

Original Research Article

Correlation of serum prostate specific antigen with clinical, radiological and pathological variables in patients with prostate enlargement

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ABSTRACT

Background: Prostate enlargement encompasses a spectrum of disorders ranging from benign to malignant. For diagnostic prostatic biopsies no clear prostate specific antigen (PSA) threshold level exists. The study correlates PSA with various clinical data (age of patient, international prostate severity score (IPSS), digital rectal examination (DRE) finding), radiological data (prostate volume) and pathological data (Gleason grade, prostate cancer stage) to aid decision making on treatment of prostate enlargement.

Methods: 101 men aged more than 50 years with fresh LUTS and grade 1 or more prostate enlargement on DRE were enrolled. They were worked up with transabdominal ultrasonography, serum PSA and prostate biopsy (when indicated). A descriptive statistical analysis was done for correlation by applying Pearson's Chi square test for significance.

Results: Mean serum PSA value was found to increase with age and higher IPSS score. Mean serum PSA levels were found to rise with grade of prostatomegaly. No significant correlation was seen between serum PSA values and Gleason grade or clinical stage of prostate cancer.

Conclusions: Serum PSA levels has a significant correlation with age. With increasing age there is increase in serum PSA levels. Serum PSA levels has a significant correlation with International prostate symptom severity scoring. Serum PSA levels has a significant correlation with prostate size measured by trans-abdominal ultrasonography. Serum PSA levels does not show significant correlation with Gleason score or clinical stage of prostate cancer.

Keywords: Prostate specific antigen, International prostate severity score, Digital rectal examination, Prostate volume, Prostate biopsy, Gleason score, Carcinoma prostate

INTRODUCTION

The term prostate enlargement encompasses benign hyperplasia of prostate (BPH) and carcinoma of prostate. Prostate specific antigen (PSA) is a glycoprotein that is expressed by both normal and neoplastic prostate tissue. PSA has a half-life of 2.2 days, and levels elevated by

different benign conditions will have variable recovery times.

Historically a concentration above 4 ng/ml was considered abnormal. Prostate cancer prevention trial (PCPT) study, which included biopsy regardless of PSA level, demonstrated that there is no level of PSA below

which prostate cancer risk falls to zero. Overall, the positive predictive value for a PSA level >4.0 ng/ml is approximately 30 percent, meaning that slightly less than one in three men with an elevated PSA will have prostate cancer detected on biopsy. A negative predictive value of 85 percent for a PSA value ≤ 4.0 ng/ml was inferred from this trial.¹ PSA levels are indicative of a continuum of risk-the higher the level, the higher the risk. These observations indicate that there is not a clear cutpoint between "normal" and "abnormal" PSA levels.²

In clinical practice, biopsies are generally performed only when the results of a PSA test or Digital rectal examination (DRE) is abnormal. This leads to misdiagnosis of most small Prostatic cancers present in many older men. Patients with lower urinary tract symptoms (LUTS) who have Serum PSA levels higher than 4 ng/ml are primarily advised to undergo prostate biopsy to rule out cancer. But PSA is organ specific but not cancer specific, so the presence of other prostate diseases such as benign prostatic hyperplasia (BPH), and Prostatitis may influence its effectiveness for cancer detection. An early detection of the cause of LUTS is necessary to offer selective treatment to the concerned subjects.

The present study is an attempt to have a comparative analysis among Serum PSA and multiple variables namely clinical (age, IPSS, DRE finding), radiological (trans abdominal ultrasound kidney, ureter, bladder and prostate (USG KUBP) and pathological (Gleason grade, clinical stage). This study may enable us to find out the extent of correlation of serum PSA levels so that a specific treatment can be instituted at an early stage.

Aims and objectives

The aim was to study the clinico pathological correlation between serum PSA and prostate enlargement.

The objectives were to evaluate the correlation between Serum PSA and age of patient; to evaluate the correlation between Serum PSA and IPSS score; to evaluate the correlation between Serum PSA and Prostate size; to evaluate the correlation between Serum PSA and Gleason grade; to evaluate the correlation between Serum PSA and prostate cancer stage.

