PROFILE AND OUTCOME OF PATIENTS UNDERGOING FINGER GUIDED TRU-CUT BIOPSY OF THEPROSTATE ATMUHIMBILI NATIONAL HOSPITAL.

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MMED Urology Dissertation
Muhimbili University of Health and Allied Sciences
October, 2018

Muhimbili University of Health and Allied Sciences
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Profile and outcome of patients undergoing finger guided Tru-cut biopsy of the prostate at Muhimbili National Hospital.

By

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A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree OfMaster Medicine in Urology of

Muhimbili University of Health andAllied Sciences
October, 2018

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for examination of dissertation entitled **Profile and outcome of patients undergoing finger guided Tru-cut biopsy of the prostate atMuhimbili National Hospital** in partial fulfilment of the requirements for the degree of Master ofMedicine in Urology of Muhimbili University of Health and AlliedSciences.

_____

Prof. Muhsin Aboud

(supervisor)

Date_____

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I, **Flavian Simula,** declare that this dissertation is my own original work and that has not been presented and will not be presented to any other University for a similar or any other degree award.

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ACKNOWLEDGEMENT

It is not possible for a single individual to cover all the aspects that have made thisdissertation into the way it is, I therefore deeply give thanks to all those who have, withsuch good grace given their time and energy to supply valuable opinions, facts or evenmoral support.

Much appreciation should go to my supervisor Prof. Muhsin Aboudfor his endless guidance and for his patience as he devoted his time towards thesupervision of this work.

My heartfelt appreciation is directed to the Head of Department General Surgery, Dr. Larry Akoko and all other members of the department for their contributionsand constructive ideas.

My sincere thanks also go to the research assistants and all men who willingly participated in thisstudy.

DEDICATION

This work is dedicated to my family, with special thanks to my beloved wife Dr. Angelina Gwassa and my lovely child Adrian

ABSTRACT

Background

Finger guided prostate biopsy is a common minor procedure done to patients with suspicious Digital rectal examination (DRE) and or raised Prostate specific antigen (PSA) to diagnose prostate cancer. Though outdated and crude it is the only available option at resource constraints hospitals. The procedure is done at outpatient setting with minimal or no preparation and anaesthesia. The outcome of the specimen obtained and associated complications have not been well studied.This study aimed toassessprofile and outcome of finger guided prostate biopsyat Muhimbili National Hospital (MNH) in Dar es Salaam, Tanzania.

Objectives

The study aimed at determining the profile of patients and outcome of finger guided Tru-cut biopsy of the prostate at MNH

Materials and methods

The study was descriptive cross-sectional conducted for a period of ten months. Data were collected using patient clinical files, structured questionnaires, Visual Analog Scale for pain, laboratory results of PSA and biopsy. Participants were followed for 1 week.Data were analyzed using SPSSstatistical software version 20

Results

The mean age of the study participants was 71.1± 9.5(41-95)years, majority between 60 to 79 years 118(68.6%).Clinical presentations were LUTS 172 (100%), back pain 118(68.6%), lower limb swelling 38(22.1%), macroscopic blood in urine 31(18%) andlower limb paralysis 30(17%)**.** Biopsy revealed mostly adenocarcinoma 95(55.2%), BPH 48(27.9%) and Inadequate sample 28(16.3%). Poorly differentiated adenocarcinoma 59(62.1%) was the most common. Adenocarcinoma detection rate was 70.9% in participants with suspicious DRE and PSA $\geq$ 4ng/dl. Factors associated with the positive rate of adenocarcinoma were back pain 81(68.6%, P<0.05), Paraplegia 24(80.0%, P<0.05), lower limb swelling 3(81.7%, P<0.05) and Macroscopic blood in urine 21(67.7%, P=0.122). Severe pain (VAS of 7 to 10) 53(30.8%), rectal bleeding 19(11%), hematuria 11(6.4%) were the common complications.

Conclusion

- Prostate cancer is a disease of elderly mostly seen in their 6^{th} decade of life and above.
- Inadequate biopsy samples were significantly high and most patients had poorly differentiated prostate cancers
- There was a late presentation of patients to hospital as many patients presented with symptoms and signs of advanced prostate cancer on their initial visit

Recommendation

- There is a need to have a guideline on Tru-cut biopsy procedure of the prostate at MNH.
- The hospital should think of buying TRUS to facilitate TRUS guided prostate biopsy rather than the old type, digit guided prostate biopsy to avoid missing the target tissue.
- Proper training for registrars and residents on prostate biopsy is needed
- Community education on prostate cancer awareness is needed

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
ACKNOWLEDGEMENT iii
DEDICATION iv
ABSTRACT v
LIST OF TABLE ix
LIST OF ABBREVIATIONS x
DEFINITION OF TERMS xi
CHAPTER ONE 1
1.0. INTRODUCTION 1
1.1. Background Information 1
1.2 Literature Review 5
1.2.1 Prostate cancer 5
1.2.2 Complication of true cut biopsy 7
1.2.3. Tru cut biopsy 9
1.3. Statement of the Problem 13
1.4. Rationale of the Study 13
1.5. Research Question 14
1.6. Conceptual Frame Work 14
1.7. Objective 15
1.7.1. Broad Objective 15
1.7.2. Specific Objectives 15
CHAPTER TWO 16
2.0. METHODOLOGY 16
2.1 Study design 16
2.2 Study area 16
2.3 Study population 16
2.4 Criteria for inclusion and exclusion 16

2.4.1 Inclusion criteria....16
2.4.2 Exclusion criteria....16
2.5 Sample Size Estimation....17
2.8 Data Collection methods....18
2.9 Data Processing and Analysis....18
2.10 Ethical Clearance....19
CHAPTER THREE....20
CHAPTER FOUR....28
CHAPTER FIVE....31
REFERENCES....32
APPENDICES....35
Appendix I : Questionnaire....35
Appendix II : Visual analogue scale....39
Appendix III: Consent Form – English Version....40
Appendix IV: Consent Form – Swahili Version....42

LIST OF TABLE

Table 1: Distribution of characteristics of 172 study participants who underwent digit guided Tru cut biopsy between July, 2017 to March, 2018 21
Table 2: Distribution of 172 study participants on knowledge and preoperative preparation for Tru cut biopsy 22
Table 3:Clinical Presentations of 172 study participants who underwent Tru-cut biopsy between July, 2017 to march, 2018 22
Table 4: Distribution of indications for biopsy and detection rate in 172 study participants who underwent digit guided prostate biopsy between July, 2017 to March, 2018 23
Table 5: Distribution of histological findings of 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018 24
Table 6: Distribution of Adenocarcinoma grade in 95 study participants who were found to have prostate cancer after digit guided prostate biopsy between July,2017 to March, 2018 25
Table 7: Age group distribution of participants with adenocarcinoma after digit guided prostate biopsy between July,2017 to March, 2018 25
Table 8: Distribution of complications among 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018 26
Table 9: Factors associated with positive cancer rate in 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018 27

LIST OF ABBREVIATIONS

CDR	Cancer detection rate
DG	Digit Guided
DM	Diabetes Mellitus
DRE	Digital Rectal Examination
FGNB	Finger Guided Needle biopsy
HIV	Human Immunodeficiency Virus
HTN	Hypertension
LUTS	Lower urinary tract symptoms
MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
PIN	Prostatic Intraepithelial Neoplasia
PSA	Prostate-Specific Antigen
TRUS	Transrectal Ultrasound
UTI	Urinary Tract Infection
VAS	Visual Analog Scale

DEFINITION OF TERMS

- Suspicious DRE:DRE which reveals a hard and or nodular prostate, it may also include obliterated median sulcus of the prostate and fixed rectal mucosal
- Elevated PSA: PSA level equal or above to 4ng/mL
- Knowledge: Awareness of the Tru-cut biopsy of the prostate procedure. Being able to know the preparations as a patient and complications that may occur duringand after the procedure
- Rectal bleeding: Continuing or on and off bleeding per rectum after Tru-cut biopsy
- Antibiotic prophylaxis:Use of antibiotics within 24hrs before the Tru-cut biopsy
- Infectious complications: fever (37.8o C), febrile UTIand sepsis within 3 to 5 days after the procedure
- Hematuria: Blood in urine after Tru-cut biopsy

CHAPTER ONE

1.0. INTRODUCTION

1.1. Background Information

Prostate biopsy is a procedure of taking a sample of tissue from prostate gland for histopathological analysis. This procedure is usually done to patients with suspicious DRE and or raised PSA. The use of PSA alone as an indication for biopsy should be avoided especially if PSA it is slightly elevated as some noncancerous conditions such BPH andprostatitis may raise the PSA making patients undergounnecessary procedures.

