QUALITY OF LIFE OF POST HORMONAL MANIPULATION IN PROSTATE CANCER PATIENTS IN DAR ES SALAAM

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QUALITY OF LIFE OF POST HORMONAL MANIPULATION IN PROSTATE CANCER PATIENTS IN DAR ES SALAAM

By

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A dissertation Submitted in partial Fulfilment of the Requirements for the Degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences dissertation entitled; **Quality of life of post hormonal manipulation in prostate cancer patients in Dar Es Salaam** in partial fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences.

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Date

DECLARATION AND COPYRIGHT

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

Signature……..**.....** Date…….

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DEDICATION

To my dear and lovely wife, Christavia Likoko and our beloved children Debora and Dennis Jr for their support, patience and care also for the encouragement they gave me throughout my study period because despite being together I was so occupied with studies schedule on top of this research work.

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ABSTRACT

Introduction

Cancer of the prostate is the most common malignancy and the second most common cause of cancer deaths among American men. This is a disease of aging and is common in Africa where most patients present late. Treatment of prostate cancer is there fore often palliative, and impact on treatment quality of life (QOL) become very important. Androgen deprivation therapy (ADT) also known as hormone manipulation is the main stay of treatment choices and quality of life of this patients post hormonal manipulation should be known.

Objectives

To explore change in quality of life post hormonal manipulation in prostate cancer patients.

Methodology

A cross sectional descriptive study conducted among patients who present with recurrent symptoms of advanced prostate cancer three months post hormonal manipulation in the department of surgery Muhimbili National Hospital, Ocean Road Cancer Institute and Tumaini Hospital in Dar es salaam. Three quality of life domains were used .Data was collected from interview, patient's notes and patient's or relatives cellular phone numbers were recorded to facilitate data collection. Data analysis done using SPSS soft ware.

Results

Fifty four patients were enrolled in the study with mean age 72.6 years and range from 52-86 years. I n this particular study, there is a decrease in quality of life post hormonal manipulation across three domains (psychological functioning, physical functioning and daily activity performance)

Conclusion

Hormonal manipulation in prostate cancer contributes to a decrease physicaly, psychologicaly and performance status quality of life.

Recommendations

1 Multicentre study should be done to further explore QOL issues in patients with HRPC

2 Further studies should also done on HRPC

TABLE OF CONTENTS

CERTIFICATION ii

DECLARATION AND COPYRIGHT iii

ACKNOWLEDGEMENT iv

DEDICATION v

ABSTRACT vi

TABLE OF CONTENTS vii

LIST OF TABLES x

LIST OF FIGURES xi

LIST OF ABBREVIATIONS xii

CHAPTER ONE 1

1.0 INTRODUCTION AND LITERATURE REVIEW 1

1.01 Risk Factors 1

1.02 Familial and genetic influence. 2

1.03 Age 2

1.04 Hormonal 2

1.2 Spread of Disease 2

1.2.2 Spread by Blood Stream 2

1.2.3 Lymphatic Spread 3

1.3 TNM classification system 3

1.4 Clinical Features 4

1.5 Treatement Modalities 5

1.6 HRPC 8
1.7 Hematological problems 12
1.8 Lymph edema 12
1.9 Rectal Obstruction/infiltration 12
1.10 Pelvic pain 13
1.11 Neurological problems 13
1.12 Psychological dysfunction/ impaired quality of life 13
1.13 Quality of Life of Prostate Cancer Patients Treated with ADT 14
1.14 STATEMENT OF THE PROBLEM 18
1.15 RATIONALE 19
1.16 RESEARCH QUESTIONS 19
1.17 STUDY OBJECTIVE 19
1.17.1 Broad Objective 19
1.17.2 Specific Objectives 19
CHAPTER TWO 20
2.0 MATERIALS AND METHODOLOGY 20
2.1 Study design 20
2.2 Study area 20
2.3 Study population 20
2.4 Inclusion criteria 20
2.5 Exclusion criteria 20
2.6 Sample size 20
2.7 Data collection 21

2.8 Data Analysis 21
2.9 Ethical clearance consideration 22
2.10 Study Limitation 22
CHAPTER THREE 23
3.0 RESULTS 23
CHAPTER FOUR 38
4.0 DISCUSION 38
4.1 Age 38
4.2 Prominents symptoms before and after hormonal manipulation 38
4.3 Psychological functioning in relation of post hormonal manipulation 39
4.4 Daily activity performance 39
4.5 Physical health 40
CHAPTER FIVE 41
5.0 CONLUSION 41
5.1 RECOMMENDATION 41
REFFERENCES 42
APPENDIXES 51
Appendixes I: Informed Consent – English Version 51
Appendix II: Informed Consent – Swahili Version 53
Appendix III: Questionnaire – English Version 55
Appendix III: Questionnaire – Swahili Version 59

LIST OF TABLES

Table 1: Social demographic characteristics of study population (n=54)……..24

Table 2: Distribution Table showing number percentage changes of prominent symptoms (before and after) hormonal manipulations……..27

Table 3: Proportion of response on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation…28

Table 4: Mean score and standard deviation on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation……...29

Table 5: Mean score and statistical test on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation……...30

Table 6: Proportion of response on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation…...32

Table 7: Mean score and standard deviation on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation……...33

Table 8: Mean score and statistical test on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation……...34

Table 9: Proportion of response on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation…….35

Table 10: Mean score and standard deviation on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation……...36

Table 11: Mean score and statistical test on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation…….37

LIST OF FIGURES

Figure 1: Distribution of manipulation used……..25

Figure 2: Prominent symptoms before and after hormonal manipulation…….26

LIST OF ABBREVIATIONS

MNH	Muhimbili National Hospital
MUHAS	Muhimbili University of Health and Allied Sciences
ORCI	Ocean Road Cancer Institute
QOL	Quality of Life
HRPC	Hormone Refractory Prostate Cancer
HRQoL	Health Related Quality of Life
BOO	Bladder Outlet Obstruction
CAB	Combined Androgen Blockade
TNM	Tumor Node Metastasis
PSA	Prostate Specific Antigen

CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

Cancer of the prostate is the second leading cause of cancer death in Europe and North America [1]. It is the most common in African-America, Japanese and Chinese populations[2].This is a disease of aging and is common in Africa where most of the patients present late. It should be suspected in men older than 50 who present with symptoms of prostatism. They should be promptly investigated to exclude cancer.

It has been suggested that more aggressive screening of men in this age group would facilitate early diagnosis [3-4]

Prostate cancer incidence has increased in many countries since early the 1990s. Although much of this increase can be correlated with the introduction of wide spread use of prostatic specific antigen testing (PSA). In Denmark despite the absence of extensive cancer screening, the incidence increased from 11per 100,000 in 1943 to 30.9 per 100,000 in 1998 [5.]This findings suggest that some of the worldwide increase of prostate cancer incidence reflects a true increase in the number of patients with clinical prostatic cancer rather than simple result of increased in detection[6.]

Prostate cancer was reported to be number one cancer in Nigeria and constitute11% of all males cancer, with prevalence of 127 cases per 100,000 men [7].A survey carried at Kilimanjaro Christian Medical Centre found that carcinoma of the prostate accounted for 9.6% of all malignancies and ranked third in frequency of all cancers in men. [8]

1.01 Risk Factors

The specific causes of initiation and progression of prostate cancer is not known, however both genetic and environmental factors play a role in origin and evolution of this disease.

1.02 Familial and genetic influence.

Eighty five percent of PCa is sporadic and 15% is familial or hereditary.

Hereditary PCa accounts for 43% of familial PCa.Familial PCa is carcinoma in a man with one or more affected relatives. Heridatary PCa is defined as; PCa in a nuclear family with three or more affected members, carcinoma in three successive generation or carcinoma in two affected family members affected at <55yrs.

The risk for development of PCa is higher in those with an affected first-degree relative.[10] High rates of concordance in monozygotic than dizygotic brothers.[11] Relative risk increases according to the number of affected family members, degree of relatedness and age of on set.[12]

1.03 Age

The probability of PCa developing in a man of 40 year is 1:10,000 for men 40-59 is 1:103, for men 60-79 is 1:8 (smith general urology)

1.04 Hormonal

Androgens influence the development, maturation, and maintenance of the prostate.

Higher incidence of PCa observed in African Americans, may be related to elevated levels of circulating androgen compare to caucasian. African American has a 15% higher total circulating testosterone (T) level than whites.[13]

1.2 Spread of Disease

1.2.1 Local Spread

Locally advanced tumors tend to grow upward to involve the seminal vesical, the bladder neck, trigone. The later spread distally to involve the sphincter mechanism. Further upward extension can obstruct distal ureter and rarely the rectum.

