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Original Article

Clinicoradiological Profile and Treatment Outcomes in Prostate Cancer at a Tertiary Care Cancer Center in India

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Abstract

Introduction: Prostate cancer is the most common solid cancer in men and is responsible for 11% of all cancer-related deaths. There are limited data available regarding clinicoradiological (prostate-specific membrane antigen [PSMA]-positron emission tomography [PET]/computed tomography [CT], magnetic resonance imaging, and bone scan) characteristics, treatment outcomes, and correlation of clinicoradiological characteristics with treatment outcomes of prostate cancer patients from India, especially in the era of PSMA-PET/CT scan. **Methodology:** This was a single center, retrospective, observational study, conducted for 6 months. We retrospectively collected the data of 332 prostate cancer patients treated between January 2015 and December 2017 at our institute. **Results:** Three hundred and thirty-two patients were enrolled and were divided into three groups depending on the stage and treatment modality, i.e., Group A, B, and C containing 205, 47, and 80 patients, respectively. The median age was 67 years, and the median prostate-specific antigen (PSA) was 19.3 ng/ml. Lower urinary tract symptoms (83.4%) and bone pain (8.1%) were the common presenting symptoms. PSMA-PET/CT scan revealed regional lymph node metastasis in 56.5% patients, bone metastasis in 35.7%, and visceral metastasis in 11.5% patients, respectively. In patients treated with curative intent, radical prostatectomy was performed in 61.74% of patients, whereas radiation therapy was performed in 47 (14.15%) patients. Among those treated with palliative intent, androgen deprivation therapy (ADT) alone (40) was the most preferred therapy followed by the combination of ADT with docetaxel (28) or abiraterone (12). Significantly (P = 0.006), a greater number of patients who were treated with ADT alone progressed to castration-resistant prostate cancer (CRPC) compared to those on combination ADT with either abiraterone or docetaxel. No significant difference was seen in the disease progression when treatment arm containing ADT with docetaxel was compared to ADT with abiraterone. **Conclusion:** Patients with metastatic disease had a higher median PSA level and also had a higher likelihood of having Gleason score 8–10. Among patients who were treated with palliative intent for metastatic disease, disease progression to CRPC state was significantly higher in those treated with ADT alone compared to those treated with either ADT + docetaxel or ADT + abiraterone.

Keywords: *Abiraterone, docetaxel, prostate cancer, prostate-specific membrane antigen-positron emission tomography/computed tomography*

Introduction

Prostate cancer is the most common solid cancer in men and is responsible for 11% of all cancer-related deaths.[1,2] However, remarkable racial and ethnic differences in the incidence have been reported, ranging from 4.4/100,000 to 118.2/100,000 persons in India and the USA, respectively.[3] The selection of therapy in prostate cancer is mainly influenced by the presence or absence of metastasis.[4] Patients with localized or locally advanced prostate cancer are treated with curative intent. Patients with metastatic prostate cancer are treated with palliative intent. The treatment for localized prostate cancer is either surgery (radical prostatectomy) or radiation therapy (RT). The treatment for locally advanced prostate cancer is generally RT along with androgen deprivation therapy (ADT). Treatment for metastatic prostate cancer is ADT with or without docetaxel chemotherapy or abiraterone oral therapy and RT to symptomatic sites. The suppression of androgen receptor signaling through ADT has remained the mainstay of treatment for metastatic prostate cancer for more than 70 years.[5]

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Although ADT offers near-certain remissions lasting 1–2 years in most patients, cancer cells become resistant to the emergence of metastatic castration-resistant prostate cancer (mCRPC).[5] About 10%–20% of men with prostate cancer present with metastatic disease, and in many others, metastases develop despite treatment with surgery or radiotherapy.[6] Docetaxel chemotherapy demonstrated an improvement in overall survival (OS) and has become the mainstay of treatment in mCRPC. In recent years, several other compounds have shown survival benefits in mCRPC, such as abiraterone, enzalutamide, cabazitaxel, radium-223, and sipuleucel-T, either before or after docetaxel.[7]

Despite the availability of several medications and newer imagining techniques, there are limited data available regarding clinicoradiological (prostate-specific membrane antigen [PSMA]-positron emission tomography [PET]/computed tomography [CT], magnetic resonance imaging [MRI], and bone scan) characteristics, treatment outcomes, and correlation of clinicoradiological characteristics with treatment outcomes of prostate cancer patients from India, especially in the era of PSMA-PET/CT scan. Therefore, the present study was planned to determine the clinicoradiological profile and treatment outcomes of prostate cancer patients at a tertiary care cancer center in India.

