Memorial Sloan Kettering Cancer Center

Breast cancer screening in high risk and symptomatic Nigerian women

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Cancer is a growing problem in Low- and Middle-Income Countries (LMIC)

- By 2050, 70% of the predicted 24 million people with cancer will reside in LMIC
- Lancet Oncology Commission on Global Cancer Surgery: majority of cancer patients require surgical intervention
- Lifestyle changes, higher life expectancy, improved infectious disease treatments

Kingham TP, et al. *Lancet Oncology* 14:e158-167 (2013)
Sullivan R, et al. *Lancet Oncology* 16(11):1193-224 (2015)

Africa Research Group for Oncology (ARGO) Consortium

Research → Training → Treatment/Outcomes

Goals:
1. Improve outcomes for cancer patients
2. Perform clinically meaningful research
3. Create a model that can be replicated elsewhere
4. Career development in Nigeria and MSK

Fischer SE,...Kingham TP. *Annals of Surgical Oncology* 24(3):627-31 2016

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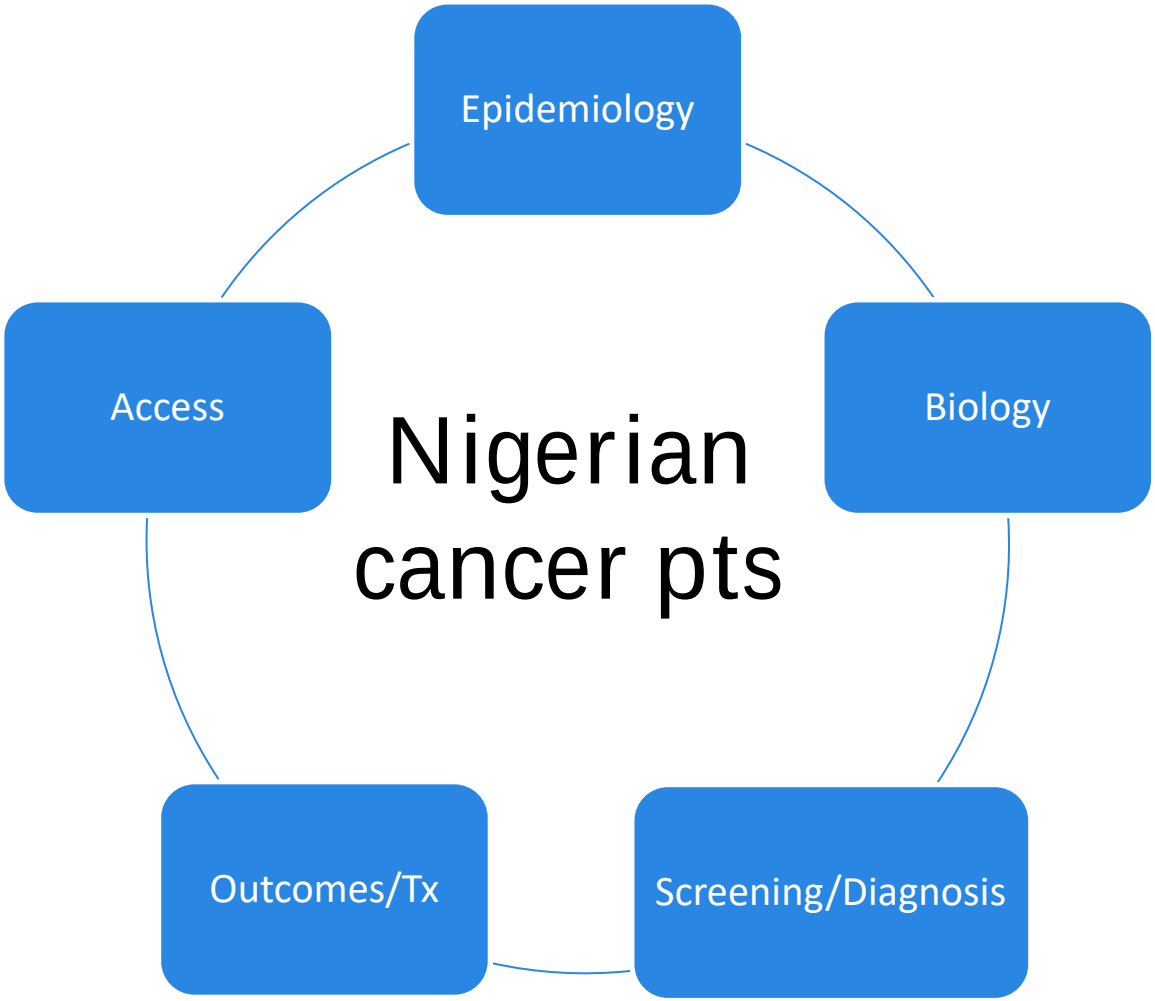
Epidemiology
Biology
Screening/Diagnosis
Outcomes/Tx
Access
Nigerian cancer pts