METHODS

Study place was Department of General Surgery and Department of Urology, Army Hospital (Research & Referral), Delhi-10. It is a tertiary care urological centre of armed forces with modern diagnostic facilities.

Study population was derived from the serving and retired military personnel and their dependent families who are referred from all over the country. Hence, the population within reasonable limits would represent the general population of the country.

Study period was from May 2015 to Apr 2017. Sample size was 101 patients.

Inclusion criteria were patients aged more than or equal to 50 years with LUTS and grade 1 or more prostate enlargement on DRE.

Exclusion criteria were patients aged less than 50 years, past history of prostatic surgery and Patients with features of UTI. Patients with LUTS due to other structural or functional bladder outlet obstruction such as stricture urethra, neurological lesions and stone disease were excluded. Known cases of carcinoma prostate, pelvic radiotherapy, fibrotic or calcified prostate were also excluded.

Study design undertaken as a prospective descriptive study.

Study technique: The study was approved by the Institutional Ethical Committee and all patients gave informed written consent. All patients presenting with LUTS underwent DRE and were worked up with USG KUBP, Serum PSA and biopsy (if indicated) after obtaining consent.

DRE was carried out with the patient lying in left lateral position and the following were assessed: size of the prostate gland with any asymmetric enlargement of the lateral lobes, tenderness of the prostate gland, consistency of the prostate gland (Firm/Hard/Variable consistency), surface nodularity and the consistency of these nodules, mobility of the rectal mucosa over the prostate gland and the tone of the anal sphincter.

A trans-abdominal ultrasound examination was done to assess the size of the prostate gland. Size was graded as follows. Grade I was less than 25 cmm, Grade II was 26 to 50 cmm, Grade III 51 to 75 cmm and Grade IV more than 75 cmm.

Serum PSA specimen were collected in 5 ml sterile EDTA tubes (BD vacutainers®). The samples were centrifuged within 20 minutes of collection at 2000 g for 10 min and sera was frozen at -20° c until tested. The total prostate specific antigen (tPSA) was assessed at the hospital pathology lab using IRMA technique (Diagnostic System Laboratories Inc, Texas, U.S.A.)

Patients with suspicious DRE finding (defined as hard nodular fixed prostate) or increased Serum PSA levels (defined as more than 4 ng/ml) underwent prostate biopsy. Other patients were followed up with serum PSA levels, thereby dividing patients into two groups. Group 1 with suspicious DRE or elevated serum PSA underwent biopsy. Group 2 who had benign feel of prostate on DRE and normal serum PSA levels were only followed up. Patients of both groups were followed up every 3 months and clinical, ultrasonological and biopsy findings were recorded in the study performa

Biopsy specimen collection and processing was done starting with Sodium phosphate enema at 0600 hrs on the day of biopsy and oral antibiotic cover (single oral dose of tab ciprofloxacin (500 mg)-Tinidazole (500 mg) in the morning 2 hrs prior to biopsy to patients. Patients were placed in the left lateral decubitus position with knees and hips flexed 90 degrees. An arm board was attached parallel to the table and a pillow placed between the knees. Ultrasound was done using ultrasonography unit and a transrectal 7.5 MHZ biplane probe under local anesthesia (2% lignocaine jelly). 12 cores (6+6) of tissue targeting the peripheral zone at the apex, midgland, and base, as well as laterally directed cores on each side of the prostate were taken. The cores biopsies were taken using automated biopsy gun with a disposable 18G Core needle (C. R. Bard Inc, New Jersey, U.S.A). The specimen obtained was sent in two bottles labelled as Right and Left separately to the hospital Pathology Lab and reported upon by one of the institutional pathologists. A written consent was obtained prior to the prostate biopsy. Pre biopsy workup and investigations were done in all patients prior to biopsy. Investigations included were complete blood counts, coagulation profile, blood sugar, urine examination and culture, blood culture. Vital parameters including pulse, BP, temperature and respiratory rate were recorded pre and post biopsy. The post-biopsy patients were kept for observation for 06 hours and discharged accordingly with the advice to continue antibiotic for 48 hours and to attend OPD or emergency room in case symptoms of fever, dysuria, hematuria, hematospermia or bleeding per rectum arises. Patients were followed up firstly at 3 months interval and after 6 months interval.