Methodology

The present study was a single center, retrospective, observational study, conducted for a period of 6 months at a tertiary care cancer hospital. Patients with histopathologically confirmed prostate cancer, ≥40 years of age, who underwent PSMA PET and/or MRI scan and/or bone scan and who received treatment between January 2015 and December 2017, were included in the study. All patients were evaluated for radiological characteristics of prostate cancer such as tumor size, lymph node (LN) metastasis, bone metastasis, and visceral metastasis. Patients were also evaluated for clinical characteristics, including histopathology, performance status, comorbidities, Gleason's score, and baseline prostate-specific antigen (PSA). Stage-specific short-term treatment outcomes, including the incidence of biochemical and radiological recurrence for localized disease and time to CRPC, time to clinical progression, and time to serological progression for metastatic disease, were determined.

The sample size was calculated based on the primary objective of the study, i.e., radiological characteristics of prostate cancer patients, which was reported 79% in previous study.[2] With a margin of error of 5% on either side and confidence interval 95%. The sample size came to a minimum of 255 patients. The *P* values were calculated using Fisher's exact test.

The protocol was reviewed and approved by the scientific committee and thereafter by the Ethics Committee of the Institution. This research was carried out in accordance with the Basic Principles defined in ICMR "ethical guidelines for biomedical research on human participation." Waiver of consent was sought and granted. Confidentiality of the data was maintained throughout the study period.

For analysis, all patients were divided into three groups:

- Group A – Patients with localized prostate cancer treated with radical prostatectomy
- Group B – Patients with localized or locally advanced prostate cancer treated with RT with or without ADT
- Group C – Patients with metastatic prostate cancer treated with palliative intent.

Results

In the present study, 332 patients were enrolled and were divided into three groups, i.e., Group A, B, and C containing 205, 47, and 80 patients, respectively. The median age of study participants was 67 (41–90) years, and the median PSA was 19.3 (0.57–4000) ng/ml. The median PSA level of those in Group A was 13.7 (0.57–310) ng/ml, in Group B was 24 (2.9–734.4) ng/ml, and in Group C (metastatic) was 88 (3.8–4000) ng/ml. Hypertension (53.9%) and diabetes (27.4%) were the most common comorbid conditions [Table 1]. Lower urinary tract symptoms (83.4%) and bone pain (8.1%) were the common presenting symptoms in patients with symptomatic prostate cancer. Majority of patients (92.1%) had performance status <2 and Gleason score ≤7 (52.4%) [Table 1].

MRI was done in 277 patients, and radiological characteristics on MRI showed that 52.34% patients had T2 disease and 35% had T3 disease, whereas LN metastasis was seen in 20.2% of patients. Bone scan was done in 175 patients and revealed bone metastasis in 13.7% of patients. PSMA-PET/CT scan was done in 182 patients and revealed regional LN metastasis in 56.5% patients, bone metastasis in 35.7%, and visceral metastasis in 11.5% patients, respectively [Table 2]. Treatment with curative intent was provided to 252 (75.90%) patients while with palliative intent to 80 (24.09%) patients. In patients with curative intent, radical prostatectomy was performed in 205 patients, whereas RT was done in 47 patients. Among those treated with palliative intent, ADT alone (40) was the most preferred therapy followed by the combination of ADT with docetaxel (28) or abiraterone (12).