Outline

- Breast cancer background
- Study overview
- Methods
- Results
- Next steps/future directions

Breast cancer across the globe

USA

5-yr OS stage III disease:
USA: 85%[1]

Nigeria

Nigeria: 28%[2]

[1] Noone AM, et al. SEER Cancer Statistics. SEER website 2019
[2] Makanjuola SB, et al. Radiother Oncol. 111(2):321-326. 2014

Breast Cancer in Nigeria

- Widespread population-based breast cancer screening of asymptomatic, average-risk women may not be feasible due to personnel and infrastructural challenges

- Limited radiology resources
  - ~300 radiologists in the country (MSK ~200)
  - one per ~500,000 people (US has 50x that)

Delbeke, D and Segall GM. Status and trends in Nuclear Medicine in the United States http://jnm.snmjournals.org/content/52/Supplement_2/24S.full.
Adesunkanmi AR, et al. Breast 2006;15(3):399-409.
RAD-AID Nigeria Country Report. https://www.rad-aid.org/resource-center/country-reports

Background: iBreast Exam (iBE)

- 510(k) FDA cleared
- Highly portable, hand-held device
- Utilizes pizoelectric finger tactile pressure sensors to electronically palpate the breast

Broach et al. World Journal of Surgical Oncology (2016) 14:277
https://www.ibreastexam.com/

Background: iBreast Exam (iBE)

- Used by community health workers with minimal training

- Purpose - > assess for findings that warrant further evaluation
  - NOT to distinguish benign from malignant lesions

- Hypothesize iBE may be a particularly useful screening tool in settings where breast imaging is a limited resource

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Study Overview

- Provide high-risk or symptomatic Nigerian women with breast cancer education

- Evaluate participants
  - Clinical Breast Exam (CBE)
  - iBE
  - Mammography
  - Ultrasound

- Inform future screening efforts to decrease disparities

Study Goals

- To determine efficacy of education on high-risk Nigerian woman (knowledge and willingness to screen)
- To train staff (community health nurses) to utilize the iBE device
- To determine sensitivity and specificity of the iBE for detecting breast lesions overall (as seen on imaging) and suspicious lesions
- To compare the sensitivity and specificity of iBE to CBE by trained clinicians
- To compare imaging and pathology findings of lesions detected and missed on iBE

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Staff Training

- 4 nurses iBE trained
- Didactic and remote learning
- Completed test patients prior to study

Breast Cancer Educational Program

Breast cancer related educational materials assembled: lecture, video and print materials

Patient Knowledge Assessment & Education

- Validated survey obtained:

Breast Cancer Awareness Measure

Development and validation of the African Women Awareness of CANcer (AWACAN) tool for breast and cervical cancer

J. Moodley[1,2,3]*, S. E. Scott[4], A. D. Mwaka[5], D. Constant[1], J. N. Githaiga[1], T. S. Stewart[6], A. Payne[2], L. Cairncross[7], N. I. M. Somdyala[8], F. M. Walter[9]

CANCER RESEARCH UK

Moodley, J et al. 2019 PLOS ONE. 14. e0220545. 10.1371/journal.pone.0220545.
Linsell L et al. Eur J Cancer 2010 May;46(8):1374-81.

