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# A Study on Utility of Serum Prostate Specific Antigen Level and USG of Prostate to Differentiate Most Common Benign Diseases and Carcinoma of Prostate Gland

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## ABSTRACT

*Various studies have been conducted in the world to find out the correlation between the histopathology with the serum PSA level of different prostatic diseases. The serum PSA level is raised above 10 mg/ml in carcinoma and between 0 to 4 ng/ml in the benign prostatic lesion. Our study was intended to find the correlation of histopathology of prostatic diseases with serum PSA levels and ultrasound findings. Clinical history, ultrasound findings and serum PSA levels were collected from the patient's record and a histopathological study was done in 114 cases between January 2015 to January 2017. Out of 114 cases studied histopathological 14 cases were adenocarcinoma, 14 cases were prostatic intraepithelial neoplasia and rest were BHP with or without prostatitis. The mean serum PSA level (39.27ng/ml) in malignancy cases was statistically significantly higher than that (7.25ng/ml) of benign conditions. Only 6.98% of BPH were found below 4ng/ml serum level. Serum PSA level 4-10ng/ml was the 'grey zone', at this level around 85% of BPH and PIN cases were overlapped with 28% of carcinoma cases. Out of all ultrasound findings suggestive of carcinoma, only 57.1% of cases were confirmed to be carcinoma by histopathological study.*

**Key words:** Carcinoma, Prostate gland, Histopathology, Male reproductive system

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## INTRODUCTION

Prostate, an accessory gland of the male reproductive system, gives rise to various pathological conditions leading to disease related morbidity in a considerable number of males in their late adulthood. Benign prostatic hyperplasia (BPH), carcinoma prostate and prostatitis are the three pathologic processes which frequently affect the prostate gland [1,2,].

Prostatitis is a significant health problem with prevalence rates of 11-16% in different parts of the world. More than 2 million consultations for prostatitis are required every year in the United States and prostatitis is the most common reason for men under 50 to consult a urologist [3,4]. The histological evidence of BPH can be seen in approximately 20% of men by 40 years of age, a figure that increases to 70% by age 60 and to 90% by age 80 [3,5]. Carcinoma prostate is the leading cause of new cancer in men, second to lung cancer as a leading cause of cancer-related death in men in America. In India, it is the 4thmost common cancer and 5th cause of cancer related death in men [2,3,5,6].

The normal level of total serum PSA is usually less than 4 ng/ml, but it varies according to the age of the patient. [7] Various studies in India and outside show that the serum PSA level increases due to prostate Gland diseases and the level of increase is more in carcinomas than in benign conditions. Studies also show that the Transrectal ultrasonography of the Prostate can help in diagnosing the cancers up to a significant percentage [8-10].

According to the authors' knowledge, no such kind of studies has been conducted in the state of Odisha (Eastern

part of India) in the last 10 years. So we want to find the common types of prostatic lesions, the age distribution of the disease and how the level of serum PSA and USG of the Prostate will be helpful in differentiating the benign and carcinomatous conditions of the gland.

## MATERIALS AND METHODS

The present study was a hospital-based cross-sectional study carried out onpatients with prostatic diseases coming to the Department of Pathology, in a medical college hospital in Odisha for histopathological examination of prostatic tissue over a period of two yearsfrom January 2015 to January 2017.

### Inclusion criteria

All the patients having suspected prostatic diseases were referred to pathology department for the histopathological report of prostatic tissue.

### Exclusion criteria

Patients having inadequate clinical data, insufficient and autolysed prostatic tissue.

### Sample size

A total of 124 cases were taken in the study at the beginning. Out of which 10 cases were excluded either due to autolysis of specimen or lack of adequate clinical data. So finally 114 cases were included in the study for final analysis.

### Ethical clearance

Ethical clearance for the study was obtained from the institutional ethical committee.

### Collection of data

The patient's clinical profile including signs and symptoms, radiological and laboratory findings and serum PSA level were taken from the patient's hospital-based record in a semi-structured proforma.

