COMPARISON OF FINE NEEDLE ASPIRATION CYTOLOGY AND FINE NEEDLE SAMPLING WITHOUT ASPIRATION IN THE DIAGNOSIS OF PALPABLE BREAST LUMPS IN MULAGO HOSPITAL.

BY

DR. ALEMA ONIRA NELSON, MBChB (MUST)

A DISSERTATION SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES IN PARTIAL FULL FILLMENT FOR THE AWARD OF THE DEGREE OF MASTERS OF MEDICINE (SURGERY) OF MAKERERE UNIVERSITY KAMPALA

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DECLARATION

I, Dr. Alema Onira Nelson, do hereby declare that this dissertation is my original work and has not been submitted to any other University for the award of any academic qualification. Views expressed herein are mine unless otherwise stated and where applicable the source references have been indicated.

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DATE AWARDED: 16/01/2010
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DEDICATION

This book is dedicated to my dear parents Joseph and Margret,

for their invaluable love, prayers and inspirations

towards my achievements.
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LIST OF ABBREVIATIONS

SOPD  Surgical out patient Department
FNB   Fine Needle Biopsy
FNAC  Fine Needle Aspiration Cytology
FNS   Fine Needle Sampling
PI    Principal Investigator
UOQ   Upper Outer Quadrant
UIQ   Upper Inner Quadrant
LOQ   Lower Outer Quadrant
LIQ   Lower Inner Quadrant
NRTHM National Referral and Teaching Hospital Mulago
OPERATIONAL DEFINITIONS.

**Fine Needle syringe:** A syringe with 23 needle gauge

**FNAC:** A technique of biopsy that employs suction in extracting material for diagnostic cytology.

**FNB:** A diagnostic procedure for harvesting cellular materials and tissue fragments used to identify tumours.

**FNS:** A technique of FNB that employs capillary action to harvest cells for diagnostic purposes

**BREAST LUMPS:** Swelling in the breast, both cancer and non-cancerous lesions.

**Good quality smear:** Cells are not obscured by blood.

**Poor quality smear:** Cells are obscured by blood.

**A Cluster:** Defined as more than or equal to 10 epithelial cells seen

**Adequate smear:** Defined as moderate (epithelial cells clusters easy to find) or abundant (epithelial cells clusters seen in almost every field).

**Inadequate smear:** Defined as few (occasional epithelial cell clusters) to no epithelial cell clusters seen.

**Sensitivity:** Is the proportion of positives that are correctly identified by the test

**Specificity:** Is the proportion of negatives that are correctly identified by the test
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ABSTRACT

Introduction

Open biopsy of the breast used to be the main traditional method of diagnosis of breast lumps. This was traumatic and done under anaesthesia. In 1921, Fine Needle Biopsy (FNB) was introduced by Guthrie in the United States to diagnose cancer. It is now used world wide. The techniques of FNB are: Fine Needle Aspiration Cytology (FNAC) and Fine Needle Sampling (FNS) without aspiration. FNAC is the technique used in Mulago Hospital.

Various studies have shown that FNAC technique depends on suction and thus; yields hemorrhagic material for cytological study, is painful, is many times traumatic and results in haematoma formation. Further more, patients are apprehensive because of the needle mounted on the syringe unlike FNS without aspiration.

FNS has been performed on various masses (Ear Nose and Throat lymph node and, thyroid lesions) with good diagnostic accuracy of 95.7%, 95.3 % and, 90%, respectively. However for breast masses no adequate studies have been documented as regards the use of FNS.

This study was undertaken to find out if there is a difference in diagnostic accuracy in using FNAC and FNS without aspiration in the diagnosis of palpable breast lumps in Mulago Hospital.
Objective:
To determine if there is a difference in diagnostic accuracy in using FNS and FNAC in patients with palpable breast lumps undergoing breast biopsy in Mulago Hospital.

Methods:
This was a cross-sectional study conducted between October 2008 and January 2009 in the Breast Clinic Surgical Outpatient’s Department (SOPD) of Mulago National Referral and Teaching Hospital, Kampala – Uganda. A total of 110 women with age range 16 years to 53 years, with average age of 21.7 years with palpable breast mass of 2 cm and above (in the widest diameter by ultrasound) were subjected to FNS, FNAC and excision biopsy of the lump or mastectomy where appropriate after consent. Cytodiagnoses of all the cases were compared to the histodiagnoses of the biopsies to establish the sensitivity, specificity and diagnostic accuracy. Patients were excluded if they had breast lumps less than 2 cm (in the widest diameter by ultrasound), refuse to have FNS, FNAC and excision biopsy and also those very sick- (ASA III and above).

Data was collected using questionnaires and analyzed using Epi info 6, STATA statistical package and presented in forms of tables. Statistical data analysis was performed with Chi² test, where appropriate. Statistical significance was determined at P<0.05.
Results:

A total of 180 patients with complaints related to the breasts were seen. Out of 180 patients, 70 patients were screened out of the study hence 110 patients enrolled into the study.

The eligible patients provided consent, 10 patients were excluded (patients had breast lumps less than 2cm in the widest diameter on ultrasound) and finally 100 patients were recruited into the study.

The 100 patients were subjected to both FNS and FNAC, 15 patients were dropped-out because they failed to return for excision biopsy.

Finally a total of 85 patients had FNS, FNAC and excision biopsy/ mastectomy done and these 85 patients were analyzed.

The study findings demonstrated that both FNS and FNAC have the same sensitivity of 83.3%, specificity of 100% and diagnostic accuracy of 98.7% in the diagnosis of palpable breast lumps.

The study also demonstrated that FNS had good quality smears in 88.2% of the patients as compared to FNAC smears which was 58.8%of the patients.

The FNS smears were adequate in 95.3% of the patients as compared to FNAC smears which was adequate in 90.6% of the patients.
Conclusion:

There is no difference in the diagnostic accuracy of FNS and FNAC in the diagnosis of palpable breast lumps. These findings may suggest that it is probably the adequacy of the cells harvested rather than the quality of the cells harvested which determines the difference in the diagnostic accuracy of the two techniques.
CHAPTER ONE

1.1 INTRODUCTION

During the time of Halsted in the 1850s, open biopsy of the breast used to be the main traditional method of diagnosis of breast lumps \(^1\). This was traumatic and done under anaesthesia.

In 1921, Fine Needle Biopsy (FNB) was introduced by Guthrie in the United States to diagnose cancer \(^2\), which was later popularized by Martin and Ellis \(^3\).

