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ORIGINAL RESEARCH

Ultrasound-guided Breast Biopsy in the Resource-limited Setting: An Initial Experience in Rural Uganda

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Abstract

Purpose: To describe the methodology and initial experience behind creation of an ultrasound-guided percutaneous breast core biopsy program in rural Uganda.

Methods and Materials: Imaging the World Africa (ITWA) is the registered non-governmental organization division of Imaging the World (ITW), a not-for-profit organization whose primary aim is the integration of affordable high-quality ultrasound into rural health centers. In 2013, ITWA began the pilot phase of an IRB-approved breast care protocol at a rural health center in Uganda. As part of the protocol's diagnostic arm, an ultrasound-guided percutaneous breast core biopsy training curriculum was implemented in tandem with creation of regionally supplied biopsy kits.

Results: A surgeon at a rural regional referral hospital was successfully trained and certified to perform ultrasound-guided percutaneous breast core biopsies. Affordable and safe biopsy kits were created using locally available medical supplies with the cost of each kit totaling $10.62 USD.

Conclusion: Successful implementation of an ultrasound-guided percutaneous breast core biopsy program in the resource-limited setting is possible and can be made sustainable through incorporation of local health care personnel and regionally supplied biopsy materials. Our hope is that ITWA's initial experience in rural Uganda can serve as a model for similar programs in the future.

Introduction

BREAST cancer is the most common cancer among women worldwide and is the most frequent cause of cancer-related death in women in low-income countries (1). In Ugandan women, breast cancer is the second most common malignancy behind cervical cancer. The incidence of breast cancer in Uganda has been rising during the last half-century from 11 per 100,000 in 1961 to 33 per 100,000 as of 2007 and increased at a rate of 4.5% yearly between 1991 and 2006 (2-4). The increase is at least partially attributed to the progressive integration of westernized lifestyle into Ugandan society, but may also be due to improved data collection (5).

A recent study demonstrated that Ugandan women are developing cancer at an earlier age and presenting at a later stage than those in higher-income countries such as the United States, a pattern also recognized among black women in other sub-Saharan countries (6,7). Fewer than 20% of Ugandans with breast cancer are diagnosed at an early stage (I & II) while more than 80% are diagnosed at a late stage (III & IV) (8). Early diagnosis is imperative as those who are diagnosed at an early stage have better options for treatment and potential cure than those who present with late stage disease.

In the United States, breast cancer is most often pathologically diagnosed via percutaneous image-guided core-biopsy. Physicians performing breast biopsies are specifically trained in breast procedures

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and have consistent access to core-biopsy supplies. There are fewer trained health care professionals per capita in low-income countries and access to medical supplies is limited, shortcomings that are accentuated in the rural setting. Recognizing these limitations and the importance of early diagnosis of breast cancer, Imaging the World Africa (ITWA), which is the registered non-governmental organization division of Imaging the World, has begun implementation of a breast health care diagnosis and treatment algorithm in Uganda's rural Kamuli district using ultrasound volume-based scan protocols whereby cinematic sweeps are obtained over the target lesion and interpreted on-site or remotely. The diagnostic arm of this algorithm involves ultrasound-guided percutaneous core-biopsy of ultrasound-diagnosed suspicious breast masses, a service that is rendered at the point of care in the rural health care center. Although this procedure is occasionally performed at urban tertiary referral centers, many living in the rural setting do not have the financial means for travel to such a facility. Furthermore, those with the means to travel to a tertiary referral hospital are often met with day-long, if not greater, lines and unexpected fees for service.

The objective of this paper is to describe the methodology and initial experience behind creation of an ultrasound-guided breast biopsy program in rural Uganda.

Methods and materials

In March and August of 2013, ITWA radiologists, sonographers, and technologists from the United States participated in the pilot phase of an IRB-approved breast care protocol. The pilot program was implemented at Nawanyago Health Center III (HCIII) and a regional referral hospital, Kamuli Mission Hospital (KMH). In-country health care provider contacts at HCIII and KMH had been established during previous ITWA projects.

