TOPIC:

EFFICACY OF FINE NEEDLE ASPIRATE BIOPSY IN DIAGNOSIS OF HEAD AND NECK MASSES IN KENYATTA NATIONAL HOSPITAL

BY

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A dissertation submitted in part fulfillment of the requirements for the degree of Master of Medicine in Ear Nose and Throat-Head and Neck Surgery in The University of Nairobi.

2003
DECLARATION

This work is original and has not to my knowledge been submitted for a degree in any other University.

Signature

DR. MWANGI M. JONAH

This dissertation has been submitted for examination with my approval as the university supervisor.

Signature

Prof. H.O. Oburra; Associate Professor of Surgery U.o.N.
DEDICATION

To,

My dear beloved mother Damaris Wanjiku for her tireless and single handedly dedication to our education, my wife Catherine her very understanding during the hard times in my postgraduate studies and my son Carlton for his lovely smiles oblivious of my torments.
I would like to express most deep felt appreciation to the following:

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2. All my lecturers for their support during my studies and having time to read and correct my proposal.

3. The registrars, consultants, nurses and those working in cytology, histology and records; departments of KNH with whose co-operation I managed to obtain all my cases and results in good time.

4. Mr. Oyugi of KAVI for his excellent assistance on statistics and analysis of my data within a short notice.

5. My sincere gratitude to my fellow colleague and friend Dr. Njoroge Muhoho for his assistance.

6. The Almighty God for giving me sound health, critical understanding, courage and wisdom when doing my study.

7. Those who knowingly or unknowingly participated and helped in making the study be very successful.
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<td>Blood transfusion unit</td>
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<td>CT Scan</td>
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<td>DPX</td>
<td>Dibutyl Phenelyphthaline Xylene</td>
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<td>FNAB</td>
<td>Fine Needle Aspirate Biopsy</td>
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<td>H/E</td>
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<td>HIV</td>
<td>Human Immuno-deficiency Virus</td>
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<tr>
<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<tr>
<td>MPNST</td>
<td>Malignant Peripheral Nerve Sheath Tumors</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<td>NF</td>
<td>Neurofibromatosis</td>
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<td>NPC</td>
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<td>SOPC</td>
<td>Surgical Outpatient Clinic</td>
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<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TDC</td>
<td>Thyroglossal Ductal Cyst</td>
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<td>ZN</td>
<td>Ziehl-Nielsen</td>
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ABSTRACT

Objective: To evaluate the efficacy and role of FNA in the diagnosis of head and neck masses in KNH.

Methodology: A cross-sectional prospective double blind study was done. The cytologist and pathologist did not know the results of either. A total of 141 patients with head and neck masses were inducted and 122 (86.5%) patients were done open biopsy. The results were compared to calculate the correlation of the two procedures.

Results: An overall sensitivity 92.6% for all the head and neck masses was realized in this study. Male patients were 61 and 80 were female forming 43.3% and 56.7% respectively. The commonest age group affected was young adults 16-40 years with inflammatory and salivary gland masses forming 27% and 26.2% respectively. The mean duration to get FNA results was 7.29 days and 19.91 days with a statistical significance of p value < 0.001

Conclusion: The fine needle aspiration biopsy has become an invaluable tool to aid clinicians in the evaluation of the neck masses and is safe, faster, accurate, and cost-effective with minimal complications. The possibility of malignancy in any age group, especially in the late adult group, should never be overlooked. Close follow-up should be adhered to.
INTRODUCTION AND LITERATURE REVIEW

Fine needle aspiration biopsy (FNAB) also known as Fine needle aspiration for cytology (FNAC) or aspiration biopsy is a diagnostic or screening procedure done using a needle size 20-25 mounted on a 5-20ml syringe introduced into the mass or tumor and aspiration of cells or fluid done for cytology. [1] The aspirate is put onto a slide, preserved with 95% alcohol. The smear is stained and analysed by a cytopathologist. [2, 3]

HISTORICAL ASPECTS

FNA for cytological evaluation of a neck mass was first reported by Kun in 1847. However, the procedure did not gain wide acceptance in medicine at that time. [4]

In the 1930s, a pathologist in Memorial Sloan Kettering rediscovered the utility of FNA for evaluation of head and neck masses. The use of large-bore needles at that time led to frequent complications and occasional seeding of tumor along the biopsy tract. [5, 6]

The frequent morbidity associated with this procedure prevented widespread acceptance of this technique in other centers in America. FNA was commonly used for cytological examination of metastatic lesions in the neck with excellent results despite the high morbidity. [7] Since then, FNA of solitary neck masses has become a well-accepted, safe, and cost-effective tool in the diagnosis of head and neck masses. [8]

Its popularity declined in that institution, due to fear of malignant cells spreading along the needle track. Studies later done disputed that belief [14] it was popularized 3 decades ago, by Scandinavian and European investigators. [4]

It is now a firmly established first line diagnostic test for pre-operative or follow up of Head and Neck tumors. [10, 11, 12] Its role in breast [13], thyroid and skin lesions has been studied. But no conclusive study of its value in the diagnosis of head and neck masses in Kenyatta National Hospital has been done [14]. FNAB is relatively a painless, ambulatory procedure. It provides simple, rapid, cost effective, safe, and accurate diagnosis in Head and Neck tumors. [15, 16]
FNAB is used as a screening test and helps in determining the most appropriate treatment eg selection of patients for surgery. Thus, there is a need to carry out a study in Kenyatta National Hospital departments of ENT/HNS and SOPC Thyroid Clinic where head and neck masses are commonly present and FNAB routinely done to help in diagnosis before doing conventional biopsies for histopathology.
RATIONALE OF THE STUDY

Although FNAB value has been shown as a valuable screening and diagnostic tool in head and neck masses in many centers worldwide, its value in head and neck masses at the KNH, a distinct epidemiological set up in the developing world, has not been shown. It’s finding if positive would therefore be expected to facilitate early diagnosis and intervention in management of head and neck masses in our disadvantaged socio-economic set-up. Secondly, it is prudent in medical sciences to test concepts in local set ups before wholesome adoptions for use.