Although most centers are moving away from finger guided Tru-cut biopsyof the prostate, approximately 4 to 8 patients per week undergo it at MNH and no documented data onpresentations, complications, and outcome of the procedure at MNH

Through different literature reviews, no any studydone in Tanzania on the profiles, complications and histological results of finger guided Tru-cut biopsy. Most of the studies are from western countries which mostly are of ultrasound guided prostate biopsy which may not reflect our practice. Therefore, it is of utmost importance to do this research to audit our practice and have documented data about finger guided Tru-cut biopsy of the prostate at MNH.

Prostate

The prostate is the largest accessory gland of the male reproductive system, located in front of the rectum and just below the urinary bladder. Its glandular part makes up two third of the prostate, the other third is fibromuscular. The firm, walnut-size prostate surrounds the urethra.

The prostate contains four zones,three glandular zones (peripheral, central, transition) and the anterior fibromuscular zone. The zones are widely differing in susceptibility to cancer and benign prostatic hyperplasia (BPH). Approximately 70% to 80% of prostate cancer occurs in the peripheral zone

Prostate cancer is rated the second most common cancer and sixth leading cause of cancer deaths among men globally. Reports show that African men suffer

disproportionatelycompared to men from other parts of the world. It is still quite difficult to accurately describe the burden of in Africa due to poor cancer registration systems.(1)
Although the incidence of prostate cancer is increasing in the developed world, it remains under-diagnosed in the developing world where it often presents late.(2)The prevalence of prostate cancer in Tanzania like many other African countries is not known.

Prostate cancer presentation is variable, somepatients may present without any symptoms,others may present with, back pain, lower limb weakness or paralysis. DRE may reveal a hard and nodulated prostate,in advanced disease the median sulcus may be obliterated and the rectal mucosa may be fixed.

Diagnosis of prostate cancer depends on biopsy results but can be suspected in a patient with abnormal DRE of the prostate and raised total serum PSA.

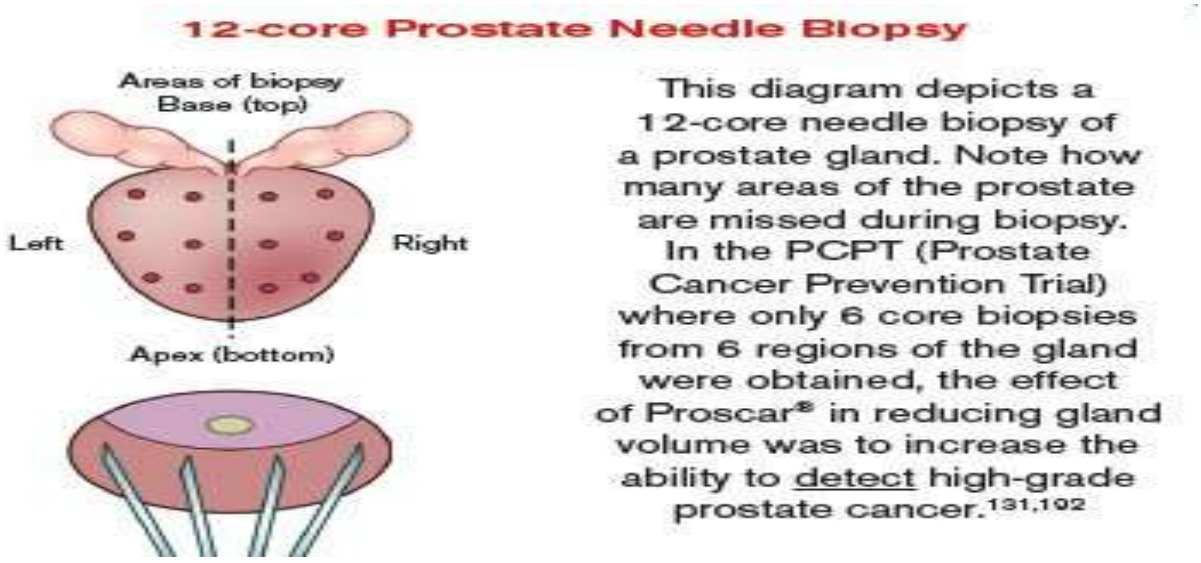
Prostate biopsy

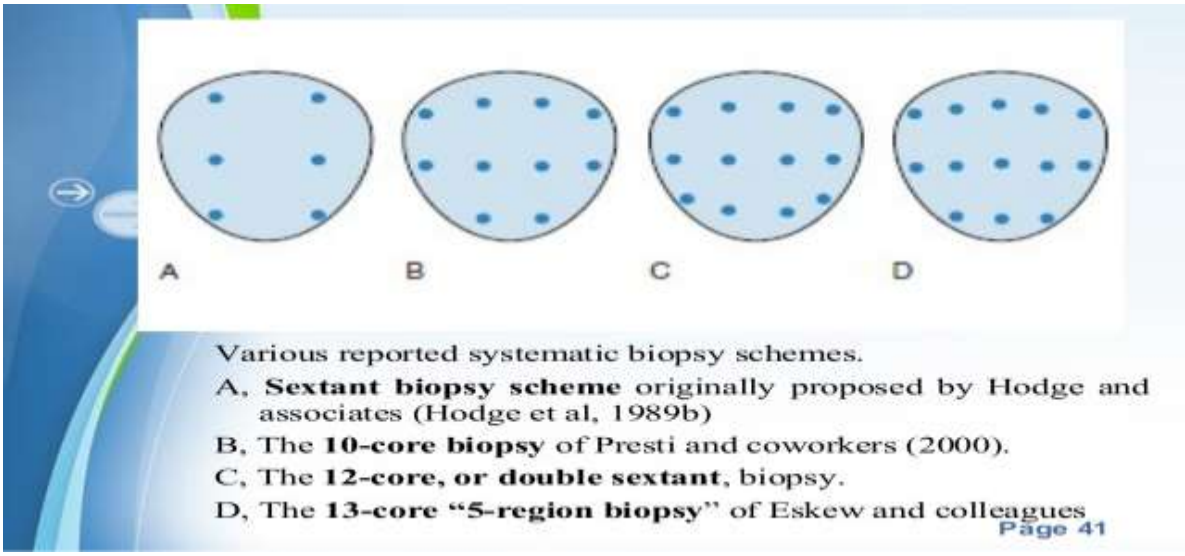
A variety of biopsy techniques have emerged including computerized and image-guided techniques, but systematic sampling with variable core numbers remains the standard in practice.

TheTru cut biopsy can be done under finger guided where a finger directs a needle to a palpable node. At Muhimbili National Hospital this is what is done. Other means of directing aneedle is by the use of ultrasound (TRUS), and through TRUS a systematic prostate biopsy can be done. TRUS is the commonest means of directing the biopsy needle. Recently, in well-developed centers, MRI is used to direct the biopsy needle in a more specific way especially in a patient with continuing raising PSA with a negative TRUS guided biopsy result.

A typical transrectal sextant biopsy involves samples from the parasagittal plane on the right and left sides of the base, midzone, and apex, with each site arbitrarily assigned by the operator. In the early 1990s, it was demonstrated that lateral displacement of the sextant resulted in an increased cancer detection rate, suggesting that core location could affect biopsy outcomes.

Early studies demonstrated that sextant biopsies had acceptable CDRs, but a considerable number of secondary cancers were detected on repeat biopsy following sextant biopsy. Several investigators demonstrated that sampling more cores improved CDR without increasing morbidity. As a result, today's biopsy protocols typically involve extracting 10–12 cores per biopsy, often from the standard sextant and other areas of the peripheral, transition, or anterior zones. Despite these observations, controversy exists about the optimal strategy for prostate biopsy with regard to core number, location, labeling, and pathologic processing.





Preprocedure preparation for Tru-cut biopsy includes stopping anticoagulant medications at least 10 days, given prophylactic antibiotics at least 1 to 3 daysand UTI treatmentbefore the procedure. Bowel preparation and application of local anesthesia before the procedure is also advised

Gleason system

Prostate cancer is graded using numbers 1 to 5 based on how much the cells in the cancerous tissue look like normal prostate tissue under the microscope.

- If the cancerous tissue looks much like normal prostate tissue, a grade of 1 is assigned.
- If the cancer cells and their growth patterns look very abnormal, a grade of 5 is assigned.
- Grades 2 through 4 have features in between these extremes.

Prostate cancer often has areas of different grade;a grade is assigned to the 2 areas that make up most of cancer. Summation of the 2 grades yields the Gleason score. The first number assigned is the grade that is most common in the tumor.

A Gleason score of 6 or less means a well differentiated or low-grade cancer. These cancerstend to be less aggressive and a slow growing

Cancers with Gleason scores of 8 to 10 is poorly differentiated or high grade. These cancers tend to be aggressive, meaning they are likely to grow and spread more quickly.