1.2.2 Spread by Blood Stream

Spread by the blood stream occurs particularly to bone. The prostate is the most common site of origin for skeletal metastases, followed in turn by the breast, the kidney, the bronchus and the thyroid gland. The bone involved most frequently by the carcinoma of the prostate are the

pelvic bones and the lower lumber vertebrae. The femoral head, rib cage and skull are other common sites

1.2.3 Lymphatic Spread

Lymphatic spread may occur (1) via lymphatic vessels passing to the obturator fossa or along the sides of the rectum to the lymph nodes beside the internal iliac vein and in the hollow of sacrum and (2) via lymphatics which pass over the seminal vesicles and follow the vas deferens for a short distance to drain into the external iliac lymph nodes. From retroperitoneal lymph nodes, the mediastinal and supraclavicular nodes can become implicated.

1.3 TNM classification system

Currently, the accepted international tumor, node, metastasis (TNM) staging system pertaining to prostate cancer includes the extent of local disease (T)' the status of the region lymph nodes (N), and distant metastasis(M) [14]

1.3.1 T status

Tumor staging is as follow:

- T-Primary tumor
- TX-Primary tumor cannot be assessed
- T0- No evidence of primary tumor
- Stage T1-2c-organ-confined disease
- Stage T3a-Extracapsular extension of the tumor
- Stage T3b-Invasion of the seminal vesicle(s)
- Stage T4-Tumor fixed or invading adjacent structures other than seminal vesicles, the bladder neck, external sphincter, rectum, levator muscles, and or pelvic floor)

1.3.2 Nodal status

Lymph node involvement is staged as follows:

- Stage NX-Regional lymph nodes cannot be assessed
- Stage N0-No regional lymph node metastasis

- Stage N1-Metastasis in regional nodes

1.3.3 Other distant sites

Distant metastatic involving staging consist of the following

- Stage MX-Distant metastasis can not be assessed
- Stage M0-No distant metastasis
- Stage M1-Distant metastasis
- Stage M1a-Distant metastasis other than regional lymph nodes
- Stage M1b-Metastasis to bone(s)
- Stage M1c-Other site(s)

1.4 Clinical Features

Only advanced disease gives rise to symptoms, but even advanced disease may be asymptomatic. Symptoms of advanced disease include:[14]

- Bladder outlet Obstruction(BOO),incontinence
- Pelvic pain and hematuria
- Bone pain
- Anemia
- Pathological fracture
- Edema of the limb
- Ureteric obstruction if bilateral renal failure
- Paraplegia

Psychological dysfunction/impaired quality of life

Male

- Erectile dysfunction
- Obesity
- Breast pain
- Sweating

- Metastatic symptoms

1.5 Treatement Modalities

- Watchful waiting with expectant management/watchful waiting with curative intent/active surveillance
- Radical prostatectomy (RP)
- Radiotherapy (XRT).
- Cryotherapy.
- Androgen deprivation therapy (ADT).
- Chemotherapy.

1.5.1 Wachful waiting

Watchful waiting with expectant management/watchful waiting with curative intent.

For elderly patients, who have been carefully selected according to tumor volume, grade, PSA and Gleason score.

Patients are then followed and definitive therapy is initiated at the onset of disease progression.

Follow up is with PSA, U/S guided biopsies and DRE.

The life time risk of diagnosis of PCa is 16% and the life time risk of death from it is only 3%.[15]

Barnes1996 treated patients with prostate cancer with watch full waiting and majority died of other causes.[16]

Actual 10 year disease specific mortality is 13%, 13% and 60% for low, moderate and high grade respectively.[17]

1.5.2 Radiotherapy and Prostatectomy

XRT **and** RP**, is for patient with early disease where cure is possible.**

Chemotherapy, ADT and sometimes XRT, is for palliative care.

1.5.3 Androgen Deprivation Therapy (ADT)

Androgen deprivation therapy (ADT) is the main treatment choices available for advanced prostate cancer patients. It is often palliative and consequently the impact of treatment on quality of life (QOL) is critical. In general men with prostate cancer are not considered curable. There is still debate about timing of androgen ablation treatments in asymptomatic patients with locally advanced or metastatic disease. The options are androgen deprivation at diagnosis or careful review, with reservation active treatment for the later development of symptoms. Patients with poorly differentiated disease are at risk of catastrophic event such as spinal cord compression. In these patients, early androgen ablation can prolong the time to complications. Symptomatic patients should be offered ADT. ADT is either medical or surgical through orchiectomy[18,19]

Hormonal manipulation in prostate cancer is the suppression of androgen production by medical or surgical castration (orchidectomy)[80]

1.5.3.1 Orchidectomy

Orchidectomy is performed to carry out androgen ablation in the treatment of locally advanced (T3 or T4) disease or of metastatic disease. In 1941, prostate cancer was shown to be responsive to such treatment by Charles Huggins, the only urologist to win a Nobel prize. Bilateral orchidectomy, whether total or subcapsular, will eliminate the major source of testosterone production.[18,19]

1.5.3.2 Medical Castration

Medical form of androgen ablation have been available since the introduction of stilboestrol .Initially there were great enthusiasm for this treatment and Honvan (phosphorylate diethylstilboestrol) could be given intravenously. Both treatments are effective in producing regression of prostate cancer but are associated with significantly increased thrombotic complication and cardiovascular mortality.

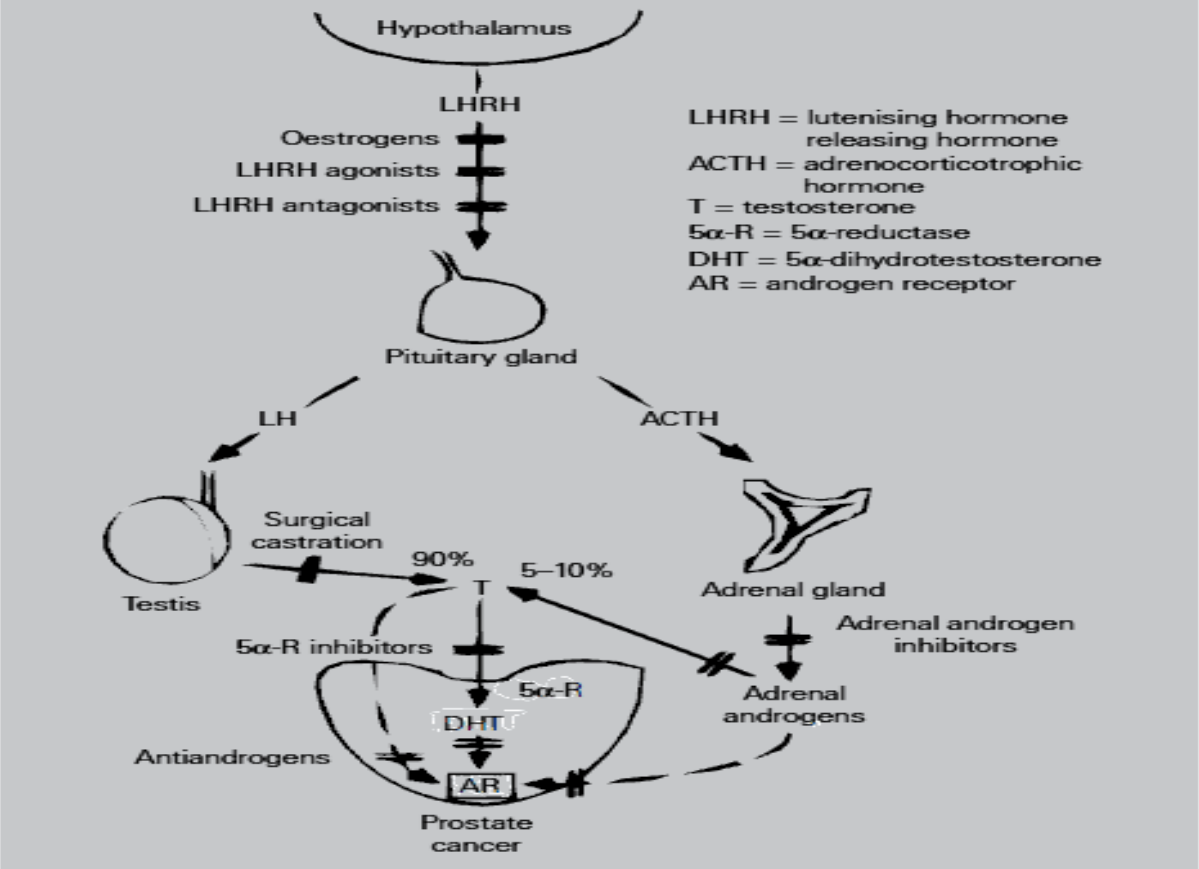
The other commonly available treatment to reduce testosterone levels to castrate range is LHRH agonists. These agents initially stimulate hypothalamic LHRH receptors, but because of their constant presence (rather than the normal diurnal rhythm) they eventualy down-

regulate the receptors, resulting in cessation of pituitary LH production and decrease in testosterone production. In the first 10 days .Serum testosterone levels may increase and it is wise to give flutamide, bicalutamide for this period. LHRH agonist may be given by monthly or 3-monthly depot injection.[18,19]

1.5.3.3 Complete Androgen Blockade

Complete androgen blockade has been advocated and the concept is that of abolishing the testicular secretion of testosterone by means of orchidectomy or the use of LHRH therapy followed by inhibiting the effects adrenal adrogenic steroid.This is accomplished by means of androgen receptor blockade with flutamide, bicalutamide or the use of cyproterone acetate.[18,19]

Figure 1. Mechanism of action of ADT



Reprinted with permission: Myiamoto et al, 2004

Despite initial response rate of 80%-90% nearly all men with advanced prostate cancer develop hormone-resistant prostate cancer after 18-36 months.[20]

These hormone refractory (HR) prostate cancer cells can grow in the absence or independent of androgens. The behavior of (HR) prostate cancers differ widely between patients.