Among those who underwent radical prostatectomy, biochemical recurrence was seen in 31.7% patients, whereas radiological recurrence was seen in 2.4% patients. These patients subsequently received early salvage RT. Biochemical and radiological recurrence was seen in 17% of patients who underwent RT. Among patients treated with palliative intent, progression to CRPC was seen in 43.7%

Table 1: Clinicopathological characteristics

Clinicopathological characteristics	Group A RP (*n*=205)	Group B RT (*n*=47)	Group C Metastatic (*n*=80)	Total number of patients (*n*=332)
Median age (years) (range)	66 (43-78)	72 (54-90)	69 (61-88)	67 (41-90)
Median PSA (ng/ml) (range)	13.7 (0.57-310.1)	24 (2.9-734.4)	88 (3.8-4000)	19.6 (0.57-4000)
Comorbidities, *n* (%)				
Diabetes mellitus	59 (20.7)	18 (38.2)	14 (17.5)	91 (27.4)
Hypertension	124 (60.4)	24 (51)	31 (38.7)	179 (53.9)
Coronary artery disease	22 (10.7)	9 (19.1)	10 (12.5)	41 (12.30
Symptoms, *n* (%)	160 (78)	40 (85.1)	77 (96.2)	277 (83.4)
LUTS	133 (64.8)	36 (76.5)	30 (37.5)	199 (59.9)
Bone pain	2 (0.9)	5 (10.6)	20 (25)	27 (8.1)
Asymptomatic diagnosed on PSA screening	26 (12.6)	13 (27.6)	2 (2.5)	41 (12.3)
Performance status, *n* (%)				
0-1	205 (100)	42 (89.3)	59 (73.7)	306 (92.1)
≥2	0	5 (10.6)	21 (26.2)	26 (7.8)
Gleason score, *n* (%)				
≤7	140 (68.2)	19 (40)	15 (18.7)	174 (52.4)
8-10	63 (30.7)	24 (51)	49 (61.2)	136 (40.9)
Not known	2 (0.9)	4 (8.5)	16 (20)	22 (6.6)

RT – Radiation therapy; RP – Radical prostatectomy; PSA – Prostate-specific antigen; LUTS – Lower urinary tract symptoms

Table 2: Radiological characteristics

Radiological characteristics	Group A RP (*n*=205)	Group B RT (*n*=47)	Group C metastatic (*n*=80)	Total number of patients (*n*=332)
MRI done, *n* (%)	*n*=199	*n*=41	*n*=37	*n*=277
T2	131 (65.8)	13 (31.7)	1 (2.7)	145 (52.34)
T3	59 (29.6)	22 (53.6)	16 (43.2)	97 (35)
T4	10 (5)	6 (14.6)	9 (24.3)	25 (9)
LN metastasis N1	20 (10)	10 (24.3)	26 (70.2)	56 (20.2)
Bone scan done, *n* (%)	*n*=118	*n*=34	*n*=23	*n*=175
Bone metastasis present	7 (5)	3 (8.8)	14 (60.8)	24 (13.7)
PSMA PET/CT done, *n* (%)	*n*=90	*n*=20	*n*=72	*n*=182
Regional LN metastatic	33 (36.6)	10 (50)	60 (83.3)	103 (56.5)
Nonregional LN metastasis - M1a	11 (12.2)	1 (5)	38 (52.7)	50 (27.4)
Bone metastasis - M1b	4 (4.4)	4 (20)	57 (79.16)	65 (35.7)
Visceral metastasis - M1c	1 (1.1)	0 (0)	20 (27.7)	21 (11.5)

MRI – Magnetic resonance image; PSMA PET/CT – Prostate-specific membrane-specific antigen positron emission tomography/computed tomography; LN – Lymph node, T – Tumor size; RT – Radiation therapy, RP – Radical prostatectomy

patients, while clinical and serological progression was seen in 40% and 43.7% patients, respectively [Table 3].