FNB is the most accurate, cost effective and simplest screening test for the rapid diagnosis of breast lumps and it has become widely acceptable as the initial test with varying degrees of sensitivities \(^4,5\).

The techniques of FNB are Fine Needle Aspiration (FNA) and Fine Needle Sampling (FNS) without aspiration. Both techniques are all cytological studies.

In National Referral and Teaching Hospital Mulago (NRTHM), the technique used is Fine Needle Aspiration Cytology (FNAC).

Various studies comparing these two techniques have shown that FNAC technique depends on suction and thus yields hemorrhagic material for cytological study, is painful, many times it is traumatic and results in haematoma formation. In addition it requires disposable syringes and needles hence is relatively expensive. Further more patients are apprehensive because of the needle mounted on the syringe unlike FNS without aspiration \(^6,7,8\).
However despite these problems from the records, on average, more than 500 biopsies for breast lesions are performed per year and also an equal number of new cases with breast lesion are seen in the Breast Clinic, in the SOPD.

FNS has been performed on various masses (Ear Nose and Throat lymph node and, thyroid lesions) with good diagnostic accuracy of 95.7%, 95.3 % and, 90%, respectively.

However, for breast masses no adequate studies have been documented as regards the use of FNS.

Therefore this study was done to determine if there is a difference in diagnostic accuracy in using FNS and FNAC in the diagnosis of palpable breast masses at the NRTHM and the results of the study shall be used to improve the diagnosis of palpable breast lumps.
1.2 PROBLEM STATEMENT

FNAC technique depends on suction and thus yields hemorrhagic material for cytological study; is painful, many times it is traumatic and results in haematoma formation.

Further more, patients are apprehensive because of the needle mounted on the syringe unlike FNS.

This therefore affects the diagnostic accuracy and adequacy of FNAC \(^6,7,8,10\).

Despite these problems NRTHM still uses FNAC in the diagnosis of palpable breast lumps.

1.3 JUSTIFICATION OF THE STUDY

From the record at the NRTHM, on average more than 500 biopsies for breast lesions are performed per year and yet the standard FNB technique used is FNAC despite its shortcomings.

FNS on the other hand provides greater ease of sampling with better control of the hand, a good perception of the lesion, more precise entry into the mass and patients are much less apprehensive when no syringe is used.

The smears obtained by FNS technique are without much blood in the background, with better cellularity and with much less artifacts \(^7,8,10\).

This therefore improves both the diagnostic adequacy and accuracy and helps in the proper management of patients with breast lumps.
This study will provide an insight into FNS as regards the diagnostic accuracy in the diagnosis of palpable breast lumps compared to FNAC in NRTHM.

1.4 OBJECTIVES OF THE STUDY

General objective

To determine if there is a difference in diagnostic accuracy in using FNS and FNAC in patients with palpable breast lumps undergoing breast biopsy in Mulago Hospital.

Specific Objectives

- To compare the sensitivity and specificity of FNAC versus FNS in the diagnosis of breast lumps in Mulago Hospital.
- To compare adequacy and quality of smear cells provided by FNAC and FNS for cytodiagnosis of palpable breast lumps.
1.5 RESEARCH QUESTION

Is there a difference in diagnostic accuracy in using FNS and FNAC in the diagnosis of palpable breast lumps in Mulago Hospital?

1.6 HYPOTHESIS

Null hypothesis:

In patients undergoing breast biopsy in Mulago Hospital, FNS has the same diagnostic accuracy as compared to FNAC.

Alternative hypothesis:

In patients undergoing breast biopsy in Mulago Hospital, FNS does not have the same diagnostic accuracy as compared to FNAC.
CHAPTER TWO

2.0 LITERATURE REVIEW.

2.1 CANCER OF BREAST

Breast Cancer constitutes a major public health issue globally with over 1 million new cases diagnosed annually, resulting in over 400,000 annual deaths and about 4.4 million women living with the disease. It is the commonest site specific malignancy affecting women and the most common cause of cancer mortality in women worldwide.\textsuperscript{11,12}

In Africa, Breast Cancer has overtaken Cervical Cancer as the commonest malignancy affecting women and the incidence rates appear to be rising.\textsuperscript{13,14}

In Uganda, Breast Cancer, is the 3\textsuperscript{rd} commonest malignancy in women (11.4\%) after Cervical Cancer (32.1\%) and Kaposi's sarcoma (17.9\%).\textsuperscript{15}

2.2 BENIGN BREAST MASSES

These are very common but their true incidence is difficult to estimate because the majority are asymptomatic and patients do not seek medical attention. It may be associated with socio-economic reasons.\textsuperscript{16} These benign breast masses include; fibro adenomas, cysts, lipomas and fat necrosis.
A study in NRTHM, Uganda in 1999, found that fibroadenomas contribute to about 29% of benign breast masses\textsuperscript{17} and a similar study still in NRTHM in 2000 showed that benign breast masses contribute to 49% of breast lumps,\textsuperscript{18}.

Therefore there is need for accurate histopathological diagnosis of these breast masses for good management of the patients.

2.3 DIAGNOSTIC MODALITIES

Several studies have shown that breast masses must be evaluated using Triple assessment\textsuperscript{19,20}. These include; systematic clinical examination, imaging (mammography, ultrasonography, ductography or Magnetic Resonance Imaging) and biopsy.

Recent studies have demonstrated that among the biopsy tests, FNB is the most accurate, cost effective and the simplest screening test for the rapid diagnosis of breast masses\textsuperscript{2,3}.

2.4 FINE NEEDLE BIOPSY

Fine Needle Biopsy (FNB), is a diagnostic procedure used to investigate lumps or masses. In this technique, a thin, hollow needle is inserted into the mass to extract cells that will be examined under a microscope.

By early 1930s, Martin H. E and Ellis E.B\textsuperscript{3} had performed over 200 needle biopsies on breast lumps. Today it has become a major diagnostic tool for breast lumps.

FNB has not only been useful in the diagnosis of breast lumps but also in lymph nodes, thyroids, soft tissue tumours\textsuperscript{21,22,23,24,25,26}.
2.5 FNB TECHNIQUES

The techniques used to obtain tissue from breast masses include; Fine Needle Aspiration (FNA) and Fine Needle Sampling (FNS) \(^6,^8\).