Cancers with a Gleason score of 7 is moderately differentiated. The rate of growth and spread tends to be in between the other 2

Complications of Tru-cut biopsy

Mild complications are relatively common, serious complications are very rare. Infectious complications include acute prostatitis and rarely sepsis. Bleeding complications include minor hematuria, hematospermia, and rectal bleeding. Other complications include Urinary retention and Vasovagal reaction

1.2 Literature Review

1.2.1 Prostate cancer

In a study done in Senegal, Screening prostate cancer by DRE and PSA. The mean age of the patients was 65.5 years, with extremes of 38 and 93 years. Age groups from 50 to 59 and from 60 to 69 were the most represented. DRE was normal in the age group from 35 to 39, and only one patient in the age group from 40 to 49 had a prostate nodule. PSA level was greater than or equal to 4ng/mL in 66 cases. A total of 5.4% patients had a PSA level greater than or equal to 10ng/mL. Only two patients in the age group from 40 to 49 had a PSA level greater than 4ng/mL. Of the 72 biopsies we performed, prostatic adenocarcinoma was found in 30.6% of the cases. It is the only type of prostate cancer we found in our series. Also in this study the prevalence of prostate cancer was 3.8%.(3)

A study done at Lagos State University College of Medicine, Ikeja, Lagos, Nigeria,4172 men were screened and complete data were available for 4110 (98.5%). The mean age was 60.8 years. DRE was abnormal in 410 men and was significantly correlated with the age of the patient and tPSA ($p<0.001$). The tPSA ranged from 0 to 438.3ng/ml with a median, mean and 95th percentile of 1.5, 2.5 and 10.0ng/ml respectively. 341 out of the 438(78%) men selected were subjected to TRBP. 43 men had histological diagnosis of CaP, giving an estimated prevalence rate of at least 1.046% or 1046 per 100,000 men of age ≥40. Only 11 (26%) had organ-confined disease while 17 (40%) had a locally advanced disease and 15 (35%) men had metastatic disease. The majority of the men, 32 (74%) were reported to have Gleason's score of ≥7. The study concluded that the prevalence rate of CaP among men aged ≥40 years in Lagos is higher than previously reported in hospital-based study. Majority have advanced and high-grade disease. (4)

In a study done atDepartment of Urology, Stanford University School of Medicineto investigate age related cancer rate in Tru-cut biopsy. The overall population median patient age was 68 years and median PSA was 6.1 ng. / ml. (4.6 to 9.0). Cancer was diagnosed in 1,020 men (44.4%), biopsy was negative in 1,101 (47.9%), high grade PIN was noted in 101 (4.4%) and biopsies were suspicious but not diagnostic for cancer in 77 (3.3%). PSA results

were available in 1,683 cases (73%) and digital rectal examination results were avail

A study done at Alexandria University Egypt, 950 patients diagnosed with prostate cancer in our database through the year 2012. Complete information was found for 216 patients. The mean age of the patients was 67 years. Mean serum total PSA, prostate volume and PSAd were 149 ng/ml, 63 grams and 3.1 ng/ml/gm respectively. 25% of patients were asymptomatic able in 648 (28%). (5) and diagnosed accidentally during screening for prostate cancer. The remaining group was presenting with LUTS, including 23 (10.6%) patients who presented initially with back pain.(6)

In a study done at Department of Oncology, Universitas Annex in Bloemfontein, Free State, from 2008 to 2010. Patients with prostate cancer were mostly (45.7%) between 65 and 75 years of age and 72.8% were in the black race group. The largest percentage of patients had a Gleason score of 8 to 10 (43.7%), PSA level > 20 ng/ml (67.9%), and a T stage ≥ T3 (62.3%).(7)

Ethnic disparity in prostate cancer has become an important issue worldwide because of the higher incidence and mortality in the African- Caribbean population.The presumed factors contributing to ethnicity related differences are socioeconomic status, cultural beliefs and genomic differences. Ongoing research in the field of genetic and molecular basis for prostate cancer disparity in African-American men has identified the following areas: - inherited risk alleles, tumor genes, androgen receptors, epigenetics.(8)

In a study done at Department of Urology,Universityof Limpopo,Medunsa, South Africa, the most common complaint was associated with urinary flow (740/920, 80.4%), including difficulty passing urine (665/920, 72.3%), dysuria (72/920, 7.8%), or obstruction/poor flow (13/920, 1.4%). While dysuria was significantly associated with a positive PCa diagnosis (9.5% (56/592) and 4.9% (16/328) of cases and controls, respectively present with this symptom; P=0.0145), urinary obstruction was negatively associated with diagnosis (present in 0.5% (3/592) and 3.0% (10/328) of PCa cases and controls respectively; P=0.0028). Compared with Black Americans, Black South Africans presented with significantly more aggressive

disease defined by Gleason score >7 (17% and 36%, respectively) and PSA?20mg/L (17.2% and 83.2%, respectively).We report exasperated disease aggression defined by Gleason score >7(P¼0.0042) and poorly differentiated tumor grade (P<0.0001) within rural versus urban localities.(9)

Biopsy-detected prostate cancer, including high-grade cancers, is not rare among men with PSA levels of 4.0ng per milliliter or less-levels generally thought to be in the normal range.(10)

In a study conducted at Makerere University, Kampala, Uganda in men aged 18 to 71 years showed there were a poor knowledge and misconceptions regarding prostate cancer. The majority of the respondents (324, 59.4%) were aged 18–28 years, 295 (54.1%) had heard about prostate cancer and 250 (45.9%) had never heard about it. The commonest source of information about prostate cancer was the mass media. Only 12.5% of the respondents obtained information about prostate cancer from a health worker, 37.4% did not know the age group that prostate cancer affects a. The most of the participants confused prostate cancer with gonorrhea and had various misconceptions about the causes of prostate cancer. Only 10.3% of the respondents had good knowledge of the symptoms of prostate cancer and only 9% knew about serumprostate specific antigen (PSA) testing. Although 63.5% thought they were susceptible to prostate cancer, only 22.9% considered getting and only 3.5% had ever undergone a serum PSA test. (11)

1.2.2 Complication of true cut biopsy

In a study conducted Kuwait University, Safat, Kuwait. Out of 300 TRUS-guided biopsies, 10 early complications were as septicemia was seen in 5 cases (1.7%). Hematuria occurred in 29 patients, 3 of which were severe, rectal bleeding and vasovagal attack occurred in 1 patient each. Ten cases (3.33%) of severe pain and intolerable pain were observed. Three out of these 10 patients completed the procedure. The procedure was terminated in 1 patient, and 6 patients required local anesthetic due to perianal area. The study concluded that 90% of Tru-cut biopsy can be done without local anesthesia and prophylactic antibiotics are needed to minimize infection complications. (12)

No major complications were seen immediately after biopsy, but one half of the men had minor rectal hemorrhage and, in a few cases, bleeding from the urethra. In a study done byMkinen T and colleague revealed that most screened (58%) and hospital-referred (65%) subjects felt no distress before biopsy. The procedure was considered unpleasant by 69% of those screened and 61% of the controls. Correspondingly, 52% and 63% of men reported moderate pain at biopsy, but only 3 of those screened (3%) and 4 controls (5%) experienced severe pain. Nevertheless, a great majority of men in both the screening (82%) and the control (86%) groups would be willing to undergo a repeat biopsy if needed. Persistent rectal bleeding and hematuria were common (13% to 35%, respectively), but less than one fourth considered this disturbing. No significant differences were seen either in complications or acceptability between the groups. The results of thestudy demonstrated that minor complications are equally frequent among men undergoing prostate biopsy for screening and other men. Despite the complications, prostate biopsy was regarded as acceptable.(13)

The study done at Department of Urology, Chonnam National University Medical School which included 827 patients, of whom 93 patients (11.2%) reported receiving antibiotics in the previous 6 months and 2.5% had a history of prostatitis. The infectious complication rate was 2.2% post prostate biopsy. Post-biopsy sepsis was reported in 2 patients (0.2%). (14)

In a study done at Clinic of Urology, Develi Hatice-Muammer Kocatürk State Hospital, Kayseri, Turkey Minor complications, such as hematuria (66.3%), hematospermia (38.8%), rectal bleeding (28.4%), mild to moderate degrees of vasovagal episodes (7.7%), and genitourinary tract infection (6.1%) were noted frequently. Major complications were rare and included urosepsis (0.5%), rectal bleeding requiring intervention (0.3%), acute urinary retention (0.3%), hematuria necessitating transfusion (0.05%), Fournier’s gangrene (0.05%), and myocardial infarction (0.05%). (15)

