COLLEGE OF HELTH SCIENCE SURGERY DEPARTMENT UROLOGY UNIT

ANALYSIS OF PROSTATIC CANCER PATIENTS' CLINICAL PRESENTATION AT TIKUR ANESSA SPECIALIZED HOSPITAL ADDIS ABABA, ETHIOPIA, 2025.

INVESTIGATOR: DR. SEWUNET MULUNEH (UROLOGY SURGERY FELLOW)

ADVISOR: DR. ADMASU MELAKU (ASSISSTANT PROFESSOR OF UROLOGY SURGERY)

A RESEARCH THESIS SUBMITTED TO UROLOGY UNIT DEPARTMENT OF SURGERY COLLEGE OF HEALTH SCIENCE IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR SUBSPECIALITY CERTIFICATE IN UROLOGY SURGERY

JULY, 2025, ADDIS ABABA

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JULY, 2025 ADDIS ABABA

Declaration

I, Dr. Sewunet Muluneh, do hereby declare that this research proposal is a result of the works of my own making except where due is made in a review of previous literature in the content and by my knowledge, has never been submitted for any prior academic award or qualification in this Institution.

Dr. Sewunet Muluneh

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Department of Surgery, Urology Unit Approval

The undersigned have examined the thesis report entitled “Analysis of clinical presentation of prostatic cancer patients at TASH: Two-year retrospective cross-sectional study” presented by Dr. Sewunet Muluneh, with registration number GSR/5686/15, a candidate for the Fellowship Certificate in Urology Surgery and hereby certify that it is worthy of acceptance.

Advisor:

Dr. Admassu Melaku Sign: _____ Date: September 8, 2025

Department of Surgery Research and Ethics Committee

Sign: _____ Date: _____

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Finally, I want to express my gratitude to all people who helped me in different ways during preparation of this work and during my study including my families, friends as well as TASH staffs who worked with me at different units.

ACRONYMS AND ABBRIVATIONS

AAU _____Addis Ababa University

ADT _____ Androgen deprivation therapy

BPH _____ benign prostatic hyperplasia

CT scan _____ computed tomography scans

CI _____ Confidence Interval

DALY's ___Disability-adjusted life years

DRE_____ digital rectal examination

EAU _____European Association of Urology

GBD _____Global Burden of Disease

ISUP_____ International Society of Urological Pathology

LHRH _____ Luteinizing Hormone-Releasing Hormone

LMICs _____ Low and middle-income countries

LUTS_____ Lower urinary tract symptoms

MRI_____ magnetic resonance imaging

PCa _____ prostatic cancer

PET scan_____ Positron emission tomography scan

PIRADS score____ Prostate Imaging Reporting and Data System

PSA _____ Prostate Specific Antigen

PSMA____ Prostate Specific membrane Antigen

SPSS _____Statistical package for Social Science

TASH _____Tikur Anbessa Specialized Hospital

Table of Contents

LIST OF TABLES

LIST OF FIGURES

APPENDICES

ABSTRACT

INTRODUCTION: Prostate cancer is second most diagnosed cancer exceeded by lung cancer only across globe and it is fifth leading cause of cancer associated mortality. It is number one cause of cancer death in men in 48 countries which includes many countries in sub-Saharan Africa. In Ethiopia, it was the third most diagnosed cancer and eighth cause of cancer death in 2013 in both sexes. In Ethiopia, in 2019 and 2020, it was second leading cancer in incidence in males with reported new cases of 2,570 & 2,720 respectively.

OBJECTIVE: The study describes clinical presentation of prostatic cancer patients seen at outpatient department of Urology unit of TASH from 31st December,2023 to 1st January ,2025 GC.

METHODS: The study was two-year cross-sectional descriptive study on prostatic cancer patients seen at Urology unit of TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC. The questionnaires were used extract data of study population from patients' chart by data collectors to collect the necessary information and phone call was used to get additional information from patients. Data collected with kobo toolbox, entered to spreadsheet and analysed by SPSS version 26. The findings of the study were summarized with Descriptive statistics and results presented in the form of text, table, and chart. Pearson chi-square test, Bi variable and multi variable logistic regression analysis used to explore association between different variables. Significant associations were declared at P-value <0.05 on multi variable logistic regression analysis.

Results: 98.4% of the patients were symptomatic at time of diagnosis with 97.7% having LUTS and 33. 9% having metastatic symptoms. 24.4% have locally advanced cancer and 34.2% have metastatic prostate cancer. The ISUP grade group 4 and 5 account for 97% of cases, PIRADS 4 and 5 account for 67.5% of cases and mean PSA at time of diagnosis was 285ng/ml.

Conclusion: 98.4% of the patients were symptomatic at time of diagnosis. Majority of patients were diagnosed with advanced of stage prostate cancer with higher Gleason's score, higher PIRADS score and high PSA at time of diagnosis. On multimodal regression analysis, Gleason's score has significant association with PIRADS score and digital rectal examination finding. TNM staging has significant association with residential area, educational status, presence of symptoms at presentation, PIRADS score and digital rectal examination in the study.

Work plan and budget: The study was conducted from March, 2025 GC to May, 2025GC with total budget of 47,491.4 Ethiopian birr.

KEYWORDS: Prostate cancer; clinical presentation; Cancer disparities; Ethiopia; Gleason score; clinical stage; advanced cancer

CHAPTER 1: - Introduction

1.1 Background

Prostate cancer was second most common cancer diagnosed after lung cancer and it was fifth leading cause of cancer death among men worldwide in 2018.In the same year Pca was reported to have new cases of 1.3 million and 360,000 deaths. Pca was reported to be leading cancer in incidence in male in 105 and leading cause of cancer death in males in 46 countries in 2018 globally. (1) The magnitude of the disease shows significant increment in 2020 with 1.4 million new cases of Pca and 375,000 new deaths worldwide due to Pca. (2) Pca was number one cause of cancer death in men in 48 countries across the globe which including many countries in sub-Saharan Africa and leading cancer in terms of incidence in 112 countries across world in 2020. (2)

The impact of Pca is by far greater in Africa and LMICs which is attributed to genetic, socio-economic and sociocultural factors. (1, 3) Global Cancer observatory 2018 report showed, PCa to have highest age-standardized incidence rate as well as highest age-standardized mortality rates in men in Sub-Saharan Africa when compared with all cancers in the region. (1) In Ethiopia, similar to other low-income countries showed significant increment of non-communicable diseases including cancer which poses significant challenge on poorly developed health system.

Pca was reported to be the third most reported cancer following breast and cervical cancer in 2013 in terms of incidence and it was eighth cause of cancer death in both sexes in 2013 in Ethiopia. (4) The successive studies indicate significant increment of burden the problem with GBD 2017 report of 1851 mortality and 33,056 DALYs due to Pca in Ethiopia. (4,5) Despite this significant challenge posed by cancer burden on the nation there is no national cancer registry system, and majority (80%) cancer patients are diagnosed at advanced stages with most of patients being poor candidates for curative treatment and there is one cancer treatment centre until 2016 at TASH nationwide.

Despite of having significant burden of Pca there are few studies done on Pca mainly focusing on awareness of prostatic cancer in Ethiopia (6, 7, 8) There another is another study one study which focus on histological features, survival patterns and determinants of mortality in Pca patients in country (9). Early detection and treatment of cancer can greatly reduce the burden of cancers related mortality and improve treatment outcomes of cancer patients.

The ministry of health of Ethiopia has developed is national cancer control plan in 2015 based on preventive strategies to tackle burden of cancer on nation in line with national health policy which focus on disease prevention. (10) Therefore, having understanding on clinical presentation of Pca patients helps in prevent ion and control of cancer by helping development of new tactics and strengthening existing one. Therefore, this study on clinical

presentation of prostatic cancer patients attending outpatient department of the Urology unit of the Tikur Anbessa Specialized Hospital (TASH) will contribute its own share in filling the existing gap with this regard and it may serve as baseline study for further investigation on the issue.

1.2. statement of the problem

GBD 2017 report show rapid rise in incidence of cancer generally and incidence of Pca specifically in Ethiopia. (4) In adults cancer related death account for 5.8% of the total national deaths across the nation. (10) Pca was reported to be the third most reported cancer following breast and cervical cancer in 2013 in terms of incidence and it was eighth cause of cancer death in both sexes in Ethiopia. (4) The successive studies indicate significant increment of burden the problem with GBD 2017 report of 1851 mortality and 33,056 DALYs due to Pca in Ethiopia. (4,5)

Ethiopia has one cancer treatment centre until 2016 at TASH nationwide located Addis Ababa with recent opening of few cancer treatment centres at teaching hospitals outside Addis Ababa. Besides, the nation has limited number of oncologists and surgical oncologists with prolonged waiting times for radiotherapy and surgery. (10) Most of patients in Ethiopia with cancer come with advanced stage of disease which negatively affect patient survival and outcome of treatment. (9, 10)

Moreover, despite of having significant burden of Pca there are few studies done on Pca mainly focusing on awareness of prostatic cancer in Ethiopia with results of the study revealing low level of awareness about prostate cancer risk factors, symptoms, screening and prevention which could contribute to late presentation of patients with advanced disease. (6, 7, 8) There another is another study one study which focus on histological features, survival patterns and determinants of mortality in Pca patients in country at TASH, oncology unit on histological characteristics, survival patterns and determinants of mortality in Pca patients in Ethiopia by Beksisa et al. which reveals 59.1% patients to have metastasis at presentation ,13.9% to have lymph node involvement and 16.8 5% to have locally advanced disease with T3 and T4 disease at time of diagnosis. Furthermore, the result of this study shows short survival after diagnosis in Pca patients with average survival time of 28 months. The two-year survival was reported to be 57%, three-year survival to be 38.9% and five-year survival to be 22% in the study. (9)

The nation has poorly developed cancer registry system with national cancer incidence estimation based on single-city population-based registry data from Addis Ababa with additional data from six regional cancer treatment centres located at teaching hospitals outside Addis Ababa. (10) Therefore, national cancer incidence was estimated based on this single-city population-based registry data from single centre which can significantly mask the true magnitude of the problem. (10)

Therefore, understanding clinical presentation of prostatic cancer patients can improve early screening and detection of prostatic cancer. It can also help to develop appropriate diagnostic facilities and treatment services, which in turn decrease disease burden and decrease morbidity and mortality of the patients, and decrease unnecessary health cost expenditure on disease.

1.3. Significance of the study

The finding of these will be important to improve participation of physicians actively in awareness creation practices for earlier presentation and on shared decision-based PSA screening practices.

The study will help physicians to understand different investigating modalities they are using in prostate cancer patients and help to improve existing gap in their practices.

The study will be valuable for physicians to understand outcome of different management options they are using and to decide on better options of intervention.

The result of the study can be valuable to compare diagnostic modalities and management options being used practically in Pca patients with the rest of the world.

The findings of study generate baseline data for further study on clinical presentation of prostatic cancer

The study finding help to alarm the community, health sector workers and officials about benefits of appropriate preventative measures including shared decision-based PSA screening practices and to improve awareness creation programs.

CHAPTER 2: LITERATURE REVIEW

Cancer is a major challenge to health with load of the problem increasing from time to time globally. According to Global Cancer Observatory of the International Agency for Research on Cancer in 2018 there are 18.1 million new cancer cases with 9.6 million deaths caused by in the same year. These numbers increased in 2020 to 19.3 million new cancer cases and about 10 million deaths caused by in the same year. (1,2)

In contrary once popularly held thought considering cancer problem of western world, it is now main cause of death and disability as globe including in underdeveloped countries. Africa and LMICs share in global cancer in number of new cancer cases from time to time with estimated burden reaching 70% being from this part of the world by 2030. (3) There are different factors for this rapid increase in the incidence of cancer in LMICs including uncontrolled population growth, improvement in life expectancy with modernization, adaptation of westernized lifestyles type, and higher infectious disease prevalence including HIV/AIDS in the region. (12)

The challenge faced by LMICs due cancer is multifaceted as the heath system is poorly developed in these countries to give appropriate response to extent of the problem due to poorly developed human resources, infrastructures and inadequate financial sources. (3) These differences between developed countries and LMICs responsible for higher case fatality from cancer in LMICs as compared to developed countries. The case fatality rate from cancer is 75%,72%, 64% and 46% in countries of low income, in countries of low-middle income, in countries of high-middle income, and in countries of high income, respectively. (3)

Prostate cancer was second most common cancer diagnosed after lung cancer and it was fifth leading cause of cancer death among men worldwide in 2018.In the same year Pca was reported to have new cases of 1.3 million and 360,000 deaths. Pca was reported to be leading cancer in incidence in male in 105 and leading cause of cancer death in males in 46 countries in 2018 globally. (1) The magnitude of the disease shows significant increment in 2020 with 1.4 million new cases of Pca and 375,000 new deaths worldwide due to Pca. (2) Pca was number one cause of cancer death in men in 48 countries across the globe which including many countries in sub-Saharan Africa and leading cancer in terms of incidence in 112 countries across world in 2020. (2)

The impact of Pca is by far greater in Africa and LMICs which is attributed to genetic, socio-economic and sociocultural factors. (1, 3) Global Cancer observatory 2018 report showed, PCa to have highest age-standardized incidence rate as well as highest age-standardized mortality rates in men in Sub-Saharan Africa when compared with all cancers in the region. (1)

since mid-1990s death due to Pca was declining in developed countries as opposed many countries in Central and Eastern Europe, Asia, and Africa where the incidence continues to rise. This difference could be due poor PSA screening practices and lack of better treatment option in the latter group. (1,2)

In 2018, in African countries Pca accounts for 18.1% of total cases of cancer diagnosed in African males. (1) Global Cancer observatory 2018 report showed, PCa to have highest age-standardized incidence rate as well as highest age-standardized mortality rates in men in Sub-Saharan Africa when compared with all cancers in the region. (1)

Most patients diagnosed with Pca in African presents late with locally advanced or metastatic prostate cancer with higher Gleason score and higher PSA value, which are predictors of advanced disease due to lack of early-detection services and low public awareness. (9, 12, 13, 14,16, 17, 19) There are also many challenges in the management of these patients in African countries including absence community-based screening , absence of effective health promotion programmes, late presentation of patients with advanced stages of cancer, lack of appropriate treatment options , lack of proper follow-up, and social norms and beliefs affecting health behaviour of patients and scarcity of urologists, pathologists, and radiotherapy and androgen-deprivation therapies. (12,16,17)

Most patients in Africa countries are managed with chemotherapy, hormonal therapy, and radiotherapy. Androgen deprivation therapy was most commonly used mode of therapy in most studies even though there is variation in the modality used based on availabilities of expert and drugs. (9,13, 16, 17) Because of its cost efficiency and simplicity of the procedure, bilateral orchiectomy is predominantly used form of treatment in many African countries. (12, 13)

Pca have worse prognosis with short survival in African American men compared to other races. (20) This probably reflects a combination of germline susceptibility and socioeconomic and environmental factors contributing these differences. (20) Even after adjusting socioeconomic status and lifestyle variation, African ancestry remains a significant risk factor for prostate cancer and it was found that black men have higher risk of getting preclinical Pca by the age of 85 years compared to the general population and they have also higher risk progression to a metastatic cancer by the time of diagnosis compared to the general population. (21)

The incidence of cancer is rising in Ethiopia similar to many African countries. There were 77,352 new cancer cases in 2020 in Ethiopia. (11) Pca was reported to be the third most reported cancer following breast and cervical cancer in 2013 in terms of incidence and it was eighth cause of cancer death in both sexes in 2013 in Ethiopia. (4) The successive studies indicate significant increment of burden the problem with GBD 2017 report of 1851 mortality and 33,056 DALYs due to Pca in Ethiopia. (4,5) Despite this significant challenge posed by cancer burden on the nation there is no national cancer registry system, and majority (80%)

cancer patients are diagnosed at advanced stages with most of patients being poor candidates for curative treatment and there is one cancer treatment centre until 2016 at TASH nationwide.