2.5.1 FINE NEEDLE ASPIRATION CYTOLOGY

A technique of biopsy that employs a fine needle gauge in extracting material for diagnostic cytology. The procedure is performed with or without local anaesthesia. The technique is aseptic and involves the following steps: \(^{27}\)

1. Place the patient in a comfortable position with the mass readily palpable during the procedure.

2. By palpation, determine the location and boundaries of the lump to be biopsied. At the same time, reassure the patient and explain the procedure.

3. Immobilize the lump with non dominant hand between the thumb and index finger

4. Insert the 23 gauge fine needle, already attached to a 10mls syringe. The syringe plunger must be fully in. The needle is introduced into the lump and the plunger is withdrawn to 5mls mark and maintained there.

5. Move the needle back and forth within the tumour, with short and quick strokes in different directions maintaining constant suction.

6. The biopsy manoeuvre is terminated when fluid appears in the hub. Before withdrawing the needle the plunger is allowed to return gently to the resting state.
Preparation of the slide.

The needle is detached from the syringe and the syringe is then filled with air. The content of the needle is squirted onto the surface of the glass slide. Material is spread on the slide by placing a second slide over the aspirated material and gently pulling apart. Slide is immediately fixed by 95% ethanol for staining with papanicolaou stain while the second slide is air dried for staining with a Romanowosky stain. The slides will then be examined by the cytopathologist.

2.5.2 FINE NEEDLE SAMPLING WITHOUT ASPIRATION

FNS without aspiration is sometimes referred to as fine needle sampling or fine needle sampling by capillary action by different authors. Therefore is no agreed term to use. Hence for purposes of clarity we chose to use Fine needle sampling without aspiration. FNS depends solely on capillary action of the fine needle and is therefore much less painful, much less traumatic and thus much more patient friendly. The smears obtained by FNS technique are without much blood in the background, with better cellularity and with much less artifacts.

FNS is performed with a 23 gauge fine needle by first immobilizing the lump with the non dominant hand and then inserting the needle without a syringe attached, followed by movement of the needle within the swelling in different directions. The biopsy manoeuvre is terminated when fluid appears in the hub.

The needle is then withdrawn and the slide is prepared in the same way as above.
2.6 OPEN BIOPSY AND HISTOLOGY

Open biopsy is excisional in type and involves removal of breast masses which will be
done under local anaesthesia for small clinically benign masses or under general
anaesthesia for malignant breast masses by the Principal Investigator (PI). The specimens
will be fixed in formalin and sent for histology.

Histology is the Gold standard for diagnosis of tumours. It involves tissues sectioned as
thin slices, after histoprocessing stained with Haematoxylin and Eosin and later examined
under a microscope by a cytopathologist.

2.7 COMPARISON OF FNS WITHOUT ASPIRATION AND FNAC.

Several studies have compared FNS and FNAC in evaluating superficial masses,
however, not much has been documented on breast lumps.

A study done by Rajasekhar et al.\textsuperscript{28} compared the two techniques, FNS and FNAC for
lymph nodes and found that the diagnostic accuracy of FNS was 95.3% which was
greater than FNAC. Similar results were obtained by Dey and Ray.\textsuperscript{9} For thyroid
lesions, studies done by Jayara and Raghuveer CV\textsuperscript{6} also compared the two techniques
and found that the diagnostic accuracy of FNS was 90%, still greater compared to FNAC.

Further more Braun H et al.\textsuperscript{29} compared FNS versus FNAC for Ear Nose and Throat
lesions and found that FNS had still a greater sensitivity of 95.7% compared to FNAC.

In a study done by Raghuveer CV et al\textsuperscript{6} whose objective was to compare the two
techniques for superficial masses, a secondary subanalysis of the data collected showed a
lower diagnostic accuracy of FNS of 70.4% and FNAC was 86%. This observation was similar to that of Kumarasinghe and Sheriffdeen\textsuperscript{10}, and also similar finding was demonstrated by Dey and Ray\textsuperscript{9}. Since these were results of subanalysis, therefore there is need to carry out a specific study aimed at comparing the diagnostic accuracy of the two techniques for the breast alone.
CHAPTER THREE

3.0 METHODOLOGY

3.1 STUDY SITE

The study was carried out from Mulago National Referral and Teaching Hospital, Kampala - Uganda in the Department of Surgery. The department of Surgery has several subdivisions and this study was carried out from Breast Clinic Surgical Out Patients Department. Mulago hospital has an estimated capacity of 1500 beds.

3.2 STUDY DESIGN

The study was a Cross-sectional study.

3.3 STUDY POPULATION/ PARTICIPANTS

Women aged 16 years and above who presented with palpable breast lumps to Mulago National Referral Hospital SOPD – breast clinic.

3.4 STUDY PERIOD

The period was four months, from October 2008 to Jan 2009.
3.5 SAMPLE SIZE ESTIMATION

Sample size was calculated using sample size estimation by categorical data;

Primary outcome: diagnostic accuracy.

Data from a previous study by Raghuveerr et al\(^a\) was used.

Proportion of patients not diagnosed by FNS (1-0.704) = 0.296 = P\(_1\)

Expected improvement in diagnostic accuracy of FNS without aspiration of 23%

Proportion of patients expected not be diagnosed with 23% improvement = P\(_2\)

P\(_2\) = 0.296 - 0.23 = 0.066.

Power = 80%.

Significance level = 0.05

The proportions to be compared are P\(_1\) = 0.296 and P\(_2\) = 0.066

Using Formula \(P_1 - P_2 / \sqrt{\bar{p} (1 - \bar{p})}\)

\(\bar{p} = 0.296 + 0.066 / 2 = 0.181\).

Calculating standardized difference using Formula \(P_1 - P_2 / \sqrt{\bar{p} (1 - \bar{p})}\)

0.23 / \sqrt{0.181 (1-0.181)} = 0.60

Using the Nomogram for calculating sample size or power\(^30\)

Connecting standardized difference 0.60 to power of 80% and reading from the central axis corresponding to the level of significance 0.05, N=85 patients.

20% loss to follow of 85 = 17 patients.

Therefore the total sample size = 102 patients.
3.6 SELECTION CRITERIA

INCLUSION CRITERIA

- Women aged 16 years and above with clinically palpable breast lumps
- Women aged 16 years and above consenting to be enrolled to have both FNS without aspiration and FNAC.

EXCLUSION CRITERIA

- Patients who are very sick- (ASA III and above).
- Patients with breast lump less than 2cm in widest diameter.
- Males

3.7 PATIENT RECRUITMENT AND FOLLOW UP

Patients who presented to the breast clinic – SOPD with complaints of breast lump were sought a verbal consent and screened by Principal Investigator (PI).