In a study conducted at Toronto University, Canada of 75,190 men who underwent transrectal ultrasound biopsy 44.6% were diagnosed with prostate cancer and 55.4% did not have prostate cancer. The hospital admission rate for urological complications within 30 days of the procedure for men without cancer was 1.9%. The 30-day hospital admission rate increased

from 1.0% in 1996 to 4.1% in 2005. The majority of hospital admissions (72%) were for infection related reasons. The probability of being admitted to hospital within 30 days of having the procedure increased 4-fold between 1996 and 2005 (OR 3.7, 95% CI 2.0–7.0, p ?0.0001). The overall 30-day mortality rate was 0.09% but did not change during the study period. (16)

1.2.3. Tru cut biopsy

A study done at Departments of Pathology and Urology, Government Medical College and Rajindra Hospital, Patiala, Punjab, India, Microscopic examination of Tru cut biopsy revealed adenocarcinoma in 59, benign prostatic hyperplasia (BPH) in 35, and inadequate biopsy in five cases. The age distribution of these 59 cases with adenocarcinoma revealed that 28 were in the 8th decade, followed by 7th, 6th, and 9th decades, respectively. The mean age was 68.20 years. The Gleason score was 5-7 in 37 patients, 2-4 in 14 cases, and 8-10 in eight cases. The highest PSA level was in Gleason's score of 8-10. Thus, the PSA levels are more in patients with high Gleason grade. The conclusion was Adenocarcinoma is the most common type of prostate carcinoma. The majority of patients had a Gleason score of 5-7, followed by 2-4, and 8-10. The more anaplastic type of cancers was present in the least number of cases.(17)

Study developed at Central Hospital Vila Real, PortugaI. Total of 155 cases the prevalence of malignancy was of 53%. Suspicious nodules were detected in 34 patients, and 25 where malignant (positive predictive value of 74%). The specificity and sensitivity for suspicious nodules were 88% and 31% respectively. Comparatively with the randomly obtained sextant specimens, the rate of findings of neoplasia was higher in the specimens obtained with puncture directed to the nodule ($p = 0.032$). Conclusion: The high positive predictive value and the high rate of findings of neoplasia in specimens of suspicious nodules should be taken into consideration in the future. The authors suggest a biopsy technique similar to the one described in the present study (sextant biopsy plus puncture directed to the suspicious nodule). (18)

In a study done at Department of Urology, Stanford University School of Medicine to Investigating number of core biopsy to be taken, optimal 10 site biopsy scheme outperformed all 6 and 8 site biopsy schemes when PSA was less than 10 ng./ml. However, at high PSA (greater than 20 ng./ml.) almost all schemes resulted in a high detection rate. The 12 site biopsy schemeoutperformed all other schemes at PSA 7 ng./ml. or less versus the optimal 10, 8 and standard sextant biopsy schemes.(5)

In one study comparing of digitally directed and ultrasound-guided transrectal biopsy of palpable prostate lesions. The rate of detection was comparable for ultrasound-guided biopsy (92.0%) or digitally guided biopsy (90.7%). Although transrectal ultrasound of the prostate has assumed a large role in the detection of prostate cancer, digitally guided biopsy still should be considered in patients with palpably abnormal prostates.(19)

In the study comparing prostate cancer detection rates and pathology results, using the Gleason grading system, of 12-core systemic random transrectal ultrasound guided prostate biopsy (SB) and 3-core finger-guided prostate nodule biopsy (FGNB). The prostate cancer detection rates were 39.9% in SB, 37.9% inFGNB, and 44.6% combination biopsy. Of the 66 patients with prostate cancer, the Gleason sum was underestimated in three patients with simple SB only and in one patient with FGNB only. The false-negative rates for SB and FGNB were 10.6% and 15.2%, respectively. The study concluded that in patients with a palpable prostate nodule, combination biopsy with systemic and nodule biopsy could avoid some misdiagnoses of prostate cancer and provide more accurate information forpathology grading.(20)

In a study investigating the adequate biopsy for prostate sampling showed that prostatic glandular elements, which are keys for histological diagnosis, were absent in a significantnumber of prostatic biopsy samples and patients. This inadequacy was most prominent in apical and far lateral biopsy specimens and found to be operator dependent.(21)

In a studycomparing TRUS-guided technique and digitally guided technique.52 patient’s participated, Successful removal of tissue of diagnostic quality was achieved in both methods.

Carcinoma was detected in 19 (36.5%). 16 of the 19 carcinomas were diagnosed by both techniques, two carcinomas were detected only by the TRUS-guided technique and one only by the digitally guided technique. (22)

In a study which was done at Groote Schuur Hospital and the University of Cape Town, South Africa, showed there was no significant differences in term of diagnosing prostate cancer between Digital and TRUS guided Tru-cut biopsy. In this study, 192 patients were included in the TRUS group and 262 DG biopsies were reviewed between 2006 and 2008. Suspicious DRE findings were present in 56.2% of DG and 43.3% of TRUS biopsies. Histology was available in 97.8% of cases. The incidence of prostate cancer was 42%. Malignant or suspicious histology was found in 45.6% of the DG group compared to 48.6% in the TRUS group ($p = 0.27$). In patients with a normal DRE, there was a trend that favored TRUS for improved cancer detection. The conclusion of the study was no superiority of TRUS over FG biopsies except when the patient had a low PSA (below 10 ng/mL) and a normal DRE. Systematic DG biopsies may be of benefit in patients presenting with a PSA over 10 ng/mL or an abnormal DRE. This may be of value in a limited resource setting where access to TRUS is restricted.(2)

In a study conducted at Departments of Urology and Pathology, University of California School of Medicine showed that, of the patients 42% (202) had cancer on biopsy. Traditional sextant biopsies missed 20%, while a sextant regimen incorporating lateral peripheral zone biopsies of the mid gland and base along with the apex missed 11% of the cancers. The combination of sextant and lateral peripheral zone biopsies (10-biopsy scheme) detected 194 cancers (96%). The 8 missed cancers were detected by lesion directed (5) or transition zone (3) biopsies. Eliminating the mid lobar base biopsies from the systematic 10-biopsy peripheral zone regimen resulting in an 8-biopsy peripheral zone regimen decreased detection from 96% to 95%. The study concluded that the 6 systematic biopsies of the peripheral zone are inadequate and a minimum of 8, including the apex, mid lobar mid gland, lateral mid gland and lateral base, should routinely be performed.(23)

In a study done at Department of Urologic Surgery, Veterans Administration Medical Center, Minneapolis, Minnesotaon the effect of prophylaxis antibiotics before prostate biopsy,227 (84%) of 269 ciprofloxacin patients and 230 (86%) of 268 placebo patients underwent a mean of four biopsies. Six ciprofloxacintreated (3%) and 19 placebo-treated (8%) patients had bacteriuria after theprocedure (*P* 5 0.009). Six ciprofloxacin recipients (3%) and 12 placebo recipients (5%) had clinical signs and symptoms of a urinary tract infection (UTI) (*P* 5 0.15). In addition, no ciprofloxacin-treated patients compared with 4 placebo-treated patients (2%) were admitted to the hospital for febrile UTI after the procedure. Ciprofloxacin reduced the expected net costs of treating infectious complications after biopsy by $23 per patient for an overall annual savings of $68,195 in the five study groups when compared with placebo. The study concluded thatSingle-dose oral ciprofloxacin reduced bacteriuria after biopsy compared with placebo in patients undergoing transrectal prostatic biopsy and provided an economic advantage. In addition, this study establishes the actual rate of bacteriuria after transrectal needle biopsy of the prostate without antibiotic prophylaxis to be 8% with a clinical rate of UTI of 5% and a hospitalization rate of 2%.(24)

1.3. Statement of the Problem

In our setting confirming the diagnosis of prostate cancer in a patient with raised PSA and suspicious DRE depends on finger guided Tru-cut biopsy of the prostate. However, what is the cut-off level of PSA has not been set as standard to be used. There are no local guideline and guidance for selection of patients for prostate biopsy

Finger guided Tru-cut biopsy has its own shortcoming and complications; it is easy to miss a suspicious node and end up on biopsying nonmalignant cells. What is the positive rate of prostate cancer in our group of patients undergoing biopsies is not known.

In awell-developed and equipped Centre TRUS guided Tru-cut biopsy with core biopsies between 8 to12 is the gold standard. This is different from our setting where no guideline to follow on the number of core biopsies to take when doing the procedure.Moreover, our pathologist may not critically examine all the core biopsies sent.

Prophylactic antibiotics are not given, rectal cleansing is not done, reusability of the biopsy needles which are not supposed to be reused and the sterility of the environment where the procedure is done predispose our patients to more complications including infections.

Through different literature reviews, nostudy has been done in Tanzania on the profiles, complications and laboratory results of finger guided Tru cut biopsy. Most of the studies are from western countries and may not reflect our practice

1.4. Rationale of the Study

This study aimed at collecting data on profile and outcome of patients underwent finger guided Tru-cut biopsy of a prostate. These data were not availableat MNH.

