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Original Article

Surgery Section

Clinicopathological Profile of Prostate Cancer Patients: A 10 years Retrospective Study from a Tertiary Care Centre, North East India

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ABSTRACT

Introduction: Prostate cancer is the second most common cancer and ranked fifth among the top causes of death among men. There is limited data on the clinical profile of prostate cancer in India, especially from North East India.

Aim: To determine the clinicopathological profile of prostate cancer patients treated at a tertiary care centre in North East India.

Materials and Methods: This retrospective study was conducted in the Department of Urology, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, India from January 2006 to January 2016. It included 66 consecutive prostate cancer patients treated over 10 years. Relevant information regarding age at presentation, presenting symptoms, investigation, stage of the disease, histological report, treatment, follow-up and death were collected from hospital records and analysed using Microsoft Excel software 2019. Continuous variables were presented as mean and standard deviation or range while categorical variables were expressed as frequencies and percentages.

Results: The mean age of the patients was 70.7 years, the majority (81.8%) were in the age group of ≥61 years. All patients except one were symptomatic at presentation. The mean Prostate Specific Antigen (PSA) was high (264 ng/mL). Histologically, 65 tumours (98.5%) were adenocarcinoma and Gleason score between 8-10 was the most common. A total of 51 patients (77.3%) had stage IV prostate cancer. Total bilateral orchidectomy was the most common treatment, performed in 84.3% of stage IV patients. Nine patients died during the study.

Conclusion: Prostate cancer was uncommon in the present study population but a majority of the patients presented with metastatic disease. Adenocarcinoma was the predominant histological type and total bilateral orchidectomy was the most common treatment, performed in the majority of the patients with stage IV disease.

Keywords: Adenocarcinoma, Gleason score, Orchidectomy, Survival

INTRODUCTION

Prostate cancer is a disease of old age and a major cause of morbidity and mortality among men worldwide. The risk factors for prostate cancer are advanced age, ethnicity, genetic factors, and family history [1]. It is the second most common cancer and ranked fifth among the top causes of death among men. In 2020, there were an estimated 1.4 million new cases of prostate cancer causing 375,000 deaths globally. The incidence rates of prostate cancer differ from place to place from a low of 6.3 to a high of 83.4 per 100,000 men. The highest rates are detected in Northern and Western Europe, and the lowest rates are seen in Asia and Northern Africa [2]. The highest incidence of prostate cancer in the world is seen in Guadeloupe (France) and the highest mortality rate is in Barbados [3]. Prostate cancer constitutes 10.6% of newly diagnosed cancer in the United States with 192,000 cases being estimated in 2020 [4]. The incidence rate of prostate cancer is estimated to be 9 per 100,000 men in the whole of India, 12.4 in Delhi, and 5.86 in Pune Metropolitan Region [5,6,7]. The incidence rates of prostate cancer in the states of North East India are low and the incidence rates per 100,000 men are 3 in Mizoram, 1.6 in Meghalaya, 1.5 in Manipur and 1 in Tripura [6]. There is limited published literature regarding the clinical profile of prostate cancer in India and in particular, from North East India [8]. The aim of this retrospective study was to find out the clinicopathological profile of prostate cancer, type and outcome of treatment of prostate cancer in a newly set-up tertiary care centre in North East India.

MATERIALS AND METHODS

This retrospective hospital-based study was conducted in the Department of Urology, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong, India, from January 2006 to January 2016. The analysis of the data was done between July 2018 and December 2018. During the study period of 10 years, 71 patients with prostate cancer attended the department. Ethical approval was obtained from the Institute's Scientific and Ethics Committee in June 2018 (approval no. NEIGR/IEC/M5/F9/18).

Inclusion criteria: Patients with pathologically confirmed prostate cancer, who underwent initial treatment and follow-up in the Department of Urology, NEIGRIHMS, Shillong, India during the study period were included in the study.

Exclusion criteria: Patients who had initial diagnosis and treatment in other hospitals and who came to NEIGRIHMS, Shillong only for follow-up were excluded from the study.