Data analysis

All the data was collected on a Microsoft Office Excel work sheet and the confidentiality of the data was preserved. The access to the result was limited to the patient concerned and the team of treating doctors. The descriptive statistical analysis was done using SPSS® software (IBM, New York, U.S.A) platform version 24.0. Correlation was performed by applying cross tabulation, Pearson's χ^2 test as test of significance. A two-tailed p value 0.05 was considered significant.

RESULTS

Figure 1 depicts age wise distribution of patients and correlation with serum PSA. The number of patients with serum PSA in the ranges <4 ng/ml, 4-10 ng/ml and >10 ng/ml were 71, 19 and 11 respectively. The number of patients in the various age groups 50-60, 61-70, 71-80 and 81-90 were 17, 49, 26 and 9 respectively. The mean age in our study was 68.5 years [range 50-90 years].

The range of serum PSA for age group 50-60 years was from 0.59 to 4.29 ng/ml, for age group 61-70 was 1.07 to 3.48 ng/ml, for age group 71-80 was 0.26 to 32.8 ng/ml, for age group 81-90 was 2.02 to 18.99 ng/ml. The

majority i.e., 37 (36.6%) of study group was in the age group of 61-70 yrs. The range of PSA level noted for the entire group was from 0.26 to 49 ng/ml respectively.

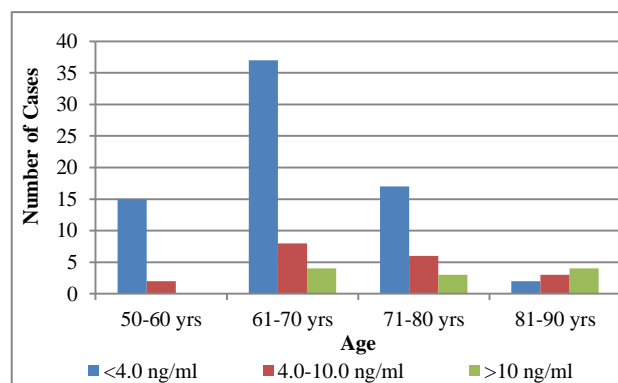


Figure 1: Age wise distribution of serum PSA.

The mean serum PSA for age group 50-60 years was 4.05 ng/ml, for age group 61-70 was 17.95 ng/ml, for age group 71-80 was 10.18 ng/ml, for age group 81-90 was 10.6 ng/ml. The mean serum PSA for the whole group was 12.7 ng/ml. The mean serum PSA level was found to increase with each decade, starting from 50 years upto 90 years ($p=0.008$).

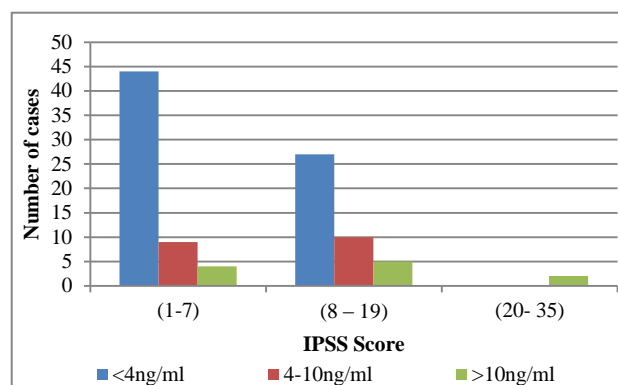


Figure 2: Correlation of serum PSA with IPSS.

Figure 2 depicts correlation of serum PSA with IPSS score. Among 101 patients, 57 (56.4%) had IPSS score in the range of 1-7 (mild), 42 (41.54%) had IPSS between 8-19 (moderate) whereas only 2 (1.98%) patients had IPSS>19 (severe).