Its findings will help in early diagnosis and intervention of head and neck tumors by ENT surgeons and Radio-oncologists. The study group, will not only enjoy close monitoring but early intervention if need be for the affected cases.

Data collected will be useful in developing guidelines in diagnosis and management of head and neck tumors in ENT department. This study is the first of its kind to be done in KNH to conclusively show the role of FNAB in head and neck tumors.
ANATOMY OF THE NECK

A mass in the neck is a common clinical finding that presents in patients of all age groups. The differential diagnosis may be extremely broad, and although most masses are due to benign processes, malignant disease must not be overlooked [7, 10]. Therefore it is important for physicians to develop a systematic approach for developing a working diagnosis and management plan for the patient.

The prominent landmarks of the neck are the hyoid bone, thyroid cartilage, cricoid cartilage, trachea, and sternocleidomastoid muscles. In females, the cricoid cartilage is often the most palpable laryngeal structure, whereas in men, the thyroid cartilage is most easily palpable. The SCM divides each side of the neck into two major triangles, anterior and posterior. The anterior triangle is delineated by the anterior border of the SCM laterally, the midline medially, and the lower border of the mandible superiorly. The anterior triangle can be further divided into the inferior carotid (muscular), superior carotid, submandibular and submental triangles.

The borders of the posterior triangles are the posterior border of the SCM anteriorly, the clavicle inferiorly, and the anterior border of the trapezius muscle posteriorly. The omohyoid muscle divides this triangle into the subclavian and occipital triangles. The splenius capitus, levator scapulae and scalene muscles form the floor of the posterior triangle.

The carotid bulb can be palpated near the anterior border of the SCM, near the level of the hyoid bone. In slender persons or those with significant atherosclerosis, it can be mistaken for an abnormal mass, especially when asymmetric. [12]

The lymphatic flow in the normal neck follows a predictable pattern and the presence of a mass in a lymphatic nodal chain location may offer clues to identifying a primary tumor or site of infection. It is convenient to use the level system to describe the location of lymph node disease in the neck as classified by the Sloan-Kettering Memorial Group. [12, 17]
Diagnostic Steps

Evaluation of the patient with a neck mass must begin with a careful and complete history and a thorough head and neck examination. A thorough review of the developmental time course of the mass, associated symptoms, personal habits, and prior trauma, irradiation or surgery is important. Inquiries about smoking and alcohol use, fever, pain, weight loss, night sweats, exposure to tuberculosis, foreign travel and occupational/sexual history should be made. In the late adult patient, symptoms of dysphagia, otalgia, and/or hoarseness with a smoking history most likely represent a neoplastic process. [18]

The examiner should not pay undue attention to the neck mass neglecting the complete examination of the head and neck. All mucosal surfaces of the nasopharynx, oropharynx, larynx and nasal cavity should be visualized by direct examination or by indirect mirror or fiberoptic visualization. The oral and pharyngeal surfaces should be digitally palpated in addition to the neck mass.

Emphasis on location, mobility and consistency of the neck mass can often place the mass within a general etiologic grouping, such as vascular, salivary, nodal/inflammatory, congenital or neoplastic.

A tender, mobile mass or a high suspicion of inflammatory adenopathy with an otherwise negative examination may warrant a clinical trial of antibiotics and observation not to exceed two weeks with close follow-up. [19]

General Considerations

The first consideration should be the patient’s age group. Three main age groups need to be considered:

1. Pediatric (0 to 15 years),
2. Young adult (16-40 years)
3. Late adult (above 40 years) and the elderly.
In general, neck masses in children are more commonly inflammatory than congenital or developmental and more commonly congenital than neoplastic. This distribution is similar in the young adult. However, the first consideration in the late adult should be neoplastic. The “rule of 80” is often applied, which states that 80% of non-thyroid neck masses in adults are neoplastic and that 80% of these masses are malignant. [7] A neck mass in a child, on the other hand, has a 90% probability of being benign.

The next consideration should be the location of the mass. The location of the mass is particularly important with respect to congenital and developmental masses, because such lesions are consistent in location. For metastatic neck masses, their location may be the key to identification of the primary tumor. It is important despite the general considerations of age and location to treat each case individually. [38]

**Diagnostic studies**

Fine Needle Aspiration Biopsy (FNAB) - currently, FNAB is the standard of diagnosis for neck masses and is indicated in any neck mass that is not an obvious abscess and persists following prescribed antibiotic therapies. FNAB separates inflammatory and reactive processes that usually do not require surgery from neoplastic lesions, either benign or malignant. [7] It also may allay patient fears for malignant disease and helps the clinician differentiate carcinoma from lymphoma, which can prevent unnecessary panendoscopy. [20, 21]

There are no contraindications to FNAB. Pulsatile neck masses may represent a carotid body tumor, and although many clinicians prefer not to biopsy this lesion, the fine gauge of the needle reduces bleeding complications. [10] Needle track seeding of tumor is not a concern with the fine needles used today. [5] FNAB can also be performed in children, however, in a child younger than 2 years of age, immobilization may be necessary. Children ages 2 to 7 can be sedated, and children above age 7 are fairly cooperative. With thyroid aspiration in the pediatric population, it is preferable to have the child asleep. [22, 30, 31, 39]

A skilled cytopathologist is critical to the efficacy of FNAB. On-site evaluation carries the advantage of assessing specimen adequacy, which reduces the number of unsatisfactory
specimens. When a cytopathologist is not available on-site, the clinician may perform the FNAB and send the fixed slide to a regional specialist for review. In these circumstances, a minimum of four separate needle passes and preparation of smears of good quality produce optimal results. [8]

**OTHER DIAGNOSTIC TESTS THAT FACILITATE EVALUATION BY FNAB**

1. **Ultrasonography**

With the current accuracy of FNAB, this study has become less important in the work-up of the neck mass. However, it is sometimes useful in differentiating solid from cystic masses and congenital cysts from solid lymph nodes and glandular tumors as guided FNAB. [21, 27]

2. **Radionucleotide Scanning**

This imaging technique can differentiate a mass from within a gland from one outside a glandular structure and can also indicate the functionality of the mass. This is particularly important for salivary and suspected thyroid gland masses. The FNAB is now preferred in the evaluation of thyroid nodules and is currently indicated for solitary thyroid nodules, multinodular goiters with a new increasing nodule and patients with Hashimoto’s who develop a new nodule. [21,23,24,25,26]