1.6 HRPC

In patients with serum testosterone castrate level, Hormone-refractory prostate cancer is defined as 2-3 consecutive rises in prostate –specific antigen (PSA) levels obtained at intervals of more than of two weeks and or documented disease progression based on findings from CT scan or bone scan or bone pain or obstructive voiding symptoms. In a subgroup of patients,

the PSA level is not elevated at diagnosis or does not rise through the entire course of the disease. The median time to symptomatic progression after a rise in PSA level of more than 4ng/ml is approximately 6-8 months.[20,21,22]

Hormone refractory prostate cancer represent treatment dilemma for practicing physicians. Despite castrate levels of testosterone, patients with metastasis disease typically demonstrate progression within 12-18months the median survival is 2-3 years[23]

There is a subset of patients, however, who may or may not have clinical metastases who develop a rising PSA after androgen deprivation therapy in the absence of obvious radiographic disease progression. These patients may be hormone refractory at an early point in the disease progression[24]

This disease can manifest as one or more of the following

i. Increasing PSA
ii. Symptomatic progression
iii. Radiological evidence of progression disease [25,26,27]

HRPC is a fatal disease with poor prognosis. Treatment options are palliative with second line ant- hormonal estrogens, local radiotherapy and chemotherapy play role to improve quality of life.[28]

Data on epidemiology of hormone-refractory prostate cancer are limited therefore inferences must be drawn from available data for prostate cancer.

In United Kingdom between 2003and 2004, 40,000 carried diagnosis of prostate cancer. The incidence of HRPC however is unknown[11].Worldwide more than 200,000 men die annually from metastatic. HRPC include more than 80,000 in Europe and an estimaed 27,000 in US [42,4]

Study done by Inouet T,Segawat T,Kamba T, etal. In Japan found that 152 patients with prostate cancer were estimated to have HRPC after androgen ablation therapy from a single institute [29]

In its advanced stages hormone refractory prostate cancer (HRPC) is an incurable condition. Although the use of early hormone manipulation coupled with monitoring of prostate specific

antigen (PSA) has led to stage migration and development of the hormone refractory state at an earlier state of disease [30,31]

When the patient have heavy tumor burden particularly with bone metastasis the time from progression to death even in post chemotherapy era is about 12-19 months [32].

Despite this poor long term outcome it is important to remember that men with this condition need treatment that does not simply involve the use of chemotherapy. Patient will develop multiple problems as their disease progresses, including lower urinary tract deformity, ureteric obstruction, skeletal morbidity, marrow failure, lymphoedema, rectal infiltration, pain and psychological difficulties.

This spectrum of the disease requires an integrated approach by uro-oncologic team supported by radiologists, skeletal surgeon, neurosurgeons and palliative care workers [33,34]

Therefore before labeling prostate cancer as an HRPC ideally all secondary hormonal manipulations must be attempted with at least androgen withdraw.

Conventionally therapy for newly diagnosed metastatic prostate cancer has not change greatly over recent decades. Since it was clinically described, hormone ablative therapy has remained mainstay for treatment for individuals with known metastatic disease or evidence of systemic recurrence after local therapy. When used surgical pharmacological castration results in decrease of serum prostate-specific antigen (PSA) and disease stabilization 85%-90% of patients. Symptoms such as bone pain and neurological compromise are initially relieved in majority of such patients. Local symptoms including urinary retention can be relieved in approximately 50% of patients with advanced prostate cancer through hormonal ablation alone [35,36]

As bone represent the most common site for disease progression, bone pain remains the major insult to quality of life in prostate cancer patient. Some 50%-75% of patient with HRPC experience bone pain and a number may never have pain adequate controlled [37,38]

1.6.1 Lower Urinary Tract Obstruction

It is a common problem however there are no good data to establish the true incidence of lower urinary tract dysfunction in men with end stage prostate cancer. Main lower urinary tract problems are bladder outlet obstruction (BOO) urinary incontinence and hematuria [39,40]

1.6.2 Ureteric obstruction

Complication occur in 2%-3% of patients with HRPC although its incidence is higher in some report [28]

This can occur by direct extension of carcinoma into the trigone and bladder or from extrinsic pressure on the urethra by the retroperitoneal lymph node metastasis however, metastasis to the wall of ureter or peri-ureteral lymphatic is less common. It can be unilateral or bilateral and may be clinically silent in early stages. Ureteric obstruction can present as flank pain, anuria, acute renal failure, sepsis or biochemical disturbance or renal insufficiency.

1.6.3 Associated skeletal lesions

Skeletal metastasis are found in 70% of patients with advanced prostate cancer and in more than 90% of the patients who die of prostate cancer[41]Clinical consequence can be bone pain, pathological fracture, spinal cord compression, hypercalcemia and hypocalcaemia.

Skeletal complications have been shown to significantly reduce health related quality of life in patients with prostate cancer[42]

1.6.3.1 Bone pain: Many patient with HRPC will have bone pain at some point in course of their disease.[41] The cause is not completely understood however it is suspected that cancer induce osteolysis may be involved. Pain can be diffused or localized and it is described as an ache, burn or stabbing sensation that increase at night.[20]The extent of the disease in the skeleton does not necessary correlates with the pain experienced [43]

1.6.3.2 Pathological fracture: Incidence of pathological fracture is around 3% but recently it has been reported to be high as - 33% in HRPC with about two third occurring in the vertebral column and the rest in the long bones. [22,44]. The risk is exacerbated with the long term use of androgen suppression and when fracture occur it is associated with significant reduction in patient survival.[23]

1.6.3.3 Spinal cord compression: Prostate cancer is second only to the lung cancer as the cause of metastatic spinal cord compression in men and 1-2% of prostate cancer patients will develop this complication [46].

In 12-19% of cases spinal cord compression is the first presenting sign.[25] Spinal cord compression most commonly occur in the thoracic and upper lumbar spine where the spine canal is narrowest [47].The most common symptom is local or radicular pain, paraplegia may develop and this can be indolent or rapid onset

1.7 Hematological problems

Anemia is common finding in HRPC patients, however true incidence is not known. It can be due to or renal failure direct consequences bone marrow infiltration by metastatic prostate cancer cells. It may be exacerbated by iron deficiency due to poor dietary intake or anemia of chronic malignancy and chronic disease. Anemia of prostate cancer develop gradually, therefore even profound anemia can be tolerated well.

1.8 Lymph edema

As prostate cancer spread it may obstruct lymphatic and venous outflow from the lower extremities and pelvis, resulting in lower extremity edema. It is rarely due to hypoalbuminemia. If the edema is unilateral, possibility of deep vein thrombosis should be considered and need to be ruled out by appropriate investigation.

1.9 Rectal Obstruction/infiltration

Direct invasion of the rectum or involvement per rectal areas by prostate cancer is common. Clinical manifestations are variable, the most common is constipation while others are rectal pain, tenesmas, rectal bleeding, bowel obstruction. A recto prostatic fistula is quite an uncommon complication. The rectal infiltration take the form of an anterior rectal mass with or without ulceration in 52% and annular stricture in 45%with anatomically separate masse in 3% of patients.

1.10 Pelvic pain

Locally advanced prostate cancer involving the rectum and sacral plexus can cause severe perineal pain of neuropathic origin or due to rectal involvement. Pain can also be due to bladder invasion or bony erosion

1.11 Neurological problems

Brain metastasis usually represents the failure of hormone deprivation therapy and the presence of disseminated disease. Metastasis to the brain can occur by direct extension from adjacent structures such as sphenoid bone .The most common intracranial sites of prostate cancer metastasis are leptomeninges 67% cerebrum25% and cerebellum 8% [47].

1.12 Psychological dysfunction/ impaired quality of life

Psychological dysfunction is common in HRPC patients and up to 25% of patients with cancer develop clinical depression which might potentially benefit from treatment. [46]

In HRPC it has been shown that depression occurs relatively early in the time course of the disease and it is present one year before death in many individuals.[47] The findings show that patients with HRPC were more increased sleep disturbances, decrease in social functioning and are in greater pain.[47]

1.13 Quality of Life of Prostate Cancer Patients Treated with ADT

When various types of prostate cancer treatment are compared, many studies report that men receiving ADT have overall worse QOL, worse physical and greater fatigue, compared to men treated with radical prostatectomy or radiotherapy. Quality of life, however did significantly decline from baseline in all men with HRPC regardless of the treatment received [48,49,50]

Gravis et al (2005) demonstrated that patient with HRPC who were being treated with docetaxel has a significant deterioration in their physical function and their ability to participate in daily activities. [51] Studies show that patients with HRPC who are on hormonal manipulations had increased physical discomfort and worry about the disease. They also reported limitations in daily activities and overall bother.[52] It was found that decreased physical functioning and greater fatigue were the common outcomes [52,18]

Study done by Pirl etal 2002 and Amelda etal, 2004 found that the incidence of depression is higher among men treated with ADT when compared to age matched health men.