In 2019 and 2020, prostate cancer is second leading incident cancer in males with reported new cases of 2,570 &2,720 respectively in Ethiopia. (11, 24) In Ethiopia, in 2019 prostate cancer had the second highest incidence rate with 2,570 new cases and it was the second highest cause of cancer death with 2,290 death and it has highest age-standardised death rate in the same year in males. (24) From 2010 to 2019 prostate cancer showed the third highest percentage change in incident cases in males. (24) Prostatic cancer is second most common cancer in 2020 in males with 2,720 new cases which account for 10.2% of newly diagnosed cancer and estimated to cause 1,600 deaths in Ethiopia that year according to Globocan 2020. (11)

According to Beksisa et al. 59.1%,13.9% and 16.8 5% patients with prostate cancer have metastasis, lymph node positive disease and locally advanced disease (T3/T4) respectively at time of diagnosis indicating advanced stage at presentation in most patients. (9) According to samrawit et al. males with Prostate cancer in Ethiopia were more likely to be diagnosed at advanced stages as compared other types cancer. (OR = 5.22; 95% CI = 1.26-21.60) This study also reported 46.7% of prostate cancers were in advanced stages at the time of diagnosis. (19)

There are few studies done on cancer prevalence in general and on prostatic cancer prevalence in particular in Ethiopia. (10) Moreover, despite of having significant burden of Pca there are few studies done on Pca mainly focusing on awareness of prostatic cancer in Ethiopia with results of the study revealing low level of awareness about prostate cancer risk factors, symptoms, screening and prevention which could contribute to late presentation of patients with advanced disease. (6, 7, 8) There another is another study one study which focus on histological features, survival patterns and determinants of mortality in Pca patients in country at TASH, oncology unit on histological characteristics, survival patterns and determinants of mortality in Pca patients in Ethiopia by Beksisa et al. which reveals 59.1% patients to have metastasis at presentation ,13.9% to have lymph node involvement and 16.8 5% to have locally advanced disease with T3 and T4 disease at time of diagnosis. Furthermore, the result of this study shows short survival after diagnosis in Pca patients with average survival time of 28 months. The two-year survival was reported to be 57%, three-year survival to be 38.9% and five-year survival to be 22% in the study. (9)

This study on Prostatic cancer can contribute in understanding pattern of the disease, clinical presentation of patients, laboratory tests and imaging modalities used and intervention offered for the patients as there are limited studies done on the topic. This in turn helps to understand the gaps in diagnostic tests and treatment used and help in deciding on

better diagnostic tests and treatment options. Besides, this study provides important data for researchers and public health policy makers on Pca patients.

Chapter 3: Objectives

3.1 General Objectives

- ✔ To analyze clinical presentation of confirmed prostate cancer patients seen at outpatient department of the Urology unit TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC.

3.2 Specific objective

- ✔ To analyze the socio demographic data of prostatic cancer patients seen at outpatient department of Urology unit of TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC.
- ✔ To understand clinical symptoms and physical examination findings in prostatic cancer patients seen at outpatient department of Urology unit of TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC.
- ✔ To analyze laboratory and imaging findings in prostatic cancer patients seen at outpatient department of Urology unit of TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC.
- ✔ To analyze treatment pattern among prostatic cancer patients seen at outpatient department of Urology unit of TASH, Addis Ababa, Ethiopia from 31st December, 2023 to 1st January, 2025 GC.
- ✔ To generate baseline data which can be utilized by researchers and policy makers for future studies on prostatic cancer patients in Ethiopia

Chapter 4: Methods and materials

4.1. Study area and study period

The study was conducted from March 2025 to May 2025 GC at outpatient department of the Urology unit of TASH, Addis Ababa, Ethiopia. The data was collected from electronic medical records of patients seen at unit from 31st December, 2023 to 1st January, 2025 GC. Tikur Anbessa Specialized Hospital was established in the early 1960s and it is found in capital city of country (Addis Ababa). Tikur Anbessa Specialized Hospital is the largest tertiary referral hospital in the country and it serve as teaching hospital under AAU with 800 hundred inpatient beds. The Addis Ababa Population-Based Cancer Registry (AAPBCR) was established in 2011 under the TASH oncology centre, to facilitate documentation of cancer cases for research and decision making in public health policy. The Addis Ababa Population-Based Cancer Registry (AAPBCR) was established in 2011 under the TASH oncology centre with additional data gathered from six regional cancer treatment centres located at teaching hospitals outside Addis Ababa and it was serving as the only cancer registry centre.

The study was conducted from March 2025 to May 2025 GC at outpatient department of the Urology unit of TASH, Addis Ababa, Ethiopia. The Urology unit of TASH under department of surgery of Addis Ababa University and provides service for various urologic conditions including outpatient service, in patient service, minor and major surgical services both open and endourologic procedures. Additionally, the unit gives medical education for under graduate medical students and post graduate education as five year post graduate training in urology speciality certificate and three-year subspecialty certificate training. The unit works in collaboration with urology units in other government hospitals in Addis Ababa including Menelik II referral hospital and yekatit 12 medical college hospitals by sending residents, fellows and consultant for training as well to participate in providing urologic service for urology patients at the hospitals.

4.2. Study design

A two-year retrospective cross-sectional descriptive study was conducted on pathologically confirmed prostate cancer patients seen from 31st December, 2023 to 1st January, 2025 GC.at outpatient department of the Urology unit of TASH.

study was conducted after obtaining ethical clearance and Permission letter for study obtained from Addis Ababa University College of Health Sciences school of medicine research ethics committee with meeting number Dos/REC/153/2025/2017 on June 30,2025 GC with protocol version number 2 and protocol version date june30,2025 GC

4.3. Study population

4.3.1. Source population

- ✔ All patients seen from 31st December, 2023 to 1st January, 2025 GC at outpatient department of Urology unit of TASH from 31st December, 2023 to 1st January, 2025 GC.

4.3.2. Study population

- ✔ All confirmed prostate cancer patients seen at the outpatient department of Urology unit of TASH from 31st December, 2023 to 1st January, 2025 GC.

4.3.3. Inclusion criteria

- ✔ All pathologically confirmed prostate cancer patients seen at the outpatient department of Urology unit of TASH from 31st December, 2023 to 1st January, 2025 GC.

4.3.4. Exclusion criteria

- ✔ All clinically suspected prostate cancer cases with no pathological confirmation seen at the outpatient department of Urology unit of TASH from 31st December, 2023 to 1st January, 2025 GC.

4.4. Sample size and sampling procedures

4.4.1. Sample size determination

- ✔ The sample size required for this study was estimated by use of Cochran and William guidelines (26), by assuming a 5% marginal error, 95% CI, and using proportion of prostatic cancer in males in Ethiopia 10.2% based on GLOBOCAN 2020. (11)
- ✔ Single population proportion formula used to calculate sample size of the study

$$n = \frac{z^2 p q}{d^2}$$

n: required sample size
z: the standard normal deviate usually set at 1.96 (which corresponds to the 95% confidence level)
P= proportion of Ethiopian males with prostatic cancer 10.2% based on GLOBOCAN 2020 (11)
q:1-p
d: absolute precision or accuracy, normally set at 0.05

$$n = \frac{(1.96)^2(0.102)\,(1-0.102)}{(0.o5)^2} = 141$$

Hence, the calculated sample size became 141, which is adjusted by correction formula as follow:

$$n_f = \frac{n}{1+\frac{n}{N}}$$

n= calculated sample size

N= Source population, all patients seen at the outpatient department of Urology unit of TASH, according 2020 data, N=535 (6)

n_f = Final sample size

$$n_f = \frac{n}{1+\frac{n}{N}} = \frac{141}{1+\frac{141}{535}} = 112$$

From the calculated Final sample size of 112, considering 10% for non-response rate, the required sample size will be 123

4.4.2 Sampling procedure

Total of 172 prostatic cancer patients were seen during study period out of which the sample was selected (n=123) using the patient's digital medical record number as a sampling frame according to ascending order using systematic sampling technique and two successive patients were included in the study and the next patient will be excluded from study until the needed number of samples is reached. Eight patients with no biopsy result documentation on their medical record form were excluded from study and replaced with other patients who were supposed to be excluded from study during sampling procedure.

4.5. Data collection procedure

Data was collected by use of questionnaires prepared in English and reviewed by research adviser before actual study. The questionnaires contents questions on socio-demographic data, information on clinical presentation of patients, laboratory and imaging results of patients, and treatment patients received.

The questionnaires were pretested on the first 10 participants to make sure that the questions were balanced and correctly constructed and so that the crucial information would

be not missed. Issues concerning clarity, accuracy and internal consistency of questions were identified before actual study and corrected before actual study.

One general practitioner was selected and he was given half day training on the objective, methodology, sampling technique, ethical issues, and data collection instrument and data collection procedure to assist data collection under the supervision of the principal investigator.

4.6. operational definitions

Asymptomatic pca is prostate cancer diagnosed with screening PSA, patients diagnosed after imaging or Digital Rectal Examination done after patient presented with unrelated symptoms or diagnosis made after prostatectomy sample send for biopsy with pre-operative diagnosis of benign prostatic hyperplasia.

Digital Rectal Examination suggestive of prostatic cancer includes enlargement with hard prostate with irregular surface, asymmetrically enlarged prostate, presence of prostatic nodule and fixed immobile prostate to surrounding structures.

Digital Rectal Examination suggestive of benign prostatic hyperplasia includes enlargement with firm prostate with smooth surface, symmetrically enlarged prostate, with no prostatic nodule or non-fixed mobile prostate to surrounding structures (rectal mucosa).

Elevated PSA value is where PSA is more than 4ng/dl.

Gleason grading system is the most commonly used to provide Histologic grade of Pca from sample obtained from prostate needle biopsy. Modified Gleason scoring system with. 5-grade group was used in this study. (27)

Clinical staging of Pca in the study was based on the TNM classification of malignant tumours according to International Union Against Cancer.8th edition. 2017. (28)

Localized Pca is cancer limited to prostate without evidence of spread. It includes T1 (Non palpable tumour and not evident by imaging discovered due to PSA elevation or on biopsy after BPH surgery) or T2 (Palpable tumour confined to prostate). (28)

Locally advanced Pca includes T3 tumour which is Palpable tumour beyond prostate with extracapsular extension or those with seminal vesicle invasion and Pca T4 Tumour which fixed to or invades adjacent structures other than seminal vesicles including bladder neck, external Sphincter, rectum, levator muscle, pelvic wall. (28)

Metastatic Pca is tumour with distant metastatic spread including spread to non-regional lymph nodes, spread to bones and spread to other distant sites. (28)

European Association of Urology risk group for biochemical recurrence was used in this study. (29)

4.7. study variables

4.7.1. Independent Variable

Socio-demographic variables

- Age
- Place of residency
- Marital status
- Educational status
- Monthly income
- Occupation

Patient-related factors

- History of smoking
- Family history
- Presence comorbidity

Clinical factors

- Presence/ absence of symptoms of prostatic cancer at time of diagnosis
- Digital rectal examination finding at time of diagnosis
- PSA level/ PSAD at time of diagnosis

4.7.2. Dependent variable

- TNM stage of Pca
- Gleason scores of biopsies at time of diagnosis
- Prostatic cancer risk group at time of diagnosis
- Type of treatment offered for prostatic cancer
- Type of imaging used
- Outcome of treatment

4.8. Data processing and analysis

The questioners were checked before data collections and data collected with kobo toolbox, coded, entered into spreadsheet, and analysed with software package for analysis version 26.0. For controlling errors 10% of the questionnaire will be double entered, also frequency checks will be done.

The findings of the study were summarized with Descriptive statistics and results presented in the form of text, table, and chart. Pearson chi-square test, Bi variable and multi variable logistic regression analysis used to explore association between different variables.

Significant associations were declared at P-value <0.05 on multi variable logistic regression analysis.

4.9. Data quality management

To address the validity of questionnaires, the questionnaires were generated with modification of previously published similar studies. (17,31,22) The questionnaires are subjected for review by advisor before use and approved by AAU College of Health Sciences school of medicine research ethics committee for use.

4.10. Ethical consideration

The proposal was reviewed and approved by research ethics committee of school of medicine of College of Health Sciences, AAU before study. Permission letter for study was obtained from AAU, College of Health Sciences school of medicine research ethics committee with meeting number Dos/REC/153/2025/2017 on June 30,2025 GC with protocol version number 2 and protocol version date june30,2025 GC.

Informed consent obtained from each study subject before review of their charts and they informed about the objective of the study. Those who was not willing to participate in the study were excluded from study.

4.11. Plan for dissemination of results

The results of study will be disseminated by publication, presentation on annual scientific meeting, conferences, seminars etc. A hard and soft copy of the study will be offered to AAU, College of Health Sciences research directorate.

Chapter 5: Results

Socio demographic data of prostatic cancer patients at TASH

Majority of prostate cancer patients at TASH during study period were between the ages of 60 and 70 years, comprising 45.5% (n = 56) of the study population. This was followed by the 70–80 age group, accounting for 30.9% (n = 38), and those above 80 years, representing 10.6% (n = 13). Those aged 50–60 years constituted 9.8% (n = 12), while only a small proportion of study population were under 50 years of age (3.3%, n = 4). These findings demonstrate that prostate cancer predominantly affects older men, with more than 86% of the cases occurring in individuals aged 60 years and above.