3. **Computed Tomography**

CT scanning of the neck has become a very helpful tool in diagnostically difficult cases. It can distinguish cystic from solid lesions, define the origin and full extent of deep, ill-defined masses, and when used with contrast can delineate vascularity or blood flow. [27] Patients with metastatic SCC to the neck from an unknown primary, CT should be obtained to detect an unknown primary lesion and to help with staging purposes. Lucent changes within nodes, size larger than 1.5cm, and loss of sharpness of nodal borders are often signs of metastatic carcinoma. [47]
Contrasted CT should be withheld in the suspected thyroid lesion is to avoid administering iodinated material that could later interfere with radioactive-iodine imaging studies or therapy. [21,28]

4. Magnetic Resonance Imaging

MRI provides much of the same information as CT. It is currently better for upper neck and skull base masses due to motion artifact on CT. With contrast it is good for vascular delineation and may even substitute for arteriography in the Pulsatile mass or mass with a bruit or thrill. [21,29]
FNA IN PEDIATRICS

Neck masses in children differ from those in adults. Children present more frequently with reactive, inflammatory lymphadenopathy. Primary or secondary malignant involvement is uncommon in children. Unfortunately, the literature on FNA in children is limited by small study size and varying results. Few studies have examined the utility of FNA in children with masses in the head and neck. [30,31]

In 1991, Silverman and colleagues examined 135 FNA specimens from multiple body sites in children. FNA had a sensitivity of 90.6%, a specificity of 100%, and a positive predictive value of 100%. They concluded that FNA allowed definitive diagnosis and therapy for malignant and/or infectious lesions in children. [22] These conclusions cannot be carried over to head and neck lesions, as only 7 FNA specimens were from the head and neck. However, the results lend support for further investigation of FNA for the diagnosis of head and neck masses in the pediatric population. Mwanda et al FNA in pediatrics and showed 70% accuracy for Burkitts lymphoma, 100% neuroblastoma. There was no false positive thus patients were not started on cytotoxics drugs for wrong diagnosis. [31]

ADVANTAGE OF FNA OVER OPEN BIOPSY

FNA has several advantages over excisional biopsy. In today's economic environment, cost savings is an important consideration in medicine. The cost of FNA is also more convenient for patients and their families. [1] The procedure requires only an office visit with minimal loss of time from work. On the other hand, excisional biopsy often requires time off from work, preoperative blood tests, and often, radiographic and cardiac testing. [5, 9]

Excisional biopsy also may interfere with further treatment. Incorrectly placed biopsy incisions may interfere with neck dissection and/or tissue oxygenation, to the detriment of radiotherapy. These complications included compromise of later tumor resection, extra excision of skin and adjacent soft tissue, tumor fungation, and local recurrence in the neck wound after surgery. [8]
LIMITATIONS OF FNA

FNA for head and neck masses has several limitations. [32] Failure to establish an accurate diagnosis may be due to sampling error. In these circumstances, repeat aspiration is suggested, and excisional biopsy may be considered. Personnel responsible for handling, processing (experienced cytotechnologist), and reading (cytopathologist) FNA samples must be well trained. Interobserver variability must be minimized. [34] Peters and colleagues in 1989 demonstrated an interobserver variability of 8% in diagnosis of FNA specimens, with a specificity of 96% and a sensitivity of 97%. [33] FNA was most accurate at diagnosing epithelial cysts and epidermoid malignancies. FNA was least effective at distinguishing lymphoid hyperplasia and chronic inflammation from lymphoma. [24]

GENERAL RESULTS OF FNA

As mentioned in the beginning of the chapter, FNA has gained renewed interest in the diagnosis of neck masses. [33] Scandinavian successes with FNA have been replicated by several large American studies for the head and neck. [4] Frable and Frable reviewed the success of FNA in 567 patients with neck masses. FNA had false-negative and false-positive rates of 2.1% and 0.7%, respectively. [34] Another study of 1300 aspirates demonstrated that FNA was 92% sensitive for neoplasms and 98% specific for the absence of tumor. Most importantly, no radical treatment resulted from false-positive diagnoses, and no treatment delays resulted from false-negative diagnoses. [32]

However, not all studies demonstrate such impressive results. Guyot and colleagues in 1990 reported FNA accuracy in diagnosis of only 80% with head and neck masses. FNA was nondiagnostic in 10% of aspirates, and false-negative rates exceeded 10%. [10]

Muchiri et al showed FNA to be accurate, rapid and procedure in breast lumps. In their study they had 71% true positive, 85% true negatives and 95% accuracy in differentiating benign from malignant lesions. [16] Although FNA is 98% specific for the absence of tumor and 95% sensitive for the presence of tumor in neck masses, improper diagnosis is commonly associated with lymphoma and lymphadenitis. [19, 31, 35]
MAIN OBJECTIVE OF THE STUDY

To evaluate the efficacy/role of FNAB in comparison to paraffin histological sections in diagnosis of head and neck masses.

SPECIFIC OBJECTIVES

1. To do FNA biopsy in all head and neck masses and correlate with open biopsy.
2. To show efficacy of FNAB in classification of head and neck masses.
3. Show demographic pattern of head and neck masses; age, sex, residence and site of mass at presentation
4. To document short falls in FNA and open biopsy in head and neck masses and to determine the length of time taken between FNA and open biopsy and obtaining results.

THE STUDY HYPOTHESIS

Null hypothesis: FNAB is not efficacious in diagnosis of head and neck masses at KNH.

Alternative hypothesis: FNAB is efficacious in diagnosis of head and neck masses at KNH.

STUDY METHODOLOGY

LOCATION

The study site was at the various clinics of KNH eg ENT and H/N, Thyroid and Dental clinics.

MEDICAL LIBRARY UNIVERSITY OF NAIROBI
STUDY DESIGN

It was a crosssectional prospective double blind study. The cytologist and pathologist did not know the results of either. Qualified cytopathologist/ pathologist who at the same time taught me how to do the procedure, did the FNA at the FNA room near BTU.