Women who met the screening criteria were enrolled into the study by the PI.

Women who didn’t meet the screening criteria were offered general treatment from SOPD.

Consenting

Eligible patients were explained the intended study, its purpose, and the voluntary aspect of their participation. Then documented informed consent was obtained by the PI.

Patients who did not consent to be enrolled into the study were not denied treatment.
Breast Lump size determination

Once consented, Ultrasound of the breast mass was done by the same radiologist to
determine the size of the breast lesion in centimetres and nature of the lesion. Those with
lump sizes less than 2cm in the widest diameter were excluded.

Equipment

Equipment used included glass slides, cover slips, antiseptic, disposable gloves, fixatives
(absolute ethyl-alcohol, modified Wright stain or Rapi-diff quick), French gauge 23
hypodermic needles, 10mls syringes, swabs, papanicolaou stain, biopsy register and
diamond pencil for labelling slides.

Patient registration

Details of the patient’s particulars including name, age, sex, hospital identification number
and laboratory number were entered in the laboratory register.

Patient positioning

The biopsies were carried out on patients lying supine on a couch.

Slide labelling

Slides were labelled with the patients’ laboratory number using a diamond pencil on one
end. An initial A for FNS specimens, B for FNAC specimens were also indicated on the
slides.

FNAC technique.

The biopsies were performed by the PI. After gloving, the skin overlying the breast lump
was cleansed with antiseptic—95% ethyl alcohol in a swab. The location of the lesion to
be biopsed was determined by palpation. The lesion was immobilized with the non
dominant hand between the thumb and index finger. FNAC performed constantly on the
lateral half of the lesion. The fine needle, already attached to a syringe was inserted into the lesion and later a vacuum created. The needle was moved back and forth within the tumour several times. The biopsy manoeuvre was terminated when fluid appeared in the hub. The needle was then removed and the sample expressed on the clean dry labelled slide.

**FNS Technique**

The FNS was performed on the medial half of the lesion maintaining the minimum distance of 0.5cm apart with a fine needle, by first immobilizing the swelling with the non dominant hand and then inserting the needle without a syringe attached, followed by movement of the needle within the swelling back and forth several times. The biopsy manoeuvre was terminated when fluid appeared in the hub. The needle was withdrawn and a syringe filled with air was then attached to it and the material expressed on clean dry labelled slides.

**Smear preparation and staining.**

The samples were expressed on the slides labelled with the patient’s laboratory number. Material was spread on the slide by placing a second slide over the aspirated material and gently pulling apart. Slide was immediately fixed by 95% ethanol and stained with papanicolaou stain while the second slide was air dried and stained with a Romanowosky stain. The slides were then covered with cover slips and examined by the cytopathologist. The PI collected the slides and re-labelled them with generated numbers from 101 to 300 which covered the laboratory numbers with their initials of A for FNS and B for FNAC.
Each generated number corresponded to the patients laboratory number and this was only known to the PI. Therefore the cytopathologist was blinded to the biopsy technique used. The slides were then presented to the cytopathologist to be examined. All smears were evaluated by the same cytopathologist.

Cytology results for both techniques were reported as; good or poor for smear quality, adequate or inadequate for smear results and inadequate, benign, atypical, suspicious of malignancy and malignant for cytological diagnosis.

These results were recorded on another register. The PI then recorded the results under their respective biopsy techniques (FNS or FNAC).

**Excision biopsy.**

This was the gold standard. Aseptic technique was observed and under local anaesthesia, the breast lumps were excised for histology after FNS and FNAC results by the PI. In case of cancer, mastectomy was performed by the PI and whole sample sent for histology. The histology results were reported as benign or malignant and these results were then recorded.

**Sample storage.**

All the samples taken were stored in the Pathology Department Archive and may be used if further studies on the samples are required.
RECRUITMENT: Patients’ flow;

Patients presenting to Breast clinic

Verbal Screening consent \& Screening

Screened (N = 180)

Eligible for enrollment, U/S

CONSENT

Recruitment. (N=100)

Excluded (N = 10) had lumps <2cm,

Dropouts (N= 15)

Both FNS and FNAC (N=85)

Excision biopsy / mastectomy

Patient followed with result.

General treatment from clinic/wards. (N = 70)
3.8 SAMPLING PROCEDURE

Consecutive sampling was done by the Principal Investigator until the required sample size was achieved.

3.9 STUDY VARIABLES

Predictor Variables

- Technique of biopsy used (FNS and FNAC)
- Size of breast lumps (widest diameter) in centimetres.
- Demographic variables.

Outcome Variables

- Adequacy of cells obtained (Adequate or inadequate)
- Quality of smears (Good and Poor).
CHAPTER FOUR

4.1 DATA MANAGEMENT

4.1.1 DATA COLLECTION

Data was collected using a standardized, pre-tested, interviewer administered questionnaire by the PI and a trained assistant.

4.1.2 DATA ANALYSIS

Data forms were edited for completeness and accuracy. Data was then entered and cleaned using EPI INFO 6 software. Analysis was done using SPSS 12.0 and STATA statistical package. Statistical data analysis was performed with \( \chi^2 \) test, where appropriate. Statistical significance was determined at \( P<0.05 \). Based on the numbers of True Positives (TP’s), False Positives (FP’s), True Negative (TN’s) and False Positives (FP’s), the diagnostic accuracy of both FNS and FNAC were calculated as follows:

Sensitivity \[= \frac{TP}{TP + FN}\]

Specificity \[= \frac{TN}{TN + FP}\]

Positive predictive value \[= \frac{TP}{TP + FP}\]

Negative predictive value \[= \frac{TN}{TN + FN}\]
Diagnostic accuracy \[= \frac{TN + TP}{TP + FP + TN + FN}\]

Diagnostic Error \[= \frac{FP + FN}{FP + FN + TP + TN}\]

Breast lump size was determined by ultrasound in centimetres. Results were presented in form of tables.

4.1.3 QUALITY CONTROL

The PI carried out all the interviews and assessment.

Data was double entered to ensure data accuracy.

All the biopsy procedures were carried out by the PI with assistance of a trained assistant and under the supervision of a senior pathologist.

The patients all underwent the same standardized procedure and both techniques were performed on the same breast lump.

All smears were evaluated by one independent senior pathologist who was blinded to the techniques used.

All specimens were labelled with patient’s identification and laboratory number.
4.1.4 ETHICAL CONSIDERATION

Informed, written consent from patients, parent/guardian was obtained as applicable.