Ultrasound-guided core-biopsy training

As part of the diagnostic arm of the protocol, ITWA developed an ultrasound-guided percutaneous core-biopsy training curriculum for participating physicians and sonographers, directly supervised by board-certified radiologists from the United States specializing in breast imaging. Trainees included a board-certified Ugandan surgeon and two Ugandan sonographers. The sonographers received their formal ultrasound training from the Ernest Cook Ultrasound Research and Education Institute (ECUREI) as well as supplementary instruction from ITWA volunteers. The surgeon performed biopsies with the sonographers assisting with holding the ultrasound probe and image optimization.

The curriculum was piloted at KMH and began with two 1-hour didactic lectures reviewing basic anatomy and pathology of the breast and ultrasound-guided core-biopsy technique. Didactic training also included education on sterile technique, data security, patient confidentiality, appropriateness, image transmission, and result management. Following the lectures, the trainees participated in supervised hands-on practice with a breast phantom until proficiency was established (Figure 1). The trainees were also afforded time for independent practice with the breast phantom. Thereafter, additional targeted training addressing specific areas for improvement was performed followed by two examinations. The first examination was a written exam designed to test trainee understanding of breast anatomy, pathology, core-biopsy technique, aseptic technique, and safety. The second examination tested trainee practical skills whereby the trainees were required to correctly perform an ultrasound-guided breast core-biopsy on the breast phantom. Upon passing the examinations, trainees were then permitted to perform ultrasound-guided biopsies on patients. The first four patient biopsies were to be directly supervised and evaluated by a radiologist proficient in ultrasound-guided breast biopsy procedures. The supervising radiologist intervened when errors were being performed. If an error was performed, the trainees would not pass the evaluation for the patient. The trainees were required to perform two subsequent biopsies without assistance of the supervising radiologist prior to establishment of proficiency. Once proficient, the trainees were then certified to perform biopsies independently. Biopsy samples were placed in formalin and sent to Kampala for pathologic interpretation. Refer to Appendix A for details regarding patient preparation, and procedure steps.

Ultrasound-guided core-biopsy supplies

Percutaneous core-biopsy supplies are not currently part of inventory at health care centers in the Kamuli District of Uganda, primarily due to cost and availability. Therefore, we sought to create low-cost biopsy kits using regionally available resources while maintaining quality and safety. First, we compiled a list of supplies used for percutaneous breast biopsies in the United States. Then, we identified availability and cost of those supplies in Uganda. In doing so, ITWA members consulted with local physicians, pharmacists, radiographers, and midwives and discussed the feasibility of obtaining the needed biopsy supplies in-country. For unavailable supplies and those deemed cost-prohibitive, alternative options were formulated.

Results

Adapting to locally available resources, keeping in mind cost and safety, supplies were acquired to create affordable and safe core-biopsy kits. A key cost-saving adaptation included substituting sterile ultrasound probe covers with condoms. A village tailor in the Kamuli District was contracted to create sterilizable reusable surgical drapes (Figure 2). Pharmacists in the nearby city of Jinja, Uganda were consulted and a regional medical supplier was contacted to negotiate prices for wholesale supply purchase.

Each biopsy kit consisted of the following single-use supplies: condom, tissue sample container, latex gloves, 16-gauge coaxial biopsy needle, lidocaine, 20 cc syringe for lidocaine, 21 and 23 gauge needles, adhesive bandage, and a scalpel blade for creation of a small skin incision for needle entry. Multi-use and bulk supplies included the following: antibiotic cream, formalin, antiseptic solution of ethylene blue and ethanol, forceps, ultrasound gel, sterile gauze, sterile drapes, and an autoclave drum (Figure 3). The cost per biopsy

Figure 1. Dr. Alphonsus Matovu and sonographer practicing ultrasound-guided core-biopsy on the breast phantom.
Figure 2. Custom-made sterilizable reusable surgical drape.
Figure 3. Dr. Christopher Stark with breast biopsy supplies.


Figure 1


Figure 2


Figure 3

of bulk and multi-use supplies were apportioned based on an assumed number of usages per item. The supply cost of each biopsy totaled $10.62 USD (Table 1). The ultrasound machine used was a Philips CX50 system previously donated to KMH by ITWA.

A surgeon at KMH was successfully trained in ultrasound-guided percutaneous breast core-biopsy technique. Two sonographers were also successfully trained to assist the surgeon in performing core biopsies. Success was measured by the surgeon's ability to perform the procedure safely and independently with the assistance of the sonographer(s). The trainees received a certificate of competency following independent demonstration of the procedure.