Histopathological study was done in the histology section of the department of pathology. After gross sectioning and serial processing, paraffin blocks were prepared from supplied tissue. Then tissue micro section cutting, followed by routine H & E staining were done and sections were evaluated by the light microscopy.

### Statistical analysis

Data obtained was coded and entered into the Microsoft Excel Spreadsheet. The continuous variables were expressed as mean standard deviation (SD) and categorical data was analyzed in terms of percentages. An appropriate statistical test was applied according to the type of data. Aprobability value 'p' of less than or equal to 0.05 was considered as statistically significant.

## RESULTS

The present hospital-based cross-sectional study was carried out on 114 patients with urinary complaints & prostate enlargement. After appropriate statistical analysis, the following result was obtained.

The age distribution (Table 1) in our study showed the lowest age 44 yrs. and the highest was 85 yrs. with the mean age for all prostatic diseases in our study being 67.21 yrs. (SD ± 7.85). The most prevalent age group was 61-70 years accounting for 54 cases (47.39%). This was followed in descending order by, 71-80 years accounting for32 cases (28.07%) and the 51-60 years age group accounting for 22 cases (19.29%).

A total number of 114 prostatic specimens were included in the study which included prostatectomy specimens, transurethral resection specimens (TURP) and 'trucut' biopsies. TURP biopsies were maximum in number, i.e., 100( 87.73 %.) Trucut biopsies were 12(10.52%) and only two (1.75%) prostatectomy specimens were received.

In various pathology (Table 2) we found as follows BPH

**Table 1: Age distribution.**

| | Distribution(n=57) | |
|---|---|---|
| Age group(Years) | Number | Percent |
| 40 to 50 | 4 | 3.5 |
| 51 to 60 | 22 | 19.29 |
| 61 to 70 | 54 | 47.39 |
| 71 to 80 | 32 | 28.07 |
| >80 | 2 | 1.75 |
| Total | 114 | 100 |

**Table 2: Various Pathology detected on histopathology.**

| | Distribution (n=114) | |
|---|---|---|
| Pathology | Number | Percentage |
| BPH without prostatitis | 64 | 56.14 |
| BPH with prostatitis | 18 | 15.78 |
| BPH with basal cell hyperplasia | 2 | 1.75 |
| Total BPH | 84 | 73.67 |
| PIN with /without BPH | 14 | 12.29 |
| Carcinoma | 14 | 12.29 |
| Others | 2 | 1.75 |
| Total | 114 | 100 |

**Table 3: Age wise distribution of disease.**

| Age group (Yrs.) | BPH without prostatitis | BPH with prostatitis | Total BPH | PIN | Carcinoma | % 0f Prostatitis | % of total BPH | % 0f PIN | % of Carcinoma |
|---|---|---|---|---|---|---|---|---|---|
| 40 to 50 | 4 | -- | 4 | -- | -- | 0 | 4.76 | 0 | 0 |
| 51 to 60 | 12 | 6 | 18 | 4 | -- | 33.33 | 21.42 | 28.59 | 0 |
| 61 to 70 | 28 | 10 | 38 | 8 | 6 | 55.55 | 45.23 | 57.3 | 42.85 |
| 71 to 80 | 20 | 2 | 22 | 2 | 8 | 11.12 | 26.2 | 14.29 | 57.15 |
| >80 | 2 | -- | 2 | -- | -- | 0 | 2.39 | 0 | 0 |
| Total | 66 | 18 | 84 | 14 | 14 | 100 | 100 | 100 | 100 |

most frequent lesion which constituted 84(73.67%) cases and BPH without prostatitis 64 (56.14%), with prostatitis 18 (15.78%) cases and two (1.75%) cases with basal cell hyperplasia. BPH associated with PIN was excluded from this entity. Carcinoma and PIN (with or without BPH) were 14(12.29%) cases each. all the carcinoma in our study came out to be adenocarcinoma and PIN was all low-grade PIN. Two cases (1.75%) among others were atrophic glands with chronic inflammation. So all total benign conditions were 86(75.42%) and premalignant & malignant were 14 (12.29%) each.