Green and colleagues (2002b) found that ADT was associated with a decrease in QOL in the following domains social, role function and cognitive function.

A study by Stone et al. 2000 found that men treated with ADT reported increased fatigue, contrary to findings of Herr and O' Sullivan 2000.The researchers compared prostate cancer patients (N=431) who had received either orchidectomy or LHRH-A as primary therapy. At 12months post diagnosis, more men receiving LHRH-A than those with orchidectomy reported statistically significant problems in the following areas: sexual function, physical discomfort and worry about prostate cancer. Across both groups over 40% of patients reported limitation in activities daily living and over 50% of both groups reported that they were bothered by their health.

The concept of quality of life has great significance in the health care arena, because the number of people living with chronic illness is growing rapidly.

In weighing options for treating life threatening diseases such as cancer, patients and health care providers are interested in knowing both the number of years a given treatment will add to life and quality of life in those added years.

HRQoL is multidimensional construct that typically include four broad categories physical, functional and emotional well being. [34] Cella states that HRQoL refers to the extent to which one or expected physical, social and emotional well being are affected by medical condition or its treatment [53]. Thus the minimum criteria for an appropriate measurement of HRQoL include

A) Measurement that incorporate the patients perspective

B) Measurements captures physical, social and mental well being

Studies on the impact of treatment on long-term health related quality of life (HRQoL) are scarce.

Relatively little is known about long-term impact of cancer as it affects individuals on daily basis. In the aggregate, long term survivors appear to score well on standard QOL.

World health organization define quality of life (QOL) as the individuals perception of their life status concerning the context of culture and value system which they live their goals, standard expectations and concern [54]

Until now no single tool or method has been shown to be ideal to measure HRQoL in all circumstances. It has been shown that very different HRQL can be obtained in the same population if different tools are used [54.] With more than 2000 publications SF-36 is the one of the most widely used HRQL used worldwide. It is self administered survey containing 36 items. It include one multiple item scale that asses 8 health domains. These include,

1. Physical functioning limitation of social activities because of health problem
2. Role physical-limitation in usual role activities because of physical health problem
3. Social functioning limitation of social activities because of physical or emotion problem

4. Bodily pain-limitation of activities due to pain
5. General mental health
6. Role Emotion-limitation in usual role activities because of emotional problem
7. Vitality
8. General health perception

These domains are measured on a summative scale with score between 0 (worst) and 100 (best)[55]

Traditionally clinicians have mainly focused on classical aspect on evaluation of cancer treatment outcome, such control symptoms, response on treatment relapse and survival, less attention has been paid to how the disease and its treatment affect HRQOL [56] QOL is multidimensional construct and its assessment covers much more than the simple estimation of treatment and disease related morbidity and is based upon the patients personal experience and evaluation of his total life situation [57]

In patient with prostate cancer change in functions for example those associated with anxiety and treatment side effects such as changes in sexual, urinary and bowel functions often affect HRQL in a patient with more advanced local stages of prostate cancer or metastatic disease [58].

QOL should contain questionnaire specific questions which include worry for prostate cancer and prognosis, bowel/pelvic pain, lower urinary tract symptoms, urinary incontinence, bowel function, sexual function [59,60].

Studies show that clinicians frequently underestimate their patient wish for information and discussion while overestimating patient desire to make decision [61,62]

It is important to note that while conducting QOL assessment study methodological problem and limitations should be considered. Firstly because sociodemographic characteristics differ between cohorts in various QOL studies the results are not always comparable[63].Most studies do not include sociodemographic factors Eton et al 2001 found that less formal education was associated with poor QOL in patient with prostate cancer[64]. Study of patients with advanced prostate cancer, patients with less formal education and lower income had faster decline in most QOL domains on SF-36.[65]

Penson et al 2001 found that patient with prostate cancer with lower income had significantly lower baseline QOL scores in all domains of the SF-36.[66]Poor, less educated and minority men also have less knowledge about prostate cancer before and after they get disease.[67]

In a study by Moinpour et al (1998) randomized double blinded trial to compare the QOL of prostate cancer patients (N=739) treated with orchidectomy plus either flutamide or placebo, found that at three and six months, the flutamide arm reported significantly worse emotional functioning than the placebo arm.

Study done by Bacon et al 2001; found that men treated with ADT had a significantly greater decrease in role function (eg. Work related activities and activities of daily living than men without prostate cancer.

Vitality outcome associated with hormonal therapy such as fatigue, depression were worse among patients received hormonal therapy. [68]

Vitality investigated support and psychological care needs of men with prostate cancer shows more commonly reported need were fears about cancer spread (44%) concern about those close to you (43%). Men of advanced disease have greater level of depression and anxious, decreased social functioning and increased sleep disturbances.[69]

Study done by Steginga et al show that patients with HRPC received hormonal manipulation t were commonly reported for fears about cancer spreading, concern about worries to those close to them.[70] Study showed individual on hormonal treatments were more frequently associated with decreased social, role functioning and that cancer patients suffer from persistent emotional, social distress and cognitive functioning[71]

1.14 STATEMENT OF THE PROBLEM

Prostate cancer is the form of cancer that develops in the prostate gland in the male reproductive system. Treatment of men with localized prostate cancer at diagnosis usually consists potentially curative radical prostatectomy or radiation therapy. However a majority of these men progress to a condition known as advanced prostate cancer. The treatment of choice for this stage of disease is androgen ablation therapy which has been found to be palliative, offering survival. The majority of patients of advanced disease eventually progress to androgen independent stage (AID) also known as Hormone refractory prostate cancer (HRPC), which is unresponsive to further hormone therapy. Patients with HRPC increasingly develop symptoms as a result of advanced local and or metastatic disease during their progression to death. Quality of life has been increasingly more important for men diagnosed with prostate cancer. The disease has significant impact on quality of life . and while the goal of palliative therapy is to alleviate symptoms, the majority of studies suggest that prostate cancer patients receiving ADT experience a decrease in QOL [29,30]

The baseline QOL of patients treated at MNH, ORCI and Tumaini hospitals with HRPC is unknown. Much of the available data pertains to American and Western European populations and may not be applicable in Tanzania. There is a need to identify the baseline quality of life of our patients with HRPC in order to guide future research

This study also will provide baseline data about QOL issues of patients with prostate cancer hence help to plan early management to patient with this condition.

1.15 RATIONALE

The findings from this study would shed light on understanding quality of life of post hormonal manipulation in hormonal refractory prostate cancer patients. Information from this study will also provide psychological and physical health sequalae experienced by patients after hormonal manipulation.

Findings also will help clinicians to be able to inform their patients with HRPC in our settings the outcomes and anticipated prognosis post hormonal manipulation.

1.16 RESEARCH QUESTIONS

1. What are the quality of life changes of patients with prostate cancer post hormonal manipulation

1.17 STUDY OBJECTIVE

1.17.1 Broad Objective

To explore the change in quality of life after hormone manipulation in HRPC in Dar es salaam

1.17.2 Specific Objectives

1. To determine the socio-demographic characteristics of patients undergoing hormone manipulation for HRPC at MNH, ORCI, and Tumaini hospitals
2. To explore prominent symptoms of prostate cancer pre-hormone manipulation
3. To explore prominent symptoms of prostate cancer post-hormone manipulation
4. To explore perceived changes of quality of life in patients with HRPC post hormonal manipulation in physical health, psychological functioning and self care

CHAPTER TWO

2.0 MATERIALS AND METHODOLOGY

2.1 Study design

A cross- sectional descriptive study was conducted in the Department of Surgery, Muhimbili National Hospital, Ocean Road Cancer Institute and, Tumaini Hospital, in Dar es salaam from March to December 2014 and involving all patients with symptomatic HRPC post hormonal manipulation. Data was collected through face to face interview with patients and review of case notes, through mobile phones based conversations.

2.2 Study area

Study was conducted MNH, Ocean Road Cancer Institute and Tumaini Hospital in Dar es salaam .These are hospitals that have urological facilities which are used to manage patients with cancer of the prostate in Dar es salaam.

2.3 Study population

Study participants included all inpatients and outpatients attending urology clinics in MNH, Ocean road cancer institute and Tumaini hospital with cancer of prostate who were subjected to hormonal manipulation and presented with recurrent symptoms.

2.4 Inclusion criteria

All patients with HRPC who have been subjected to hormonal manipulation and at least three months post hormonal manipulation who presented with recurrent symptoms/signs.