STUDY POPULATION

All patients with head and neck masses sent for FNA in ENT Clinic and Thyroid clinic or from other departments and wards in KNH. The principal investigator interviewed and informed consent sought for inclusion in the study. Those who met the criteria were inducted and their details entered in the study proforma.

Thorough history was taken and physical examination done.

FNAB was done on all head and neck masses before conventional open/ excisional biopsy on the mass or primary site. Both results were compared.

Inclusion criteria:

- All patients referred to the ENT or thyroid clinic for FNA of head and neck masses.
- Patients referred with FNA results to ENT clinic for open biopsy from other units within KNH.
- Patients suspected to have metastatic tumors to cervical lymph nodes.
- Patients from other departments for FNA or open biopsy with head and neck tumors within KNH.

Exclusion criteria:

- Patients suspected to have vascular disorder e.g. aneurysms, hemangiomas or carotid body tumors.
- Those patients or guardians who declined to be inducted in the study.
- Patients with ulcerated head and neck masses
SAMPLE SIZE AND DURATION OF STUDY:

The sample size was determined using the formula: [36,38]

\[ n = \frac{Z^2 \alpha/2 \cdot p(1-p)}{d^2} \]

Where \( n \) = minimum sample size acceptable to the study.

\( Z \) = standard errors from mean corresponding to 95% confidence level.
\( \alpha \) = level of significance.
\( p \) = efficacy of FNA (85%).
\( d \) = absolute precision (5%).
\( Z^2 \alpha/2 \) = 1.96

In this study the minimum acceptable sample size was 138 patients. On average the number of patient done FNA in one week were 12, thus it took a period of 3 months to collect enough data for analysis. But in this study the total of 141 patients were inducted and followed up.
Materials required:

- 21-23 gauge fine needle.
- Ten or five ml syringe.
- Clean pairs of gloves.
- Slide carrying container.
- Glass slides for putting aspirate.
- 95% alcohol to fix the slide.
- Stains: Pap stain, H&E and MGG.
- Container for sharp disposal.
METHOD OF FNA PROCEDURE

FNA is a simple office procedure requiring a few minutes to complete. If cytotechnologist and pathologists are available, diagnosis can often be made the same day. The most important step in FNA is patient positioning. The patient is positioned to allow the most optimal digital palpation of the mass. A 21-gauge needle is commonly used. Larger needles may be used, but they involve a higher risk of complication, including tumor seeding. [5] The skin overlying the mass is prepared with a prepackaged, sterile, alcohol prep sponge containing 70% isopropyl alcohol. For right-handed surgeons, the mass is grasped with the left hand and held in a fixed and stable position. Topical or infiltrative anesthesia is not recommended unless the patient is anxious or a child. A 20-cc disposable syringe with an attached 21-gauge needle is placed just under the skin surface. [27]

Negative suction is applied to the syringe. Adequate negative pressure (-300 cm H2O) is created and maintained with the syringe plunger pulled back to 10 cc. The mass is entered, and multiple passes are made without exiting the skin surface. Approximately 6 passes through the mass are recommended. If a cyst is encountered, it should be completely evacuated, and fluid and capsule should be sent for cytology. The vacuum on the syringe is then released, and the skin is exited.

A small drop of aspirated fluid is placed on a glass slide. A smear is made by laying another glass slide on top of the drop of fluid and pulling the slides apart to spread the fluid (see photographs 1 & 2). Wet smears are placed in 95% ethyl alcohol and treated with the Papanicolaou technique and stains. These stains offer excellent cellular detail and may indicate the cellular origin of metastatic tumor. Specimens should be air dried and prepared for Wright-Giemsa stain when the differential diagnosis includes salivary, lymphoproliferative, and/or fatty tumors. Several common technical errors lead to inadequate specimens, as follows:

(1) Aspirating a mass without a syringe holder.

(2) Aspirating a mass without moving the needle back and forth through the specimen.

(3) Aspiration of air after the biopsy is completed and the needle is withdrawn, allowing the specimen to be lost in the syringe.
(4) Other non-technical errors of specimen collection include the collection of necrotic and/or fibrotic specimens. [23]

Photograph 1 showing the smear technique for plating a sample aspirate. After a small drop of fluid is placed on a glass slide, a second slide is used to smear the aspirate evenly over the surface of the slide. The slide is then prepared for cytological evaluation.

Photograph 2 showing an aspirate being placed on glass slide. After the 20-cc disposable syringe with an attached 21-gauge needle is placed under the skin surface and the mass is aspirated, a small drop of aspirated fluid is placed on a glass slide.
PROCEDURE OF PREPARING SECTIONS FOR HISTOPATHOLOGY

Specimens from open or incision biopsy are preserved in formalin and taken to the histology laboratory well labeled. In the laboratory the technologists put the specimen in three changes of formalin 30 minutes each for proper fixation. Dehydration of the specimen is done using ascending order of alcohol concentration 70%- 90%. For the tissues to mix with paraffin wax its put in two changes of chloroform, first one hour and second for three hours.

To provide internal support to the tissue it is put in two changes of paraffin wax. Cooling the wax into blocks for easier sections provides external support. The blocks are mounted on microtome machines and using microtome knife thin sections of less than 5 micrometer are made.

The thin slices are mounted on the slide and melting the wax in the oven does de-waxing. De-waxed slide is put in xylene to remove all the wax. The prepared slide is stained routinely with H/E stains or other special stains eg Giemsa, ZN and others. Cover glass is mounted on the stained tissues using DPX. [29]

Finally the prepared slide is read and reported by the pathologists.
ETHICAL CONSIDERATIONS:

Informed consent was obtained from all patients before induction into the study. The patient or guardian gave the consent voluntarily. The study was done after being approved by Ethical Committee of KNH. Results arising from the FNA and open biopsy were treated as confidential. Both results were communicated to the patients and counseling done. Not all patients were done open biopsy eg confirmed TB adenitis, non Hogkins lymphoma as treatment was given on the basis of FNA results.

Patients were treated using conventional modalities after FNA or open biopsies results. Any complications were to be accorded appropriate treatment. The patients were not to incur any extra cost, as FNAB is the first line of investigation for patients with head and neck masses.