Discussion

As part of the diagnostic arm of an IRB-approved breast care protocol, the ITWA breast biopsy-training curriculum is the first of its kind to be implemented in rural Uganda. With 84% of Ugandans living in the rural setting, a gross national income (GNI) per capita of $680, and an increasing incidence of breast cancer, the utility of a safe and cost effective method of breast biopsy that could be performed at the point of care was recognized (9). Although ultrasound-guided biopsies are occasionally performed at urban centers in Uganda, most rural clinics do not have such resources. Instead, a patient in the rural setting presenting with a palpable mass will most commonly undergo excisional biopsy as the method of obtaining tissue for pathological diagnosis.

Excisional biopsy compared to a percutaneous ultrasound-guided approach can increase the risk of complications such as infection and bleeding. Furthermore, data suggests that the sensitivity and specificity of ultrasound-guided core biopsies is similar to that of open biopsy procedures and is safer and often better tolerated than surgical excision (10). However, the procedure requires technology, supplies, and training resources that are not routinely available at Ugandan rural health clinics. Therefore, identification of what supplies, if any, could be obtained regionally and at low cost was necessary. One of the essential supplies required for ultrasound-guided biopsy is a clean probe cover. Although not sterile, condoms are an acceptable alternative to a conventional sterile probe cover in percutaneous breast core-biopsy, which is considered a clean procedure (11). Furthermore, condoms are less expensive and easier to allocate in the rural setting. Maintaining a clean field with sterile drapes is also vital to patient safety. A local village tailor was contracted to produce heavy-duty center-hole canvas drapes, which could be sterilized many times prior to discarding. Purchasing the drapes locally from the village tailor was less expensive than from a regional medical supplier and also served to support the local economy. Through collaboration with local healthcare professionals, the remaining biopsy materials were allocated regionally and at a cost affordable to most Ugandans, both of which are necessary for long-term sustainability of a rural ultrasound-guided biopsy program.

An additional component of a sustainable ultrasound-guided biopsy program is trained medical professionals to perform the procedure. Given the scarcity of such individuals, we created a training program specific to breast biopsy and then trained a local surgeon from KMH to perform the procedure with sonographer collaboration. Training a local surgeon to perform these biopsies and sonographers to assist brings a breast cancer diagnosis closer to the patient's home and can obviate the need for a costly, time consuming, and logistically challenging trip to a tertiary referral center.

Table 1. Core-biopsy kit supply cost per unit. Conversion rate of 1 US dollar (USD) per 2515 Ugandan shillings (UGX).

Supply (units)	Cost (Ugandan Shilling/UGX)	Cost (US Dollar/ USD)	Notes
Ultrasound Probe Cover/ Condom (1)	300.00	$0.12	Box of 20 condoms = $2.38 USD (6,000 UGX) or $0.12 per condom
Ultrasound Gel (1 oz)	402.40	$0.16	5L (169 oz) container = $27.83 USD (70,000 UGX) or $0.16 per ounce
Formalin (2 oz)	2,364.10	$0.94	1L (34 oz) container = $15.90 USD (40,000 UGX) or $0.47 per ounce. 2 ounces needed per biopsy sample
Tissue Sample Container (1)	255.00	$0.10	
Ethanol/Antiseptic solution (1.5 oz)	804.80	$0.32	2.5L (85 oz) container = 17.89 USD (45,000 UGX)or $0.21 per ounce
Sterile Drapes (1)	75.45	$0.03	4 meters of cloth = $7.16 USD (18,000 UGX). Cost of tailoring 5 drapes = $7.95 USD (20,000 UGX). Total cost of cloth and tailoring 5 drapes (USD) = $15.11 or $3.02 per drape. $3.02 divided by an estimated lifetime of 100 uses per drape = $.03 per drape per use
Non-sterile Gloves (4)	704.20	$0.28	Box of 100 gloves = $7.16 USD (18,000 UGX) or $0.07 per glove. Four gloves needed for each biopsy
Disposable 14 Gauge Core Biopsy Needle (1)	17,605.00	$7.00	
Lidocaine (10 ml)	1,006.00	$0.40	20 ml vials = 0.80 USD (2,000 UGX) or $0.04 USD per ml. 10 ml used per biopsy
20 cc syringe and 21g needle (1 each)	804.80	$0.32	Box of 50 syringe and needle pairs = $15.90 USD (40,000 UGX) or $0.32 per pair. One pair needed per biopsy
23g needle (1)	50.30	$0.02	Box of 100 = $1.98 USD (5,000 UGX) or $.02 per needle. One needle needed per biopsy
Adhesive bandage (1)	50.30	$0.02	Box of 100 = $2.39 USD (6,000 UGX) or $0.02 per adhesive bandage
Scalpel blade (1)	201.20	$0.08	Box of 100 = $7.95 USD (20,000 UGX) or $0.08 per blade
Sterilizable Metal Forceps (1)	75.45	$0.03	Each forceps = $5.96 USD (15,000 UGX). $5.96 divided by an estimated lifetime of 200 uses = $0.03 per use
Sterile Gauze (1 10 cm x 10 cm piece)	377.25	$0.15	Box of 36 10 cm x 10 cm pieces of sterile gauze = $5.56 USD (14,000 UGX) or $0.15 per piece. One piece estimated per biopsy
Autoclave Drum (1)	1,031.15	$0.41	Each drum = $81.50 USD (205,000 UGX) divided by an estimated lifetime of 200 uses = $0.41 per use
Antibiotic Cream (approximately 6g)	603.60	$0.24	Each 30g tube = $1.20 USD (3,000 UGX) divided by an estimated 5 uses per tube = $0.24 per use (6g)
Total	$26,711.00	$10.62	