2.5 Exclusion criteria

All patients of prostate cancer who underwent hormonal manipulation who are very sick to respond to the interview and patients who had hormonal manipulation with no recurrent symptoms/signs.

2.6 Sample size

Convenience basis was used to obtain sample size where by in each hospital all patients with prostate cancer and are at least three months post hormonal manipulation who present with

recurrent symptoms at the time of data collection were included, where by 16 recruited from Muhimbili National Hospital,10 patients from Tumaini Hospital and 28 patients from Ocean Road Cancer Institute making total of 54 patients.

2.7 Data collection

Data were collected by using structured questionnaire set-in form of closed question. The questionnaire was developed in English and there after translated into Kiswahili in which patients registration number and phone number were recorded to ease tracing them. Structured questionnaires were to collect demographic and clinical data as well as symptoms/signs and quality of life indicators. The patients were interviewed by researcher and researcher assistants.

2.8 Data Analysis

Data extracted from questionnaires were transferred to the computer soft ware program SPSS where data cleaning and coding was performed. Prominent symptoms before and after hormonal manipulation like bone break, lower limb weakeness, lower limb swelling, pelvic pain, back ache, Hematuria, UTI and quality of life indicators were analysed.

Data analysis using frequency and cross-tabulation, mean score before and after hormonal manipulation calculated with appropriate statistical test.

The statistical significance was tested using t-test and the results were considered to be significant when p-value is less than 0.001.

2.9 Ethical clearance consideration

- This study was conducted in accordance with existing ethical guidelines. Ethical clearance for the study was sought from The MUHAS ethical committee.
- There were no harm, what so ever to the patient by participating in the study as they were undergoing their treatment protocols as usual. Information collected was kept confidential even after the study.
- Description of study was given to the participant to ensure they understood and received knowledge about the study so as to make independent informed choice.
- A written consent was obtained from each participant prior to enrolment

2.10 Study Limitation

1. Although numerous publications address QOL instruments and relative merits of assessing QOL there is no consensus on the appropriate reporting of QOL measures and no common metric that allows for ready comparison between studies
2. Because many investigations in HRPC are non comparative treatment studies, determining whether QOL deterioration is related to therapy, natural disease progression or combination of treatment and disease progression remain difficult.
3. This dissertation is limited to a time frame work of one year hence the research was a short period of follow up. As a result of the short time period, only a small cohort of patients could be recruited. They may not be representative of the general population
4. Survey based studies are subject to recall bias. This may have significantly confounded the pre-ADT reported quality of life measures.

CHAPTER THREE

3.0 RESULTS

3.1 Social demographic characteristics of study population

A total of 54 patients were enrolled in the study. These were patients who were suspected to have recurrent symptoms at least three months post hormonal manipulation. Among these population 16(29.6%) were from Muhimbili National Hospital, 10(18.6%) from Tumaini Hospital and 28(51.8%) from Ocean Road Cancer Institute.

Study population's age ranged between 52-86 years. The peak aged group were age more than 76 years 22(40.7)%.The mean age was found to be 72.6 years and standard deviation (SD=7.7),95% CI (70.6-74.7).

The minimum age of a group was 52 years and maximum age was 86 years. Table 1

Table 1: Social demographic characteristics of study population (n=54)

Character	Specific variable	Frequency (n)	Percentage (%)
Age (Years)			
	Less than 65	10	18.5
	66 to 70	13	24.1
	71 to 75	9	16.7
	More than 76	22	40.7
Education level			
	No formal education level	13	24.1
	Primary education level	27	50.0
	Secondary education level	12	22.2
	University education level	2	3.7
Residence			
	Urban	31	57.4
	Rural	23	42.6
Health Facility			
	Muhimbili national hospital	16	29.6
	Tumaini hospital	10	18.6
	Ocean Road hospital	28	51.8

The mean age was found to be 72.6 years (SD=7.7), 95% CI (70.6 – 74.7)

3.2 Description of surgical or medical manipulation made

Orchidectomy and Bicalutamide used by 27 patients , 20 patients use combination of all three and 5 patients used Zoladex and Bicalutamide while 2 patients use only Zoladex.

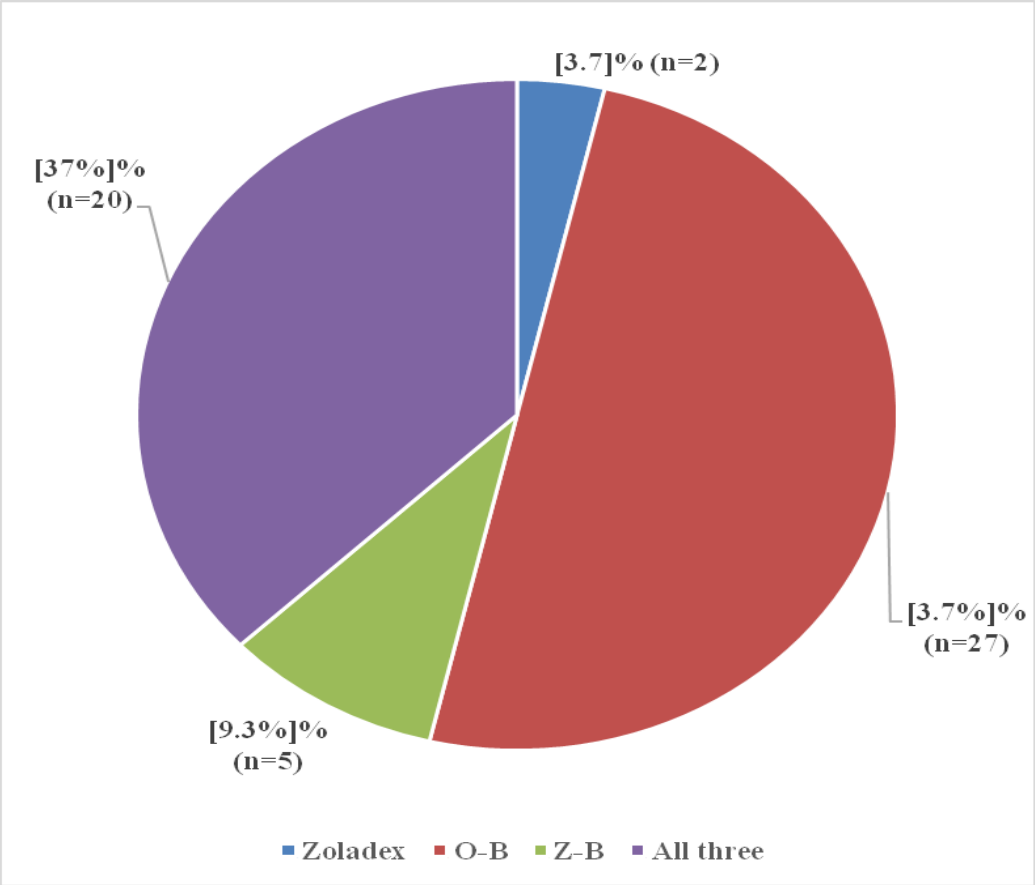


Figure 1: Distribution of manipulation used

3.3 Prominent symptoms before and after hormonal manipulation

The most prominent symptoms pre-hormonal manipulation were UTI (75.3%), Hematuria (60.4%), back ache (34.6%), pelvic pain(14.8%) and fracture. After hormonal manipulation symptoms of, back ache (93.3%), and pelvic (85.2%) become worse followed by lower limb swelling (57.4%), fractures(46.3%) and lower limb weakness(46.3%).