Amongst the 57 patients with mild IPSS, 44 (43.5%) patients had Serum PSA <4 ng/ml, 9 (2.9%) had Serum PSA between 4 to 10ng/ml and 4(6.9%) had serum PSA >10 ng/ml. Out of 42 patients with moderate IPSS score, serum PSA of <4 ng/ml, 4-10 ng/ml and >10ng/ml, was noted in 27 (26.7%), 10 (9.9%) and 5 (4.9%) respectively.

Mean serum PSA in patients with mild, moderate and severe LUTS were 3.8ng/ml, 5.9 ng/ml and 14.5 ng/ml respectively. The range of serum PSA in patients with

IPSS score of 1-7, 8-19 and 20-35 were from 0.49 to 49 ng/ml, 0.26 to 32.8 ng/ml and from 14.02 to 15.02 ng/ml respectively ($p=0.0009$).

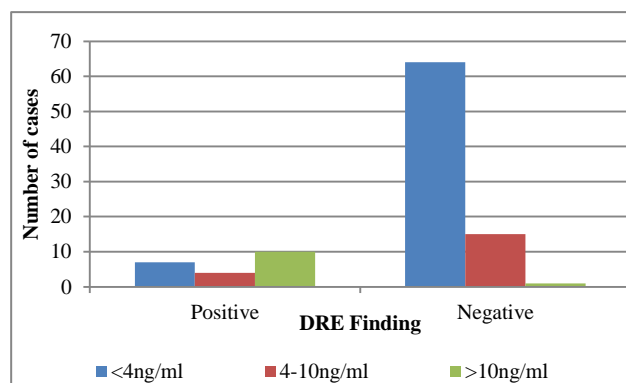


Figure 3: Correlation of serum PSA with DRE findings.

Figure 3 depicts correlation of serum PSA levels with findings on DRE. The number of patients who had DRE suspicious of malignancy (hard, nodular prostate), within serum PSA ranges of <4 ng/ml, 4-10 ng/ml and >10 ng/ml were 7 (6.9%), 4 (3.9%) and 10 (9.9%) respectively. A total of 21 (20.79%) patients had DRE suspicious of malignancy, whereas 80 (79.2%) had DRE suggestive of a benign prostate enlargement.

The range of serum PSA which was noted in patients with suspicious DRE was from 1.4ng/ml to 49ng/ml respectively. The range of serum PSA noted in DRE negative group was from 0.26 ng/ml to 10.9 ng/ml respectively. The mean Serum PSA amongst patients with DRE suspicious of malignancy was 13.9 ng/ml, whereas in the benign DRE finding group, the mean serum PSA was 2.5 ng/ml ($p<0.00001$).

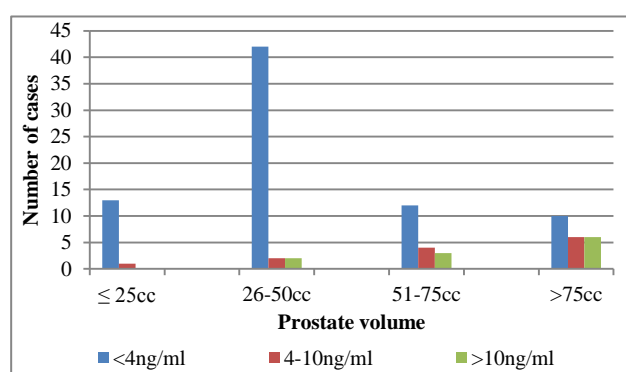


Figure 4: Correlation of serum PSA with prostate volume.

Figure 4 depicts correlation of serum PSA levels with ultrasound KUBP, size of prostate. Out of 14 patients with Grade I prostate enlargement (<25 gms), 13 (12.87%) had Serum PSA less than 4 ng/ml and 1 (0.99%) patient had Serum PSA between 4 to 10 ng/ml.

Forty six patients (45.5%) had Grade II enlargement on USG (25-50 gms) out of which 42 (41.58%) patients had Serum PSA <4 ng/ml, 2 (1.98%) patients had serum PSA between 4 ng/ml – 10 ng/ml and 2 (1.98%) patients had serum PSA >10ng/ml.