The risk factor analysis showed that among patients who underwent radical prostatectomy, those with a Gleason score of 8–10 and those with pathological T3 and T4 disease had significantly increased risk of biochemical recurrence (P = 0.001). Among patients who underwent RT, those with performance status ≥2 had significantly increased risk of biochemical recurrence compared to those who had a performance status 0–1 (P = 0.0018). Among patients treated with palliative intent, serological complete response (PSA <0.2 ng/ml) was achieved in greater number of patients treated with ADT + abiraterone (42%) or ADT + docetaxel (32%) as compared to ADT alone (13%) [Table 4]. Significantly (P = 0.006), a greater number of patients who were treated with ADT alone progressed to CRPC than those on combination ADT with abiraterone or docetaxel. However, no significant difference was seen in the disease progression when treatment arm containing ADT with docetaxel was compared to ADT with abiraterone.

Discussion

The present study was conducted to determine and correlate the clinicoradiological characteristics and treatment outcomes of prostate cancer patients in India. We enrolled 332 patients retrospectively and divided all patients into three groups depending on the stage and treatment they received. Median PSA was significantly higher in patients with metastatic disease treated with

palliative intent (Median PSA = 88 ng/ml) compared to patients with localized disease treated with radical prostatectomy (Median PSA = 13.7 ng/ml) and RT (median PSA = 24 ng/ml). High Gleason Score of 8–10 was present in a greater number of patients with metastatic disease (61%) as compared to those with localized disease who underwent radical prostatectomy (31%). These clinicopathological characteristics have been compared to a study that was done at HCG Bengaluru, India.[8] In this study, the mean age was 67.6 ± 8.8, Gleason score < 4, 4–6, 7–8, and 9–10 score was present in 3 (1%), 62 (24.1%), 125 (47.7%), and 70 (27.7%), respectively. The localized disease was present in 164 (63.1), locoregional in 28 (10.7%), and distant spread in 68 (26.2%) patients. Similarly, in a study conducted by Akin *et al*.,[9] the median age was 60 (41–75) and median PSA was 5.9 (2.1–28.0 ng/ml).

MRI revealed that a majority of patients (52.34%) were in Stage T2, and LNs were involved in 20.2% patients. Sensitivity and specificity of MRI to detect tumor size and LNs metastasis was also highlighted in a study conducted by Akin *et al*.,[9] which reported sensitivity and specificity as 75% and 87%, respectively, and concluded that MRI can be used to detect, localize, and stage transition zone prostate cancers. The presence of tumor size T1, T2, T3, and T4 was reported in 1 (1%), 127 (86%), 18 (12%), and 2 (1%), respectively, in this study. Patients with intermediate/high risk localized disease and regional LN positive disease on MRI, and those with suspected metastatic disease clinically, underwent ^{68}Ga-PSMA PET/CT scan. PSMA-PET/CT scan revealed that regional LN metastasis was seen in 56.5% patients, and bone and visceral metastasis was seen in 35.7% and 11.5% patients, respectively.

A radical prostatectomy is a treatment option in patients with low-, intermediate-, or high-risk localized prostate cancer and for men with locally advanced disease without tumor fixation to adjacent structures and without clinical evidence of LN involvement. The results from our study can be compared to the study done at the Mayo Clinic[10] between 1987 and 2003 which included 7591 prostate cancer patients who underwent radical prostatectomy. This study included 2795 intermediate-risk prostate cancer patients. The median follow-up was 7.7 years. At 5 years, 78% were free from biochemical relapse, and at 10 years, 65% remained biochemically progression-free. This study also included 1513 patients with high risk or very high-risk prostate cancer. The median follow-up was 7.7 years. The biochemical relapse-free survival rates at 5 and 10 years were 68% and 55%, respectively. For high-risk patients, the 10-year local recurrence-free survival rate was 90%, and the 10-year systemic progression-free survival rate was 89%.