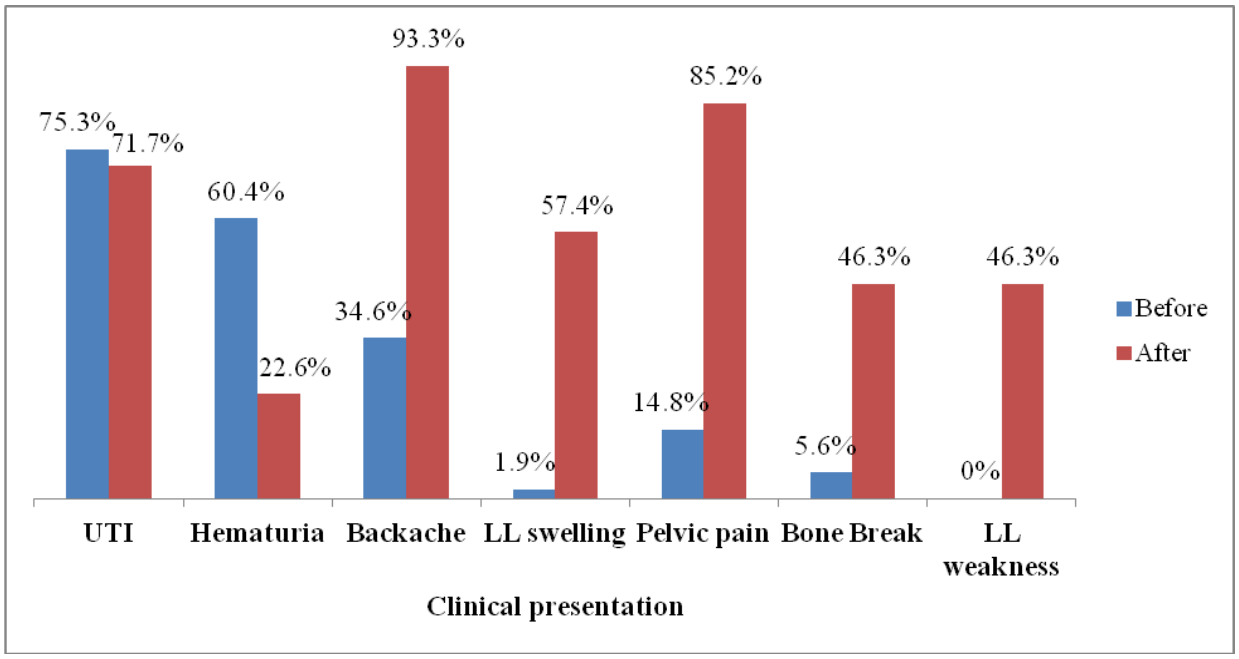


Figure 2: Prominent symptoms before and after hormonal manipulation

The mean number of symptoms before manipulation was found to be 1.89 with 95% CI (1.6 – 2.13) whereas after manipulation the mean was found to be 4.24 with 95% CI (3.83 – 4.63). The observed difference in mean was found to statistically significant (p<0.001)

Table 2: Distribution Table showing number percentage changes of prominent symptoms (before and after) hormonal manipulations.

Prominent symptoms	Percentage changes (%)
UTI	3.8
Hematuria	37.8
Backache	-58.7
Lower limb swelling	-55.5
Pelvic pain	-70.4
Bone break	-40.7
Lower limb weakness	-46.3

Negative percentage change means increase in symptoms as previous observed

3.4 Psychological functioning in relationship to pre and post hormonal manipulation

The assessment of psychological functioning as one of the quality of life was done by asking patients a series of questions. In this domain the respondents were asked to report changes experienced before and after starting hormonal manipulation. A scale of questions asked based on 1(strongly disagree) to (strongly agree) 5 and their proportion response. Table 3

The respondents ranked issues they consider important in improving or worsening their quality of life

Table 3: Proportion of response on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation

Variable	Before					After				
	No	Rarely	Often	Always	Consecutive	No	Rarely	Often	Always	Consecutive
Experience lack of interest **/Depression**	14 (25.9)	36 (66.7)	1 (1.9)	3 (5.6)	0 (0)	3 (5.6)	0 (0)	11 (20.4)	35 (64.8)	5 (9.3)
Experience difficult in falling asleep	22 (40.7)	23 (42.6)	6 (11.1)	2 (3.7)	1 (1.9)	0 (0)	1 (1.9)	12 (22.2)	29 (53.7)	12 (22.2)
Experience anxiety/fear	10 (18.5)	29 (53.7)	11 (20.4)	1 (1.9)	3 (5.6)	1 (1.9)	2 (3.7)	6 (11.1)	31 (57.4)	14 (25.9)
Experience moodiness/temper or anger	19 (35.2)	29 (53.7)	3 (5.6)	2 (3.7)	1 (1.9)	0 (0)	4 (7.4)	12 (22.2)	30 (55.6)	8 (14.8)

Table 4: Mean score and standard deviation on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation

Quality of life indicators	BEFORE				AFTER				
	Mean	**SD**	**Minimum**	**Maximum**	**Mean**	**SD**	**Minimum**	**Maximum**	**p-value**
Experience lack of interest/depression	**1.88**	0.702	1	4	**3.71**	0.856	1	5	<0.001
Experience difficult in falling asleep	**1.85**	0.906	1	5	**3.98**	0.726	1	5	<0.001
Experience anxiety/fear	**2.27**	0.965	2	5	**4**	0.835	1	5	<0.001
Experience moodiness/temper or anger	**1.83**	0.841	1	5	**3.77**	0.793	1	5	<0.001

Table 5: Mean score and statistical test on perceived changes on psychological functioning among patients with Prostate Ca before and after hormonal manipulation

Quality of life indicators	Mean score		
	Before	After	*p-value
Experience lack of interest/depression	1.88	3.71	<0.001
Experience difficult in falling asleep	1.85	3.98	<0.001
Experience anxiety/fear	2.27	4	<0.001
Experience moodiness/temper or anger	1.83	3.77	<0.001

**Statistics on paired sample t-test*

Before hormonal manipulation the respondents had low mean score compared after hormonal manipulation.

Before hormonal manipulation patients had minimal symptoms of lack of interest, difficult in falling asleep, anxiety and, experienced temper or angry/moodiness. These symptoms were noted to worsen after hormone manipulation. This indicate that patients experience bad QOL post hormonal manipulation this may be due to disease progression or side effect of manipulation.

Mean score of lack of interest was 1.88 before while after hormonal manipulation rose to 3.71.

Mean score of experience difficult in falling asleep 1.85 before while after hormonal manipulation rose to 3.98.

Mean score of experience anxiety/fear 2.27 before and rose to 4 after hormonal manipulation.

These data suggest a statically significant difference of psychological functioning changes before hormonal manipulation and after hormonal manipulation (p value <0.001).Table 4 and 5

3.5 Daily activity performance

The score that were used for daily activity performance were 1=strongly disagree, 2=Disagree, 3=I don't know, 4=agree, 5=strongly agree. Table 6

When asked about daily activity performance, patients reported a decrease in their ability to walk more than a kilometer after hormone manipulation. They similarly reported a decreased ability to dress themselves (Table 7). These data indicated a decrease in daily function following hormone manipulation. The same 1-5 scale as above was used

Table 6: Proportion of response on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation

Variable	BEFORE					AFTER				
	Strong Disagree	Disagree	Neutral	Agree	Strong Agree	Strong Disagree	Disagree	Neutral	Agree	Strong Agree
Decrease vigorous activities	2 (3.7)	35 (64.8)	9 (16.7)	8 (14.8)	0 (0)	0 (0)	0 (0)	1 (1.9)	41 (75.9)	12 (22.2)
Decrease ability to climb stairs	3 (5.6)	25 (46.3)	24 (44.4)	2 (3.7)	0 (0)	0 (0)	1 (1.9)	1 (1.9)	45 (83.3)	7 (13)
Decreased ability to walk more than km	6 (11.1)	34 (63)	9 (16.7)	4 (7.4)	1 (1.9)	0 (0)	2 (3.7)	0 (0)	30 (55.6)	22 (40.70
Decrease ability to dress oneself	9 (16.7)	32 (59.3)	10 (18.5)	3 (5.6)	0 (0)	0 (0)	2 (3.7)	0 (0)	41 (75.9)	11 (20.4)

Table 7: Mean score and standard deviation on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation

Quality of life indicators	BEFORE				AFTER				
	Mean	**SD**	**Minimum**	**Maximum**	**Mean**	**SD**	**Minimum**	**Maximum**	**p-value**
Decrease vigorous activities	**2.44**	0.792	1	4	**4.21**	0.451	3	5	<0.001
Decrease ability to climb stairs	**2.45**	0.665	1	4	**4.08**	0.47	2	5	<0.001
Decrease ability to walk more than km	**2.27**	0.828	1	5	**4.33**	0.673	2	5	<0.001
Decrease ability to dress oneself	**2.15**	0.754	1	4	**4.12**	0.584	2	5	<0.001

Table 8: Mean score and statistical test on perceived changes on daily activities (self care) among patients with Prostate Ca before and after hormonal manipulation

Quality of life indicators	Mean score		
	Before	**After**	***p*-value**
Decrease vigorous activities	2.44	4.21	<0.001
Decrease ability to climb stairs	2.45	4.08	<0.001
Decrease ability to walk more than km	2.27	4.33	<0.001
Decrease ability to dress oneself	2.15	4.12	<0.001

**Statistics on paired sample t-test*

3.6 Physical health

The assessment of physical health as one of the quality of life was done by asking domain of these questions 1(strongly disagree to strongly agree).Table 9

Mean score of limitation of daily activities 2.4 before hormonal manipulation raised to 4.12 after hormonal manipulation.

Mean score for cut down amount of time they spent on daily work was 2.35 before hormonal manipulation raised to 4 after hormonal manipulation.

Mean score of getting tired shortly perfuming their work was 2.42 before hormonal manipulation which raised to 4.23 after hormonal manipulation.

The results show that the difference on physical health statistically significant P-value < 0.001

Means that there was worsening of their daily or regular activities due to their physical health. Table 10 and 11.