Nineteen (18.81%) patients had grade III enlargement (51-75 gms) out of which 12(11.88%) patients had serum PSA <4 ng/ml, 4 (3.96%) patients had serum PSA between 4-10 ng/ml and 3(2.97%) patients had PSA >10 ng/ml. Twenty two patients (21.78%) had Grade IV enlargement on USG (>75 gms) out of which 10 (9.90%) patients had Serum PSA <4 ng/ml, 6 (5.94%) patients had serum PSA between 4-10 ng/ml and 6 (5.94%) patients had PSA > 10ng/ml. The mean prostate volume in our series was 52.8 cc.

The ranges of serum PSA for grade I, grade II, grade III and grade IV prostate enlargement were from 0.49 to 5.72 ng/ml, 0.78 to 14.02 ng/ml, 0.26 to 32.8 ng/ml and 0.75 to 49 ng/ml respectively. The mean Serum PSA amongst patients with prostate sizes <25 gms, 25-50 gms, 51-75 gms and >75 gms were 1.50 ng/ml, 2.63 ng/ml, 6.51 ng/ml and 10.48 ng/ml respectively ($p=0.023$).

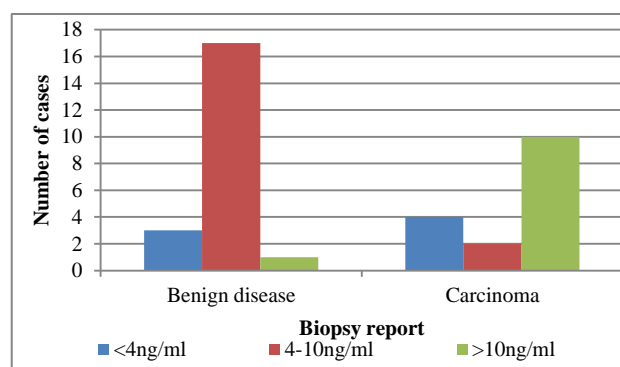


Figure 5: Correlation of serum PSA with biopsy report.

Figure 5 depicts correlation of biopsy findings of serum PSA. A total of 37 patients underwent biopsy on the basis of either DRE suspicion or raised serum PSA levels, out of which 21 (20.58%) had benign disease, whereas 18 (17.8%) had adenocarcinoma. Remaining 64 (63.3%) patients did not undergo biopsy.

Amongst the malignancy group, the number of cases of serum PSA levels graded as <4 ng/ml, 4 ng/ml -10 ng/ml and >10 ng/ml were 4 (3.96%), 2 (1.98%) and 10 (9.90%) respectively. The range of serum PSA in malignancy group was from 2.02 ng/ml to 49 ng/ml. The mean Serum PSA in malignancy group was 14.70 ng/ml.

Amongst the benign group, (BPH as well as prostatitis) the number of patients of serum PSA levels graded as <4, 4 to 10 and >10 ng/ml were 3 (2.97%), 17 (16.8%) and 1 (0.99%) respectively. The range of serum PSA in benign group was from 1.4 ng/ml to 10.91 ng/ml. The mean

serum PSA in patients having prostatitis was 5.82 ng/ml (Range 5.72 to 5.92 ng/ml) whereas the mean Serum PSA of BPH patients was 5.77 ng/ml. The mean total PSA of the entire biopsy group was 11.03 ng/ml (Range 1.4 ng/ml to 49 ng/ml).

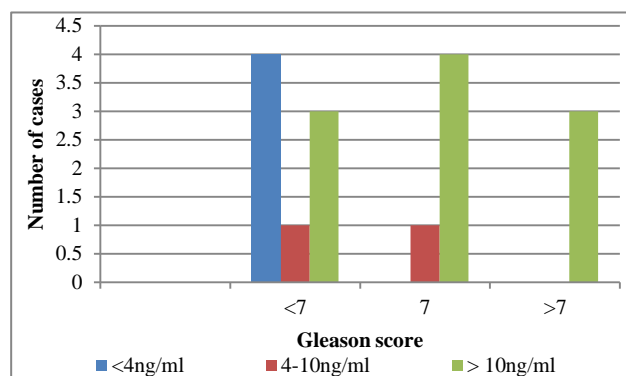


Figure 6: Correlation of serum PSA with Gleason grade of prostate cancer.