A translator was used where necessary.

All participants were made aware of the risks and benefits of the study.

Patients were at liberty to withdraw from the study at anytime and this did not affect their rights to receive medical care.

All the information obtained was kept confidential, and was only used for the purpose of this study.

Examination of patients was carried out in the presence of a female nurse.

The patients were not charged for Ultrasound of the breast lumps and biopsy procedures performed.

Approval for the study was sought from the Department of Surgery, Ethical Research Committee Mulago National Referral and Teaching Hospital and the Faculty of Medicine Research and Ethics Committee before the study is conducted.
4.1.5 DATA DISSEMINATION

The findings of this study were compiled into a report. The report will form the basis of a dissertation to be submitted to the school of graduate studies in partial fulfillment for the award of the degree of masters of medicine (surgery) of Makerere University. This will be presented to the Department of Surgery.

Copies of the report will be availed to Sir Albert Cook Library, School of Graduate Studies Makerere University Kampala.

4.1.6 STUDY LIMITATION

1. The population of patients seen in Mulago Hospital may not be representative of the general population.

2. Use of only one senior cytopathologist to analyses the biopsy results which otherwise would be done by two senior cytopathologists to compare results.

3. Study was time bound hence the period was short which could not allow large sample size to be collected.
CHAPTER FIVE

5.0 RESULTS

Figure 1: The study profile.

From October 2008 to January 2009, a total of 180 patients of age range 16 years to 53 years (mean age of 21.7 years) with complaints related to the breasts were seen in the Breast outpatient's clinic and invited to participate in the study.

Out of 180 patients, 70 patients were not eligible for the study hence 110 patients were enrolled into the study.
The eligible patients provided consent, 10 patients were excluded (patients had breast lumps less than 2cm in the widest diameter on ultrasound) and finally 100 patients were recruited into the study.

The 100 patients were subjected to both FNS and FNAC, 15 patients were dropped-out because they failed to return for excision biopsy.

Finally a total of 85 patients had FNS, FNAC and excision biopsy/ mastectomy done.

Data analysis included only the 85 patients.
Table 1 Study population characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>85 (100%)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>16-19</td>
<td>45 (53)</td>
</tr>
<tr>
<td>20-29</td>
<td>33 (39)</td>
</tr>
<tr>
<td>30-53</td>
<td>7 (8)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>74 (87.1)</td>
</tr>
<tr>
<td>Married</td>
<td>8 (9.4)</td>
</tr>
<tr>
<td>Divorced</td>
<td>3 (3.5)</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>73 (85.9)</td>
</tr>
<tr>
<td>One or more</td>
<td>12 (14.1)</td>
</tr>
<tr>
<td><strong>Age at menarche (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>14 (1.5)</td>
</tr>
<tr>
<td>&lt;15</td>
<td>58 (68.2)</td>
</tr>
<tr>
<td>15+</td>
<td>27 (31.8)</td>
</tr>
<tr>
<td><strong>Tribe</strong></td>
<td></td>
</tr>
<tr>
<td>Ganda</td>
<td>49 (57.7)</td>
</tr>
<tr>
<td>Other</td>
<td>36 (42.3)</td>
</tr>
</tbody>
</table>

The majority (53%) of the patients were aged 16-19 years, of this 86% were nulliparous, mean age at menarche was 14 years. Majority had never married (87.1%) and Ganda comprised 57.7% of the total patients under study.
Table 2 Association between histology and lump characteristics

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>MALIGNANT/Total (%)</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lump size (widest diameter, cm)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-5</td>
<td>3/58 (5.2)</td>
<td></td>
</tr>
<tr>
<td>&gt;5</td>
<td>3/27 (11.1)</td>
<td>0.246</td>
</tr>
<tr>
<td><strong>Lump side</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>2/40 (5.0)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>4/45 (8.9)</td>
<td>0.485</td>
</tr>
<tr>
<td><strong>Lump location</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper outer quadrant</td>
<td>6/49 (12.2)</td>
<td></td>
</tr>
<tr>
<td>Other quadrant</td>
<td>0/36 (0.0)</td>
<td>0.029</td>
</tr>
<tr>
<td><strong>Lump tenderness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>¾ (75)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3/81 (3.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Lump margin</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regular</td>
<td>2/79 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Irregular</td>
<td>4/6 (66.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Lump mobility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile</td>
<td>4/82 (4.9)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Immobile</td>
<td>2/3 (66.7)</td>
<td></td>
</tr>
</tbody>
</table>

Breast lumps in the upper outer quadrant, tender lumps, those with irregular margins and immobile/fixed lumps were more malignant at histology.

Most of the breast lumps were in between 2-5 cm in the widest diameter, only 5.2% were malignant. The distribution of lumps was almost the same on both right and left breasts.
Table 3 Distribution of FNS and FNAC cytology diagnosis by Histology (N=75)

<table>
<thead>
<tr>
<th>HISTOLOGY</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BENIGN</td>
</tr>
<tr>
<td></td>
<td>N (%)</td>
</tr>
<tr>
<td>FNS</td>
<td>69</td>
</tr>
<tr>
<td>BENIGN</td>
<td>69 (98.6)</td>
</tr>
<tr>
<td>MALIGNANT</td>
<td>0 (0)</td>
</tr>
<tr>
<td>FNAC</td>
<td>69 (98.6)</td>
</tr>
<tr>
<td>MALIGNANT</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

**Calculation of Sensitivity, Specificity, NPV, PPV, Diagnostic accuracy and Error.**

These were determined from a total of 75/85 patients who had either malignant or benign results on all the tests (FNS, FNAC and histology).