Out of 71 patients who were enrolled, 66 patients fulfilled the inclusion criteria and were included in the analysis. Five patients were excluded from the analysis based on the exclusion criteria. The majority of the patients were diagnosed at the study institute. Few patients who were diagnosed elsewhere and referred to this department for further management were also included in the study. The biopsy slides of these patients were re-examined by the pathologists and these reports were considered final. If the biopsy slide was inadequate for the definitive report, these patients underwent repeat prostate biopsy.

Diagnosis of prostate cancer was suspected on clinical grounds like Lower Urinary Tract Symptoms (LUTS), Acute Urinary Retention (AUR), haematuria, nocturia associated with hard and fixed prostate with or without raised Prostate Specific Antigen (PSA) (≥4 ng/mL), and prostate ultrasound findings [9]. Transrectal ultrasound-guided six-core biopsy along with biopsy of the obvious nodule was performed as these patients had hard and fixed prostates or locally advanced cancers. Extended biopsy was performed only in three

cases. Five patients were diagnosed to have prostate cancer after Transurethral Resection of the Prostate (TURP).

Based on microscopic appearance, prostate cancers were divided into Gleason grades from 1 to 5, grade 1 being the most well-differentiated tumour and grade 5, being the least differentiated tumour. One Gleason grade for the most predominant pattern in the biopsy and a second Gleason grade for the second most predominant pattern are added together to determine the Gleason score [10]. The prostate cancers were divided into well-differentiated (Gleason score of ≤6), moderately differentiated (score of 7), and poorly differentiated (score of 8-10) tumours [11].

All 66 patients underwent complete blood count, kidney and liver function tests, urinalysis and culture, and chest X-ray. The majority of patients underwent ultrasound of the abdomen and a few patients also underwent Kidney, Bladder, and Ureter (KUB) X-ray. Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and bone scan were performed in 6, 15 and 22 patients respectively, depending on the clinical indication for diagnostic and staging purposes.

Based on histopathological and imaging findings, clinical staging of prostate cancer was done as follows [12-14]:

- Stage 1: Incidentally detected prostate cancer after TUPR or prostate cancer found on needle biopsy due to raised PSA;
- Stage 2: Localised prostate cancer;
- Stage 3: Locally advanced prostate cancer;
- Stage 4: Metastatic prostate cancer.

The patients with metastatic disease (stage 4) underwent Androgen Deprivation Therapy (ADT) with either total bilateral orchidectomy or Luteinizing Hormone-Releasing Hormone (LHRH) agonists. Channel TURP was done for patients with bladder outlet obstruction. Patients with locally advanced disease (stage 3) were offered radiotherapy and ADT. Patients with local disease (stages 1 and 2) were offered the option of active surveillance, open radical prostatectomy, or referred for robotic prostatectomy (since robotic surgery facility was not available at the institute). After discharge, the patients were followed-up every six months. At each follow-up, results of uroflowmetry, complete blood count, serum PSA, kidney and liver function tests, and appropriate radiologic imaging were noted. Any deaths reported by the relatives and the patients who died in NEIGRIHMS, Shillong were also recorded. Relevant information regarding age at presentation, clinical presentation, investigation, and stage of the disease, histological report, treatment given, duration of follow-up, and deaths were recorded.

STATISTICAL ANALYSIS

Continuous variables were presented as mean and standard deviation or range while categorical variables were expressed as frequencies and percentages. Data analysis was done using Microsoft Excel software version 2019.

RESULTS

The age range of the study sample was from 47 to 93 years with a mean age of 70.7 years [Table/Fig-1]. The modal age group of the presentation was 71 to 80 years, accounting for 34.9 % of cases [Table/Fig-2]. A total of 35 patients (53%) had symptoms lasting for more than one year. Not a single patient had a history of vasectomy. The most common symptoms were LUTS in 27 (40.91%), AUR in 22 (33.33%), and haematuria in 14 (21.21%) patients. Five patients also complained of bone pain, weakness in lower limbs, and paraesthesia. Nocturia was the main symptom in two patients. Serum PSA was estimated in 63 patients and the average value of PSA was 264 ng/mL. It was below 10 ng/mL in two patients (3.2%), between 10-20 ng/mL in five patients (7.9%), between 20-100 ng/mL in 19 patients (30.2%) and more than 100 ng/mL in 37 patients (58.7%).