Conclusion

Implementation of an ultrasound-guided percutaneous breast core-biopsy program in the resource-limited setting is possible and can be made sustainable through incorporation of local health care personnel and regionally supplied core-biopsy materials. Our hope is that ITWA's initial experience in rural Uganda can serve as a model for similar programs in the future.

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Conflict of interest

The authors report no conflict of interest.

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Appendix A

Core biopsy supplies

- Ultrasound probe cover/condom
- Ultrasound gel
- Formalin
- Tissue sample container
- Ethanol/antiseptic solution
- Sterile drapes
- Non-sterile gloves
- Disposable 14 gauge core biopsy needle
- Lidocaine
- 20 cc syringe for lidocaine
- 21 gauge needle to draw lidocaine into syringe
- 23 gauge needle for lidocaine injection
- Adhesive bandage
- Scalpel blade for skin incision
- Sterilizable metal forceps
- Sterile gauze
- Antibiotic cream

Equipment setup

1) On an equipment tray or table, place down a sterile drape. On the drape, place the above listed supply items with the exception of the tissue sample container and formalin, which can be placed on a non-sterile surface.
2) Turn on the ultrasound machine, select the linear transducer, and optimize settings for breast imaging

Patient preparation and biopsy procedure

1) Obtain informed consent
2) Position the patient on their back with the arm on the side of the breast lesion over head and the other arm by the side. For lateral lesions, a foam wedge or towels under the ipsilateral shoulder can help flatten the breast as the patient rolls toward midline.
3) Scan the breast to confirm lesion location prior to cleaning (familiarize yourself with lesion location and nearby sensitive anatomy such as skin, pectoralis muscle, and large vessels)
4) Plan needle approach
    a. Shortest distance from skin to lesion is ideal
    b. Needle path should be parallel to chest wall
5) Clean the skin over the breast lesion with antiseptic solution and place sterile drape(s) around lesion
6) Draw up lidocaine into syringe
7) Place sterile ultrasound probe cover on probe
8) Place a small amount of ultrasound gel on breast over target lesion
9) Under ultrasound-guidance, make a small skin wheal with lidocaine and anesthetize tissues around target lesion

10) Make a small incision with scalpel blade at center of wheal
11) Under ultrasound-guidance advance coaxial trocar needle tip through incision to margin of lesion (ideal needle tip position will vary depending on lesion size – goal is for sample notch to traverse the lesion)
12) Remove trocar needle from cannula, making sure to hold cannula in place
13) Load biopsy needle into cannula
14) Prepare the patient (countdown, 1-2-3, etc.) then deploy needle with ultrasound-guidance making sure to visualize the needle in its entirety
15) Remove biopsy needle, holding cannula in place, and place sample into formalin with aid of sonographer
16) Repeat for a total of 3 cores
17) Remove both needles and hold pressure at skin entry site
18) Place Band-Aid at skin entry site
19) Dispose of sharps