**(A). FNS versus Histology**

Sensitivity  = Positive in disease

\[
\frac{TP}{TP + FN} = \frac{5}{5 + 1} \times 100\% = 83.33\%
\]

Specificity = Negative in disease

\[
\frac{TN}{TN + FP} = \frac{69}{69 + 0} \times 100\% = 100\%
\]

Positive predictive value  =  

\[
\frac{TP}{TP + FP} = \frac{5}{5 + 0} \times 100\% = 100\%
\]

Negative predictive value  =  

\[
\frac{TN}{TN + FN} = \frac{69}{69 + 1} \times 100\% = 98.6\%
\]
Diagnostic accuracy 
\[
\frac{TN + TP}{TP + FP + TN + FN} = \frac{69 + 5}{69 + 5 + 1} \times 100\% = 98.7\%
\]

Diagnostic Error 
\[
\frac{FP + FN}{FP + FN + TP + TN} = \frac{1 + 0}{1 + 0 + 69 + 5} \times 100\% = 1.33\%
\]

(B). FNAC versus Histology

Sensitivity 
\[
\frac{TP}{TP + FN} = \frac{5}{5 + 1} \times 100\% = 83.33\%
\]

Specificity 
\[
\frac{TN}{TP + FP} = \frac{69}{69 + 0} \times 100\% = 100\%
\]

Positive predictive value 
\[
\frac{TP}{TP + FN} = \frac{5}{5 + 0} \times 100\% = 100\%
\]

Negative predictive value 
\[
\frac{TN}{TN + TP} = \frac{69}{69 + 1} \times 100\% = 98.6\%
\]
Diagnostic accuracy  
\[ = \frac{TN + TP}{TP + FP + TN + FN} = \frac{69 + 5}{69 + 5 + 1} \times 100\% = 98.7\% \]

Diagnostic Error  
\[ = \frac{FP + FN}{FP + FN + TP + TN} = \frac{1 + 0}{1 + 0 + 69 + 5} \times 100\% = 1.33\% \]

Table 4 Diagnostic properties of FNS and FNAC as compared to histology

<table>
<thead>
<tr>
<th>Properties</th>
<th>Biopsy Techniques, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FNS</td>
</tr>
<tr>
<td>SENSITIVITY</td>
<td>83.3</td>
</tr>
<tr>
<td>SPECIFICITY</td>
<td>100</td>
</tr>
<tr>
<td>POSITIVE PREDICTIVE VALUE (PPV)</td>
<td>100</td>
</tr>
<tr>
<td>NEGATIVE PREDICTIVE VALUE (NPV)</td>
<td>98.6</td>
</tr>
<tr>
<td>DIAGNOSTIC ACCURACY</td>
<td>98.7</td>
</tr>
<tr>
<td>DIAGNOSTIC ERROR</td>
<td>1.33</td>
</tr>
</tbody>
</table>

The two tests had the same sensitivity, specificity and diagnostic accuracy of 83.3%, 100% and 98.7% respectively.
Table 5 Smear characteristics by Biopsy Techniques

<table>
<thead>
<tr>
<th></th>
<th>FNS N (%)</th>
<th>FNAC N (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>85 (100)</td>
<td>85 (100)</td>
<td></td>
</tr>
<tr>
<td>Quality</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>75 (88.2)</td>
<td>50 (58.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Poor</td>
<td>10 (11.8)</td>
<td>35 (41.2)</td>
<td></td>
</tr>
<tr>
<td>Adequacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate</td>
<td>81 (95.3)</td>
<td>77 (90.6)</td>
<td>0.1490</td>
</tr>
<tr>
<td>Inadequate</td>
<td>4 (4.7)</td>
<td>8 (9.4)</td>
<td></td>
</tr>
</tbody>
</table>

FNS had good quality smears in 75 (88.2%) of patients as compared to FNAC which had in 50 (58.8%).

FNS smears were adequate in 81 (95.3%) of the patients as compared to FNAC which had 77 (90.6%) of adequacy.
CHAPTER SIX

6.0 DISCUSSION

6.1.0 Study population characteristics.

The study population characteristics in this study did not show any significant variations with data from other studies. However, one study by Fleming N.T et al showed a peak age of 30-34 years and predilection to race. Majority of the population in the current study is young and not married yet and may be because they have good health seeking behavior. Since the study was done in Buganda, that may explained why Ganda comprised the majority of the patients in this study. No study in Uganda has described tribal predilection to breast lumps.

6.2.0 Association between histology and lump characteristics

6.2.1 Lump size

The size of breast lumps has significant influence on FNB outcomes. In this study this was not the case. Study done by Jombwe et al in Kampla and Franzens S et al showed statistical significance. The findings in this study may be attributed to the small sample size. However, the indeterminate results were still got from breast lumps of 2-5 cm in the widest diameter.
6.2.2 Lump location

The location of breast lumps and their distribution vary greatly among patients. However in this study, the majority of the breast lumps were found in the upper outer quadrant, and all the malignant lumps were found in this quadrant which was statistically significant (p-value = 0.029). These findings are in support of data from other studies \(^1,33,34\). This may be because most of the breast tissue is in the outer quadrant. However one study \(^17\) found that most cancers were beneath the nipple and this is not unusual.

6.2.3 Lump tenderness, margin and mobility.

The breast lump tenderness, irregularity of the margins and immobility may give you a clue of what type of lump one is dealing with. The current study demonstrated a clinical correlation of these clinical findings with malignancy with p-values = < 0.001. Findings were similar to study by Jombwe et al\(^{17}\). However, usually most malignant lumps are non tender, but if there is inflammation they may become tender and also because of the adhesions from the inflammation, the lump margins are irregular and are fixed to the surrounding tissues as it is in this case.
6.3.0 Calculation of the sensitivity, specificity and accuracy of FNS and FNAC. This study demonstrated significantly a high diagnostic accuracy of both FNS and FNAC as compared to Raghuveer CV et al\textsuperscript{6} who found the diagnostic accuracy of FNS to be 70.4\% and that of FNAC as 86\%. Also similar findings were obtained by Dey et al\textsuperscript{9}, Kumarasinghe et al\textsuperscript{10}. However Jombwe et al\textsuperscript{17} and Frable et al\textsuperscript{31} did similar studies, though with FNAC alone, they found the diagnostic accuracy of FNAC as high as (98.1\% and 94.4\% respectively) as that found in this study (98.7\%). Also a study done by Rajasekhar et al\textsuperscript{28} who compared the two techniques, FNS and FNAC for lymph nodes, found that the diagnostic accuracy of FNS was 95.3\% greater than FNAC. These differences may be attributed to the fact that the previous studies\textsuperscript{6,9,10} had results of subanalysis. The previous studies\textsuperscript{6,9,10} seem to agree that FNS is better for cancers than FNAC due to associated fibrous stroma in the benign lesions which require aspiration, but in this study it was not the case. Therefore the current study demonstrated high diagnostic accuracy of FNS consistently with other studies irrespective of whether it is breast lumps or other superficial masses.

The false negative rate of 1.43\% is acceptable compared to other studies\textsuperscript{5,17} ranging from 1.7-19\% and also a low diagnostic error of 1.33\% as supported by previous data from Jombwe et al\textsuperscript{17}, whose diagnostic error was 1.90\% for FNAC.
6.4.0 Distribution of smear characteristics with biopsy techniques.