Variables	Result
Age (Mean±SD in years)	70.7±10.4
Screening-detected prostate cancer n (%)	1 (1.5)
Family history n (%)	1 (1.5)
Symptomatic patients n (%)	65 (98.5)
Serum creatinine (mg/dL)	11 (16.7)
Diabetes mellitus n (%)	9 (13.6)
Hypertension n (%)	19 (28.8)
PSA median, range (ng/mL)	125.4, 7 to 2541
Maximum urine flow rate (Mean±SD in mL/sec)	9.8±4.2
Adenocarcinoma n (%)	65 (98.5)
Bilateral orchidectomy n (%)	46 (69.7)
Mortality n (%)	9 (13.6)

[Table/Fig-1]: Patients and treatment characteristics (N=66).
SD: Standard deviation; PSA: Prostate specific antigen

Age group (Years)	Number	Percentage
41-50	4	6.1
51-60	8	12.1
61-70	19	28.8
71-80	23	34.9
81-90	11	16.7
91-100	1	1.5
Total	66	100

[Table/Fig-2]: Age distribution of patients.

For staging, ultrasonography was the most common investigation, which was performed in 52 patients (78.8%). Ultrasonography detected liver secondaries, enlarged lymph nodes, ascites and ureteric involvement in 24 patients (46.15%). A bone scan, done in 22 patients, detected bone secondaries in 15 patients (68.18%). MRI and CT scans (skeletal survey) were done in suspected bone secondaries if the patients could not afford bone scanning. At the time of the study, the facility for the bone scan was not available in Shillong and patients had to go to another city for bone scanning. MRI, done in 15 patients, detected secondaries in 13 patients; CT scan, done in six patients, detected secondaries in four patients. Local invasion was detected by CT and MRI in seven patients.

Out of 66 patients in this study, 65 patients (98.5%) were diagnosed to have adenocarcinoma; one patient was reported to have small cell carcinoma. Gleason score was available in 53 patients. The most common Gleason score was 8-10 (poorly differentiated) which was reported in 33 patients (62.3%), followed by a score 7(moderately differentiated) in 17 patients (32.1%) and a score of 6 or less (well differentiated) in 3 patients (5.7%).

Total 51 patients (77.3%) had stage 4 disease, seven patients (10.6%) stage 3 and five patients (7.6%), stage 2 and three patients (4.5%), stage 1 diseases [Table/Fig-3]. For androgen deprivation therapy, a total of 46 patients (69.7%) i.e., 43 patients with stage 4 disease and three patients with stage 3 disease, underwent bilateral orchidectomy and eight patients received LHRH agonist (Leuprolide or Triptorelin). Sixteen patients received tablets of Bicalutamide and two patients received the tablet of Abiraterone along with orchidectomy or Luteinizing Hormone-releasing Hormone (LHRH) agonists. None of the patients received injection of docetaxel and LHRH antagonist during the study period.

Three patients had stage 1 cancer. One patient had screening-detected prostate cancer and he underwent High-Frequency Focused Ultrasound (HIFU) treatment at another centre. The other two patients opted for robotic prostatectomy and they were referred to another centre as a robotic surgery facility was not available in this centre. In the present study, no patient received radiation therapy in this centre, as this facility was not available at the time of the study.