Regarding marital status, married men at the time of diagnosis were dominates the rest, accounting for 63.4% (n = 78) of the respondents. Widowed patients formed the next largest group at 28.5% (n = 35), reflecting the age profile of the study cohort. Single and divorced individuals accounted for 5.7% (n = 7) and 2.4% (n = 3), respectively. The high proportion of married and widowed participants is consistent with the demographic trend of prostate cancer predominantly affecting older, previously or currently partnered men.

In terms of educational attainment, the largest segment of patients had completed secondary education, comprising 33.3% (n = 41). This was followed by those with tertiary education at 26.8% (n = 33), indicating that nearly 60% of patients had education beyond the primary level. Meanwhile, 19.5% (n = 24) of participants had completed only primary education. Illiteracy was reported in 20.3% of cases, with 7.3% (n = 9) of participants unable to read and write and 13.0% (n = 16) identified as literate without formal schooling.

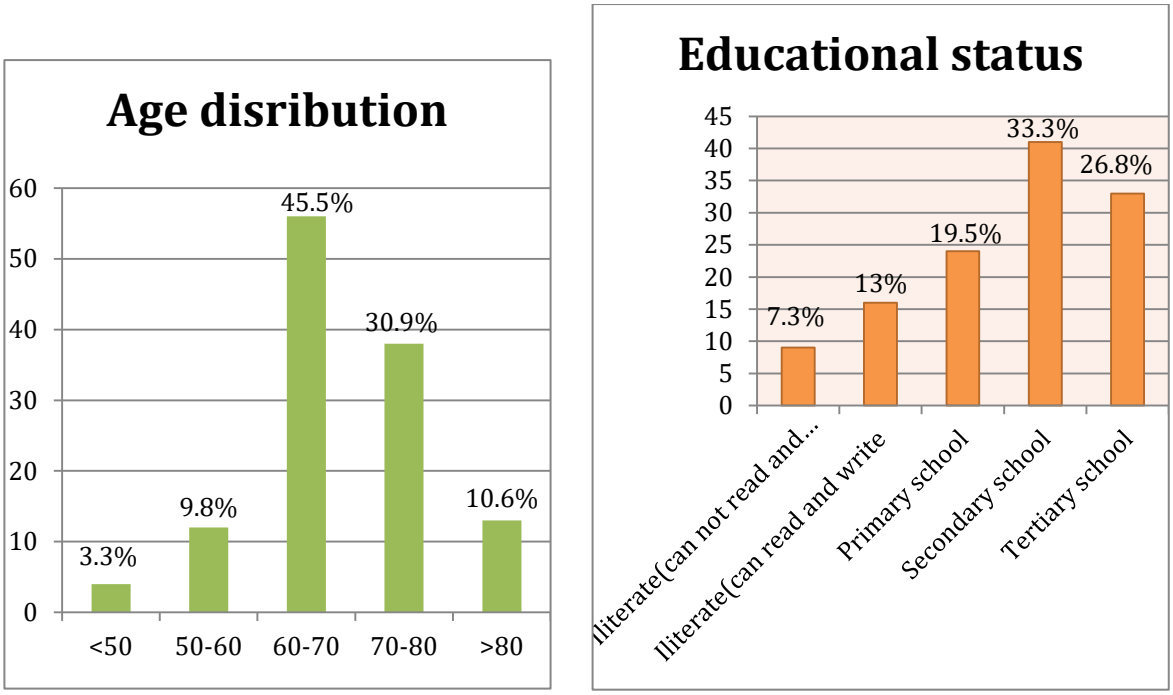


Figure1: Age distribution and educational status of prostatic cancer patients at TASH, July 2025

Most frequently reported occupational status among participants was unemployment, which accounted for 39.8% (n = 49) of cases. This is likely reflective of the advanced age and associated retirement status of the patient population. Government employees represented 26.8% (n = 33), while merchants made up 21.9% (n = 27). Daily laborers and those categorized under "other" occupations comprised 6.5% (n = 8) and 4.9% (n = 6), respectively. Among participants categorized under “Other”, one participant was a farmer, while the remaining five participants worked in the private sector.

The religious distribution of Pca patients in the study showed that predominantly affected patients were followers of the Ethiopian Orthodox Church, comprising 58.5% (n = 72) of the participants. Muslim patients made up 26.8% (n = 33), while Protestant Christians represented 14.6% (n = 18). This distribution reflects the broader demographic patterns observed in urban Addis Ababa, where Orthodox Christianity is the predominant faith.

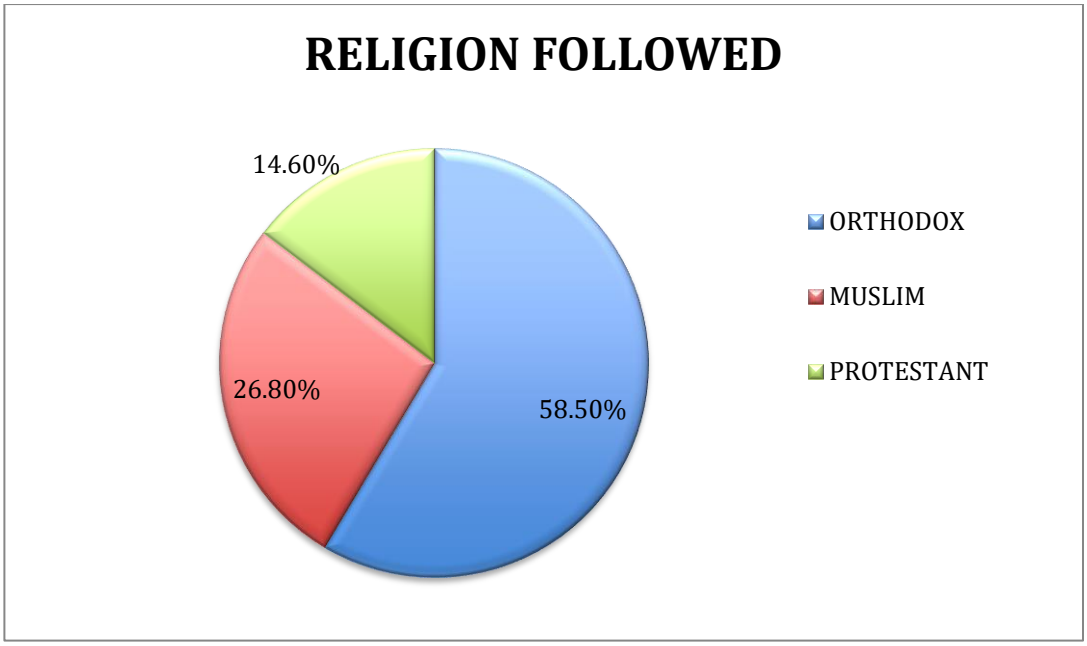


Figure 2: Religion followed by prostatic cancer Patients TASH July, 2025

Regarding residential area considerable proportion of the study participants resided in urban settings, representing 81.3% (n = 100), while only 18.7% (n = 23) of patients were from rural areas. This urban predominance likely reflects both the location of TASH in Addis Ababa and the higher likelihood that urban residents will access specialized medical services, such as cancer diagnostics and treatment.

Analysis of monthly income levels revealed that the majority of participants earned between 5,000 and 10,000 Ethiopian Birr, comprising 52.0% (n = 64) of the respondents. Another 30.1% (n = 37) reported income in the 2,500 to 5,000 Birr range, and 12.2% (n = 15) had income levels exceeding 10,000 Birr per month. A smaller proportion earned between 1,100 and 2,500 Birr (5.7%, n = 7). One data point recorded income in the 5,000 to 1,000 Birr range, which appears to be a typographical error and may warrant correction. Overall, the income data suggests that most patients had moderate earnings, which may influence their ability to access and adhere to treatment.

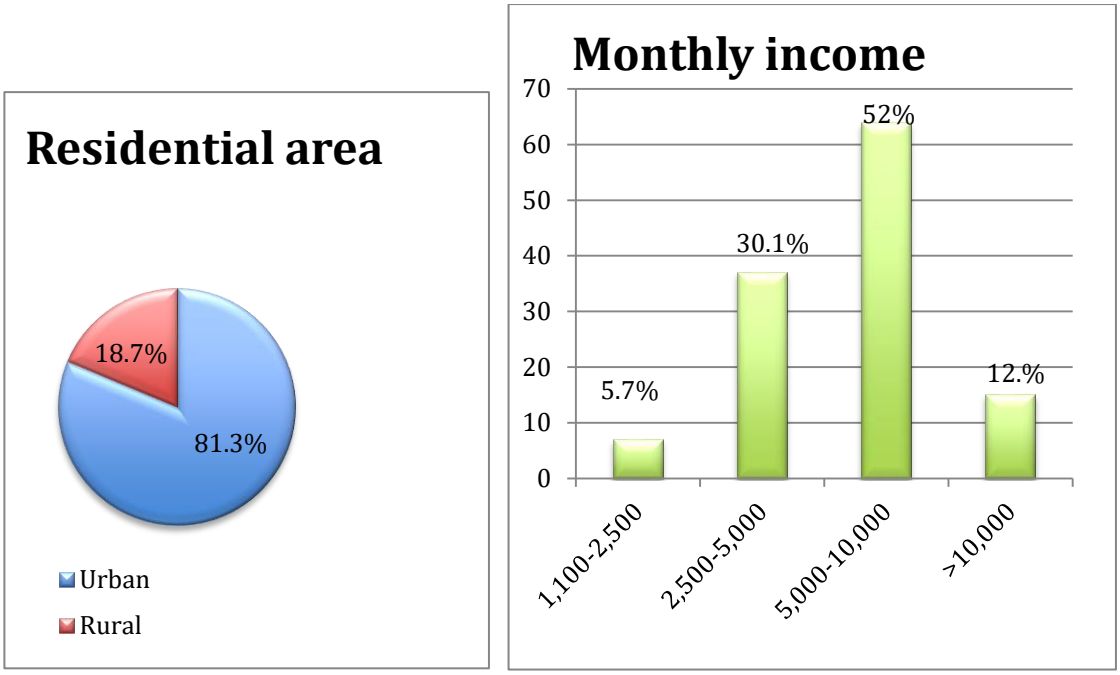


Figure 3: Residential area and monthly income among prostatic cancer patients at TASH, July 2025

Table 1: Socio-demographic characteristics of prostatic cancer patients at TASH July, 2025

Frequencies of 1. Age

1. Age	Counts	% of Total	Cumulative %
50-60	12	9.8%	9.8%
60-70	56	45.5%	55.3%
70-80	38	30.9%	86.2%
<50	4	3.3%	89.4%
>80	13	10.6%	100.0%

Frequencies of 2. Marital status

2. Marital status	Counts	% of Total	Cumulative %
Divorced	3	2.4%	2.4%
Married	77	62.6%	65.0%
Single	7	5.7%	70.7%
Widowed	35	28.5%	99.2%
Married	1	0.8%	100.0%

Frequencies of 3. Educational status

3. Educational status	Counts	% of Total	Cumulative %
Illiterate (can't read &write)	9	7.3%	7.3%
Illiterate (read & write)	16	13.0%	20.3%
Secondary	41	33.3%	53.7%
Tertiary education	33	26.8%	80.5%
primary	24	19.5%	100.0%

Frequencies of 4. Occupation

4. Occupation	Counts	% of Total	Cumulative %
Daily labor	8	6.5%	6.5%
Government Employee	33	26.8%	33.3%
Merchant	26	21.1%	54.5%
Others(specify)	6	4.9%	59.3%
Unemployed	48	39.0%	98.4%
Merchant	1	0.8%	99.2%
Unemployed	1	0.8%	100.0%

Frequencies of Others(specify)

Others(specify)	Counts	% of Total	Cumulative %
Farmer	1	16.7%	16.7%
private	5	83.3%	100.0%

Frequencies of 5. Religion

5. Religion	Counts	% of Total	Cumulative %
Muslim	33	26.8%	26.8%
Orthodox	72	58.5%	85.4%
Protestant	18	14.6%	100.0%

Frequencies of 6. Residential area

6. Residential area	Counts	% of Total	Cumulative %
Rural	23	18.7%	18.7%
Urban	100	81.3%	100.0%

Frequencies of 7. Monthly income (in Birr):

7. Monthly income (in Birr):	Counts	% of Total	Cumulative %
1100-2500	7	5.7%	5.7%
2500-5000	37	30.1%	35.8%
5000-10000	63	51.2%	87.0%
>10000	15	12.2%	99.2%
5000-1000	1	0.8%	100.0%

Family history of Pca, Lifestyle and Behavioral Characteristics

A small proportion of the study population, 5.7% (n = 7), reported have first-degree relative previously diagnosed with prostate cancer, while the vast majority (94.3%, n = 115) reported no such familial history. Among those with a positive family history, 57.1% (n = 4) had an affected father, 42.8% (n = 3) had a brother with prostate cancer. Further analysis showed that 42.8% (n = 3) of the seven participants with a family history had relatives diagnosed after the age of 65, while the remaining 57.1% (n = 4) did not specify age at time of diagnosis. No participant reported having more than one affected first-degree relative or second degree relative with prostate cancer. These findings underscore the limited presence of familial prostate cancer in this population and suggest that sporadic cases may predominate over hereditary ones in this Ethiopian clinical context.

A majority of the study participants (78.6%, n = 92) reported not engaging in regular physical exercise, while only 7.7% (n = 9) exercised consistently, and 13.7% (n = 16) did so occasionally. Regarding alcohol consumption, more than half of the participants (53.3%, n =

65) drank alcohol occasionally, while 42.6% (n = 52) had never consumed alcohol. A small fraction (4.1%, n = 5) consumed alcohol daily or regularly.

Cigarette smoking was uncommon among the study cohort. Most participants (93.4%, n=114) had never smoked, while 6.6% (n = 8) reported occasional smoking. These indicates that majority of Pca patients at TASH did not have substantial exposure to tobacco or habitual alcohol consumption, and very few engaged in regular physical activity.

Clinical Presentation of prostatic cancer patients

The overwhelming majority of participants (98.4%, n = 121) reported experiencing at least one symptom at presentation and only 1.6% (n = 2) were asymptomatic at presentation. This suggests advanced stage of cancer in most patients at time of presentation as prostatic cancer is asymptomatic at early stage.