In this study, we found that, FNS had good quality smears (smear cells which are not obscured by blood) as compared to FNAC. This is similar to data from Bhattacharya S et al, Misra M et al, Kumarasinghe MP et al studies⁷,⁸,¹⁰, but we also found that, the adequacy of cells (moderate or abundant epithelial cell clusters) in both FNS and FNAC was the same. This is contrary to the above studies⁷,⁸,⁹ which found that FNS had more adequate cells harvested than FNAC. These findings may suggest that it is probably the adequacy of the cells harvested rather than the quality of the cells harvested which determines the difference in the diagnostic accuracy of the two techniques. This could explain why FNS and FNAC in this study had the same diagnostic accuracies since the difference in the adequacy of cells harvested was not statistically significant. This therefore disproves the statement that because FNS has better quality of cells, it is expected to have higher diagnostic accuracy than FNAC. Also the fact that in the studies above⁷,⁸,¹⁰, it is not clear if the cytopathologist was blinded or not which could have caused bias in assessment, but it was not the case in this study. Therefore this probably suggests that the findings in this study may not be by chance.
CHAPTER SEVEN

7.0 CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

There is no difference in the diagnostic accuracy of FNS and FNAC in the diagnosis of palpable breast lumps.

Both FNS and FNAC have the same sensitivity and specificity in the diagnosis of palpable breast lumps.

Although FNS had good quality smears as compared to FNAC, there is no difference in adequacy of smears provided by both FNS and FNAC.

RECOMMENDATIONS

FNS is an accurate diagnostic tool in the management of palpable breast lumps and may be employed over FNAC.

Further research is needed as regards the patients’ acceptability and discomfort of FNS without aspiration and FNAC in the diagnosis of palpable breast lumps.

There is need to carry out the same research with a large sample size so as to generalize the research findings.
REFERENCES


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16. Templeton A.C (1971), Tumors of breast in Uganda; *Association of Surgeons of East Africa Conference, Kampala, Uganda, Dec, 1971*


30. Douglas G Altman, Sample size, Practical statistics for medical research, 455-460; 1999


34. Ojara, EA (1976). Cancer of the breast in Mulago Hospital. MMED Dissertation Makerere University 1976


APPENDIX 1:

CONSENT FORM

Dr. Alema Onira Nelson, a graduate student of the Department of Surgery Makerere University is carrying out a study to compare fine needle aspiration cytology versus fine needle sampling without aspiration in the diagnosis of palpable breast lumps in Mulago hospital.

Informed Patient Consent

I am informed that this study is being done as partial fulfilment for the award of the degree of Masters of Medicine (Surgery) for the Principal investigator. Before I agree to participate in the study, I must understand its purpose, how it may help me and any risks to me and what is expected of me as part of the study.

Purpose of the study

To determine if there is a difference in diagnostic accuracy in using FNS without aspiration and FNAC in patients with palpable breast lumps undergoing breast biopsy in Mulago National Referral and Teaching Hospital

Risks to me as a participant

Complications expected include: pain, minor bleeding, swelling at the site of procedure, infection at the operation site and anaesthetic complications in case of Mastectomy.
Benefits to the participant

Participants will benefit by having their biopsies of the breast lumps processed and availed to them faster for further management by their clinician.

Confidentiality

All the information obtained will be kept confidential to myself, and will only be used for the purpose of this study.

Questions

Participants of the study are free to ask questions or seek any clarifications about the study from the PI, at any time without hesitation or fear.

Telephone contact: **0772-386012. (Dr Alema Onira Nelson).**

For any Ethical issues regarding the study, you can contact the Chairman of the Faculty of Medicine Research and Ethics Committee for any clarifications.

Telephone Contact: **0772-437351. (Dr Charles Ibingira)**

Rights to withdraw from the study

The participant is free to withdraw from the study without being denied any medical care.

You will be provided with a copy of the consent form if you so wish.

STATEMENT OF CONSENT

I have the information above and understood the contents. I have been fully explained the nature and purpose of the study, risks and benefits in a language I understand. I also understand that I can withdraw from the study at any time and this will not affect my rights to receive medical care.
Sample storage.

I do understand that the samples taken from my breast may or may not be kept in the Department of Pathology after processing and analysis for further studies with my full knowledge. Therefore I do or do not (Cross out as appropriate) accept my sample to be kept in the department of Pathology for further studies.

I hereby sign for myself/my daughter (Cross out as appropriate) as a proof to participate in the study.

Name ..........................................................................................................................

Signature/thumb print..................................................Date........................................

Witness. Name............................................................................................................

Signature/thumb print..................................................Date........................................

I have explained the purpose of the study to the participant to the best of my knowledge and she has fully understood the purpose, benefits and risks to her.

Signature .................................................................Date........................................

(Principal Investigator).
APPENDIX II

CHILD ASSENT FORM

I, .......................................................... understand that my parents
(mom and dad)/ guardian have/has give permission (said is okay) for me to take part in
the study “comparison of fine needle aspiration cytology and fine needle sampling
without aspiration in the diagnosis of palpable Breast lumps in Mulago Hospital”
by Dr Alema Onira Nelson.
I am taking part because I want to. I have been told that I am free to withdraw from the
study without being denied any medical care.

Minor’s Signature.................................Age........Years. Date......................

Witness ......................................................Date...........................................

(Parents or Guardian)
EKIWANDIKKO EKIRAGA OKUKIRIZZA OKWETABA MUKUNONYEREZA

Nze Dr. Alema Onira Nelson, omuyizi mu tendekero lyokulongosa mu Makerere Univasisite era nga ndimukukola kunonyereza nga ngerageranya enkoola bbiri ezokugyibwaako olusaayi otwokeberebwa mu balwadde abalina ebizimba mu mabere mu dwaliro lye mulago.

Enyajula

Ntegezeddwa nti okunonyereza kuno kukolebwa nga ekyetaggo kya diguri eya masters eri oyo anonyereza.Nga sinakiriza nina okutegeera ekigendererwa, engei gyenganyurwam, obuzibu obuyinza okubaawo ne netagiisa nze ng’omu kwabo abaali mukunonyereza.

Ekigendererwa

Kugerageranya enkola ebbiri ezokugyibwaako olusaayi ku bizimba byamabere mu balwadde abomudwaliro lye mulago.

Obuzibu obuyinza okubaawo

Tewaali kizibu kyamanyi, naye wayinza okubawo okulumizibwa okutonotono, okuvaamu oyusayisayi n’okuzimba awo ewakoredwakko.

