FNAB have successfully been incorporated into breast cancer screening programs, but the cytopathologic samples are sent to a centralized location, which eliminates the benefits of on-site interpretation.[25] The addition of ROSE to our screening approach offers the added advantage of ability to triage at point of care, minimizing the opportunities for loss to follow-up. Although our study size was small, all four participants with abnormal ROSE results received a follow-up assessment at the hospital, whereas prior screening campaigns in Tanzania have reported follow-up rates of 53%-80%.[26]

TABLE 3. Clinical Characteristics of Screening Participants With Suspected Malignancy on Rapid On-Site Evaluation

Sex	Age	Tumor Site	Position (O'Clock)	Distance From the Nipple (cm)	Size (cm)	Cytologic Diagnosis
F	42	Bilateral	2	2	5	Inflammation
F	34	Right	12	1	3	Fibrocystic change
F	45	Left	11	8	5	Adenocarcinoma
F	54	Bilateral	2	2	6	Inflammation

Prior studies have found that numerous patient- and health system–level factors contribute to delays in receiving cancer care, including loss to follow-up. Primary patient-level reasons for not following up include travel costs, time restraints, and long distances to healthcare facilities, whereas key health system–level delays include difficulty with navigating the referral system, inadequate facility capacity to provide treatment, and delays in receiving biopsy results.[26,27] Nonetheless, the cohort is small and additional investigation into reducing both patient- and health system–level barriers to accessing breast cancer screening, diagnostic, and treatment services is needed.

Implementation of CBE, FNAB, and ROSE into breast cancer early detection programs will require a multidisciplinary team of healthcare providers and would serve as one of the several critical components. Based on an assessment of breast healthcare services in 2016, the Breast Health Global Initiative developed a resource-stratified, phased implementation framework for an early breast cancer detection program in Tanzania.[28] The first and foundational phase of this implementation strategy focuses on training to improve the ability to systematically triage and diagnose palpable breast disease. The current concordance between cytology and final pathologic diagnosis at this center has shown to be 96% based on 88 cases from an ongoing pilot study,[29] but dissemination of FNAB and ROSE will require quality assurance measures to maintain high concordance. To increase accessibility to high-quality CBE and FNAB, systematic training not only of surgeons, who are often the first consultants who patients are referred to, but also of primary healthcare workers, including clinical officers and nurses, in community clinics or district hospitals is necessary. Structured education, particularly for primary healthcare workers, on breast cancer risk factors, signs and symptoms, and management, as well as the development of standardized protocols for breast cancer early detection, diagnosis, and referral will be important in reducing provider-related delays. Limited cancer knowledge among community clinic–level healthcare providers in Tanzania has been shown to be a barrier in cancer control strategies, but training in basic oncology has shown to be effective and feasible.[30] In addition to clinician education, community education on breast cancer screening may lead to improvements in earlier diagnosis in Tanzania by prompting women to seek medical care for self-detected abnormalities.[31]

Because ROSE typically requires the presence of a skilled pathologist, the integration of innovations such as telepathology or the development of a mobile phone application that would automate classification of the FNAB specimens, similar to those already available for melanoma and cervical cancer, would help to increase the availability of pathology services.[32,33] Moreover, the integration of radiologists and systematic adoption Breast Imaging-Reporting and Data System reporting will also be important

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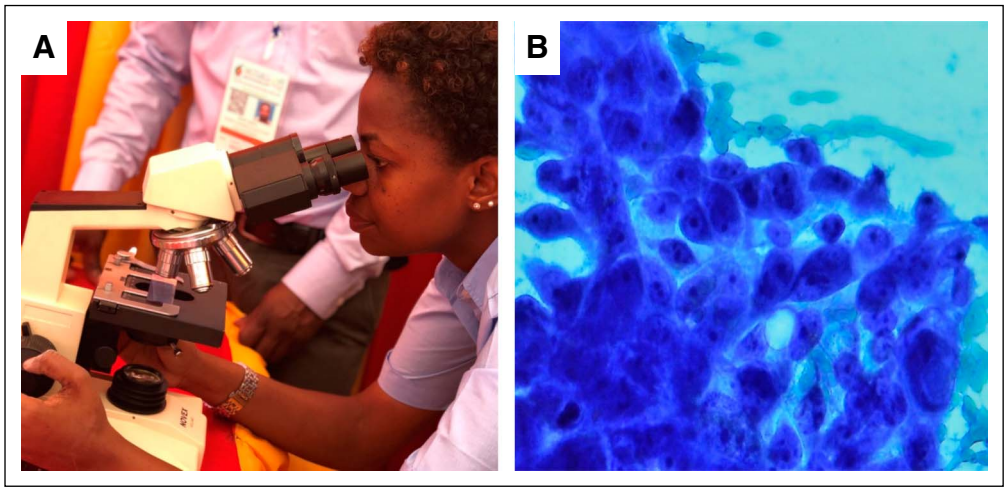