Patients who had open/ excisional biopsy done on them were covered with analgesics and antibiotics. The results of the study were published and made available for use by members of medical fraternity.
RESULTS

A total of 141 aspirates for cytology of head and neck masses were done in the study. Histology was done in 122 cases (86.5%). Data was analysed using statistical program for social sciences (SPSS version 11) and the results were as follows: salient finding about the results are presented at the beginning of the discussion.

There were 61 (43.3%) males and 80 (56.7%) females (fig.1) forming a ratio of 0.7:1. Majorities were female possibly because large percentages were thyroid masses.
Those inducted in the study were of the age ranging from 1 1/2 months to 84 years with a median age of 27 yrs. The commonest age group with head and neck masses was 16-40 years (56%). This was because of inflammatory disorders, thyroid masses and salivary tumours, which are common in the young adults.
41.1% of patients seen for FNA with head and neck masses were from central province, followed by Eastern province (fig.3) possibly because of the proximity to KNH.
27% of cases were found to be inflammatory disorders eg. TB adenitis, parotitis, cervical adenitis and abscesses due to HIV infection. 26.2% (fig.4) of diagnosis made was salivary tumours making the 2nd commonest head and neck masses in our study.
Most of the patients 52.5% were not done any other investigation other than the baseline investigation eg. total blood count, urea and electrolytes before being taken to main theatre for excisional biopsy.
Most of our patients (86.5%) done FNA and open/ excision biopsy were in good general condition. There was no need to do other investigations other than the blood parameters for excision biopsy.
95.1% of all open biopsy done there was no complication. However 2.4% and 0.8% had facial nerve and vocal cord paralysis post superficial parotidectomy and thyroidectomy respectively. Thus need to look at these complications separately after those procedures in KNH.
There is a tendency of the sensitivity of FNA to increase with the size of the mass.
Table 1: Sensitivity of FNA in head and neck masses

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<th>FNA</th>
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<tr>
<td>Negative</td>
<td>9</td>
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<tr>
<td>Total</td>
<td>122</td>
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Sensitivity = 92.6%

Table 2: diagnosis by FNA of groups of head and neck masses and their sensitivity

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<th>Diagnosis</th>
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Table 3: Durations taken for the results of FNA and open biopsy.

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>142</td>
<td>7.29</td>
<td>3.98</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>FNA/ days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>122</td>
<td>19.91</td>
<td>9.22</td>
<td>5</td>
<td>56</td>
</tr>
<tr>
<td>open biopsy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It took a minimum of one day for FNA result to be out compared to 5 days for open biopsy. Mean duration 7.29 days for FNA and 19.91 for open biopsy (p value <0.001).
### Table 4: sex distribution of diagnosed condition

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metastatic disease</td>
<td>13 (25.5%)</td>
<td>2 (2.8%)</td>
<td>15</td>
</tr>
<tr>
<td>Thyroid mass</td>
<td>1 (2%)</td>
<td>19 (27.1%)</td>
<td>20</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>6 (6.1%)</td>
<td>1 (1.4%)</td>
<td>7</td>
</tr>
<tr>
<td>Salivary tumours</td>
<td>13 (25.5%)</td>
<td>24 (34.3%)</td>
<td>37</td>
</tr>
<tr>
<td>Inflammatory disorders</td>
<td>12 (12.2%)</td>
<td>14 (20%)</td>
<td>26</td>
</tr>
<tr>
<td>Salivary diseases</td>
<td>1 (2%)</td>
<td>1 (1.4%)</td>
<td>2</td>
</tr>
<tr>
<td>Congenital masses</td>
<td>3 (3.05%)</td>
<td>9 (12.9%)</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>49 (100%)</td>
<td>70 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

Most of the patients with metastatic disease in the neck were men with an odds ratio of 11.8 (2.34-80.20) p value of 0.0002.
### Table 5: Consistency by FNA sensitivity

<table>
<thead>
<tr>
<th>Consistency</th>
<th>FNA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive/ %</td>
<td>Negative / %</td>
</tr>
<tr>
<td>Soft</td>
<td>4 (80%)</td>
<td>1 (20%)</td>
</tr>
<tr>
<td>Firm</td>
<td>93 (93%)</td>
<td>7 (7%)</td>
</tr>
<tr>
<td>Cystic</td>
<td>19 (100%)</td>
<td>-</td>
</tr>
</tbody>
</table>

Cystic masses had a sensitivity of 100% due to the fact that the fluid aspirated was centrifuged and the precipitate analysed as compared to firm masses, which had a sensitivity of 93% and soft masses 80%.
DISCUSSION

In our study a total of 141 patients were inducted and followed for a period of four months. We managed to do 122 (86.5%) excisional biopsies for correlation purposes. Nineteen (13.5%) were treated on the basis of their FNAB results eg. patients with chronic parotitis, Burkitts lymphomas and other lymphomas.

There were 61 (43.3%) males and 80 (56.7%) females with a male: female of 0.7: 1. the majority were female in this study as thyroid masses were common. No other figure has been quoted to show male: female ratio in head and neck masses, except on a study of laryngeal carcinoma in KNH of 11:1 by Dr Fat-hiya Abdalla and nasopharyngeal carcinoma by Dr Muchiri of 2.2:1 in the year 2003.

Those inducted in the study were of ages ranging from two months to 84 years. This showed a median age of 27 years and that FNA is safe and can be done in all age groups. The average mean duration of illness before a patient presented the hospital was 52 weeks a probable indicator of our patient health care seeking habits is late with grossly enlarged masses.

The overall sensitivity for all head and neck masses done FNA was 92.6%, which compared well with a study done in 1990 by Schwartz and colleagues demonstrated a sensitivity of 92%. Thus FNA can be done safely in all accessible tumours in head and neck region. In this study aspirates were done in various anatomical regions as follows and correlated with excisional biopsy.

Thyroid masses

In this study 20 patients with thyroid masses were done FNAB, thyroid functions test and thyroid ultrasound. Majority of the aspirate showed simple goiter, nodular goiter, colloid goiter and thyroid cyst in 50, 10, 30, and 10% respectively. All these were benign lesions with none malignant lesion seen. Sensitivity of FNA in thyroid masses in our study was 95% (tab.2).