Table 9: Proportion of response on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation

Variable	BEFORE					AFTER				
	Strong Disagree	Disagree	Neutral	Agree	Strong Agree	Strong Disagree	Disagree	Neutral	Agree	Strong Agree
Cut down amount of time spend on daily work	0 (0)	41 (75.9)	9 (16.7)	3 (5.6)	1 (1.9)	0 (0)	1 (1.9)	2 (3.7)	47 (87)	4 (7.4)
Accomplish less to do daily work	13 (24.1)	21 (38.9)	17 (31.5)	3 (5.6)	0 (0)	2 (3.7)	1 (1.9)	0 (0)	38 (70.4)	13 (24.1)
Getting tired performing work or other activities	6 (11.1)	29 (53.7)	8 (14.8)	10 (18.5)	0 (0)	0 (0)	0 (0)	1 (1.9)	32 (59.3)	21 (38.9)
Limited in the kind of work/ other activities	3 (5.6)	36 (66.7)	7 (13)	8 (14.8)	0 (0)	1 (1.9)	1 (1.9)	0 (0)	34 (63)	17 (31.5)

Table 10: Mean score and standard deviation on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation

Quality of life indicators	BEFORE				AFTER				
	Mean	**SD**	**Minimum**	**Maximum**	**Mean**	**SD**	**Minimum**	**Maximum**	**p-value**
Cut down amount of time spend on daily work	**2.35**	0.673	2	5	**4**	0.434	2	5	<0.001
Accomplish less to do daily work	**2.15**	0.87	1	4	**4.12**	0.769	1	5	<0.001
Getting tired performing work or other activities	**2.42**	0.929	1	4	**4.38**	0.525	3	5	<0.001
Limited in the kind of work or other activities	**2.4**	0.808	1	4	**4.23**	0.724	1	5	<0.001

Table 11: Mean score and statistical test on perceived changes on physical health among patients with Prostate Ca post-hormonal manipulation

Quality of life indicators	Mean score		
	Before	**After**	***p*-value**
Cut down amount of time spend on daily work	2.35	4	<0.001
Accomplish less to do daily work	2.15	4.12	<0.001
Getting tired performing work or other activities	2.42	4.38	<0.001
Limited in the kind of work or other activities	2.4	4.23	<0.001

**Statistics on paired sample t-test*

CHAPTER FOUR

4.0 DISCUSION

Cancer of prostate is the second leading cancer death in Europe and North America. This is a disease of aging and is common in Africa, where most patients present late. [1,2]The treatments depend on the stage of disease. Advanced tumors are treated by hormonal manipulation. Despite the initial response rate of 80%-90% nearly all men with advanced prostate cancer develop hormonal resistant prostate cancer (HRPC) after 18-36 months and the treatment then becomes palliative. Consequently impact of treatment on quality of life become pivotal.[20,21,22]

4.1Age

The incidence of HRPC rises with age but there is a geographical variation. The median 72.6years age of the study population and the youngest patient was 52 years. This is comparable from another study which was done in Singapore which showed that the youngest age of the patient with HRPC was 53 years and median age was 70 years and range 53-86 years.[73]This study findings is in line with other studies that HRPC is the disease of elderly though young males are not spared. Majority of patients have primary education (50%) and no formal education (24.1%), this may be because they lack knowledge about prostate cancer. This study also go in line with study done by Smith GE et al found that less educated and minority men has less knowledge about prostate cancer before and after they got disease.[67]

4.2 Prominents symptoms before and after hormonal manipulation

In this study prominent symptoms before hormonal manipulation were UTI (75.1%), haematuria (60.4%) and back ache. After hormonal manipulation UTI and haematuria improved from UTI 75.1% to71.1% and haematuria from 60.4% to 22.6%.

Back ache and pelvic pain become worse after hormonal manipulation, patients presenting with back ache in this study were 93% and pelvic pain 85.5% .This study findings can be compared with other studies reported patients with back ache, pelvic pain in patients with

HRPC.[20,41,43,74]The back ache and pelvic pain may be due to hormonal resorption lead to osteoporosii or due to progression of the disease.

In this study pathological fractures were 46.6% and this finding is in line with other study which reported pathological fractures were 33%.[44] T he fact that our patients had a higher incidence pathological fractures may be is due to long term use of androgen suppression or sampling error .

Lymphoedema usually results from lymphatic obstruction rather than hypoalbuminemia. This results to lower limb swelling.[74]In our study 57.4% of patients present with lower limb swelling.[74]

4.3 Psychological functioning in relation of post hormonal manipulation

Psychological issues impact heavily on QOL in patients of HRPC post hormonal manipulation. Constant anxiety, lack of interest/depression, experiencing difficult in falling asleep, and moodiness all contribute to poor QOL. In this study most of respondents reported worsening in psychological functioning after hormone manipulation .These findings are in line with study done by Pirl etal 2002 and Amelda etal found that the incidence of depression is higher among men treated with hormonal manipulation. Other studies show patients with HRPC treated with hormonal manipulation reported to have fears about disease, greater level of depression and anxiety and increased sleep disturbance [68,69]

4.4 Daily activity performance

Findings in this study show respondents were limited in their daily activities post hormonal manipulation. Patients reported decreased their ability to walk a kilometer and decreased the ability to dress themselves. This is in line with study done by Bacon et al 2001 found that men treated with ADT had significantly greater decrease in role functioning than men without prostate cancer.

4.5 Physical health

This study shows that there is worsening of their daily activities or regular activities of patients with HRPC treated with hormonal manipulation due to their physical health. This is a similar to a study done by Gravis et al and others that shows patients with HRPC who were in docetaxel had significant deterioration of physical functioning such as cut down amount of time to spend in their daily activities and getting tired shortly. Other studies show that patients with HRPC treated with hormonal manipulation reported limitation of their daily activities and decreased physical functioning due to their physical health.[18,51,52]

Study done by Herr and O'sullivan found that patients with hormonal refractory prostate cancer post hormonal manipulation have poor QOL ,decrease in physical functioning i.e limitation in the kind of work they do due to their physical health.

CHAPTER FIVE

5.0 CONLUSION

1. Majority of patients with HRPC had poor QOL post hormonal manipulation
2. Hormonal manipulation surgical or medical remain treatment of choice for HRPC patients in Dar es salaam
3. Most symptoms become worse post hormonal manipulation for the patient with HRPC

5.1 RECOMMENDATION

1. Further multicenter studies should be done to explore QOL issues in patients with HRPC post hormonal manipulation
2. Clinicians should specifically ask about QOL issue in patients with hormone refractory prostate cancer
3. Further studies should also be done on HRPC

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APPENDIXES

Appendixes I: Informed Consent – English Version

INFORMED CONSENT TO PARTICIPATE IN THE RESEARCH

Introduction Aim of this study is to determine the clinical presentations among the patients with hormone refractory prostate cancer in our society. The participation is freely and voluntarily. If you decide not to participate in the research it will not affect the access to the health services at any health facility in the United Republic of Tanzania including MNH, Tumaini hospital.

Benefits There are no direct benefits a participant gets in this research but you will be appreciated as one of contributors in findings about the facts on Hormone refractory prostate cancer in Muhimbili National Hospital, Ocean Road Cancer Institute, Tumaini Hospital and University teaching hospital.

Risks The participants will not get any serious risks from this research

Confidentiality The information obtained from this research will be confidential and will only be used for improvement of our management in hormone refractory prostate cancer and knowledge to health personnel's.

I will be glad **to** receive your consent in the participation for this research.

DR MNDEME, Hamisi Omari

Signature …….. Investigator

Communication For any query concerning this research, please do not hastate to contact

DR MNDEME Muhimbili University of Health and Allied Sciences (MUHAS). P.O Box 65013. Mobile +255 767368439

If you have queries concerning your rights as a participant in the research, please contact:

Prof Mainen Moshi, The Director of research and publications Muhimbili University of Health and Allied Sciences (MUHAS). P.O Box 65001 Dar es salaam. Tel 0713622244

I will be grateful if you will agree to participate in this study.

I…… Participant)

I have read and understood the information provide to me as it is written also my questions have been properly answered by the investigator. I personally without any coercion I agree to participate in this research.

Name of Participant …… Tel…….

Signature…… Date……

Appendix II: Informed Consent – Swahili Version

FOMU YA RIDHAA KUSHIRIKI KATIKA UTAFITI

Utangulizi_Lengo la utafiti huu ni kujua hali halisi ya tatizo la saratani ya tezi ya prostate. Ushiriki katika utafiti huu ni hiari. Iwapo utahiari kutoshiriki utafiti, haitaadhiri huduma upatazo katika kituo/hospitali yoyote katika Jamhuri ya Muungano wa Tanzania ikiwemo MNH ,Tumaini hospitali.

Faida_ Hakuna faida ya moja kwa moja utakayopata kutokana na kushiriki katika utafiti huu bali utadhaminiwa kama mojawapo wa watu waliochangia kupatikana kwa taarifa juu ya ukweli kuhusu hali halisi na kwa kiasi gani juu ya tatizo la saratani ya tezi ya prostate katika jamii yetu

Madhara Washiriki hawatapata madhara yoyote makubwa kutokana na utafiti huu

Usiri Taarifa zote zipatikanazo kutokana na utafiti huu zitatunzwa kwa usiri mkubwa na zitatumikuboresha utoaji wa huduma na kuboresha matibabu ya saratani ya tezi ya prostate Tanzania.