Figure 6 shows amongst 16 patients with biopsy proven adenocarcinoma, 8 patients (7.92%) had Gleason score <7, 5 (4.95%) had Gleason score of 7 and 3 (2.97%) had Gleason score >7.

For Gleason score <7, the number of patients with serum PSA <4 ng/ml, 4-10 ng/ml and >10 ng/ml was 4, 1 and 3 respectively. For Gleason score of 7, the number of patients of serum PSA <4 ng/ml, 4-10 ng/ml and >10ng/ml was nil, 1 (5%) and 5 (30%) respectively. For Gleason score >7, the number of patients of serum PSA <4 ng/ml, 4-10 ng/ml and >10 ng/ml was nil, nil and 3 (20%) respectively.

The minimum Gleason score noted was 6. The maximum Gleason score noted was 8. It was seen in four cases and the range of serum PSA was from 2.36 ng/ml to 49 ng/ml.

No significant correlation was seen between serum PSA values and Gleason grade of prostate cancer. p value 0.356.

Figure 7 shows amongst 16 patients with biopsy proven adenocarcinoma, 1 (0.9%) patient had cT1c disease, whereas cT2 and cT3 were seen in 13 (12.8%) and 2 (1.98%) patients respectively.

For cT1c, the number of patients of serum PSA <4 ng/ml, 4-10 ng/ml and >10 ng/ml was nil, 1(0.9%) and nil respectively. For cT2, the number of patients of serum PSA <4 ng/ml, 4-10 ng/ml and >10 ng/ml was 4 (3.9%), 1(0.9%) and 2 (1.98%) respectively. For cT3, the number of patients of serum PSA <4 ng/ml, 4-10 ng/ml and >10 ng/ml was nil, nil and 2 (2.9%) respectively.

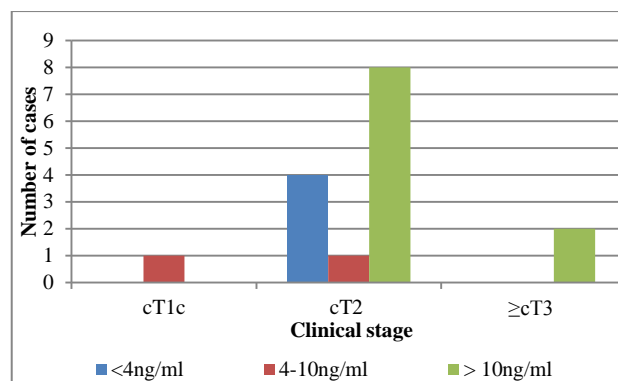


Figure 7: Correlation of serum PSA with clinical stage of prostate cancer.

Clinical stage T2 formed majority of biopsy proven adenocarcinoma cases (81%). Stage T1 and T3 formed 10% each. However there was no significant correlation between serum PSA levels and clinical stage of prostate cancer (p=0.07).

DISCUSSION

The mean age in our study was 68.5 years [range 50-90years]. This compares favorably with the study done by Sunanda De et al who found mean age of study group to be 66 years.³ Josephine et al found mean age to be 65 years.⁴

Our study shows that with the increase in age group, there is increase in serum PSA levels. The results of our study were comparable with PSA best practice statement 2009 age specific PSA range for Asian population⁵. According to their study, serum PSA levels showed an increasing trend with age. For the age group 40-49 years serum PSA was 0-2.0 ng/ml, 50-59 yr was 0-3.0 ng/ml, 60-69 yr was 0-4.0 ng/ml and for age group 70-79 yr it was 0-5.0 ng/ml.