Table 2 : Distribution of symptoms among prostatic cancer patients at TASH July, 2025

Symptoms	Frequency	Percentage
Urinary frequency	92	82.9%
Hesitancy	58	49.2%
Dribbling	46	39.0 %
Bone pain or pathologic fractures	34	27.7%
Hesitancy + dribbling	27	22%
Haematuria	17	14.0%
AUR	10	8.3%
Hesitancy + intermittency	7	5.8%
Sense of Incomplete voiding	7	5.8%
Flank pain	6	5.0%
Lower limb weakness	6	5.0%
Nocturia	5	4.5%
Urge incontinence	5	4.5%
Bone pain or pathologic fractures + Lower limb weakness	4	3.2%

Erectile dysfunction	1	0.8%
Asymptomatic (Elevated PSA on screening)	1	0.8%
Asymptomatic (post TURP biopsy diagnosis)	1	0.8%

Voiding LUTS was the most commonly presenting symptom in the study population and it was presenting symptom in 97.5% (n=118). The specific complaints include hesitancy in 49.2%, (n = 58), dribbling in 39.0 % (n = 46), poor stream in 6.8% (n = 8), and combinations of Hesitancy with dribbling was reported in 22% of patients, and 5.9% had hesitancy with intermittency.

Storage LUTS were also highly prevalent and it was reported by 91.7% (n = 111) of patients. The most frequent storage symptom was increased frequency of urination (82.9%, n = 92), while nocturia and urge incontinence were present in 4.5% (n = 5) each.

Only 5.8% (n = 7) of patients experienced post-void symptoms. Incomplete voiding was the most reported symptom in this category 5.8% (n = 7) while post-void dribbling was not reported independently in this cohort. Hematuria was present in 14.0% (n = 17) of patients, while 8.3% (n = 10) experienced AUR. These symptoms were often reported in combination with voiding and storage LUTS, reflecting the complex presentation of advanced cases.

Flank pain was documented in 5.0% (n = 6) of the participants. Sexual dysfunction was exceedingly rare, with only one case (0.8%) reporting erectile dysfunction; no cases of hematospermia or decreased ejaculate volume were reported by patients.

Metastatic symptoms were reported by 33.9% (n = 41) of patients. Among these, the most frequent complaint was bone pain or pathologic fractures (82.9%, n = 34). Additional symptoms included lower limb weakness (14.6%, n = 6) and combined presentations with both bone pain and lower limb symptoms (9.8%, n = 4). Other symptoms included lower extremity edema and incontinence, though these were rare or absent in this cohort. One patient (0.8%) reported pain during defecation and tenesmus under “Other” metastatic manifestations.

Among the patients who were asymptomatic, diagnosis of prostate cancer was made in one case (0.8%) was diagnosed via screening PSA elevation, highlighting a limited use of screening for early detection in this cohort. The other one (0.8%) patient diagnosis was made after sample was sent for biopsy after prostatectomy.

Comorbidity Profile

A notable proportion of patients (40.6%, n = 50) reported at least one comorbid condition, while the remaining 59.40% (n = 73) did not report any. Among those with comorbidities, the

most common diagnosis was hypertension (HTN), present in 19.5% (n = 24) of cases. HTN was frequently observed in combination with other conditions such as:

- HTN + Diabetes Mellitus (DM): 13.0% (n = 8)
- HTN + chronic kidney disease (CKD): 0.8% (n = 1)
- HTN + CKD + DM: 0.8% (n = 1)
- HTN + Myocardial Infarction (MI): 0.8% (n = 1)
- HTN + Other conditions: 1.6% (n = 2)

Isolated diabetes mellitus was reported in 4.8% (n = 6) of cases, and CKD alone in 0.8% (n = 1). Additional comorbidities included asthma, hypothyroidism with dyslipidemia, and peripheral arterial disease and HIV are reported each by one patient. No patients reported cirrhosis, COPD, or other major cardiac conditions as primary comorbidities outside the HTN-related clusters.

Only 1.6% (n = 2) of participants reported being diagnosed with another type of cancer in addition to prostate cancer. The specific diagnoses reported included right breast cancer (n = 1) and bladder cancer (n = 1), each accounting for 50% of the subgroup with secondary cancers.

Among the study participants, digital rectal examination findings were incompletely documented in 59.3% (n = 73) of cases. In 34.1% (n = 42), the DRE was suggestive of prostate cancer, while in 4.9% (n = 6) it was consistent with benign prostatic hyperplasia. A small number (1.6%, n = 2) were classified as “none of the above.” This reflects notable gaps in documentation and indicates the need for standardization in clinical reporting. But, if we compare data patients report as benign and malignant enlargement, the digital rectal examination has positive predictive value with sensitivity of 87.5% (42/48) which can be due late presentation of patients with advanced which can be detected easily on digital rectal examination.

With respect to T clinical staging, documentation was available in only 33.1% (n = 39) of patients and it was undocumented for majority of cases 66.9 % (n=84). Among those staged, the most commonly documented T-stage was T4 (13.8%, n = 17), T3A (8.1%, n = 10) and T3B (2.4%, n = 3) which together account for 24.4 %(n=30) suggesting that a substantial proportion of cases have locally advanced disease. Other stages included T2A (2.4%, n = 3), T2B (1.6%, n = 2), T2C (1.6%, n = 2), T1C (0.8%, n=1) and T1B (0.8%, n=1) which together account for 7.3 %(n=9) suggesting that a small proportion of cases have localized disease. Among patients having T- staging no patient in low-risk group, 1.6%, n=2 is in intermediate risk group and 5.7% n=7 is in high-risk group according to D’Amico risk classification for biochemical recurrence. (29) Majority of the patients have Metastatic disease at time of

presentation which account for 34.9% (n = 43) of cases. In remaining 19.5% (n=24) of cases there is no documentation to categorize the patients into one category and 13.8% (n=17) of cases have involvement of regional lymph nodes.

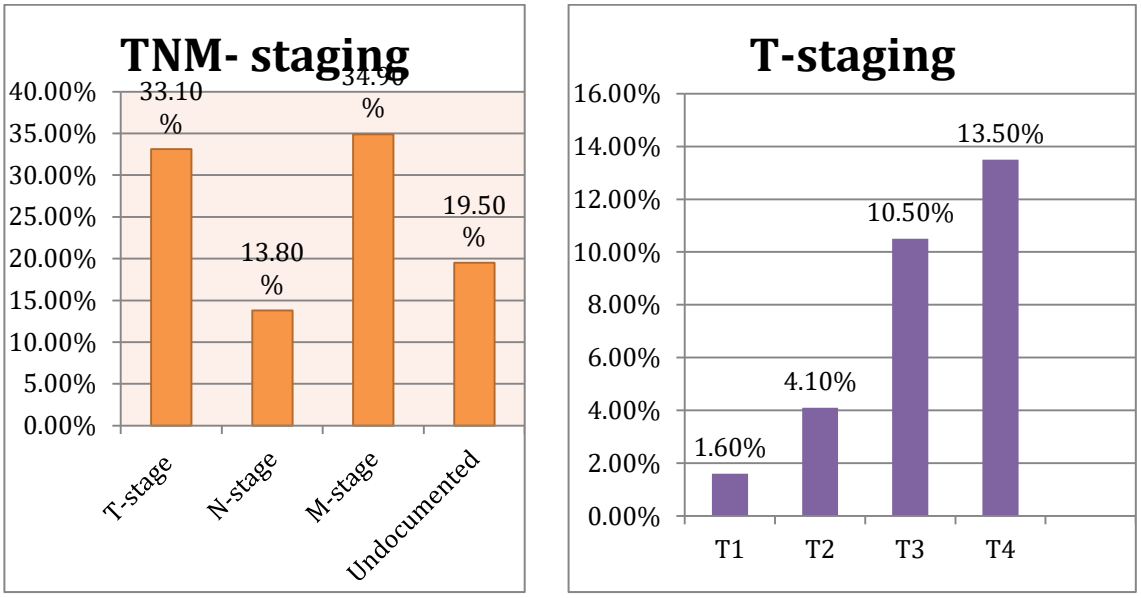


Figure4: TNM staging of prostatic cancer patients at TASH, July 2025

Laboratory Parameters at Diagnosis

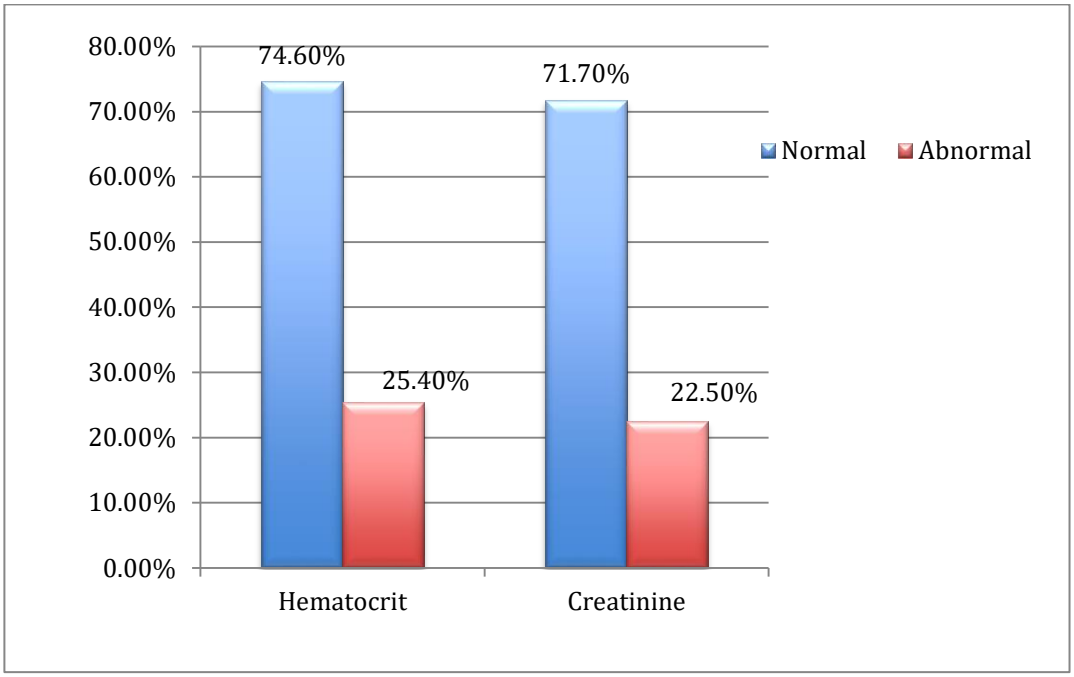
Hemoglobin, Renal Function Test and Prostate-Specific Antigen (PSA) Levels at Diagnosis

At the time of diagnosis, 25.4% (n = 31) of patients were found to have low hemoglobin or hematocrit levels, while the remaining 74.6% (n = 91) had values within the normal range. This indicates that a substantial minority of patients may have presented with anemia, which can be associated with either chronic disease or bone marrow involvement in advanced-stage prostate cancer.

Creatinine levels at diagnosis showed that 22.5% (n = 27) had elevated serum creatinine levels (>1.2 mg/dL), possibly indicative of obstructive uropathy or systemic illness. The majority, 71.7% (n = 86), had normal renal function, while 5.8% (n = 7) were undocumented.

A total of 110 participants were analyzed for serum prostate-specific antigen (PSA) levels, with 13 cases missing data. Elevated PSA levels were reported in the vast majority of patients (99.9%, n = 109), while only 0.9% (n = 1) had PSA within normal limits at diagnosis. Among those with elevated PSA, the distribution of PSA values was highly skewed towards advanced elevation: 83.6% (n = 92) had PSA levels greater than 20 ng/ml, 10% (n = 11) had PSA levels between 10–20 ng/mL, 5.5% (n = 6) had levels between 10–20 ng/mL and only 0.9% (n = 1) had PSA within normal limits at diagnosis. These results strongly suggest late presentation and reinforce the advanced clinical stage observed in many of the patients. The

PSA values exhibited a highly skewed distribution, reflected by a wide range and large standard deviation. The mean PSA level was 285 ng/ml, while the median was notably lower at 108 ng/mL, and the mode was 100 ng/ml, PSA values ranged from a minimum of 3 ng/mL to a maximum of 6859 ng/mL, with a standard deviation of 734, indicating substantial variability and the influence of extreme values.



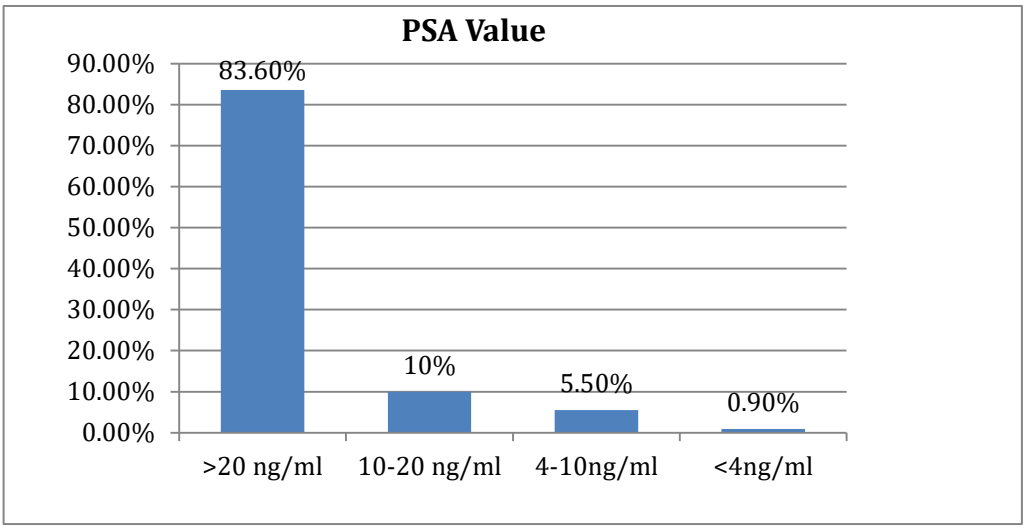


Figure 5: Haematocrit , creatinine and PSA value among prostatic cancer patients at TASH July, 20255

PSA Density

A descriptive statistical analysis was conducted on Prostate-Specific Antigen Density (PSAD) values collected from 89 participants. The analysis revealed that the mean PSAD was 10.8, while the median value was substantially lower at 1.56, indicating a highly right-skewed distribution. The mode was 1.67; however, more than one mode existed in the dataset, and only the first was reported. The standard deviation was notably high at 49.9, reflecting considerable variability in PSAD values. The observed range spanned from a minimum of 0.0794 to a maximum of 333, further underscoring the presence of extreme values and potential outliers. Additionally, 34 observations had missing PSAD values, which may warrant consideration in subsequent analyses or imputation strategies. Overall, these results highlight a wide and skewed distribution of PSAD in the study population.