Nitashukuru kupata ridhaa yako ya kushiriki utafiti huu.

DR MNDEME, Hamisi Omari

Sahihi ……Mtafiti

Mawasiliano

Kwa maswali yoyote yahusuyo utafiti, tafadhali usisite kuwasiliana na mtafiti DR MNDEME,Omari Hamisi simu ya mkononi +255 767368439 Chuo Kikuu cha Afya na Sayansi za Tiba(MUHAS) SLP 65013. Iwapo una swali juu ya haki yako kama mshiriki katika utafiti wasiliana na:

Prof. Mainen Mushi, Mkurugenzi wa machapisho na utafiti, S.L.P 65001 Dar es salaam. Simu .0713622244

Mimi …… (Mshiriki)

Nimesoma na kuelewa habari zilizotolewa kwangu kama zilivyoandikwa na pia nimejibiwa maswali yangu kwa usahihi na mtafiti. Mimi bila kushawishiwa nimekubali kushiriki utafiti huu.

Jina la Mshiriki ……SIMU……

Sahihi…….(Mshiriki)

Tarehe……

Appendix III: Questionnaire – English Version

ID: _____

Part 1: Demographic Profile

1. Name of Health facility_____
2. File Number:_____
3. Age_____
4. Residency 1. Urban ( ) 2. Rural ( )
5. Education 1. No Formal Education ( ) 2.Primary ( ) 3. Secondary ( ) 4. College ( )
6. PSA at diagnosis_____

Part 2: Manipulation Used and Symptoms/Signs

7. Hormonal Manipulation Used 1. Ochidectomy ( ) 2. Zoladex ( ) 3.Bicalutamide ( ) 4.Total androgen blockade ( )
8. Pre and Post Treatment Symptoms/Signs

No	**Sign/Symptom**	**Pre-Treatment**		**Post-treatment**	
		Yes	**No**	**Yes**	**No**
1.	Lower Urinary Tract Symptoms (BOO)				
2.	Haematuria				
3.	Back pain				
4.	Limb edema				
5.	Loin pain				
6.	Paraplegia				
7.	Fracture of bones				

9. PSA level post treatment 1st._____, 2nd_____ 3rd_____
10. Additional treat ment (chemotherapy)
    a) 1st line –docetaxel

Part 3: Quality of Life

11**. Psycological functioning:**

Mental/emotional state

Rate the following questions with respect to frequency (Circle the correct answers in both sides)

BEFORE							**AFTER**				
SN	Quality of life Indicators	Never	Rarely	Occasionaly	Regularly	Constant	Never	Rarely	Occasionaly	Regularly	Constant
1	Do you experience depression or lack of interest	1	2	3	4	5	1	2	3	4	5
2	Do you experience difficult falling or staying asleep?	1	2	3	4	5	1	2	3	4	5
3	Do you experience fear and anxiety?	1	2	3	4	5	1	2	3	4	5
4	Do you experience of moodiness, temper or angry?	1	2	3	4	5	1	2	3	4	5

12. The following items are about activities you might do during a typical day. Does pain limit you in these activities. If so how much (circle the correct answer)

BEFORE							**AFTER**				
SN	Quality of life indicators	Strongly disagree	Disagree	**I don't know**	Agree	Strongly agree	Strongly disagree	Disagree	**I don't know**	Agree	Strongly Disagreed
1	Decrease vigorous activities such as running lifting heavy objects	1	2	3	4	5	1	2	3	4	5
2	Decrease your ability to climb several flight of stairs	1	2	3	4	5	1	2	3	4	5
3	Decrease your ability to walk more than a kilometer	1	2	3	4	5	1	2	3	4	5
4	Decreased your ability to dress your self	1	2	3	4	5	1	2	3	4	5

13. Have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Before							**After**				
SN	Quality of life Indicators	Strongly Disagree	Disagree	**I don't know**	Agree	Strongly Agree	Strongly Disagree	Disagree	**I don't know**	Agree	Strongly Disagree
1	Cut down amount of time you spend on your daily work	1	2	3	4	5	1	2	3	4	5
2	Accomplish less than you want to do on your daily work	1	2	3	4	5	1	2	3	4	5
3	Getting tired shortly performing your work or other activities	1	2	3	4	5	1	2	3	4	5
4	Were limited in the kind of work or other activities	1	2	3	4	5	1	2	3		

THANK YOU FOR YOUR PARTICIPATION

Appendix III: Questionnaire (Swahili Version)

Namba ya mhojiwa _____

Part 1: Taarifa binafsi

1Jina la kituo cha afya_____

2.Namba ya faili:_____

3.Umri_____

4.Makazi 1. Mjini ( ) 2. Vijijini ( )

5.Kiwango cha elimu 1. Sikusoma ( ) 2.Elimu ya msingi ( ) 3 Sekondari ( ) 4. Chuo ( )

6.PSA at diagnosis_____

Part 2: Manipulation zilizotumika na dalili zake

7. Hormone Manipulation zilizotumika 1. Ochidectomy ( )2. Zoladex ( ) 3.Bicalutamide ( ) 4.Total androgen blockade ( )

8.Dalili kabla na baada ya matibabu

Na	**Dalili**	**Kabla ya matibabu**		**Baada ya matibabu**	
		Ndiyo	**Hapana**	**Ndiyo**	**Hapana**
8.	Maambukizi kwenye njia ya mkojo				
9.	Kukojoa damu				
10.	Maumivu ya mgongo				
11.	Kuvimba miguu				
12.	Maumivu ya nyonga				
13.	Kulemaa miguu				
14.	Kuvunjika mifupa				

9. Kiwango cha PSA baada ya matibabu 1st._____, 2nd_____ 3rd_____

10. Additional treat ment (chemotherapy)

a) 1st line –docetaxel

Sehemu ya 3: Hali ya ubora wa maisha

11**. Matokeo ya kisaikologia(Psycological functioning):**

Mental/emotional state-Tumia viwango vifuatavyo kujibu maswali yafuatayo:

Zungushia jibu sahihi pande zote mbili "kabla" na "Baada"

KABLA							**BAADA**				
SN	Kiashirio cha hali ya ubora wa maisha	Hapana	Maracha che	Mara kwa mara	Mara nyingi	Mfululizo	Hapana	Mara chache	Mara kwa mara	Mara nyingi	Mfululizo
1	Je unauzoefu wa kuwa na msongo wa mawazo na kutopendelea vitu mbalimbali?	1	2	3	4	5	1	2	3	4	5
2	Je unashida ya kupata usingizi au kutopata usingizi	1	2	3	4	5	1	2	3	4	5

	kabisa?										
3	Je unauzoefu wa kuingiwa na hofu na wasiwasi?	1	2	3	4	5	1	2	3	4	5
4	Je unauzoefu wa kuwa na hasira, jazba na uchungu	1	2	3	4	5	1	2	3	4	5

12. Vipengele vifuatavyo ni juu ya shughuli uzifanyazo kila siku.Je maumivu uliyonayo yanakupunguzia utekelezaji wa shughuli hizo?Kama ni hivyo ni kwa kiwango gani? (zungushia jibu lililosahihi)

KABLA							**BAADA**				
SN	Kiashirio cha hali ya ubora wa maisha	Sikubalia ni kabisa	Sikubalia ni	**Siju i**	Nakubalia na	Nakubalia na kabisa	Sikubalia ni kabisa	sikubalia ni	**Siju i**	Nakubalia na	Nakubalia na kabisa
1	Kupunguzi a kufanya shughuli za nguvu kama kukimbia na kubeba vitu	1	2	3	4	5	1	2	3	4	5
2	Kupunguzi a uwezo wa	1	2	3	4	5	1	2	3	4	5

	kupanda ngazi										
3	Kupunguzia uwezo wa kutembea zaidi ya kilometa moja	1	2	3	4	5	1	2	3	4	5
4	Kupunguzia uwezo wa kujihudumia mwenyewe kama kuvaa	1	2	3	4	5	1	2	3	4	5

13. Ulishawahi kuwa na matatizo yafuatayo katika kazi zako au shughuli zako za kila siku kutokana na hali yako ya kiafya??

KABLA							**BAADA**				
SN	Kiashiria cha hali ya ubora wa maisha	Sikubaliani kabisa	Sikubaliani	**Siji**	Nakubaliana	Nakubaliana kabisa	Sikubaliani kabisa	Sikubaliani	**Siji**	Nakubaliana	Nakubaliana kabisa
1	Kupungua za muda unaotumia katika shughuli zako za kila siku	1	2	3	4	5	1	2	3	4	5
2	Kutotimiza malengo katika shughuli zako za kila siku	1	2	3	4	5	1	2	3	4	5
3	Kuchoka										

	haraka katika utekelezaj i wa shughuli zako za kila siku	1	2	3	4	5	1	2	3	4	5
4	Kushindw a kufanya kazi au shughuli zakoza kila siku	1	2	3	4	5	1	2	3		

AHSANTE KWA KUSHIRIKI