Many studies have examined the utility of FNA in the diagnosis of suspicious thyroid masses. Klemi and colleagues in 1991 examined 186 aspirates from the thyroid gland. Among histology-confirmed cases, FNA of thyroid nodules had a specificity of 100%, sensitivity of 55%, and accuracy of 95% [38] Jayarman and colleagues in 1985 studied 308 cases of solitary thyroid nodules with FNA. The aspirates accurately diagnosed the pathology in 207
of 216 (95.8%) colloid adenomatous goiters. [25] This figures correlate very well to our study findings.

Fine-needle aspiration of thyroid masses has become the standard of care, replacing Ultrasonography and radionuclide scanning in the assessment of thyroid nodules, although ultrasound may be performed to determine if the mass is cystic or to guide FNAB for small nodules. It has been shown that FNAB has decreased the number of patients being treated with surgery, increased the number of malignant tumors found at surgery, and doubled the number of cases being followed up. Unsatisfactory aspirates should be repeated, and negative aspirates should be followed up with a repeat examination and FNAB a month later. [23,25,26,38,39,40]
Lymphoma

In our study 6 patients were diagnosed to have lymphoma on FNA in a total of 7 patients, with a sensitivity of 85.7% (tab.2). It occurs in all age groups but common in pediatric and young adults. The study findings compared very well to other study elsewhere [41].

Progressive enlargement of a lateral neck mass is often the only sign of disease in the head and neck. Systemic signs of fever, hepatosplenomegaly and diffuse adenopathy should be sought. The mass often appears discrete, rubbery and nontender. FNAB is the first line diagnostic test, and when it suggests lymphoma, an open biopsy with histologic examination is appropriate. Work-up of head and neck lymphoma includes CT scans of the chest, abdomen, head and neck and bone marrow biopsy. [20, 24, 41] Carter and colleagues examined 158 FNA specimens from 143 patients 1988. Two of the 118 needle aspirates diagnosed as lymphoma were falsely positive, while 3 of 13 diagnosed as suspicious for lymphoma was found to be benign. The histological sub classification of lymphoma on FNA was identical to the histological sub classification on excisional biopsy in only 85% of specimens. [41] The accurate cellular diagnosis of lymphoma depends on changes in lymph node architecture, specifically the ablation of germinal centers, follicles and sub capsular sinus. However, when the previous cytoarchitecture of a lymphoma specimen is known, FNA is reliable at predicting recurrence. [31]

A few reports have suggested that Hodgkin lymphoma can be accurately diagnosed by FNA. Hodgkin lymphoma is suggested by the presence of Reed Sternberg cells in the setting of numerous lymphocytes on FNA. [24, 31] However, because this cell type is found in other conditions (eg, non-Hodgkin disease of the large-cell type), pathological identification of Hodgkin disease still requires additional tissue for surrounding cellular elements. [24] The role of FNA in the diagnosis of non-Hodgkin lymphoma is controversial. The diagnostic yield of FNA is low because differentiating non-Hodgkin lymphoma of thyroid from lymphocytic thyroiditis and anaplastic thyroid carcinoma is difficult. [5]

Future studies combining FNA with flow cytometry and immunohistochemistry may increase the accuracy of lymphoma diagnosis without the need for excisional biopsies. [20]
Flow cytometry uses a beam of laser light to identify cell surface antigens. Tagged antibodies bind to cell surface antigens on lymphocytes, allowing the identification of non-Hodgkin
lymphoma. Recently, flow cytometry has been utilized to help diagnose pathology on FNA [20] Cannon and Richardson in 2000 retrospectively examined the use of FNA and flow
cytometry in 11 cases of isolated neck masses diagnosed as lymphoma [42] FNA of the one
patient with Hodgkin disease favored a mesenchymal neoplasm, and flow cytometry was
noncontributory. In the other 10 patients, FNA indicated lymphoma in 7, and flow cytometry
revealed clonal lymphocytic abnormalities in all 10, but open biopsies were performed to
more accurately characterize these lymphoid proliferations. [20, 31] In our study we had very
few cases, thus in this study not reflective of the efficacy of FNAB in patients with
Lymphoma. A study should be carried out to show the efficacy of FNA in Lymphoma.

Salivary tumors

In our study 37 (26.6%) patients were inducted and aspirates were from salivary gland (fig.4).
All the aspirates were correlated with histology reports, with an FNA sensitivity of 89.2%
(tab.2). Most of the tumors were benign and only three patients had adenocystic carcinoma
about 8.1%.

The diagnostic test of choice is open excisional biopsy, either submandibular gland excision
or parotidectomy. However, FNAB has been shown to reduce the number of patients being
treated with surgery by 33%. [34, 43] Some apparent neoplastic lesions on exam may be
intraparotid lymph nodes, localized sialadenitis, benign lymphoepithelial lesions or cysts.

The accuracy of FNAB in salivary glands is greater then 90% and more exact in benign than
malignant tumors. Its sensitivity is 90% with a specificity of approximately 80% for salivary
glands. If signs of malignancy are noted, FNAB may facilitate surgical planning and patient
counseling. In the case of the unknown primary, the surgeon and patient must be prepared for
a total parotidectomy and facial nerve dissection with possible nerve sacrifice. [34, 43, 44]

Use of FNA for isolated salivary gland masses is broadly accepted. The positive predictive
value of FNA for benign salivary lesions is 94%, and 100% for malignant masses. In 1992,
Frable and Frable studied 227 aspirations from salivary glands. FNA had 92% sensitivity for
tumor and specificity of 99% for the absence of tumor. Of the 185 salivary gland neoplasms
confirmed by histology, 182 of the FNA specimens accurately diagnosed the tumor. Of the
133 benign tumors aspirated, only 2 were confirmed by histology to be falsely negative. The diagnostic efficiency was 96.4%, with an overall predictive value of a positive aspiration for a malignancy of 98.3%. [32, 34]

In 2000, Costas et al studied 112 aspirations from salivary glands. Their results were less rewarding with a sensitivity and specificity of 84.8% and 93.7%, respectively. [43] Another study in 2000 by Cohen et al showed that FNA of salivary masses had a sensitivity and specificity of 66% and 88%, respectively, for lesions found to be malignant on final histology. These results suggest that FNA alone may not be sufficient to rule out salivary malignancies and that further clinical evaluation, including surgical resection, may be necessary. The accuracy of FNA in salivary gland tumors is acceptable but worrying to differentiate benign and malignant tumors due to the morphological architecture of the cells under the microscope being similar. Thus FNA might not be conclusive and excision biopsy is recommended to classify benign and malignant salivary lesions.