PSAD values were categorized into four intervals: <0.1, 0.1–0.15, 0.15–0.2, and >0.2. Out of the total 89 observations, only 3 values (3.4%) fell below 0.1, while 2 values (2.2%) were within the 0.1–0.15 range. The interval 0.15–0.2 contained 3 values (3.4%), and the vast majority of observations, 81 values (91.0%), were greater than 0.2. This indicates a strong right-skewed distribution, with most PSAD measurements concentrated at higher values above 0.2. The scarcity of lower PSAD values may reflect an overall trend toward elevated PSAD levels within the sample population.

Table3: PSAD distribution among prostatic cancer patients at TASH, July 2025

PSAD Category	Count	Percentage
<0.1	3	3.37
0.1–0.15	1	1.12
0.15–0.2	2	2.2
>0.2	83	93.25

PSA Follow-Up after Diagnosis and Treatment

Follow-up of serum PSA levels post-treatment (diagnosis or intervention) was available for 37.4%, n=46 of the patient cohort. The most common follow-up time point was at 3 months, reported in 26.1% (n = 12) of patients, followed by follow-up at 6 months (19.6%, n = 9) and at 12 months (15.2%, n = 7). Other time points such as 24 months (10.9%, n = 5), 9 months (4.3%, n = 2), and combinations of multiple follow-up intervals was available for 23.9%, n=11. The scattered distribution of follow-up intervals suggests a lack of standardized post-treatment surveillance protocol.

When follow-up PSA values were compared with baseline (diagnosis time), only 2.2% (n = 1) showed a recorded decrease at 12 months. At 3 months and 6 months, PSA reduction was observed in 34.7% (n = 16) of patients, while 63.0% (n = 29) showed no decline. At 9 months, a PSA reduction was noted in 8.7% (n = 4), indicating poor biochemical response in the majority of patients at this point in time. These findings suggest suboptimal PSA monitoring practices and raise concern about inadequate treatment follow-up or limited treatment response in a significant proportion of patients.

Table 4: Time of follow up PSA among prostate cancer patients at TASH, July,2025

Follow up month	COUNT	ERCENTAGE
3 months	12	26%
6 months	9	19.6%
9 months	2	10.9%
12 months	7	15.2%
24 months	5	10.9%
Mixed pattern	11	23.9%
Total	46	100

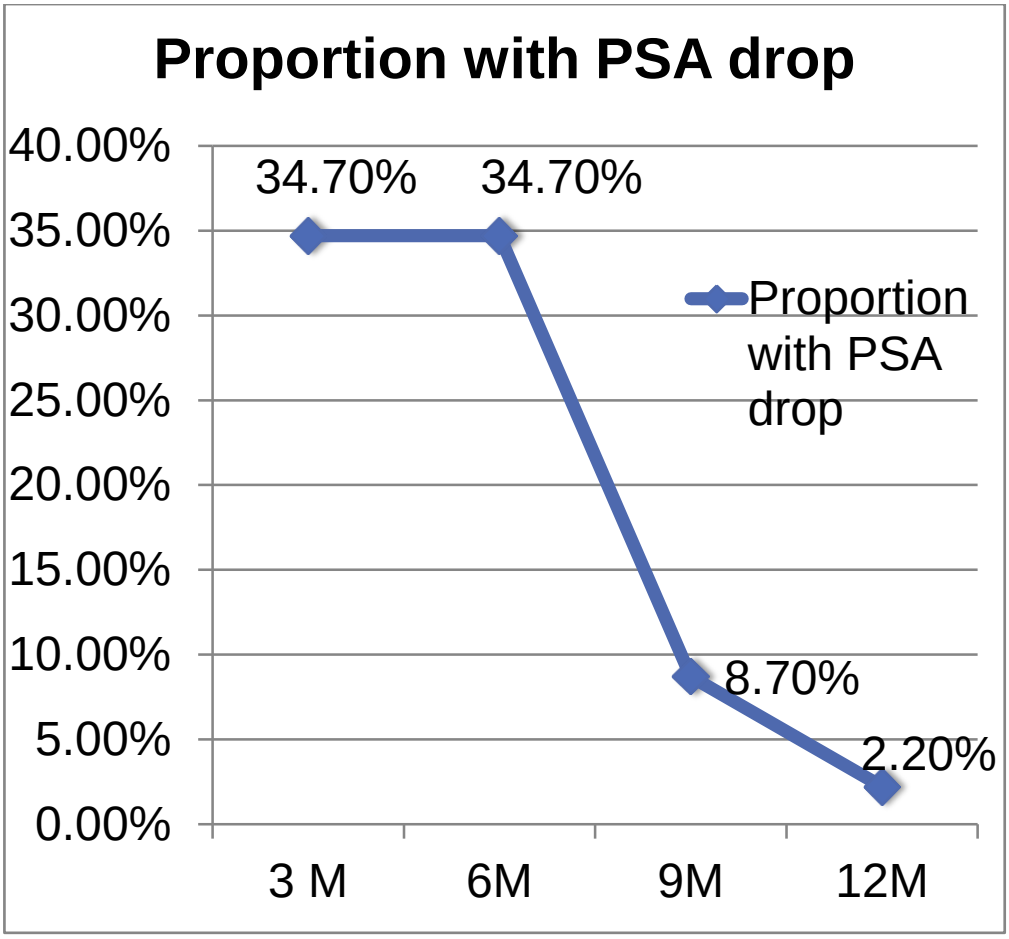


Figure 6: Distribution of patients showing drop in PSA on follow up among Prostatic cancer patients at TASH, July 2025

Gleason Score of initial Biopsy

Among the patients with documented Gleason scores, the most commonly reported grade was ISUP Grade Group 5 (Gleason scores 9 or 10), accounting for 23.7% (n = 28), followed by ISUP Grade Group 2 and 4 (each 15.3%, n = 18), and ISUP Grade Group 3 (11.9%, n = 14). Only 7.6% (n = 9) of patients had low-grade tumors (ISUP Grade Group 1). Notably, 26.3% (n = 31) of cases had no documented Gleason score. These findings highlight a pattern of high-grade disease as ISUP grade group 4& 5 account for 79% of cases suggesting advanced stage disease at presentation.

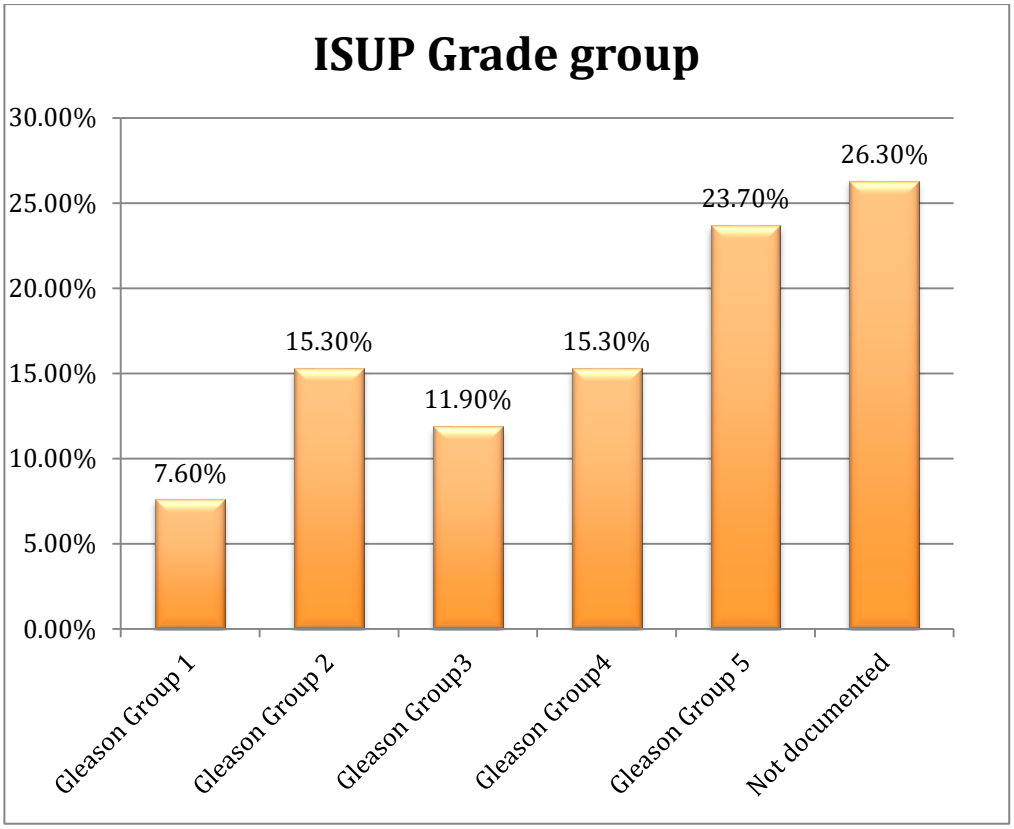


Figure7: ISUP Gleason group of prostatic cancer patients at TASH July, 2025

Imaging Modalities Used in Workup, Prostate Volume and PIRADS score on Imaging

A wide array of imaging techniques was utilized as part of diagnostic workup. The most frequently used imaging modality was ultrasound (US) of the prostate combined with MRI, accounting for 57.7% (n = 71). This was followed by stand-alone US of the prostate (20.3%, n = 25) and MRI of the prostate alone (10.5%, n = 13). Use of abdominopelvic CT was limited (8.13%, n = 10), and 3.2% of cases had incomplete or undocumented imaging data. The ultrasound is used as baseline investigation in almost all patients in our centre and prostate MRI is used for local staging and for targeted biopsy. Abdominopelvic CT scan is used for local staging in some patients but mostly it is used for suspected metastasis. We do not have other imaging modalities like bone scan, Choline PET/CT and Prostate-specific membrane antigen-Positron emission tomography/Computed tomography for detecting lymph node and distant metastasis.

MRI was most commonly performed prior to biopsy (65.3%, n = 64), which is important doing targeted biopsy and risk stratification. In the remaining 34.7% (n = 34) of patients, MRI followed histopathologic diagnosis, perhaps for staging or treatment planning purposes.

Among the 83 patients with documented Prostate Imaging Reporting and Data System (PIRADS) scores, a significant proportion exhibited imaging characteristics highly suggestive of clinically significant prostate cancer. Specifically, 44.6% (n = 37) of cases were classified as PIRADS 4, and 22.9% (n = 19) as PIRADS 5, together representing over two-thirds of the imaged cohort. These scores correlate with a high likelihood of histologically confirmed malignancy and typically warrant targeted biopsy and indicates high probability of locally advanced disease. An additional 30.1% (n = 25) were categorized as PIRADS 3, indicating equivocal findings, while PIRADS 1 and 2 were rare (1.2% each), reflecting a very low suspicion of cancer in these patients.

Prostate volume was reported in 96 patients, while 27 (21.9%) had missing documentation. The mean prostate volume was 73.9 cm^3, with a median of 77.0 cm^3 and a mode of 90.0 cm^3, indicating that most patients had moderately to markedly enlarged prostates. The standard deviation was 30.9 cm^3, reflecting wide variability in gland size. Volumes ranged from a minimum of 3 cm^3 to a maximum of 197 cm^3, with multiple patients clustered toward the higher end of the distribution. These findings are consistent with the high prevalence of lower urinary tract symptoms in study population.

Initial Management Strategies

Initial treatment decisions were predominantly centered on androgen deprivation therapy (ADT). ADT monotherapy was instituted in 74.0% (n = 91) of patients, and when inclusive of those receiving ADT in combination with either radiation therapy or cytotoxic chemotherapy, the total proportion rose to 85.4% (n = 105). This reflects ADT as a cornerstone in the management of locally advanced or metastatic prostate cancer, particularly in resource-constrained or non-surgical settings either alone or in combination with other modalities.

Radiation therapy was used as a sole modality in 7.3% (n = 9) of cases, 0ut of this it is used for curative intent in 4.1 %(n=5) and in 3.25% (n = 4) as modality to palliate metastatic symptoms. It is used in combination with ADT in 8.9% (11) patients with advanced disease. Cytotoxic chemotherapy was less frequently employed, either alone 1.7% (n=2) or in conjunction with ADT 2.4 %(n=3), possibly reflecting use in metastatic or castration-resistant disease.

Active surveillance was used in 1.6% (n = 2) of patients, suggesting a subset with low risk or favorable intermediate risk group localized disease. Notably, no patients underwent radical prostatectomy as an initial intervention, which is due to use radiation for intermediate or high risk localized disease and most of patients present with advanced disease where surgery as option of management has no role and advanced age at presentation also makes patients not candidates for surgery. Watchful waiting, a less intensive monitoring approach, was rarely utilized 0.8% (n=1), suggesting that clinicians in this cohort tended toward proactive management strategies.