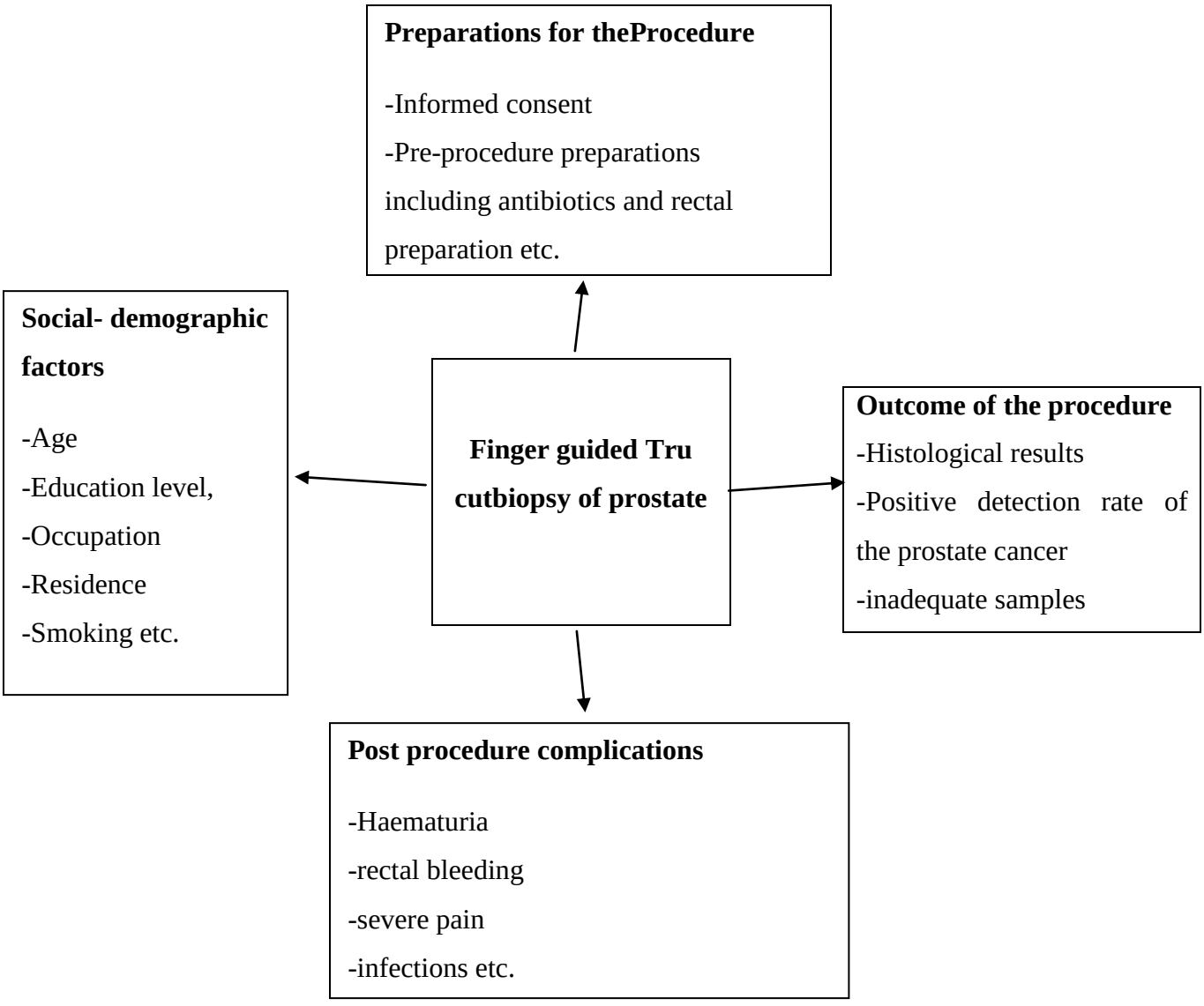
The study identified the profile of patients, pre-procedure preparations, positive rate for prostate cancer and distribution of the grades, factors associated with positive cancer rate and type of complications of digital guided Tru-cut biopsy of the prostate at MNH.

This will contribute to the advancement of knowledge on Tru cut biopsy of the prostate and provision of specific guidelines onprostate biopsy at MNH and country at large. This study also audited our practice of finger guided Tru-cut biopsy of the prostate at MNH.

1.5. Research Question

What is the profile of patients and outcome of finger guided Tru cut biopsy of the prostate at MNH?

1.6. Conceptual Frame Work



1.7. Objective

1.7.1. Broad Objective

To determine the profile of patients and outcome of finger guided Tru-cut biopsy of the prostate at MNH

1.7.2. Specific Objectives

- To determine the profile of patients undergoing finger guided Tru-cut biopsy of the prostate at MNH
- To determine the pre-procedure preparations used for patients undergoing finger guided Tru-cut biopsy of the prostate at MNH
- To determine the positive rate for prostate cancer and distribution of the grades in patients undergoing finger guided Tru-cut biopsy of the prostate at MNH
- To determine the factors associated with positive cancer rate in patients undergoing finger guided Tru-cut biopsy of the prostate at MNH
- To assess the type of complications of finger guided Tru-cut biopsy of the prostate at MNH

CHAPTER TWO

2.0. METHODOLOGY

2.1 Study design

It was a descriptive cross-sectional hospital-based study.

2.2 Study area

The study was conducted at MNH-Urology department. MNH is a National Referral Hospital, Research Center and University Teaching Hospital with 1,500 bed facility, attending 1,000 to 1,200 outpatients per day, admitting 1,000 to 1,200 inpatients per week. MNH-Urology department has 64 male bed facility,with an average of 250 outpatients per week and 1 Tru-cut biopsy per day.

2.3 Study population

The study population included all consecutive patients with suspicious DRE or raised PSA or both who consented toundergo digital guided Tru cut biopsy procedures at MNH fromMay-2017to March- 2018

2.4 Criteria for inclusion and exclusion

2.4.1Inclusion criteria

All male patients with suspicious DRE and or raised PSA who consented for Tru cut biopsy procedures at MNH.

2.4.2 Exclusion criteria

Male patients with suspicious DRE and or raised PSA who underwentTru cut biopsy procedures at MNH but were not willing to consent to participate in the study.

2.5Sample Size Estimation

The sample size estimation was based on the prevalence of adenocarcinoma of 3.8% (P=0.38) from Senegal (3). To achieve a statistically significant result the sample size was calculated by using the following formula according to Silva (1999).

$$N = \frac{Z2P(1-P)}{e2}$$

N = Estimated minimum sample size of the study

Z = Standard normal deviation of 1.96 corresponding to 95% confidence interval

P = Proportional of prostate cancer in population fromprevious studies.

E = acceptable (tolerable) marginal error of 3%

Therefore,

$$N = \frac{(1.96)2 \text{ X } 0.038 (1-0.038)}{(0.03)2} = 156$$

Estimated minimum sample size of the study =156

Adjusting for the non-response rate which is 10%, the minimum sample size was172 patients.

2.6. Sampling procedure

Convenience sampling was used where all elderly men with suspicious DRE or Raised PSA or both were consecutively recruited until the sample size was reached. All men with suspicious DRE or Raised PSA or both who were eligible were included in the study

2.7. Pretesting of the questionnaire

Pilot survey and Pretesting of the questionnaire was done at Muhimbili National Hospital in order to evaluate the proper filling of the questionnaire and whether the questions were actually understood by respondents before the commencement of data collection.

2.8Data Collection methods

Patient clinical files, examination findings, questionnaires,laboratory, andbiopsy results were used for data collection.Structured standard questionnaires wereused to obtain social-demographic and clinical data from patients and the patient's file. All patients were recruited on the day of the procedure, identified by hospital number, age and where they came from.All patients involved in the study were requested to sign an informed consent form.

DRE findings and PSA level were obtained from patients file. Patients comorbidities not associated with the prostate cancer like DM and those due to prostate cancer like lower limb paralysis were obtained from the patients.

Biopsy was taken by positioning the patients in lithotomy position, using a gloved finger with a non-anesthetic lubricant on it, prostate needle of either size 16G or 18G was directed towards the prostate through an anal opening and tissue was taken randomly, then, soaked in formalin containing labeled bottle and immediately sent for histopathology laboratory for analysis. Biopsy results were followed after 2 weeks and the results were recorded

Pain was graded immediately after the procedure using Pain Visual Scale. Patients were followed up for one week to asses any complications that may result because of the procedure. Follow up was done through aphone call on the 2^{nd} and 7^{th} day.

2.9Data Processing and Analysis

Data were collected, cleaned, and entered into a computer and analyzed by using SPSS version 20, then analyzed by charts, ratios, and percentages, whereby bivariate analysis of variables were done to assess associations.