**Carotid body and Glomus tumors**

In this study none of the tumors were from this category as pulsatile tumors was one of the exclusion criteria. 100% of tumors were non-pulsatile in the study. However, FNAC can be done using a very fine needle and cytologists reports many red blood cells. [45] But its role in diagnosis of carotid body tumors has been overtaken by other diagnostic modalities e.g. CT scans and angiography.

These tumors are rare in the pediatric patient. In adults, they classically appear in the upper anterior triangle at the carotid bifurcation as a pulsatile, compressible mass, which is mobile from side to side. A bruit or thrill is present and in glomus vagale tumors, the ipsilateral tonsil may pulsate and/or deviate to the midline. In the elderly patient, close observation or treatment with irradiation to arrest growth is adequate. In young patients, a small tumor should be resected under hypotensive anesthesia. Preoperative embolization is used routinely. Preoperative measurement of catecholamine release should precede removal. [10, 45]
Lipoma

Only one patient was done open biopsy with a negative FNA had lipoma in our study. Lipomas are ill defined, soft masses usually appearing in patients over the age of 35 years. They are usually asymptomatic and diagnosed by clinical findings. Diagnosis is confirmed by excisional biopsy. [46] FNA is done and stained for fat cells with special stains.

Inflammatory disorders

In this study 26 (27%) patients of the aspirates were inflammatory disorders, which included TB adenitis, cervical abscesses and cervical adenopathy. The patients suspected to have TB adenitis were done mantoux skin test and chest x-rays. 89.5% of patients done those tests were positive for TB adenitis and were put on treatment. A sensitivity of 96.2% was realized in our study (tab.2). This is very high as compared to the one in other studies. [19, 35]

Acute lymphadenitis is very common at some point in almost everyone’s life, especially during the first decade. The presentation with marked tenderness, torticollis, trismus and dysphagia with systemic signs of infection are seldom a diagnostic challenge to the clinician and the source of the reactive lymphadenopathy is usually easily identified. Initial treatment with directed antibiotic therapy and follow up is the rule.

Inflammatory nodes generally regress in size. If the lesion does not respond to conventional antibiotics a biopsy is indicated after complete head and neck work-up. Equivocal or suspicious FNAB in the pediatric nodal mass requires an open excisional biopsy to rule out lymphoma or granulomatous disease. [15, 19, 35]

Granulomatous lymphadenitis usually develops over weeks and months, often with minimal systemic complaints of findings. The glands tend to be firm, with some degree of fixation and injection of the overlying skin. They may suppurate and drain only to reform. Tuberculosis is now commonly seen in our population and is more common in adults within the posterior triangle. [19] Atypical mycobacterial infection usually involves anterior triangle lymph nodes often with brawny skin, induration and pain. Undergoes spontaneous resolution with or
without antibiotic treatment. Atypical mycobacterial infection usually responds to complete surgical excision. [35]

HIV patients present with generalized lymphadenopathy and commonly get tuberculosis. In our study 3.5% of the patient done ELISA test for HIV was positive and 12% had a positive mantoux test for TB. Thus there is need to look at HIV manifestations in otolaryngology patients. When FNA and Mantoux test are used together accuracy is enhanced for diagnosis of tuberculosis. Tuberculous lymphadenitis often presents in the head and neck. FNA specimens have cytological evidence consistent with tuberculosis. 80% of FNA specimens positive for tuberculosis have been confirmed by open biopsy but in our study we had a very high sensitivity of 96.2%. FNA histology includes granulomatous inflammation and/or caseation necrosis. The sensitivity of FNA for tuberculosis increased from 70% to 90% when combined with skin testing. [19, 35]

**Metastatic nodal disease**

In our study 10.6% of the aspirates showed metastatic neck nodal disease from nasopharyngeal, hypopharyngeal, laryngeal and tonsillar carcinoma. 73.3% were nasopharyngeal metastasis in level II and III. In the study the sensitivity level was 100% of all the 15 patients done.

If the clinical evaluation of a neck mass does not lead to a definitive diagnosis, malignancy must be excluded. An asymptomatic cervical lump is the presenting symptom in about 12% of head and neck cancer cases. [29] Of these cancers, approximately 80% are squamous cell carcinoma (SCCa). FNA is routinely used for the histological diagnosis of isolated neoplastic neck masses. [10] Although FNA may not be the method of choice for all neck masses, recent studies demonstrate a specific advantage of FNA for the diagnosis of several specific disease entities. [34] Schwarz and colleagues in 1990 demonstrated that FNA had an overall sensitivity of 92% and a 100% positive predictive value for the diagnosis of SCCa of the head and neck. [46] Birchall and colleagues further demonstrated that FNA of neck masses was 100% specific for SCCa of the neck. [47] The predictive power of FNA in diagnosing head and neck SCCa allows physicians to narrow the search for the primary tumor. Furthermore, FNA can be a powerful tool for diagnosing cervical recurrence of head and neck SCC without the economic costs and morbidity of excisional biopsy.
Biopsies should be performed on any suspicious mucosal lesions observed or in any suspicious areas noted on CT or MRI. If no lesions or imaging abnormalities are noted, biopsies of the nasopharynx, tonsils (including an ipsilateral tonsillectomy for jugulodigastric nodal disease), base of tongue, and pyriform sinuses should be obtained. It is important at this time to examine thoroughly all areas of the aero digestive mucosa, including the esophagus, to identify the primary or any synchronous lesions, which occur in between 10% and 20% of patients with head and neck malignancies.