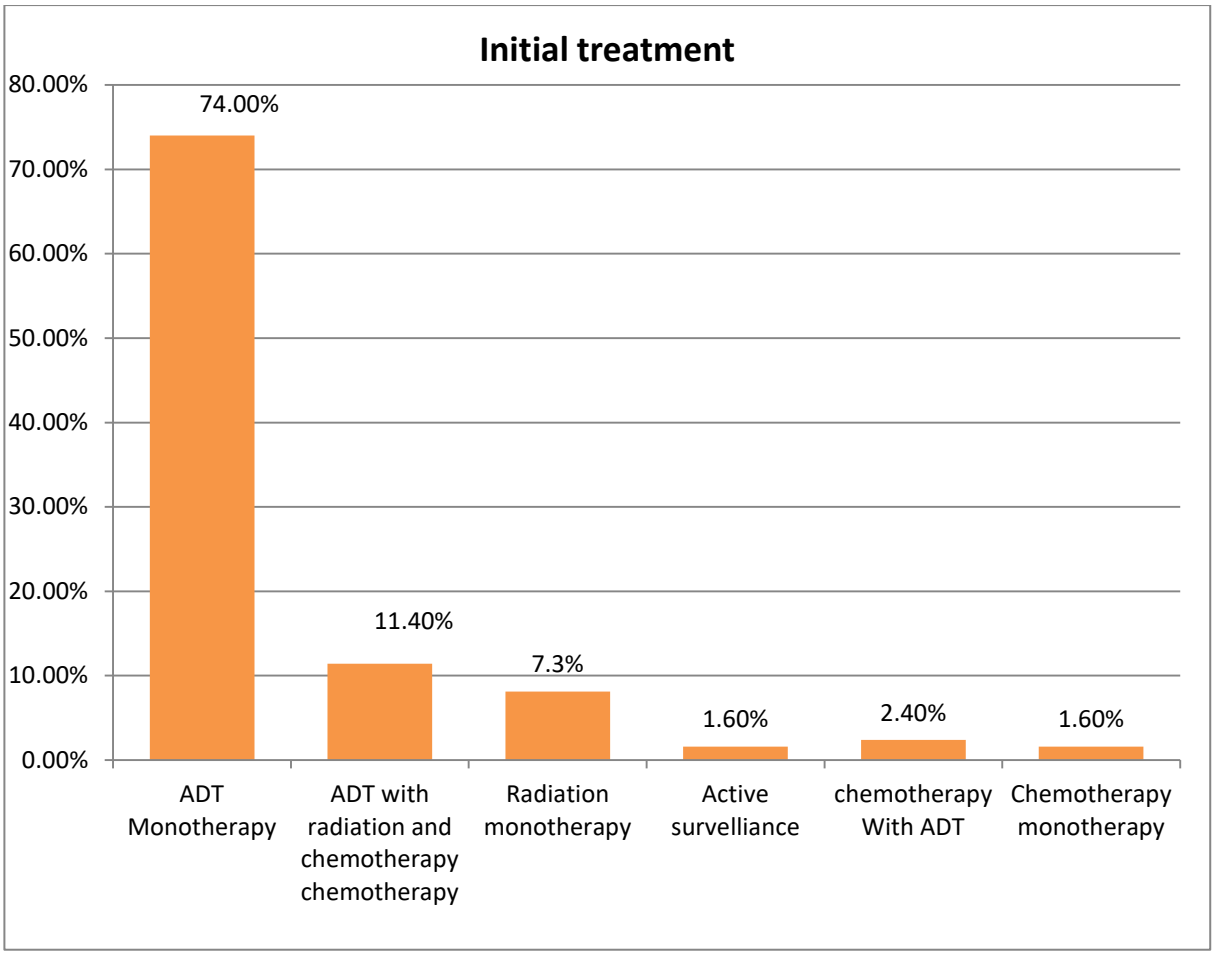


Figure8: Initial treatment given for prostatic cancer patients at TASH July, 2025

Modalities of Androgen Deprivation Therapy (ADT)

Among patients initiated on androgen deprivation therapy, multiple pharmacologic and surgical approaches are available. The most frequently utilized modality was bilateral orchiectomy, observed in 50.0% (n = 53) of the ADT cohort. This surgical castration method remains a cost-effective and definitive intervention in resource-limited settings and reflects long-standing practices in Ethiopian urologic oncology.

Pharmacologic castration through LHRH agonists, including agents such as goserelin (Zoladex), was also prevalent, used in 39.6% (n = 42) of cases. Additionally, antiandrogens (specifically bicalutamide) were utilized in only 7.7% (n= 6) of patients, Combination modalities were reported in a small number of cases 4.7% (n = 5) which includes orchiectomy with adjunctive LHRH agonist therapy and LHRH agonist with antiandrogens (specifically bicalutamide).Importantly, no patients received adrenal blocking agents (Inhibition of Androgen Synthesis) , First Generation steroidal antiandrogen like Cyproterone

acetate, or Nonsteroidal Second Generation like Enzalutamide and Apalutamide approaches as part of their initial ADT regimen.

This distribution of therapeutic modalities highlights a strong reliance on irreversible surgical castration due to its cost effectiveness, lack continues supply LHRH agonist in government hospital and unavailability of agents like Nonsteroidal Second-Generation antiandrogens like Enzalutamide and Apalutamide in the country.

Management Shifts and Duration of Initial Treatment

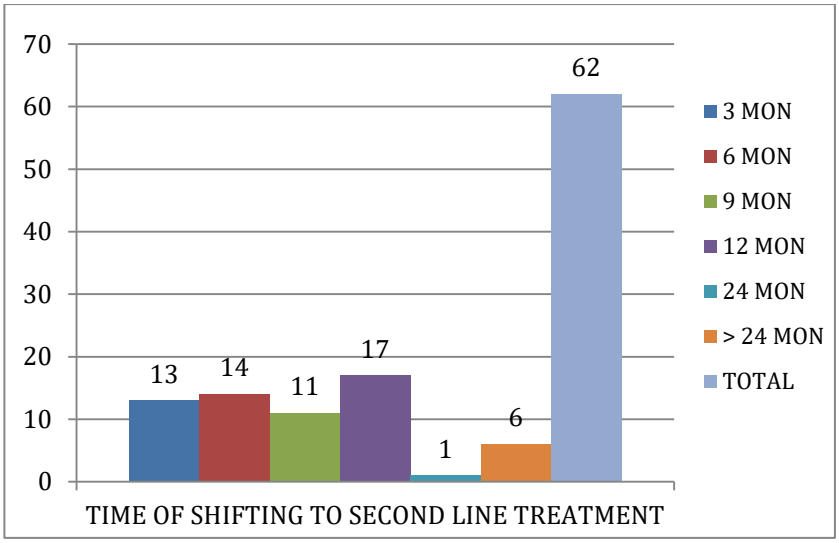
Nearly half of study population 50.4% (n=62) shifted to different form of treatment from initial one though duration of shift to alternative treatment variable ranging from 3-24 month. Among patients whose management was eventually shifted to an alternative option, the duration of initial management prior to the shift varied. The most frequently reported duration was 12 months, accounting for 27.4% of cases (n=17). This was followed by 6 months (22.6%, n=14) and 3 months (21.0%, n=13). A smaller proportion of patients shifted initial management at 9 months (17.7%, n=11) or 24 months (1.6%, n=1). These findings indicate that while most patients are monitored and managed for up to a year, a considerable number shift to an alternative approach within the first 6 months. Though, our study focuses on two-year period, 9.7% (n=6) patients shifted to alternative treatment after 24 months as we were able get data beyond 24 months for some patients included in the study at beginning of the study and one could expect more patients shifting to alternative treatment with longer duration of follow up.

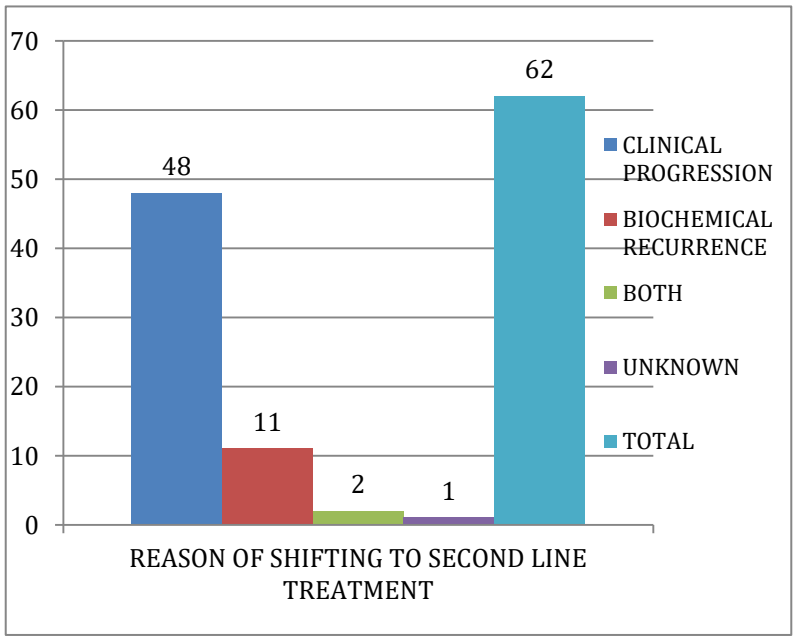
Reasons for Transitioning to Alternative Management

The predominant reason for shifting from initial management was clinical progression, defined as the development of local symptoms in previously asymptomatic patients or the emergence of metastatic disease from a previously non-metastatic state. This accounted for of 77.4% (n=48) the cases. Biochemical recurrence was cited in 17.7% (n=11), while a combination of clinical progression and biochemical recurrence accounted for 3.2% (n=2). Incomplete data for clinical conclusion was a relatively rare reason, documented in only 1.6% (n=1) of the cases. This pattern underscores the clinical vigilance in response to disease progression rather than relying solely on biochemical indicators.

Second-Line Treatment Strategies

Following the shift to alternative management, the majority of patients received radiation therapy, comprising 56.4% (n=35) of the cases. Cytotoxic chemotherapy was the second most utilized approach at 22.6% (n=14), followed by combined radiation therapy and cytotoxic chemotherapy 17.7%, n=11) and less frequently employed strategies is androgen deprivation therapy 3.2 %, (n=2). Subgroup analyses indicated that radiation therapy continued to be the most prevalent second-line modality (67.7% of applicable cases), followed by cytotoxic chemotherapy (35.5%).





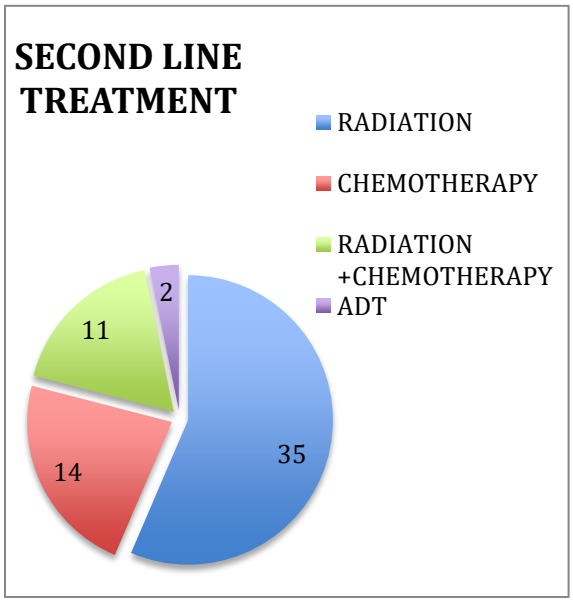


Figure 9: Time of shift to second line treatment, reason of shifting and second line treatment used for prostatic cancer patient TASH, July2025

Measures of Association

Different statistical Tests including Pearson Chi-square test, Linear Regression and Multinomial Logistic Regression Analysis were used to assess degree association between different variables included in the study, which is summarized in table, and we will discuss those variables having significant association. (32-35)

Table 5: summary of Statistical Tests used to assess association between variables among prostatic cancer patients TASH, July 2025

Variables	Statistical Test	Significant ($p < 0.05$)	Pseudo R^2 / R^2
Family History vs Age Group	Pearson's Chi-square	No ($p = 0.81$)	N/A
TNM Stage vs Residential Area	Multinomial Logistic Regression	No ($p > 0.9$)	0.0222
Presenting Symptoms vs Gleason Score	Multinomial Logistic Regression	No ($p > 0.89$)	0.0241
Gleason Score vs Residential Area	Multinomial Logistic Regression	Yes for 1–2, 2–5 ($p < 0.001$)	0.0675
Gleason Score vs PIRADS	Multinomial Logistic Regression	Yes ($p < 0.001$)	0.421
Gleason Score vs Education	Multinomial Logistic Regression	Mixed (varied p-values)	0.421
Gleason Score vs Family History	Multinomial Logistic Regression	No ($p > 0.05$)	0.421
Gleason Score vs DRE	Multinomial Logistic Regression	Yes (BPH findings, $p < 0.001$)	0.421
PSA Level vs Age	Linear Regression	No ($p > 0.05$)	0.0378
PSA Level vs Occupation	Linear Regression	No (NaN values)	0.0378
PSA Level vs Residential Area	Linear Regression	No ($p = 0.629$)	0.0378
PSA Level vs Symptoms	Linear Regression	No ($p = 0.681$)	0.0378
TNM Stage vs DRE	Multinomial Logistic Regression	Yes (T3B, T4: $p < 0.001$)	0.367
TNM Stage vs Residential Area	Multinomial Logistic Regression	Yes, for T2A ($p < 0.001$)	0.367
TNM Stage vs Symptoms	Multinomial Logistic Regression	Yes ($p < 0.001$)	0.367

TNM Stage vs Education	Multinomial Logistic Regression	Yes ($p < 0.001$)	0.367
TNM Stage vs PIRADS	Multinomial Logistic Regression	Yes ($p < 0.001$)	0.367

Linear Regression Analysis of Predictors of Serum PSA Level and other factors

As higher baseline value indicates advanced disease linear regression model was conducted to identify potential predictors of serum Prostate-Specific Antigen (PSA) levels, using a sample of 110 participants. The independent variables included age category, status, residential area, and the presence of prostate-related symptoms. The overall model fit was poor, with a coefficient of determination (R^2) of 0.0378, suggesting that only 3.8% of the variability in PSA levels could be explained by the included predictors. The correlation coefficient (R) was 0.195, indicating a very weak linear relationship between the independent variables and PSA levels. But association between PSA none of the above variables didn't show significant association which could be due to wide variation in PSA value of study population

Linear regression analysis for PSAD and Gleason Score (GS)

A linear regression analysis was conducted for a sample size of 52 to investigate the association between Gleason Score (GS) groupings and serum Prostate-Specific Antigen Density (PSAD) values with assumption of both higher Gleason score and higher PSAD density indicates advanced with positive association. The model demonstrated a modest fit, with an R value of 0.464 and a coefficient of determination (R^2) of 0.215, indicating that approximately 21.5% of the variation in PSAD could be explained by differences in Gleason score categories.

Compared to the reference group, all GS groupings exhibited a statistically significant negative association with PSAD values. Specifically, individuals with GS 4–5 had significantly lower PSAD levels ($\beta = -63.4$, SE = 24.1, $p = 0.012$), while GS 3–5 ($\beta = -67.5$, SE = 26.8, $p = 0.015$) and GS 2–5 ($\beta = -75.0$, SE = 35.2, $p = 0.038$) similarly showed inverse relationships. Although the GS 1–2 comparison also had a negative coefficient ($\beta = -74.5$), it did not reach statistical significance ($p = 0.061$), falling slightly above the conventional threshold.

These findings suggest a counterintuitive pattern where higher GS categories are associated with lower PSAD values in this cohort. This may reflect underlying clinical heterogeneity, data sparsity, or measurement variation, and further investigation with larger samples and stratified modeling is warranted.