In descriptive analyses, categorical variables were summarized using proportions and then presented in tables, continuous variables in mean and standard deviation. Bivariate analysis was done to find any associations between the dependent variable (prostate cancer) and the independent variables (back pain, lower limb swelling, hematuria, paralysis).

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2.10Ethical Clearance

Ethical clearance and study approval was sought from MUHAS Institutional Review Board and MNH review board.

The study protocol followed the Helsinki Declaration ethical guidelines of 1975 and all study participants signeda consent form after being given adequate information. Permission to collect data was obtained from the Teaching, Research, and Consultancy Coordination Unit of the MNH,confidentiality of the subjects was observedby storing the data in a password protected computer which can only be accessed by the principal investigatorand no additional intervention was done above the standard of care.

CHAPTER THREE

RESULTS

3.1 Characteristics of study participants

A total number of 172 participantsattended MNH betweenJuly ,2017 to March, 2018 were eligible and consented toparticipate in the study. The participants were from 92 Districts of Tanzania, of all the participants, Ilala, Kinondoni, and Temeke Districts contributed 9 (5.2%) participants each, Kisarawe and Lushoto Districts contributed 5(2.9%) participants each, Kibaha and Same Districts contributed 4(2.3%) each. Of the remaining, 9 Districts contributed 3(1.7%) participants each, 20 Districts contributed 2(1.2%) participants each and 55 Districts contributed 1(0.6%) participant each

As shown in table 1 below, the study found that the mean age of the study participants was 71.1 ± 9.5(41-95) years, most of them aged between 60 to 79 years 118(68.6%) and majority had a primary education level 89(51.1%)

Participants who had the same disease presentation as there first degree relative were 12(7%) and among them, only one aged below 60 years. Cigarette smoking was reported by 31(18%) of the participants

Table 1: Distribution of characteristics of 172 study participants who underwent digit guided Tru cut biopsy between July, 2017 to March, 2018

Variable	No	%
Age (Mean, SD, minimum, maximum)	71.1 ± 9.5(41-95)	
Age group (n,%)		
40 to 59	17	9.9
60 to 79	118	68.6
80 to 99	37	21.5
Education level (n,%)		
No formal	62	36
Primary school	89	51.7
Secondary school	17	9.9
University/College	4	2.3
Same disease presentation as there first degree relative (n,%)	12	7
History/Current cigarette smoking (n,%)	31	18
Current alcohol intake (n,%)	39	22.7
Diabetes mellitus (n, %)	8	4.7
Hypertensive (n,%)	24	14
HIV (n,%)	2	1.2

3.2 Study participants on knowledge and preoperative preparation for Tru cut biopsy

As shown in table 2 below, the study found that 61(35.5%) of the participants knew the reason for the Tru cut biopsy. However, none had a knowledge of any preparation needed or complications that may occur from the procedure.

All participants on antibiotics 45(26.2%) were given for other reason rather than prophylaxis and none of the participants underwent bowel preparation before the Tru cut biopsy procedure.

Table 2: Distribution of 172 study participants on knowledge and preoperative preparation for Tru cut biopsy

Knowledge and preparation	**No (%)**	
Participants knew the reason for the procedure	61	35.5
Knowledge of the procedure	00	00
On antibiotics	45	26.2
Bowel preparation	00	00

3.3 Clinical Presentation of study participants

As shown in table 3 below, the study found that clinical presentations of the participants were LUTS 172 (100%), back pain 118(68.6%), lower limb swelling 38(22.1%), macroscopic blood in urine 31(18%) lower limb paralysis 30(17%) and urine retention/ on catheter 124 (72.1%)

Table 3:Clinical Presentations of 172 study participants who underwent Tru-cut biopsy between July, 2017 to march, 2018

Clinical Presentation	**Frequency %**
LUTS	172 100
Back Pain	118 68.6
Blood in urine(microscopic)	31 18
Paraplegia	30 17.4
Lower limb swelling	
-unilateral	179.9
-bilateral	2112.2
Urine retention, On catheter	124 72.1

3.4 DRE and PSA in determining prostate cancer

As shown in Table 4 below, indications of prostate biopsy were suspicious DRE, raised PSA or both.

The study found that participants with normal DRE and PSA of ≥4ng/dl, and participants with suspicious DRE and PSA ≥ 4ng/dl, Adenocarcinoma detection rate was 20.4 and 70.9 respectively

One participant was found to have abnormal DRE and PSA less than 4 and, in this group, the study found a detection rate of 100

Table 4:Distribution of indications for biopsy and detection rate in 172 study participants who underwent digit guided prostate biopsy between July, 2017 to March, 2018

Patient Group	No. Pts	No. Ca	Positive Detection Rate
Normal DRE - PSA 4 or more	54	11	20.4
Abnormal DRE - PSA less than 4	1	1	100
Abnormal DRE - PSA 4 or more	117	83	70.9

3.5 Histological findings

As shown in Table 5 below, the study found the following histological type, adenocarcinoma 95(55.2%), BPH 48(27.9%) and Prostatitis 2(1.2%).

Other histologic types included non-specific inflammation 1(0.6%), schistosome egg 1(0.6%), rectal mucosa 1(0.6%), fibrous tissue 1(0.6%) and benign fibrous tumor 1(0.6%)

Inadequate sample occurred in 28(16.3%) of the participants

Table 5: Distribution of histological findings of 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018

Histological results	**Frequency**	**%**
Adenocarcinoma	95	55.2
BPH	48	27.9
Others		
Prostatitis	2	1.2
Nonspecific inflammation	1	0.6
schistosome egg	1	0.6
Rectal mucosal	1	0.6
Fibrous tissue	1	0.6
Benign fibrous tumor	1	0.6
Inadequate /unrepresentative	28	16.3

3.6 Distribution of Adenocarcinoma grade

As shown in Table 6 below, the study found the following grade, poorly differentiated adenocarcinoma 59(62.1%), moderately differentiated adenocarcinoma 29(30.5%), well differentiated adenocarcinoma 5(5.2%) and 2(2.1%) participants grade was not categorized because the sample was not adequate

Table 6:Distribution of Adenocarcinoma grade in 95 study participants who were found to have prostate cancer after digit guided prostate biopsy between July,2017 to March, 2018

Adenocarcinoma	Frequency	%
Well differentiated (GS ≤6)	5	5.2
Moderately differentiated (GS =7)	29	30.5
Poorly differentiated (GS =8-10)	59	62.1
Not categorized	2	2.1

3.7 Age distribution of participants with adenocarcinoma

The study found that the mean age of participants who were found to have adenocarcinoma was 71.9± 9.74(41-95)

As shown in Table 7 below, adenocarcinoma was more common in the age group 60-79 and 80 to 99 with 67(56.8%) and 22(59.5%) respectively compared to age group 40 -59, 6(35.3%)

Table 7:Age group distribution of participants with adenocarcinoma after digit guided prostate biopsy between July,2017 to March, 2018

Age group	Adenocarcinoma (n, %)		Total(n)
	Yes	no	
40-59	6 (35.3)	11(64.7)	17
60-79	67 (56.8)	51 (43.2)	118
80-99	22(59.5)	15 (40.5)	37

3.8 Complications of Tru cut biopsy of the prostate

As shown in Table 8 below, the study found that severe pain 53(30.8%), rectal bleeding 19(11%) and hematuria 11(6.4%) were the most complications reported

Urine retention occurred in 2(1.2%) and fever occurred in 1(0.6%)

Traumatic complications manifested as rectal bleeding and most participants with hematuria responded adequate with conservative management and persisted less than three days

One patient was admitted because of clot retention

Table 8:Distribution of complications among 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018

Complications	**Frequencies**	**(%)**
Severe Pain (7-10)	53	30.8
Hematuria	11	6.4
Rectal bleeding	19	11
Fever (presumed septicemia)	1	0.6
Urine retention	2	1.2
Others (clot retention)	1	0.6

3.9 Factors associated with the positive cancer rate

As shown in Table 9 below, the study found that back pain, Paraplegia, and lower limb swelling were statistically significant associated with adenocarcinoma 81(68.6%, $P<0.05$),24(80.0%, $P<0.05$) and31 (81.7%, $P<0.05$) respectively

Macroscopic blood in urine was not statistically significant associated with adenocarcinoma 21 (67.7%, $P=0.122$)

Table 9:Factors associated with positive cancer rate in 172 study participants who underwent digit guided prostate biopsy between July,2017 to March, 2018

Associated factors		Adenocarcinoma			P value (X^2)
		Yes	**No**	**Total**	
Back Pain	Yes	81 (68.6%)	37(31.4%)	118(100%)	0.0001
	No	14(25.9%)	40 (74.1%)	54 (100%)	
	Total	**95 (55.2%)**	**77 (44.8%)**	**172 (100%)**	
Paraplegic patient	Yes	24 (80.0%)	6 (20.0%)	30 (100%)	0.003
	No	71 (50.0%)	71 (50.0%)	142 (100%)	
	Total	**95 (55.2%)**	**77 (44.8%)**	**172 (100%)**	
Blood in urine	Yes	21 (67.7%)	10 (32.3%)	31 (100%)	0.122
	No	74 (52.5%)	67 (47.5%)	141 (100%)	
	Total	**95 (55.2%)**	**77 (44.8%)**	**172 (100%)**	
Lower Limb swelling	Yes	31 (81.7%)	7 (18.3%)	38 (100%)	0.001
	No	64 (47.8%)	70 (52.2%)	134 (100%)	
	Total	**95 (55.2%)**	**77 (44.8%)**	**172 (100%)**	

CHAPTER FOUR

DISCUSSION

This study has provided insight into finger guided Tru cut biopsy at the only NationalHospital in Tanzania. The findings are likely to reflect the practice in most other resource-limited healthcare facilities.