In our study the mean serum PSA values for mild, moderate and severe IPSS was 3.8, 5.9 and 14.5 ng/ml respectively. There was significant correlation between the IPSS and serum PSA levels (p<0.05). Our study was comparable to study done by Park et al who showed significant linear correlation of PSA with IPSS (p<0.001).⁶ They found mean serum PSA levels in mild, moderate and severe IPSS cases to be 1.028, 1.047 and 1.060 respectively. The high serum PSA in our study can be attributed to higher levels of serum PSA in Asian population.⁷

In our study mean size of prostate was 52.8cc. There was a significant correlation (p<0.05) noted between the prostate size and Serum PSA. Our study was comparable to study by Carvalho GF et al who showed significant correlation of serum PSA with prostate size ≥54.6 cc (p=0.01).⁸ In a study by Baruah et al a positive correlation was observed between prostate volume and

serum PSA level ($p=0.001$).⁹ In their study, mean prostate volume was 43.9 ± 3.117 cc and mean serum PSA was 2.55 ± 0.555 ng/ml.

A total of 37 patients out of 101 in our study underwent biopsy. 6 patients (5.94%) underwent biopsy solely on the basis of suspicious DRE. 14 patients (13.8%) underwent biopsy solely on the basis of elevated serum PSA. Rest 17 (16.8%) patients had suspicious DRE as well as elevated serum PSA. In a study done by Dobruch et al 10.2% cases underwent biopsy for suspicious DRE and 46.1% for elevated serum PSA only.¹⁰ In their study, 43.7% cases were biopsied for both suspicious DRE and elevated PSA.

Correlation of serum PSA levels in detection of Adenocarcinoma prostate was significant. (p value < 0.05). Sixteen patients (15.8%) had biopsy proven prostate cancer. The mean Serum PSA in malignancy group was 17.6 ng/ml. Twenty one (20.5%) patients had benign reports on biopsy. The mean Serum PSA in patients having prostatitis was 5.82 ng/ml (Range 5.72 to 5.92ng/ml) whereas the mean Serum PSA of BPH patients was 5.77 ng/ml. Results of our study were comparable to numerous studies which showed higher incidence of Adenocarcinoma with higher Serum PSA levels. Anushree et al found patients with PSA values >20.1 were 8.21 times more likely to be malignant than benign on biopsy.¹¹ Sunanda De et al found that for serum PSA >10.0 ng/ml, sensitivity was 85%, specificity was 72.5% and PPV was 60.7%, for detection of carcinoma prostate.³

In our study, amongst 16 patients who were biopsy proven prostate cancer, 8 patients (7.92%) had Gleason score <7 , 5 (4.95%) had Gleason score of 7 and 3 (2.97%) had Gleason score >7 . P value in our study was 0.167. In a study by Lima, NG et al the PSA levels were higher in the groups with Gleason score of 7 and >7 ($p<0.05$). However there was no significant correlation between mean PSA level and Gleason score of <7 ($p>0.05$).¹² Dobruch et al also found weak correlation of Gleason score of serum PSA in their study on 377 patients with LUTS who underwent TRUS guided prostatic biopsy.¹⁰

In our study out of 16 patients who were biopsy proven prostate carcinoma, among 16 patients with biopsy proven adenocarcinoma, 1 (0.9%) patients had cT1c disease, whereas cT2 and cT3 were seen in 13 (12.8%) and 2 (1.98%) patients respectively. This is comparable to the study done by Dobruch et al who found cancer confined to the prostate in 330 (87.5%) cases.¹⁰ However we found poor correlation with prostate cancer stage of serum PSA levels, p value was 0.07.

CONCLUSION

From our study it was concluded that serum PSA levels has a significant correlation with age wherein mean

serum PSA levels rises with increasing age. Serum PSA levels has a significant correlation with International prostate symptom severity scoring wherein mean serum PSA level rises with severity of LUTS. Serum PSA levels has a significant correlation with prostate size measured by trans-abdominal ultrasonography wherein serum PSA levels rises with grade of prostatomegaly. However serum PSA levels do not show significant correlation with Gleason score or clinical stage of prostate cancer.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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