Table 6: Linear regression analysis table for association between Gleason Score (GS) groupings and serum Prostate-Specific Antigen Density (PSAD)

GS Group	Estimate (β)	SE	p-value
4–5	-63.4	24.1	0.012
3–5	-67.5	26.8	0.015
2–5	-75	35.2	0.038
1–2	-74.5	38.8	0.061

Multinomial Logistic Regression Analysis of Gleason Score (GS)

A multinomial logistic regression analysis was conducted to examine the association between Gleason score categories (1–2, 2–5, 3–5, and 4–5) and several predictor variables, including PIRADS score, educational status, family history of prostate cancer, and digital rectal examination (DRE) findings. The overall model fit was acceptable, with McFadden's pseudo-$R^2 = 0.421$, suggesting a moderate explanatory power. A Multinomial logistic regression conducted to examine association of Gleason score (GS) categories with residential area, educational status and family history of prostate cancer didn't show significant association. But PIRADS score and digital rectal examination (DRE) findings show significant association with Gleason score (GS) categories.

PIRADS scores were found to be strong and consistent predictors of Gleason score across all model comparisons. For instance, compared to PIRADS 1, PIRADS 3 ($\beta = 49.392$, $p < .001$), PIRADS 4 ($\beta = 20.193$, $p < .001$), and PIRADS 5 ($\beta = 13.896$, $p < .001$) were all significantly associated with increased odds of being in the 1-2Gleason group. Similarly, PIRADS 3 ($\beta = 51.273$, $p < .001$) and PIRADS 4 ($\beta = 20.263$, $p < .001$) remained significant predictors in the 2–5 comparison. The consistent trend across categories reinforces that higher PIRADS scores are significantly associated with higher Gleason scores.

DRE findings were highly significant in most model comparisons. In the 1-2group, a finding suggestive of benign prostatic hyperplasia (BPH) was associated with increased odds of higher Gleason score ($\beta = –15.682$, $p < .001$), while suggestive findings of cancer did not reach significance ($\beta = 2.517$, $p = .121$). This was consistent in the 2–5 group, where BPH remained a strong positive predictor ($\beta = 28.392$, $p < .001$).

Association between TNM staging and various factors

A multinomial logistic regression model was conducted to examine the association between TNM staging other variables like residential area PIRADS score, educational level, residential area, presence of symptoms, and DRE findings patients with significant

association between TNM stage and other variables except place of residence which didn't show significant association with it, based on a sample of 118 patients.

The model exhibited a moderate goodness-of-fit with a McFadden pseudo-R^2 of 0.367, indicating that about 36.7% of the variation in TNM staging was explained by the predictors included in the model.

Among patients with suggestive DRE findings of prostatic cancer, there was a significant association with advanced TNM stages. Specifically, the odds of being categorized as T3B or T4 were significantly higher for individuals whose DRE indicated suggestive signs of malignancy (e.g., Estimate for T3B: 31.287, $p < .001$).

Urban residence was significantly associated with increased odds of earlier TNM stages (e.g., T2A: Estimate = 42.833, $p < .001$), while its effect decreased or became statistically insignificant for more advanced stages like T3B and T4.

The absence of symptoms ("No" to "Do you have any of the symptoms?") was consistently associated with decreased likelihood of presenting at higher TNM stages. For instance, in T2C, the coefficient for "Yes – No" was –29.411 ($p < .001$), suggesting symptomatic individuals were more likely to present with advanced disease.

Higher educational levels were strongly associated with TNM stages. For example, individuals with tertiary education (compared to the reference group—illiterate but can read and write) were significantly more likely to present at T2C (Estimate = 35.568, $p < .001$), T3A (Estimate = 29.270, $p < .001$), and T3B (Estimate = –5.424, $p < .001$). This reflects potential differences in awareness, access to care, or health-seeking behavior.

Higher PIRADS scores (4 and 5) showed a statistically significant and strong association with later TNM stages, particularly from T2A onwards. For example, in the T3B group, PIRADS 5 had an estimate of 23.187 with $p < .001$, showing a direct relationship between imaging findings and cancer staging.

Conclusion:

In summary, PIRADS score, educational level, residential area, presence of symptoms, and DRE findings were significantly associated with TNM stage distribution. These findings suggest that both clinical presentation and sociodemographic variables influence the staging at diagnosis, potentially reflecting disparities in healthcare access, health literacy, and disease awareness.

Chapter 6: Discussion

Sociodemographic data and risk factors

Most (86 %) of the patient included the study are diagnosed with prostatic cancer after age 60 year. The age at time of diagnosis ranges from 43years to 95 years with median age of 69 years which similar with most studies from oncology unit of TASH Beksisa et al., D. M. Katabalo et al. from Uganda, Seraphin et al. from 1o countries in SSA, David et al. from united states of America reported median age at diagnosis 68years ,70years ,70years and 68 years respectively. (9,13,25,31) From above evidences one can understand that Pca commonly occurs at advanced age in general regardless of the race and geographical location globally, although they are some minor differences with regard age at diagnosis.

A small proportion of the study population, 5.7% (n = 7), reported having a first-degree relative previously diagnosed with prostate cancer and this number is slightly higher the older report from oncology unit of TASH in which case it was reported to be 2.9 % but lower than report from united states of America by David et al. in which family history was found in 15.4% with 13.5% being first degree relative , 1.4% being none first degree relative and in o.5% unknown relationship was reported.(9,31) The finding of our study has similarity with later in terms of predominance the affected being first degree relative as in our cohort all patients with family history of prostate cancer report affection of first degree relative. The study from Japan by S. Ukawa et al. 6.5% of the patients have family history of prostate cancer which is closer to finding of our cohort. (22) The Association between Family History of Prostate Cancer and Age of diagnosis of prostate cancer was checked for significance of Statistical association using the Pearson Chi-square test showing no significant association between the two with P value of p= 0.81

Occasional Cigarette smoking was reported by 6.6% (n = 8) patients which is by far lower than older report from oncology unit of TASH and report from Japan by S. Ukawa et al. in which 19% and 69.3% of the patients have history of smoking respectively. (9,22)

Clinical presentation and work up

The overwhelming majority of participants (98.4%, n = 121) reported experiencing at least one symptom at presentation which indicates advanced stage at presentation as prostatic cancer is asymptomatic at earlier stage. The patients presenting with symptom is slightly higher than study from south Africa were 91.8% of patients have at least one symptom at time of presentation but in that study in 2.9% of patients reason for visiting hospital was not reported. (17) In study from Uganda 88.2 % of the men with prostate have at least one symptom at time of presentation which is slightly higher than our cohort. (18) These findings in our cohort and other African study contradicts with study from western world where most patients are identified at earlier stage due to higher use of PSA screening as shown in the

study from United Kingdom where 28.9% of patients were having symptoms and 18% were identified after prostatectomy for presumed benign hyperplasia. (17,25,37)

The most common presenting symptoms in our cohort include LUTS in 94.6 % (97.5% Voiding LUTS & 91.7% Storage LUTS) and Metastatic symptoms in 33.9% with Bone pain or pathologic fractures (in 27.7%) and Lower limb weakness (in 5.0%) being the commonest metastatic symptoms. Other studies done in Africa also show similar result with most patients presenting with LUTS and metastatic symptoms although the proportion of specific symptoms vary from study to study. (17,18) William et al. reported among LUTS hesitancy, frequency/urgency and nocturia have highest sensitivity in predicting prostate cancer with positive predictive values of 3%, 2.2% and 2.2% when used as single symptom. In our study also frequency/urgency and hesitancy are the two most common presenting symptoms but we did not nocturia less commonly reported symptom. William et al. also reported digital rectal examination report as benign and malignant report to have highest sensitivity in predicting prostate cancer with positive predictive values of 12% and 2.8% when used as single parameter which is 87.7% and 12.5 % in our cohort with higher values in our study could be due late presentation with advanced disease and difference in methodology of study which case control study in other study. (37)

Diagnosis of prostate cancer was made in one case (0.8%) via screening PSA elevation, highlighting a limited use of screening for early detection in this cohort. In study from South Africa and United Kingdom in 3.2 % and 8% diagnosis made due to high PSA which is higher than our cohort which could be lower awareness level on PSA screening in our community as reported by Gebru T, et al., Ashenafi and Temesgen al. (6,7,8,17, 37)

A notable proportion of patients (40.6%, n = 50) reported at least one comorbid condition, with hypertension in 19.5%, Isolated diabetes mellitus in 4.8.0% (n = 6) of cases, and CKD in 0.8% (n = 1). Additional comorbidities included asthma, hypothyroidism with dyslipidemia, and peripheral arterial disease and HIV each in one patient (0.8%). The prevalence of co-morbidities in this cohort is higher than study from oncology unit of TASH and Study from Uganda even if hypertension is leading comorbidity in all three cohorts. (9,25) The higher prevalence of co-morbidities in this cohort could be due to slightly advanced age at diagnosis when compared with other studies.

Only 1.6% (n = 2) of participants reported being diagnosed with another type of cancer in addition to prostate cancer which included right breast cancer in one patient who is 85 years old male patient with mastectomy 8 years back. This case could give clue if genetic study is done for BRCA2 even if age looks old to consider BRCA associated prostate cancer. The other case was 67 years old male patient who had trans urethral resection of bladder tumor with biopsy result of non-muscle papillary urothelial cancer.

With respect T-staging, there predominance of locally advanced-stage disease (T3 and T4) which account for 24.3 %(n=33) of the cases and very small proportion 7.3% (n=6) of the

patients have localized disease (T1/T2) at time of diagnosis. Majority of the patients have Metastatic disease at time of presentation which account for 34.9% (n = 43) of cases. In remaining 19.5% (n=24) of cases there is no documentation to categorize the patients into one category and 13.8% (n=17) of cases have involvement of regional lymph nodes. In study from oncology unit of TASH patient are categorized as localized disease 16.8% (7.3% stage I and 9.5% Stage II), 13.9% locally advanced disease (Stage III) and 62.8% Stage IV (None regional lymph node involvement and distant metastasis) which has minor difference in numbers except lack of documentation larger proportion in our cohort. (9)

In study from Uganda local disease was 10%, locally advanced disease was 29.4 % and T-stage was undocumented in 66.6 % of cases. Lymph node metastases was reported in 13.9 % and Lymph node status was undocumented in 43.4 %, while Distant Metastases was reported in 42.7% and Distant Metastases was undocumented in 37.2%. (3) In Population- Based Registry Study from 10 Sub- Saharan Africa countries local disease was 21.1%, locally advanced disease was 19.7% and T-stage was undocumented in 59.2 % of cases. Lymph node metastases were reported in 6.3 % and Lymph node status was undocumented in 80.0 %, while Distant Metastases was reported in 31.0%. (13)

Over all finding of cohort similar with other African studies with predominance of metastatic disease and locally advanced disease at time of diagnosis which is due to late presentation at hospital, lack of financial capacity to pay hospital bills, seeking alternative treatment before going to the hospital and delaying referral system to patients and lack PSA screening practices. There poor documentation significant proportion of patient data with respect clinical staging. (9,13,16,25)

TNM stage distribution were significantly associated with PIRADS score, educational level, residential area, presence of symptoms, and DRE findings. These findings suggest that both clinical presentation and sociodemographic variables influence the staging at diagnosis, potentially reflecting disparities in healthcare access, health literacy, and disease awareness.

Concerning PSA result mean total prostate specific antigen (TPSA) was 285 ng/mL in this study was as higher as what has been documented in large number of studies done in developing countries even though it was not exactly similar.(3,12,18)Strikingly, 83.6% of the sample exhibited PSA levels above 20 ng/mL, underscoring a heavy skew toward markedly elevated PSA values in this clinical cohort while only 0.9% of participants had PSA levels below 4 ng/ml in previous study from oncology unit of TASH also 78.4% of patients have PSA above 20ml/ng which is slightly smaller than our cohort.(9)Similarly Tindal et al. from south Africa and Katongole et al. from Uganda reported 83.0 % and 79.2% of patients with PSA above 20ng/ml respectively with results closer to our finding, while David et al. from united states of America reported only 15.9% patients having PSA above 20ng/ml. (17,21,25) These findings indicate that African patients have elevated PSA at time of diagnosis with advanced disease predominantly at time of diagnosis.

With regard to Gleason score, among patients with documented Gleason scores pattern of high-grade disease of grade group 4& 5 account for 79% of cases suggesting advanced stage disease at presentation. In study from oncology unit of TASH high grade group account for 48.3 % of which is predominant group but with slight lower compared to our cohort. (17) There is predominance higher grade disease in other African studies even if there are slight differences in number indicating aggressive biologic behaviour of in Africans and late presentation of patients mostly and lack of PSA screening to detect earlier stage of disease. (12 ,18,25) The study shows that Gleason score is significantly associated with PIRADS score and DRE findings on multimodal regression analysis. Tindal et al. also reported association of Gleason score with residential area with rural residents having higher Gleason score indicating advanced and aggressive disease similar to our finding. (17)

Table 7: SUMMARY OF CLINICAL PRESENTATION AMONG DIFFERENT STUDIES

Author	Country	Median age	PSA>20ng/ml	ISUP GG 4&5	T1/T2	T3/T4	LN +VE	METASTATIC
Our cohor	Ethiopia	69	83.6%	79%	7.3%(u=68.3%)	24.9%	13.%	34.9%
Beksisa et al.	Ethiopia	68	78.4%	48.3 %	16.8%	13.9 %	16%	59.1%
Seraphin et al	SSA	70	28.8(17.8%)u=66.0%	18.8 %(u=54.8)	21.1%(u=59.2%)	19.7%	6.3%(u=80%)	37.3%
Tindall et al.	South Africa	71	83.0(50.1)	24.6 %	61%	39 %	-	22%
Yahaya	Uganda	70	82.9%(>4)	44.6 %	39.3%	31.75		29.8%
Katongole et al.	Uganda	70	79.2%(>10)	47.3 %	4%(U=66.6%)	29.4%	13.9(U=43.4%)	42.7(U=37.2%)
David et al.	United states of America	68	15.9%(87.5%	19.8 %	83.1%	10.5	-	13%

KEY

GX= Proportion of Gleason score undocumented in the study

LNX= Proportion of lymph node involvement undocumented in the study

MX= Proportion of distant metastasis undocumented in the study

PX= Proportion of PSA undocumented in the study

TX= Proportion of T-stage undocumented in the study

Regarding, Imaging Modalities Used in Workup the most frequently used imaging modality was ultrasound (US) of the prostate combined with MRI, accounting for 57.7% (n = 71). This was followed by stand-alone US of the prostate (20.3%, n = 25) and MRI of the prostate alone (10.5%, n = 13). Use of abdominopelvic CT was limited (8.13%, n = 10), and 3.2% of cases had incomplete or undocumented imaging data. The ultrasound is used as baseline investigation in almost all patients in our centre and prostate MRI is used for local staging and for targeted biopsy. Abdominopelvic CT scan is used for local staging in some patients but mostly it is used for suspected metastasis. We do not have other imaging modalities like bone scan, Choline PET/CT and Prostate-specific membrane antigen-Positron emission tomography/Computed tomography for detecting lymph node and distant metastasis. In this cohort there is better use of MRI alone or with us while use of ultrasound alone and use of CT scan comparable with Seraphin et al. report from across 1o SSA. (13) There is no report on use of x-ray and their better documentation on imaging in this cohort compared to Seraphin et al. report. (13)

As long as patient treatment is concerned, Androgen deprivation therapy (ADT) is predominantly used Initial treatment option, it is used as monotherapy in 74.0% (n = 91) of patients, in combination with either radiation therapy or cytotoxic chemotherapy in 8.9%(n=11) patients followed by Radiation therapy which is used as a sole modality in 8.13% (n = 10) of cases & in combination with ADT in 8.9% (11) patients with advanced disease. Cytotoxic chemotherapy alone is used in 1.7% (n=2) cases or in conjunction with ADT 2.4 % (n=3). Active surveillance was used in 1.6% (n = 2) of patients. Among patients initiated on androgen deprivation therapy bilateral orchiectomy, observed in 50.0% (n = 53) of the ADT cohort. This surgical castration method remains a cost-effective and definitive intervention in resource-limited settings and reflects long-standing practices in Ethiopian urologic oncology. Pharmacologic castration through LHRH agonists, including agents such as Zoladex, was also prevalent, used in 39.6% (n = 42) of cases. Additionally, antiandrogens

(specifically bicalutamide) were utilized in only 7.7% (n= 6) of patients, Combination modalities were reported in a small number of cases 4.7% (n = 5) which includes orchiectomy with adjunctive LHRH agonist therapy and LHRH agonist with antiandrogens (specifically bicalutamide). Importantly, no patients received adrenal blocking agents (Inhibition of Androgen Synthesis), First Generation steroidal antiandrogen like Cyproterone acetate, or Nonsteroidal Second Generation like Enzalutamide and Apalutamide approaches as part of their initial ADT regimen.