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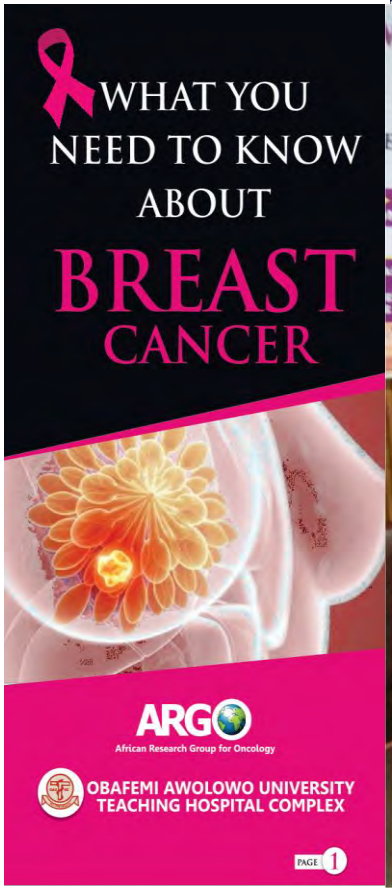
Patient Recruitment

- Breast cancer clinic at OAU
  - First degree relatives
- Radio jingles
  - English and Yoruba
- Print materials



Study

- Underwent 4 exams:
  - iBE, CBE by MD, mammogram and ultrasound
- If biopsy recommended, performed
- Treatment initiated if applicable

Data Considerations

- Imaging data considered twice:
  - Positive for any finding (benign or suspicious)
  - Positive for a suspicious finding warranting biopsy

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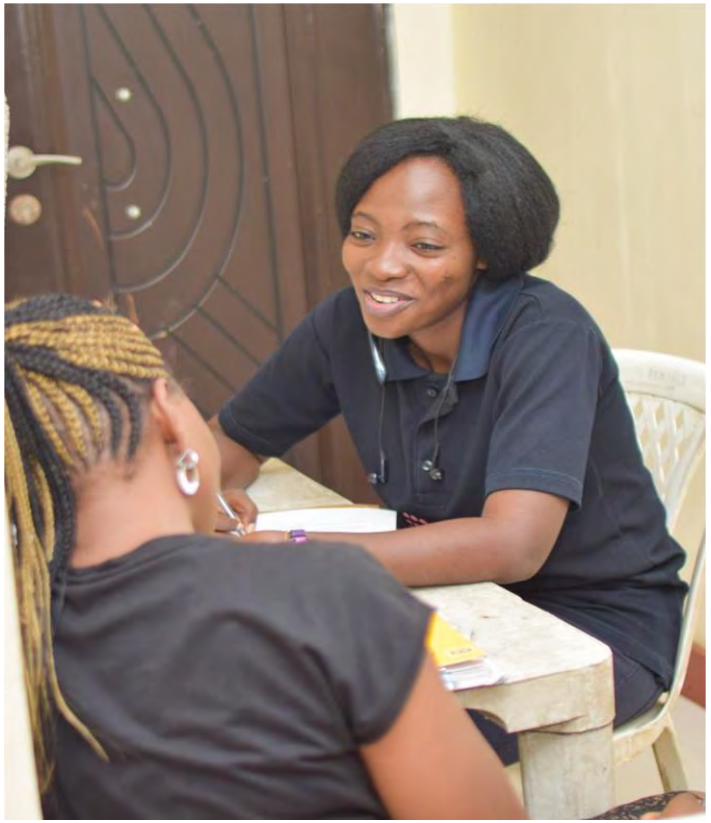
Patient Population

- 424 women total accrued

- Initial target was 400 total
  - 300 (75%) high risk
  - 100 (25%) symptomatic

Actual totals:

- 151/424 (35.6%) high risk
- 273/424 (64.4%) symptomatic



Symptomatic patients

- 88/273 (32.2%) breast lump
- 181/273 (66.3%) breast pain/discomfort
- 51/273 (18.7%) nipple discharge