FIG. 2. (A) A pathologist performing a rapid on-site evaluation of a fine-needle aspiration biopsy. (B) Photomicrograph of a toluidine blue stained slide for rapid on-site evaluation of a breast mass later confirmed to be invasive carcinoma on surgical resection.

for developing resource-appropriate early detection programs and further refine who truly needs referral for additional cancer services.

Our findings are corroborated by a similar experience at a multidisciplinary breast camp model conducted in Kenya, which illustrated an innovative program that includes breast self-awareness and breast cancer education, CBE, and point-of-care diagnostics, including FNAB with on-site interpretation and ultrasound, and may be adaptable to Tanzania.[34] Additional studies to determine whether these screening methods, and downstaging of breast cancers overall, reduce morbidity and mortality are needed.[11] Aside from diagnostic modalities, breast cancer screening also involves governmental support and strengthening multiple aspects of a health system, including patient awareness and access to care, building diagnostic capacity, and improving referral mechanisms.[11,14]

Several limitations of this study should be mentioned. First, only one of the four participating pathologists who performed FNAB had received a specialized training in ROSE. This likely explains the cases with benign final cytopathologic diagnoses, which were considered suspicious for malignancy at the screening site. Second, the low rate of breast cancer in the current study may be attributable to using CBE alone to screen patients. Although using CBE as the primary method to screen for breast cancer may miss smaller lesions, and the addition of ultrasound would increase sensitivity, false positives are more common with ultrasound screening and would possibly lead to unnecessary procedures and increased resource utilization.[33] High-resolution ultrasound needed for breast cancer screening is also cost-prohibitive and not widely available in many resource-constrained settings, including Tanzania. In addition, there have been no studies demonstrating a difference in mortality benefit between using CBE and FNAB versus US and FNAB in low-resource settings. However, US is useful as a diagnostic tool in evaluating palpable lesions and, in selected circumstances, may circumvent the need for a tissue biopsy in some masses categorized as Breast Imaging-Reporting and Data System 3. Third, clinical follow-up data were only available on the individual who had a final cytologic diagnosis of adenocarcinoma on FNAB. This patient underwent surgical resection and was confirmed to have invasive carcinoma, and is now undergoing cancer treatment. Following the current standard of care in Tanzania, participants with ROSE and final cytologic diagnoses did not receive additional follow-up. Fourth, over half of the participants who participated in this screening fair were under age 40, which may not represent the general population's breast cancer risk. The current national guidelines for breast cancer screening in Tanzania recommends that asymptomatic women start receiving CBE from a trained healthcare provider at age 30, but that symptomatic patients or patients with family history of breast cancer can start at a younger age.[13]

In conclusion, breast cancer screening is important for early diagnosis and downstaging and has the potential to improve morbidity and mortality in LMICs. Although the sample size of this study is limited, incorporating FNAB and ROSE into CBE-based screening programs may be feasible and may help expedite and optimize triage for patients with breast masses. In the future, we aim to include ultrasound as a component of on-site screening and plan to evaluate the screening method on a larger scale by collaborating with the few hospital-based screening programs that are already established in Tanzania. We also plan on conducting a cost-effectiveness analysis to compare the proposed model with other early detection and screening modalities, which will further inform screening and diagnosis guidelines in LMICs.

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Provision of study materials or patients: Dianna L. Ng, Edda Vuhahula
Collection and assembly of data: All authors
Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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