We have demonstrated from this study that themean age of patients who came for prostate biopsy was 71.1 years, however it was much higher than that found in Nigeria(4) Since most of our patients also presented with features of advanced disease, this could explain the higher mean age given that prostate cancer is an indolent disease. The extremes of age of 41 and 95. concurs with the study of Senegal (3).Positive family history of prostate disease was reported by 0.7 out of 10 but only one had less than 60 years of age, this means familial type of prostate cancer is rare in this study as it is usually present early and more aggressive(25). Cigarette smoking was reported approximately by 1 out of 5 participants. This is not a good finding as it might increase the risk of prostate cancer through exposure to carcinogens or by affecting the circulating hormones(26)

In our study we found an overall cancer detection rate of 55.2%, it is 10 times more than a multicenter study(27). This might be due to the factor that most of our study participants were those with advanced disease and thus most likely a histology result to be positive. Prostate cancer detection rate increased significantly in patients with suspicious DRE and PSA $\geq$ 4ng/dl, in contrary to the overall cancer detection rate reported above, this mirrored the multicenter study(27).

In our study, a diagnosis of adenocarcinoma of the prostate was only reached in 2/3 of the patients, the findings concur those from India(17). In the remaining, whether there was cancer or not, remains uncertain as there was no means of verification. 1 in 6 participants was reported as having an inadequate specimen for analysis, this is in contrary to a study in India(17) where inadequate specimen for analysis was very low. High inadequate samples in our study may be due to the blind introduction of the prostate needle and fewer core biopsies taken. With only about 1 patient presenting for prostate cancer biopsy at MNH per day, and with well-established radiology services, it should be possible to have TRUS guided prostate biopsy at this center. This should be instituted now than later as more patients are becoming aware of prostate cancer and the need for prompt and accurate disposition.

With 2/3 of our patients having Gleason score of 8 – 10, the undetermined patients might be in danger of more serious disease. It seems like our prostate cancer patients present more with poorly differentiated disease. This pattern corresponds with that from Free state(7) but in contrary to a study in India (17). Whether genetics determine this seen difference need to be studied as it might nock therapeutic potentials in African patients

Our study showed that traumatic complications were common but responded adequately to conservative management. This concurs to finding from Finland (13). Severe pain (VAS of 7 to 10) during the procedure were 9 times more in contrary to a study in Kuwait. (12). Repeat use of the Tru cut needle in our set up might mean using blunt needles with more complications. Adhering to manufacturers single use policy may further reduce the complications rate and improve the Tru cut yield in this environment. Our study also showed a

very low rate of Infectious complications 1(0.6%) in contrary to a study done in Korea (14) and by Cox CE and colleagues (24). Since this was reported by patients, the rates might be high is actively sought for.

This study has demonstrated that advanced cancer of the prostate should be highly suspected in elderly men with either back pain, Paraplegia or lower limb swelling especially when in combination with raised PSA and or suspicious DRE. In this study back pain occurred in more than 2/3 of patients with adenocarcinoma, the pattern is in contrary to a study done in Egypt (6) where back pain was slightly low. This can be explained by a late medical care seeking behavior and poor awareness of prostate cancer in our community.

The findings of this study have audited our practice and are likely to be useful in low income countries in planning for Tru cut biopsy guideline, stimulate to start prostate cancer awareness in the community and that ultrasound guided rather than digit guided prostate biopsy is necessary as inadequate or unrepresentative samples were high.

CHAPTER FIVE

CONCLUSION

Prostate cancer is a disease of elderly mostly seen in their 6^{th} decade of life and above.

Though pre procedure preparations were low, major complication rates were low as well

Inadequate biopsy samples were significantly high and most patients had poorly differentiated prostate cancers

There was a late presentation of patients to the hospital as many patients presented with symptoms and signs of advanced prostate cancer on their initial visits

RECOMMENDATION

- There is a need to have a guideline forthe Tru-cut biopsy procedure of the prostate at MNH.
- The hospital should think of buying TRUS to facilitate TRUS guided prostate biopsy rather than the old digit guided prostate biopsy to avoid missing the target tissue. MRI guided biopsy may be considered ina patient with continuing raising PSA with a negative TRUS guided biopsy result.
- Proper training for registrars and residents on prostate biopsy is needed as it may reduce inadequate samples
- Community education on prostate cancer awareness is needed, this may encourage early attendance to hospital.

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APPENDICES

Appendix I : Questionnaire

1. Serial No …….
2. Hospital reg. no……
3. In patient ……outpatient …….
4. Recruitment date ----/----/----
5. Age …….
6. Sex ……
7. District……
8. Educational level
    i. Primary level
    ii. Secondary level
    iii. University level
    iv. non
9. Co morbidities
    i. DM,
    ii. HTN
    iii. HIV
    iv. Others specify
    v. Non
10. 1st degree relative with prostate cancer
    i. Yes
    ii. No

11. Back pain
    i. Yes
    ii. NO
12. Patient able to walk
    i. Yes
    ii. No
13. Blood in urine
    i. Yes
    ii. NO
14. History of
    i. Alcohol
    ii. Cigarette smoking
    iii. Non
15. Lower limb swelling
    i. Non
    ii. Unilateral
    iii. Bilateral
16. On urethral/ suprapubic catheter
    i. Yes
    ii. No
17. LUTS
    i. Yes
    ii. No
    iii.

18. Fever

i. Yes

ii. No

19. Type of Prophylactic antibiotics/ on any antibiotics 24 hrs prior to the procedure

……..

20. DRE reveal hard and or nodulated prostate

i. Yes

ii. No

21. Type of Post procedure antibiotics / on a continuation of previous given antibiotics

…….....

22. Rectal preparation-cleansing/enema/laxative done

i. Yes

ii. No

23. PSA level (ng/ml)

i. Less than 4

ii. 4 to less 50

iii. 50 to less 75

iv. 75 to less than 100

v. ≥ 100

24. a) Patient know the reason for the procedure

i. Yes

ii. No

23 (b) Patient knowledge on preoperative preparation and complications of the procedure