Stage	n (%)	Treatment
4	51 (77.3)	1) Orchidectomy-32. 2) Orchidectomy and TURP-11. 3) LHRH agonist-8.
3	7 (10.6)	1) Orchidectomy and radiotherapy-3. 2) Chemotherapy-1 (small cell carcinoma). 3) Refused treatment-3.
2	5 (7.6)	Active surveillance
1	3 (4.5)	HIFU+ and RP±

[Table/Fig-3]: Clinical stage and treatment (N=66).
LHRH: Luteinizing hormone releasing hormone; +HIFU: High frequency focused ultrasound, ±RP: Radical prostatectomy

A total of 33 patients came for the first follow-up at six months (stage 4-23 patients, stage 3-4 patients, stage 2-3 patients, and stage 1-3 patients). Serum PSA was done in 20 patients and mean PSA was 60 ng/mL (range, 0.04-544 ng/mL), and the mean maximum urine flow rate (done in six patients) was 10 mL/sec (range, 6-23 mL/sec). Total of 18 patients came for a second follow-up at 12 months (stage 4-12 patients, stage 3-2 patients, stage 2-1 patients, and stage 1-3 patients). The mean PSA (done in 14 patients) was 41.1 ng/mL (range, 0.04-284 ng/mL) and no urine flow rate result was available. Only six patients came for a third follow-up at 18 months (all were in stage 4). The mean serum PSA was 31.4 ng/mL (range, 0.07-153 ng/mL) and only one urine flow rate result was available (maximum flow rate of 6 mL/sec). During these follow-up visits, imaging (bone scan and ultrasound) revealed that two patients who were initially diagnosed to have stage 2 and 3 diseases had progressed to stage 4 disease.

A total of nine patients died during the study, which were reported by their relatives and some were recorded in the hospital. Of these nine patients, three, one, four and, one patients died within one, two, three and four years of diagnosis, respectively.

DISCUSSION

Prostate cancer still remains relatively rare among the North Eastern Indians. As demonstrated in the present study, only 66 patients in a 10 year study period, showed an incidence of 6.6 cases per year. This concurs with the low age-adjusted incidence rates of prostate cancer in the States of North East India [6]. The present study is having special significance as the patients were mostly from rural areas while most of the prostate cancer registries in India are mostly urban-based and very little data came from rural India [15].

There is a marked variation in the incidence of prostate cancer worldwide, with African Americans having the highest rate and lowest incidence in Asian countries [16]. In Asia, the incidence of prostate cancer was lowest in Bhutan (1.1/100,000) and highest in Singapore (33/100,000) [17]. The high incidence in Western countries has been attributed to the extensive application of PSA testing, prostate biopsy and racial differences [17,18]. Though the incidence in Asian countries was low, the incidence of prostate cancer is rising in most Asian countries, probably due to PSA testing, better cancer registration system and environmental risk factors [19].

In this study, the majority of patients (80.3%) were in the 7th to 9th decade of life with the mean age at diagnosis of 70.7 years. The present study finding is similar to those of previous studies from India [8,16-18]. In a study of 471 prostate cancer patients by Ghagane S et al., the mean age of the patients was 70 years [13]. Similarly, Tyagi et al., Singh AN et al., and Rajput A et al. reported the mean ages of prostate cancer patients in their studies to be 69.7 years, 67.6 years and 67 years respectively [8,20,21].

The global incidence of familial prostate cancer is 9% and it is 3% in India [22,23]. In this study, a family history of prostate cancer was reported in one patient (1.5%) only. Two studies from the Indian subcontinent reported family history in 0.84% and 2% of patients respectively [13, 14].

The most common presenting symptoms in this study were LUTS, AUR and haematuria. All patients except one presented with symptomatic prostate cancer. The large proportion (98.5%) of symptomatic patients in the present study is similar to the previous studies from developing countries [8,13,14]. In a prospective study of 278 patients from Sri Lanka, it was reported that 98% of the patients presented with symptoms, the most common symptom being LUTS, seen in 50% of the patients [14]. In a study of 471 prostate cancer patients in a tertiary institute in Karnataka, it was reported that 84.5% of patients presented with bothersome symptoms [13]. Similarly, in a study of 332 patients at a tertiary care cancer centre, Rajput A et al., reported that 83.4% of the patients had LUTS [8].