- Additional symptoms: itching, tingling, axillary swelling, skin changes

- Note some patients reported more than one symptom

Patient Demographics

- Age: average 48.3 years (range 40-85 years)
- 360/424 (84.9%) married
- 390/424 (92%) have children
  - Avg 3.1 children (range 0-9)
  - Avg age 1st pregnancy 26.6 years (range 16-40)
  - 384/424 (90.6%) breastfed

Patient Knowledge Assessment

414 (97.6%) heard of breast cancer

Questioned Risk Factor	**Patients answering ”yes”**
Wearing bra all the time	213 (50.2%)
Putting money in bra	269 (63.4%)
Putting phone in bra	278 (65.6%)
Dirty air/water	114 (26.9%)

Attitudes toward screening/treatment

- 100% of women were willing to undergo breast screening/imaging
- 422/424 (99.5%) willing to screen regularly
- 419/424 (98.6%) willing to tx breast cancer
  - If not: financial reasons, religious beliefs

Overall Exam Completion

- Goal-> Each patient have 4 breast exams: CBE, iBE, US, MG

- 392 pts (92.5%) had all 4 exams done
  - 32 pts missing US, MG or both

Exam	Number of Patients Completed Exam (total n=424)	Percentage Patients Completed Exam
CBE	424	100
iBE	424	100
Ultrasound	412	97.2
Mammo*	401	94.6

*Note 2 completed mammos do not have results available currently

Results by Breast Exam Type: CBE

- Performed by 14 different physicians
- Average reported time for CBE
  - 2.7 minutes (range 1-10 minutes)
- 424/424 (100%) patients had CBE completed

iBE

- Performed by 4 different nurses

- Average reported time for iBE
  - 6.2 minutes (range 3-20 minutes)

- 424/424 (100%) patients had iBE completed

Overall Positive CBE and iBE

	CBE n (% of total examined)	iBE n (% of total examined)
Positive patients (total examined = 424)	85 (20%)	226 (53.3%)
Positive breasts (total examined = 848)	90 (10.6%)	308 (36.3%)

iBE and CBE Sensitivity and Specificity

- Breast level analysis
- Any *SUSPICIOUS* finding

	Sensitivity	Specificity	PPV	NPV
CBE	75.0	92.6	31.5	98.8
iBE	72.2	65.3	8.6	98.1

- iBE and CBE have similar sensitivities
- CBE demonstrates better specificity
- Similar NPV

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Biopsy Recommendations

- 37/424 (8.7%) patients w/biopsy rec
  - 34 based on imaging (BI-RADS 3, 4 or 5)
  - 3 by surgeon due clinical features w/o suspicious imaging

- Patients rec for biopsy
  - 5 pts high risk screening group
  - 32 pts symptomatic group

Biopsy Performance

- 30/37 (81.1%) of recommended biopsies performed
  - 15 malignant
  - 15 benign
  - 7 biopsies not yet done
    - 3 pts not reachable (not answering /phone off)
    - 3 pts declined (worried about healing, not ready, pt reports symptom resolved)
    - 1 pt scheduling issues

Cancers detected by CBE and iBE

- 15/424 (3.5%) path confirmed breast cancer
  - 1 high risk screen group, 14 symptomatic group

	CBE (%)	iBE (%)	If iBE and CBE used together (%)
Exam positive with path confirmed cancer in ipsilateral breast	13/15 (86.7%)	13/15 (86.7%)	13/15 (86.7%)**

**iBE and CBE missed the same two cancers:
- 1.7 cm mass on US (DCIS) and 1.8 cm mass on US (IDC)

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Future Directions

- Final analysis
- Longer term clinical follow up
- Longer term imaging follow up
- Enable sensitivity and specificity calculations of all modalities
- Assess patient knowledge retention
- Does iBE replace MD CBE in rural setting?

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prevent cancer FOUNDATION

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- Dr. Maigana

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- Adedamola
- Bolu
- Promise

Thank you

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