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

Africa Research Group for Oncology (ARGO) Consortium

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
Nigerian cancer pts

- Epidemiology
- Access
- Biology
- Outcomes/Tx
- Screening/Diagnosis
Outline

• Breast cancer background
• Study overview
• Methods
• Results
• Next steps/future directions
Breast cancer across the globe

USA

Nigeria

5-yr OS stage III disease:
USA: 85%¹

Nigeria: 28%²

¹ Noone AM, et al. SEER Cancer Statistics. SEER website 2019
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.
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
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

<table>
<thead>
<tr>
<th>Questioned Risk Factor</th>
<th>Patients answering “yes”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wearing bra all the time</td>
<td>213 (50.2%)</td>
</tr>
<tr>
<td>Putting money in bra</td>
<td>269 (63.4%)</td>
</tr>
<tr>
<td>Putting phone in bra</td>
<td>278 (65.6%)</td>
</tr>
<tr>
<td>Dirty air/water</td>
<td>114 (26.9%)</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Exam</th>
<th>Number of Patients Completed Exam (total n=424)</th>
<th>Percentage Patients Completed Exam</th>
</tr>
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<tbody>
<tr>
<td>CBE</td>
<td>424</td>
<td>100</td>
</tr>
<tr>
<td>iBE</td>
<td>424</td>
<td>100</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>412</td>
<td>97.2</td>
</tr>
<tr>
<td>Mammo*</td>
<td>401</td>
<td>94.6</td>
</tr>
</tbody>
</table>

*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

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<th>CBE n (% of total examined)</th>
<th>iBE n (% of total examined)</th>
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<tr>
<td>Positive patients</td>
<td>85 (20%)</td>
<td>226 (53.3%)</td>
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<td>(total examined = 424)</td>
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<tr>
<td>Positive breasts</td>
<td>90 (10.6%)</td>
<td>308 (36.3%)</td>
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<td>(total examined = 848)</td>
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iBE and CBE Sensitivity and Specificity

- Breast level analysis
- Any *SUSPICIOUS* finding

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<th>PPV</th>
<th>NPV</th>
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<tr>
<td>CBE</td>
<td>75.0</td>
<td>92.6</td>
<td>31.5</td>
<td>98.8</td>
</tr>
<tr>
<td>iBE</td>
<td>72.2</td>
<td>65.3</td>
<td>8.6</td>
<td>98.1</td>
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- iBE and CBE have similar sensitivities
- CBE demonstrates better specificity
- Similar NPV
iBE and CBE Sensitivity and Specificity

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• Similar NPV
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

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