All biopsy specimens except one were reported as adenocarcinoma, and one was reported as small cell carcinoma. In this study, the majority (58.7%) of patients had PSA above 100 ng/mL, and two patients (3.2%) had PSA below 10 ng/mL. The average PSA (264 ng/mL) in this study was higher than the average PSA (19.6 ng/mL and 37.71 ng/mL) reported in two studies in India [8,13]. A study from Sri Lanka reported that 81% of patients had PSA above 20 ng/mL [14]. In contrast, a study from Trinidad and Tobago reported that only 22.7% of patients had PSA above 100 ng/mL and the mean PSA in a study from the USA was 5.7 ng/mL [11,24].

In the present study, the most common Gleason score of 8-10 was observed in 33 patients (62.3%), followed by a Gleason score of 7 in 17 patients (32.1%) and a score of 2-6 was, seen in 3 patients (5.7%). A similar pattern was reported in studies from the Indian sub-continent [13,14]. However, a recent study by Rajput A., et al reported that the majority (52.4%) of the patients had a Gleason score of 7 or less [8]. Also, studies by Loeb S et al., and, Coard KC and Skeete DH reported a Gleason score of 6 or less to be the most common score, seen in 76.7% and 37.8% of patients respectively [24, 25].

The majority of patients (87.9%) in this study, presented with an advanced stage (stage 3 and 4). The local invasion was present in seven (10.6%) patients and distant metastasis, in 51(77.3%) patients. The patients came from all the states of North East India and the majority of these states did not have any urology service at the time of the present study. The shortage of urologic service in this region probably contributed to late diagnosis in the study patients. A similar presentation in the advanced stage was reported by other studies [13,14,26]. However, a recent study of 332 patients with tertiary care cancer from India (Delhi) showed that 61% of the patients had localized prostate cancer [8]. This could be due to more PSA testing and better awareness among patients about prostate cancer and the availability of urologic services in this region.

A previous study showed that in India, 85% of all prostate cancers are presented in the late stages (3 and 4) while only 15% were presented in the advanced stage in the United States [27]. In many Western countries where prostate cancer screening is practiced routinely, patients with prostate cancer are diagnosed at an early stage [11,24]. In India, prostate cancer screening is not practiced routinely and knowledge of prostate cancer is poor among the public. These facts probably lead to the late presentation and diagnosis of prostate cancer patients in India.

As the majority of patients in this study presented in metastatic stage, the most common type of treatment was ADT with total bilateral orchidectomy, which was performed in 84.3% (43/51) of stage IV patients. Only eight patients (15.7%) with metastatic cancer opted for medical castration using leuprolide or triptorelin. Six of these patients later underwent orchidectomy due to financial constraints.

Thus, an overwhelming majority of metastatic patients in the present study underwent surgical orchidectomy as a means of androgen ablation. Similar treatment history is reported by studies in developing countries as patients opted for this type of treatment because of

financial constraints [14,28]. On the other hand, the majority of patients with metastatic prostate cancer in developed countries opted for medical castration [29]. The follow-up was poor, which could be due to various reasons like financial problems, patients staying at a long distance from the hospital, and ignorance.

Mass screening for prostate cancer still remains a controversial topic. In developed countries, where prostate cancer screening is practiced, the majority of prostate cancer patients are diagnosed at an early stage [24]. In India, prostate cancer screening is not practiced routinely, so patients present with advanced disease. However, with the low incidence of prostate cancer in this region, screening for prostate cancer may not be justified.

Limitation(s)

Limitations of the study included the retrospective nature of the study. Also, the small number of patients in the study and the large proportion of patients lost to follow-up were the major limitations of the study. Loss of follow-up of large number of patients may underestimate the number of deaths. Also, this study included patients treated at a single institution, so it might not reflect the whole population in the region.

CONCLUSION(S)

Though the incidence of prostate cancer was 6.6 cases per year of prostate cases in the present study population, most patients were symptomatic at presentation, and the majority presented with an advanced stage of the disease. The most common histologic type was adenocarcinoma. The majority of the patients with an advanced stage of the disease underwent total bilateral orchidectomy for androgen deprivation therapy.

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