RT is a treatment option for low-, intermediate- and high-risk prostate cancer. For most intermediate-risk and all high-risk patients, ADT is given in combination with RT. The results of our study can be compared with a single-institution series of 2047 men treated with RT between 1998 and 2004.[11] RT was administered with doses ranging from 66 to 86 Gy in the Scandinavian Prostate Cancer Group 7 trial, 875 men with locally advanced or high-risk prostate cancer were randomly assigned to 3 months of combined androgen blockade

Table 3: Treatment outcomes

	n (%)
Group A: Patients who underwent radical prostatectomy (*n*=205)	
Incidence of biochemical recurrence	65 (31.7)
Incidence of radiological recurrence	5 (2.4)
Group B: Patients who underwent RT (*n*=47)	
Incidence of biochemical recurrence	8 (17)
Incidence of radiological recurrence	8 (17)
Group C: Patient treated with palliative intent (*n*=80)	
Clinical progression	32 (40)
Serological progression	35 (43.7)
Progressed to CRPC	35 (43.7)

CRPC – Castration-resistant prostate cancer, RT – Radiation therapy

Table 4: Comparison of clinicoradiological characteristics and treatment outcome in metastatic prostate cancer patients according to treatment modalities (*n*=80)

Characteristics	ADT alone (*n*=40)	ADT + docetaxel (*n*=28)	ADT + abiraterone (*n*=12)
Median age (years)	71 (54-88)	63 (41-75)	66 (56-81)
Median PSA (ng/ml)	69 (5.85-2562)	135.6 (3.8-4000)	38.5 (10.91-1590)
Gleason score, *n* (%)			
≤7	5 (12.5)	7 (25)	2 (16.6)
8-10	21 (52.5)	19 (67.8)	10 (83.3)
Not known	14 (35)	2 (7.1)	0
Bone metastasis, *n* (%)	27 (67.5)	21 (75)	9 (75)
Nonregional lymph nodes metastasis, *n* (%)	17 (42.5)	16 (57)	6 (50)
Visceral metastasis, *n* (%)	12 (30)	7 (25)	1 (8.3)
Progressed to CRPC, *n* (%)	25 (62.5)	10 (35.7)	1 (8)
Achieved serological complete response, *n* (%)	5 (12.5)	9 (32)	5 (41.6)

ADT – Androgen deprivation therapy; PSA – Prostate-specific antigen; CRPC – Castration-resistant prostate cancer

followed by RT (minimum cumulative dose 70 Gy) with lifelong ADT, or to 3 months of combined androgen blockade followed by lifelong ADT alone without RT.[12] With a median observation time of 12 years, the 15-year prostate cancer-specific mortality significantly decreased in those treated with ADT plus RT compared with ADT alone (17% vs. 34%). The median OS also significantly increased with the combination of ADT plus RT (14.9 vs. 12.5 years). Within the limitations of short follow-up, the findings in our study can be compared to the findings from this landmark study. In our study, 32% patients in radical prostatectomy group and 17% patients in RT group developed biochemical recurrence. Another notable point is that a majority of the patients in this study were treated by moderate hypofractionation regimen which has shown equivalent effectiveness.

In our study, 80 patients were treated with palliative intent. ADT alone was the most preferred therapy followed by the combination of ADT with docetaxel or abiraterone. Progression to CRPC was seen in 35 (43.7%) patients in this group, whereas clinical and serological progression was seen in 40% and 43.7% patients. The median time to CRPC in patients who have progressed (n = 35) was 10 months. Disease progression to castration-resistant state was significantly higher in patients treated with ADT alone (63%) compared to those treated with ADT + Docetaxel (35%) or ADT + Abiraterone (8%). Furthermore, a higher number of patients achieved serological complete response (PSA < 0.2 ng/ml) in ADT + docetaxel group (32%) and ADT + abiraterone group (42%) compared to ADT alone group (13%). These findings suggest that a combination treatment of ADT + Docetaxel or ADT + abiraterone is superior to ADT alone in patients with metastatic prostate cancer. Similar findings have also been reported in recently published large randomized trials, including CHAARTED, LATITUDE, and STAMPEDE studies.[13-15] In CHAARTED trial,[13] median time to biochemical, symptomatic, or radiographic progression was 20.2 months in the ADT + docetaxel group as compared with 11.7 months in the ADT-alone group. The rate of a complete serological response was 27.7% in the combination group versus 16.8% in the ADT-alone group. These treatment outcomes are comparable to our study patients who were treated with ADT alone or ADT + Docetaxel. In LATITUDE trial,[14] the median radiographical progression-free survival was 33.0 months in the ADT + abiraterone group and 14.8 months in the ADT alone group. In abiraterone + ADT group, the median time to PSA progression was 33.2 months. These treatment outcomes are comparable to our study patients who were treated with ADT alone or ADT + Abiraterone.