i. Yes

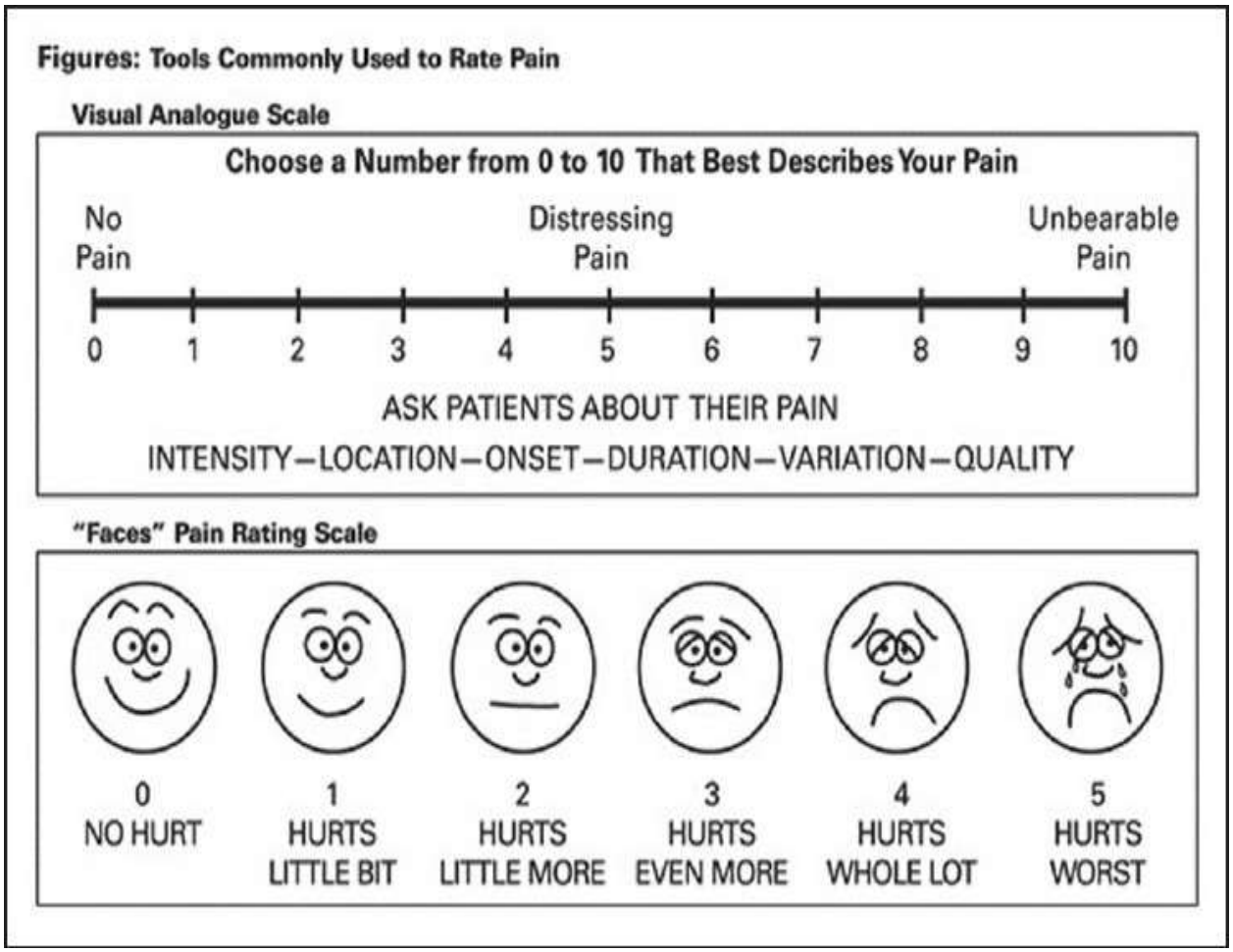
ii. No

25. Pain grade during the procedure by using visual Analogue scale (1 up to 10) …….
26. No of biopsy cores taken (1 up to 15) ……..
27. Complications reported (within 30 days)
    i. Hematuria
    ii. Rectal bleeding
    iii. septicemia
    iv. urine retention
    v. others
    vi. non
28. Admission within one week due to urological complains, mention …….....
29. Biopsy results
    i. Inadequate sample
    ii. Rectal mucosal, non-prostate tissue
    iii. Adenocarcinoma
    iv. BPH
    v. Others
30. Grade/Gleason score number. …….
31. How long does the biopsy result come out?
    i. Within one week
    ii. Within two weeks
    iii. Within three weeks
    iv. Within four weeks
    v. More than four weeks

Appendix II : Visual analogue scale

The visual analogue scale or visual analog scale (VAS) is a psychometric response scale which can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end-points.

VAS will be used to grade the amount of pain a patient feels when undergoing a digital guided Tru-cut biopsy



Appendix III: Consent Form – English Version

ID no_____

Consent to participate in the study assessing the profile and outcome of patients undergoing finger guided Tru-cut biopsy of a prostate atMuhimbili National Hospital

Greetings! My name is Dr. Flavian Simula, a postgraduate student at Muhimbili University of Health and Allied Sciences.

The purpose of the study

To assess the profile and outcome of patients undergoing finger guided tru-cut biopsy of a prostate atMuhimbili National Hospital

What participation involves

If you agree to participate in the study, of course after having a suspicious DRE and or raised PSA as entrance criteria, you will be asked some questions concerning your demographic data and your disease.

This will be followed by taking a tissue from your prostate through the anus to be examined and then your will be followed up closely for 7 days for any complications due the procedure, during the follow up time you will be phoned at day 2 and day 7 from the day of the procedure and you will be requested to come to the hospital between the 2^{nd} and 3^{rd} week for further evaluation and to be given the results of your prostate tissue.

Confidentiality

All information collected on the questionnaires and the result of your tissue will be entered into a computer with an identification number. The questionnaires will be handled with great secrecy in order to maintain confidentiality throughout the study.

Risks

Risks associated may be but not always pain, blood in urine, rectal bleeding, urine retention, local and sometimes systemic infections

Right to withdraw and alternatives

Taking part in this study is completely voluntary. If you choose not to participate in the study, you will continue to receive all services that you would normally from the hospital

Benefits

If you agree to participate in this study, there is no direct benefit apart from knowing if you have prostate cancer or not, rather the results of this study will be used for the future plan of the whole process of Tru cut biopsy.

Who to contact

If you have any question about the study, you should contact Dr. Flavian Simula on +255 717497880.

I you have questions/concerns about your rights as participant, you may contact
Dr. Bruno Sunguya,
The Director of research and publications,
Muhimbili University of Health and Allied Sciences (MUHAS),
P.O Box 65001,
Dar es salaam

Phone + 255754757577

Signature

I ..... have read the content of this form. My questions have been answered. I agree to participate in this study.

Signature of participant .....

Signature of witness .....

Date of signed consent ..../...../2017

Participant agrees ___ participant does NOT agree ____

Appendix IV: Consent Form – Swahili Version

Namba ya utambulisho .....

Hati ya ukubali wa kushiriki kwenye utafiti utakaoangalia aina ya wagonjwa na matokeo yatokanayo na kutumia kidole kuelekeza sindano na kuchukua nyama ya kupima kwenye tezi dume katika Hospitali ya Taifa Muhimbili .

Salaam! Naitwa Daktari Flavian Simula, mwanafunzi wa uzamili katika chuo kikuu cha Tiba za Afya cha Muhimbili.

Lengo la utafiti

Lengo la utafiti huu ni kuangalia aina ya wagonjwa na matokeo yatokanayo na kutumia kidole kuelekeza sindano na kuchukua nyama ya kupima kwenye tezi dume katika Hospitali ya Taifa Muhimbili

Ushiriki wako ni wa namna gani?

Ukikubali kushiriki, na hii ni baada ya vipimo vya awali vya tenzi dume kuashilia uwezekano wa kuwa na saratani ya tezi dume, utaulizwa maswali kuhusiana na taarifa zako binafsi na zile zinazohusiana na ugonjwa wako

Baada ya hapo utachukuliwa nyama ya kipimo kwenye tezi dume kwa kutumia sindano kupitia sehemu ya aja kubwa na utafuatiliwa kwa ukaribu kwa muda wa siku 7 baada ya kipimo kuangalia matatizo yeyote yatakayoletwa na kitendo cha uchukuaji nyama kwenye tezi dume, katika huo muda utapigiwa simu siku ya 2 na 7 kutoka siku uliochukuliwa nyama, na utaombwa kuja Hospitali kati ya wiki ya pili na ya tatu kwa ajiri ya ufuatiliwaji zaidi na kuchukua majibu ya nyama iliyotolewa hapo nyuma

Usiri

Taarifa zote zitakazokusanywa kwenye dodoso na majibu ya nyama, vitatambulika kwa namba na sio jina ili kuongeza usiri. Usiri huu utalindwa hata baada ya kukamilika kwa utafiti huu.

Madhara

Unaweza kupata, lakini sio lazima kwamba utapata maumivu, kutokwa na damu sehemu ya aja ndogo na au kubwa, mkojo kuziba kwa muda, maambukizi ya vijidudu kwenye tezi dume au kwenye damu

Haki ya kujitoa

Ushiriki wako kwenye utafiti huu sio wa kulazimishwa. Ukiamua usishiriki, utaendelea kupata huduma za hospitali kama kawaida.

Faida

Hakuna faida ya moja kwa moja kwenye ushiriki wako katika utafiti huu zaidi ya kujua kama una saratani ya tezi kibofu au lah. Utafiti huu utatumika zaidi kupanga mipango ya baadae kuhusu kitendo kizima cha uchukuzi wa nyama kutoka kwa tezi kibofu kwa ajiri ya kupima na kujua kama mtu ana saratani au lah.

Mawasiliano

Ukiwa na maswali yoyote kuhusu utafiti huu, wasiliana nami Dr. Flavian Simula simu namba +255 717497880.

Ukiwa na maswali kuhusu haki zako kama mshiriki, wasiliana na

Dr. Bruno Sunguya

Mkurugenzi wa utafiti na machapisho,

Chuo Kikuu cha Afya na Tiba Muhimbili (MUHAS),

S. L. P 65001, Dar es salaam

Simu + 255754757577

Sahihi

Mimi_____ nimekubali kushiriki utafiti huu baada ya maswali yangu yote kujibiwa.

Sahihi ya mshiriki _____

Sahihi ya shahidi _____ tarehe __/__/201_

Mshiriki amekubali _____ Amekataa ____