Byenganyulwam

Nja kufuna ebivuude mu kukebera olusayisayi mumangu ddala era ekyo kinyambe okufuuna obujanjabi amangu

Byoona ebinkwattakko bija kumibwa nga byakyaama era bijjakukozesebwa ukunonyereza kunno kwokka.
Ebibuuzo

Ndiwadde mbe okubuuza kyembasitgedde okuva eri akuliira okunonyereza kuno obudde bwoona kusiimu ye eno; 0772-386012 (Dr Alega Onira Nelson)

Ebyo byonna ebikwatta kudemmbbe lyange mukunonyereza kuno ndi wadde mbe okubuuza akuliira akakikko ke somero lyabasaawo akalondola abanonyereza dokita Charles Ibingira kusiimu eno empereddwa; 0772-437351.

Eddembe lyange ong’omuntu

Ndiwadde mbe okubivaamu ate nesitukibwakko kintu kyona gamba nga okumimwa obujanjabi.

Nja kuwebwa kopi yekiwandikko kino bwemba nga njagadde.

Okuterekebwa kwebinzigyidwakko.

Ntegedde mbe ebinzidwakko okuva kubere biyinza okuterekebwa mu kitongole kya Pathology bikoze sebwe mukunonyereza mumaaso. Nolwekyo nzikirizza/sikiriza (sazamum nga bwekyetaggisa) okutereka era nokoze sebwe mukunonyereza mumaaso ebinzigyidwakko.

OKukirizza okwetta bh mukunonyereza

Ntegezedwa era ntegedde bulungi ebipendererwa byokunonyereza kuno, ebuzibu obujinza okubawo mululimi lwentegetera.Ntegezeddwa mbe nsoboola okubivaamu ne sifuuna kubonerezebwa kwoona gamba nga obutafuuna bujanjabi. care. Ndi waddedbe okukiriza ebinzigyidwakko okuterekebwa okukoze sebwa momaaso oba nedda.

Erianya .......................................................... ..........................................................

Omukono/Ekinkumu..........................Date..........................
Abaddewo

Omukono/Ekinkumu Date

Nkoze kyoona ekisooboka oknyonyola ekigendererwa kyokunonyercza kuno eri oyo akwetabyemu era attegedde bulungi ekigendererwa, obuzibu obuyinza okubaawo ne byanaganyulwaamu.

Omukono Date

(Anonyereza).
APPENDIX II

EKIWANDIKKO EKY’ABO ABATANETTUKKA

Nze, ..............................................................ntgedde nti azzadde bangc banzikirriza okwettaba mukunonyereza kuno okwokugerageranya enkoola bbiri ezokugyibwaako olusaayi otwokeberebwa mu balwadde abalina ebizimba mu mabere mu dwaliro lye mulago okukulirwa dokita Alema Onira Nelson.

Netabyemukunonyerezza lwakwaggala kwange. Ntegezzedwa nti ndiwaddembe okuvamu ate nesibonerezzebwa mungeri yonna nga obutafunna bujanjabi.

Omukono/ekinkumu................................................emyaka.......Years.

Date.................

Abaddewo(omukono/ekinkumu)...........................................Date...............
APPENDIX III: QUESTIONNAIRE

FINE NEEDLE ASPIRATION CYTOLOGY VERSUS FINE NEEDLE SAMPLING WITHOUT ASPIRATION IN THE DIAGNOSIS OF PALPABLE BREAST LUMPS IN MULAGO HOSPITAL.

A. DEMOGRAPHIC DATA

1. Name ........................................ Date ........................................
2. Study number ............................... IP/OP No ..............................
3. Tribe ........................................ LAB No ..............................
4. Address ..................................... (Village) ............................... (District)
5. Marital status
   1= Single
   2= Married [ ]
   3= Divorced

B. RISK FACTORS

6. Menarche ................................. (Years)
7. Parity ........................................
8. Gravidity.
   1= yes
   2= No [ ]
9. Lactation
   1= yes
   2= No [ ]
10. Hormonal contraception use
    1= yes
    2= No [ ]
11. Menstruation
    1= premenstrual
    2= postmenstrual [ ]
12. Age at 1st conception .......................... (Years)

13. History of breast cancer in the family
   1= yes
   2= No

14. If yes
   1= mother
   2= sister
   3=Aunt
   4= others (specify)..........................

15. Early breast disease

   1= yes

   2= No

16. If yes

   1= cancer
   2= abscess
   3=mastitis
   4= fibroadenoma
   5= cysts
   6= others (specify)..........................
C. CLINICAL PRESENTATION

17. Presenting complaints

Lump in the breast [ ]

Axillary swelling [ ]

Nipple discharge [ ]

Nipple retraction [ ]

Pecaud’orange [ ]

Others (specify) .................................................................

18. Breast lump

A). Size (cm) [ ]

1= 2-5

2= >5

B). Side [right] [left]

C). Location

1= UOQ

2= UIQ

3= LOQ [ ]

4= LIQ

5= beneath the nipple
D). Tenderness

1 = yes  [    ]  
2 = No   [    ]

E). Mobility

1 = yes  [    ]  
2 = No   [    ]

F). Consistency

1 = soft

2 = cystic

3 = firm  [    ]

G). Margins

1 = regular

2 = irregular  [    ]

19. Axillary nodes

1 = yes

2 = No  [    ]

If yes

a) mobility

Free

Fixed  [    ]

b) Location
1 = Apical
2 = Central
3 = Posterior
4 = Pectoral

20. Evidence of metastatic disease
1 = Yes
2 = No

D. RADIOLOGY

21. Radiological (ultrasound)

1 = Benign
2 = Malignant

E. ASPIRATION TECHNIQUES

<table>
<thead>
<tr>
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<th>FNS</th>
<th>FNAC</th>
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<tbody>
<tr>
<td>22. Smear quality</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>1 = Good</td>
<td></td>
<td></td>
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<tr>
<td>2 = Poor</td>
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<tr>
<td>23. Smear result</td>
<td>[ ]</td>
<td>[ ]</td>
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<tr>
<td>1 = Adequate</td>
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2 = Inadequate

24. Cytological diagnosis

C1 = Inadequate
C2 = Benign
C3 = atypical
C4 = Suspicious of malignancy
C5 = Malignant

If Benign

1 = Fibroadenoma
2 = cyst
3 = breast abscess
4 = Lipoma

F. EXCISIONAL BIOPSY RESULT

25. Histology

1 = Benign
2 = Malignant