Risk factor analysis among our study patients showed that among patients who underwent radical prostatectomy, those with a Gleason score of 8–10 had significantly increased the risk of biochemical recurrence compared to those who have Gleason score ≤7. Furthermore, patients with tumor size of T3 and T4 had significantly increased risk of biochemical recurrence than those who had tumor size T2. Advanced age, higher baseline PSA, performance status, and regional nodal metastasis did not increase the risk of biochemical recurrence among patients who underwent radical prostatectomy. Among patients who underwent RT, those with a performance status ≥2 had significantly increased risk of biochemical recurrence compared to those who had a performance status 0–1. Advanced age, higher baseline PSA, higher Gleason score, greater tumor size, and regional nodal metastasis did not increase the risk of biochemical recurrence in this patient subgroup. Comparable findings were seen in the Prostate Cancer Intervention Versus Observation Trial where 731 men with localized prostate cancer were randomly assigned to radical prostatectomy or to observation.[16] With a median follow-up of 10 years, prostate cancer mortality was lower in those assigned to radical prostatectomy compared with observation in men with a serum PSA ≥10 ng/mL (5.6% vs. 12.8%, P = 0.02) and among men with high-risk prostate cancer (9.1% vs. 17.5%, P = 0.04).

Among patients treated with palliative intent, serological complete response was seen better with those treated with ADT + abiraterone (41.6%) than those treated with ADT + Docetaxel and ADT alone. Significantly (P = 0.0060), increased number of patients progressed to CRPC, who were treated with ADT alone than those on combination of ADT with Abiraterone/ Docetaxel. No significant difference was seen in the disease progression when treatment arm containing ADT with docetaxel was compared to ADT with abiraterone. Similar results were seen in Latitude and Stampede trial[14,15] where the combination of ADT with abiraterone and docetaxel was better as compare to ADT alone. No head-to-head comparison studies are available to compare the effect of abiraterone and docetaxel along with ADT.

Strengths of the study include the fact that it is one of the largest studies on prostate cancer from India reported so far. Another strength is that our study describes clinical characteristics, radiological characteristics, including PSMA-PET/CT scan as well as treatment outcomes in a single study. This adds to the comprehensive nature of the study. Furthermore, the fact that this study includes all consecutive prostate cancer patients (all stages and risk category) treated at our center reflects the actual/real-life picture of prostate cancer and its outcomes in Indian patients. This adds to the strength of our study.

Limitations of the study include the retrospective nature of the study. As with any retrospective study in oncology, baseline radiological investigations are not uniform in all patients. Another limitation is that follow-up of patients in this study is short. Hence, we could only describe few outcome measures of prostate cancer management,

including biochemical/radiological recurrence (in localized disease) and progression to CRPC (in metastatic disease). In view of short follow-up, we could not describe OS outcomes of our patients as this need longer follow-up. We intend to continue this study for a longer period to describe survival outcome of our patients.

Conclusion

This is one of the largest studies on prostate cancer from India which reports clinicoradiological and pathological profile of prostate cancer patients. We conclude that the most common site of metastasis was bone followed by nonregional LNs followed by visceral metastasis. Patients with metastatic disease had a higher median PSA level and also had a higher likelihood of having Gleason score 8–10. Among patients who underwent radical prostatectomy, higher Gleason score and greater T size were associated with a higher risk of biochemical recurrence.

We also conclude that among patients who were treated with palliative intent for metastatic disease, disease progression to CRPC state was significantly higher in those treated with ADT alone compared to those treated with either ADT + docetaxel or ADT + abiraterone. Among these patients, a higher number of patients achieved complete serological response (which is a surrogate for OS) in ADT + docetaxel group and ADT + abiraterone group as compared to ADT alone group.

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Conflicts of interest

There are no conflicts of interest.

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