This distribution of therapeutic modalities highlights a strong reliance on irreversible surgical castration due to its cost effectiveness, lack continues supply LHRH agonist in government hospital and unavailability of agents like Nonsteroidal Second-Generation antiandrogens like Enzalutamide and Apalutamide in the country

In the study TASH oncology unit, the treatment offered were reported as ADT in 81.8%, radiation in 75.2%, surgery in 50.4%, chemotherapy in 5.1% and combination treatment in 27% of cases. (9) There is similarity with our study in terms of predominance ADT but there is relatively higher number of patients who are treated with radiation which could be due referral patients from different hospital to the unit as it is among few radiotherapy centers available in the country. If patients second line treatment is included for comparison the proportion of patients treated with radiation followed by chemotherapy will increase in our cohort as most patients are treated by these modalities. Over all the treatment modalities used in our cohort will be in descending order ADT, radiotherapy, chemotherapy and active surveillance making similar with Beksisa et al finding except surgery. They also higher number patients 69(50.4%) being treated with surgery which includes radical prostatectomy was done in 58 (84%) and transurethral resection of the prostate (TURP) was performed for 11 (16%). In our study, no patients underwent radical prostatectomy as an initial intervention, which is due to use radiation for intermediate or high risk localized disease and most of patients present with advanced disease where surgery as option of management and advanced age at presentation also makes patients not candidates for surgery. We also didn't include patient who underwent transurethral resection of the prostate (TURP) for symptomatic relief of lower urinary tract as it is targeted to relief symptoms only. In study from Tanzania also ADT is most utilized option of treatment as sole treatment modality or combination with Chemotherapy and Radiotherapy but they used goserelin and/or bicalutamide as modality of ADT but no report of orchidectomy unlike our study where it is dominant form of ADT and no report of radical prostatectomy in that cohort also. (16) In study from Uganda Chemotherapy, ADT, Radiotherapy and surgery were most commonly used treatment options in descending order of use with bicalutamide as most commonly used modality of ADT and orchiectomy in few cases. Chemotherapy was more used than in our study this could be due higher proportion of patients with advanced disease than our study which was reported to be 99%. (25) In Population- Based Registry Study from 10 Sub-Saharan African countries ADT in form orchiectomy, combined androgen blockade, gonadotropin- releasing hormone agonists, antiandrogen alone (mainly with bicalutamide),

and diethyl stilboestrol in descending order of use was dominant form of treatment alone and with other treatment modalities. (13)

Nearly half of study population 50.4% (n=62) shifted to different form of treatment from initial one though duration of shift to alternative treatment variable ranging from 3–24-month due clinical progression, biochemical recurrence or both with radiotherapy and chemotherapy being most commonly used second line treatment and ADT used in few patients as second line treatment. Radiotherapy which was used as most common second line treatment is used mostly for patients who developed metastatic symptoms. This indicates most our patients present with advanced with poor response to initial treatment which could be due to castration resistance but it is documented in few patients' chart and it difficult to interpret from results of testosterone and follow up PSA results as it is randomly documented. This results also congruent with the finding older study from oncology unit of TASH in which overall median survival time was 28 months with 2-, 3- and 5-year survival of 57%, 38.9% and 22%, respectively indicating poor patient response to treatment they are offered due late presentation of patients with aggressive disease. (9).

CHAPTER 7: Strength and limitation of study

Strength

- It focuses on common male genitourinary tract malignancy with significant contribution in terms of morbidity and mortality on which there is scarce study in the country
- The finding of the study may serve as baseline data for further study on prostatic cancer.
- The study tries to touch broader areas about prostatic cancer further analysis can be done on specific areas like risk factors, patient symptoms, laboratory and imaging results and treatment patterns and their outcome.
- The finding is important to alarm concerned bodies like urologists, oncologists, health system managers and public health professionals concerning prostate cancer screening and management

Limitation

- As study is based on secondary data it does not allow Intervention in study subjects
- Cause effect relationship establishment is impossible due to cross-sectional study design

CHPTER 8: Conclusion and recommendations

Conclusion:

- 98.4% of cases were symptomatic at presentation with 97.7% having LUTS and 33. 9% metastatic symptoms.
- The ISUP grade group 4 and 5 account for 97% of cases while PIRADS 4 and 5 account for 67.5% of cases and mean PSA at time of diagnosis was 285ng/ml.
- 24.4 % have locally advanced and 34.2% have metastatic prostate cancer with higher Gleason's score and high PSA at time of diagnosis.
- ADT used in treatment of 85.4 % of cases with orchiectomy being the commonest means of ADT used in 50.1% of cases.
- Nearly half of study population 50.4% (n=62) shifted to different form of treatment from initial one within 3-24 month.
- On multimodal regression analysis, Gleason's score has significant association with PIRADS score and digital rectal examination finding, While TNM staging has significant association with residential area, educational status, presence of symptoms at presentation, PIRADS score and digital rectal examination in the study.

Recommendations

- It is recommended to improve access to shared decision-making prostate cancer screening, as there are very few patients diagnosed with prostatic cancer due to elevated PSA.
- It is better to have public health professionals' engagement to increase community awareness on prostate cancer symptoms to increase patients diagnosed early diagnosis and to improve linkage to care.
- It better have national or institutional guidelines pertaining to patient diagnosis and management prostate cancer
- It recommended to improve documentation as some of the data are incomplete
- Prospective study with larger sample size is recommended

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Annexes

Annex I: Consent for Participation on study about clinical pattern of prostate cancer patients seen at outpatient department of the Urology unit at Tikur Anbessa Specialized Hospital (TASH), Addis Ababa, Ethiopia from January 2023 to December 31st 2025 GC

Consent form

We are collecting some information on clinical presentation of prostate cancer patients seen at outpatient department of the Urology unit of TASH. We want to know kindly if you are willing to participate in the study. The information we gather remain confidential and the study has approval from research ethics committee of AAU college of health science school of medicine. if you are willing proceed to questions and if not, we can stop before proceeding farther,

Data collector name: _____sign _____Date_____

Supervisor name: _____sign _____Date_____

Annex 2: Questionnaire for the research on study about clinical pattern of prostate cancer patients seen at outpatient department of the Urology of TASH

Part I: Socio-demographic data

Code_____

Date _____

Items no	Items	Answer
101	Age	1.<50 2.50-60 3.60-70

		4.70-80 5.>80
102	Marital status	1. Single 2. Married 3. Widowed 4. Divorced
103	Educational status	1. Illiterate (can't read and write) 2. Illiterate (can read and write) 3. Primary school 4. Secondary school 5. Tertiary education
104	Occupation	1. Unemployed 2. Daily labour 3. Merchant 4. Government Employee 5. Others(specify)
105	Religion	1.Orthodox 2. Muslim 3. Protestant 4. Others(specify)
106	Residential area	1.Urban 2.Rural
107	Monthly income (in Birr):	1.1100 2.1100-2500 3.2500-5000 4.5000-10000 5.>10000

PART II: PROSTATE CANCER RISK FACTORS

Code_____

Date _____

Items no	Items	Response
201	Do you have any relative/s who ever had prostate cancer?	1.yes 2. No 3.Uncertaine
202	IF yes to question 201, who is he?	1.Father 2.Brother 3.One affected first-degree relative diagnosed at age < 65 years 4.One Affected first-degree relatives diagnosed at age >65 years 5.Two or more affected first-degree relatives diagnosed at any age 6. second degree-relative diagnosed at any
203	Do you do regular physical exercise?	1.yes 2. No 3.occationally
204	Do you drink any form alcohol?	1. Daily/regularly 2. Occasionally 3.Never
205	Do you smoke Cigarettes?	1. Daily/regularly 2.Occasionally

		3.Never
206	Are you diagnosed with other type of cancer?	1. yes 2. No
207	If yes to 206, specify	

PART III: PROSTATE CANCER PATIENT SYPTOMS AND PHYSICAL EXAMINATION FINDING

Code_____

Date _____

301	DO YOU HAVE ANY OF THE SYPTOMS?	1.Yes 2.NO
302	If your response to 301, is yes which symptom do you have?	1.urinary symptoms Voiding /obstructive LUTS 1.Hesitancy 2.Dribbling 3.Poor stream 4.Intermittency 5.Terminal dribble Storage /Irritative LUTS

		1.Urgency 2.Urge incontinence 3.Nocturia 4.Frequency Post void symptoms 1.Post void dribbling 2.Incomplete voiding Haematuria AUR 2.Flank pain 3.sexual symptoms Hematospermia Decreased ejaculate volume Erectile dysfunction 3.Metastatic symptoms Bone pain(pathologic fracture) Anemia Lower limbs weakness Lower limb oedema Urinary or faecal incontinence 4.Others (Specify)
303	If your response to 301, is no how diagnosis did made?	1.Screening PSA Elevation 2.Work up for enlarged prostate on imaging 3.Biopsy report after prostatectomy done for benign prostatic hyperplasia

		4.Digital rectal examination done for other reason 5. Others (Specify)
304	What is Digital rectal examination report?	1 Suggestive of prostatic cancer 2.Suggestive of benign prostatic hyperplasia 3.None of the above 4.Incomplete documentation
305	If documented what clinical T stage?	1.T2A _____ 2. T2B____ 3.T2C_____ 4.T3A_____ 5. T3B_____ 6.T4_____ 7. Not documented_____
306	Does the patient have any comorbidity?	1.no ____ 2.yes ____
307	If yes to above question (306), specify	1. HTN 2.DM 3.CKD 4. OTHER MALIGNACY 5.MI 6.OTHER CARDIAC DISEASE 7. COPD 8. CIRROCIS 9.OTHER (SPECIFY)_____

PART IV: PROSTATE CANCER LABORATORY AND IMAGING FINDING

Code_____

Date _____

401	Did patient have low haemoglobin /haematocrit at time of diagnosis?	1.Yes 2.No
402	Did patient have elevated PSA at time of diagnosis?	1.Yes (in number_____)

		2.No
4O3	If your response to 402, is yes what is PSA value at time of diagnosis?	1) PSA<10ng/ml 2) PSA 10-20ng/ml 3) PSA >20 ng/ml
404	Follow up PSA after DX/ RX	1.Base line (at time of DX) _____ 2. At 3-month _____ 3. At 6-month _____ 4. At 9-month ____5. At 12-month _____ 6. At 15-month ____7. At 18month _____ 8.At 24-month _____
405	What is initial Gleason score report on biopsy?	1) ISUP Grade group 1 2) ISUP Grade group 2 3) ISUP Grade group 3 4) ISUP Grade group 4 5) ISUP Grade group 5
406	What was creatinine value at time of diagnosis?	1.≤ 1.2mg /dl 2.>1.2mg/dl
407	Which imaging modality is used as part of work up?	1.US of prostate 2.CT of prostate 3.MRI of prostate 4.other (specify)
408	What was prostate volume reported on imaging?	
409	If reported on what imaging what is the PIRADS of the patient?	1.PIRADS 1 2. PIRADS 2 3. PIRADS 3 4. PIRADS 4

		5. PIRADS 5
410	Did imaging report suggest prostatic cancer?	1.Yes 2.No
411	If TNM staging was done, what is the stage of cancer?	1.T stage 2.N stage 3.M stage 4.Not done/Incomplete report
412	If MRI is done,was it before or after biopsy	1.Before Biopsy 2.After biopsy

PART V: PROSTATE CANCER TREATMENT GIVEN

Code_____

Date _____

500	What initial treatment offered to patient?	1.Watchful waiting 2.Active surveillance 3.Radical prostatectomy 4. RADIATION THERAPY 5. Androgen Deprivation Therapy 6. Cytotoxic Chemotherapy

501	If Androgen Deprivation Therapy is used as initial treatment option which of the following is used?	1.Orchiectomy 2. LHRH AGONIST (Gsoline/Zoladex) 3. ANTIANDROGEN(Bicalutamide/casodex) 4. LHRH antagonist 4. Adrenal Blocking agents 5. Oestrogen therapy (DES) 6.other(specify)
502	If patient management shifted to alternative management option for how long initial management continued?	1.3 months 2. 6 months 3. 9 months 4.12 months 5. 15 month 6.18 month 7.24 month 8.> 24 month
503	If patient management shifted to alternative management option what the reason to shift from initial management?	1. clinical progression(development of local SX in asymptomatic patient or development of metastatic Disease from non-metastatic Disease) 2. Biochemical Recurrence 3. Incomplete data for conclusion
504	What was second line treatment used after shifting to alternative Mx?	1.Watchful waiting 2.Active surveillance 3.Radical prostatectomy 4. RADIATION THERAPY

		5. Androgen Deprivation Therapy 6. Cytotoxic Chemotherapy