If a negative/equivocal FNAB is obtained yet suspicion for malignancy persists, an open excisional biopsy of the cervical lymph node may be performed. A result of adenocarcinoma or lymphoma dictates closure of the wound and further workup and staging procedures prior to further treatment decisions. [31]

**Congenital lesions**

8.5% of all the aspirates were of congenital masses (fig.4) with a sensitivity of 91.7% (tab.2). The most congenital mass was Thyroglossal cyst 41.6%. The females formed 75% of the patients with congenital masses (tab.4). Others were branchial cyst and ranula making 16.6% and 25% respectively.

**Branchial Cleft Cysts**

A branchial cyst usually presents as a smooth, fluctuant mass underlying the SCM (Second arch – most common) and often seems to appear rapidly after an upper respiratory tract infection. If infection is recent, skin erythema and tenderness may be present. Occasionally, purulent material may be expressed if a sinus tract is present. These masses most commonly occur in late childhood or early adulthood, but may occur later in life also.

The more common 2nd branchial cleft cyst often has a tract coursing medially over the 12th nerve between the internal and external carotids to the tonsillar fossa. The less common 1st branchial cyst occurs along the inferior or angle of the mandible or below the ear lobe. Close association with the facial nerve is possible, so excision of this type may necessitate a total parotidectomy with facial nerve dissection. In general, treatment is with initial control of infection, followed by surgical excision. Methylene blue injection into a draining tract prior
to excision may facilitate removal. [12, 27, 30] FNA yields acellular smear with cholesterol crystals. [30]

**Thyroglossal Duct Cysts**

This is the most common congenital neck mass, which presents as a midline or near midline mass that usually elevates on swallowing or protrusion of the tongue. This clinical finding distinguishes the TDC from other midline masses, such as lymph nodes, dermoids or ectopic thyroid tissue, which are included in the differential. Treatment is surgical removal including the midportion of the hyoid bone (Sistrunk procedure) after resolution of infection. [12, 27, 30] FNA shows mucoid smear with squamous cells. [30]
CONCLUSION

- It's evident from this study that the efficacy of FNA is very high with an overall sensitivity of 93.6% in the diagnosis of head and neck masses.

- Duration of FNA reports is short with a mean duration of 7 days as compared to 20 days of open biopsy thus patient management is quicker as in case of TB adenitis and Lymphomas.

- FNA is safe with no recorded complications in this study.
The main constraints met in this study were:

1. Theatre space for the patients who required open biopsy in main theatre especially for those who had benign tumors.

2. Filing of the results after being reported in the laboratory was very slow and sometimes we had to use carbon copy report from the laboratory file.
RECOMMENDATIONS AND FUTURE ASPECTS IN FNA

1. Fine aspiration can be used as a first line diagnostic tool for all head and neck masses as its accurate, safe, fast, acceptable and cost effective to the patient.

2. The delay in reporting the FNA should be looked at by training more cytopathologist as in other centers results come out in matter of hours.

3. Radio-oncologist should consider accepting patients with FNAB results especially nasopharyngeal carcinoma and institute treatment as the efficacy is very high.

4. ENT registrars should be taught aspiration biopsy technique to reduce the delay in doing the FNA, as it’s an easy procedure.

5. ENT department should be allocated more main theatre space for oncology patients once oncology department is established or ENT clinic satellite theatre is used on one day for open biopsies.

6. In future ultrasound guided FNA should be done to improve the sensitivity of head and neck masses.

7. Detailed study for each condition should be carried out to show the efficacy of FNAB.
APPENDIX-I

INFORMED VOLUNTARY CONSENT:

I___________________________________of _______________________do hereby consent to
/my son /daughter to be included in study to show the Efficacy of FNA in head and neck
tumors in comparison to open biopsy in KNH. The benefits of the study include early
diagnosis which will mean early intervention / treatment. This study shall include history of
illness; clinical examination, FNA and open biopsy will be done where necessary.

IPNo. ____________________
Study No. ________________
I understand that I do not have to be included in the study if I change my mind and however I
will still be eligible to enjoy the normal health facilities and treatment like any other routine
patient.

The nature of the study has been explained to me by Dr. ______________________, and
I have not been promised any material gain to be included in this study.

Signed________________________ (Parent/ Guardian/ Patient).

Date_________________________.

I have explained the nature of THE study of efficacy of FNA to above participant.
Signed________________________.

KUKUBALI KWA Mgonjwa/AMA MCHUNGANJI KWA UTAFITI WA UBORA
WA FNAC

Mimi__________________________Kutoka________________________
Mama/baba/mchungaji________________________
Nambari ya mgonjwa_______________
Nambari ya utafiti_______________

Ninakubali kuwa mmoja wa wagonjwa watakao husika na utafiti wa ubora wa FNAC
ikilinganishwa na matokeo ya nyama kwa kukata (open biopsy) kutoka kwa uvimbe wa
kicwa na shingo katika Hospitali Kuu ya Kenyatta. Utafiti huu utahusu historia ya
ugonjwa,uchunguzi wa daktari kwenywe kliniki na chumba cha upasuaji ambapo kijisehemu
kitatolewa kwa uchunguzi zaidi na pia kipimo kutolewa kwenywe uvimbe kwa njia ya sindano
(FNA).

Sahihi ya mgonjwa______________________Tarehe______________
Sahihi ya Daktari______________________Tarehe______________
APPENDIX II
PATIENTS PROFORMA.

STUDY No.______________________.

IPNo. ____________________________.

Age: ___________________. Sex________.

Residence___________________________

DATE. ________________________________________.

Major complains

Duration

Any previous treatments eg open biopsy, FNA or I&D.

General examination

Head and neck examination

Mass

i. Site

ii. Size

iii. State of overlying skin

iv. Consistency

v. Mobility

vi. Tenderness

vii. Pulsatile

Date of FNA __________________ Date of FNAC _____________________________.
<table>
<thead>
<tr>
<th>Cytological diagnosis</th>
</tr>
</thead>
</table>

Date of open biopsy ___________ Date of results ________________________

<table>
<thead>
<tr>
<th>Histological diagnosis</th>
</tr>
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Complications of FNA

<table>
<thead>
<tr>
<th>Complications of open biopsy</th>
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APPENDIX 111

MAP OF KENYA SHOWING DISTANCE FROM NAIROBI


Data Set Export File: kneadmin2.e00
USGS, EROS Data Center
**BIBLIOGRAPHY**