Highest number of BPH 38 (45.23%) cases were seen in 61-70 yrs. age group followed by 22(26.2%) cases in age group 71-80yr followed by 18 (21.42%) cases in 51-60 age group. Age group 40-50 yrs. and more than 80 yrs. had four (4.76%) and two (2.39%) case respectively. Among prostatitis (all cases found to be associated with BPH) most cases10 (55.55%) were present in age group 61-70 yrs., than six (33.33%) cases in 51-60 yrs. age and only two(11.12%) case in age more than 80 yrs. was found. Similarly PIN was more prevalent in 61-70 yrs. age eight (57.3%) cases; 51-60 yrs. had four (28.59%) cases and two (14.29%) case in 71-80 yrs. age group. But carcinoma was more prevalent in 71-80 yrs. age group having eight (57.15%) cases and six cases (42.85%) in 61-70 yrs. age group. So benign conditions and PIN were more common in 61-70 yrs. while carcinoma was in 71-80 yrs. (Table 3 and Figure 1).

8 cases–DRE finding not available, 10 cases – USG finding not available. Prostatomegaly with increasing volume from grade 1 to grade 3. Out of 114 patients, 68 (59.64%) cases on DRE (Digital Rectal Examination) and 56(49.12%) cases on USG showed grade 2 enlargement of the prostate. Grade 3 enlargement was present in 38(33.33%) cases on DRE and 48(42.10%) cases on USG. Grade 1 enlargement was not at all documented. Hence grade 2 was a frequent finding (Table 4).

DRE findings suggestive of carcinoma were present in 20 cases out of 114 cases. Out of these 20 cases, ten (50%) cases were confirmed to be carcinoma Ina histopathology study. Similarly out of 14 cases suggesting carcinoma on USG, eight (57.14%) cases were found as carcinoma ina histological study (Table 5).

86.04% (74) benign cases, 85.72% (12) cases of PIN and 28.53% (4) cases of carcinoma had serum PSA levels in 4-10 ng/ml while 71.47% (10) of carcinoma, 14.28% (2) case of PIN and only 6.98% (6) cases of the benign condition were in serum PSA level >10ng/ml. A normal level (<4ng/ml) was seen in only 6.98% (6) benign cases (Table 6).

## DISCUSSION

In this study, maximum patients with prostatic lesions were in the age group of 61 to 70 yrs of life (47.39 %) with the mean age of diagnosis being 67 yrs. Other Indian or Asian studies have shown that the mean age at diagnosis was 63 years and the prevalent age group

**Table 4: Prostatomegaly detected by DRE and USG.**

| Prostatomegaly Grade | | Number | Percentage |
|---|---|---|---|
| DRE | Grade 1 | -- | -- |
| | Grade 2 | 68 | 59.64 |
| | Grade 3 | 38 | 33.33 |
| USG | Grade 1 | -- | -- |
| | Grade 2 | 56 | 49.12 |
| | Grade 3 | 48 | 42.1 |

**Table 5: Number of cases s/o carcinoma on DRE & USG Vs. histopathology finding.**

| | Histopathology finding | | | |
|---|---|---|---|---|
| | Benign | PIN | Carcinoma | % showing carcinoma |
| DRE s/o malignancy (n=20) | 6 | 4 | 10 | 50 |
| USG s/o malignancy (n=14) | 4 | 2 | 8 | 57.14 |

**Table 6: Serum prostate specific antigen (PSA) level against gold standard (histology).**

| PSA (ng/ml) | Benign (N=86) | % in Benign | PIN (N=14) | % in PIN | Carcinoma (N=14) | % in Carcinoma |
|---|---|---|---|---|---|---|
| >10 | 6 | 6.98 | 2 | 14.28 | 10 | 71.47 |
| 4 to 10 | 74 | 86.04 | 12 | 85.72 | 4 | 28.53 |
| <4 | 6 | 6.98 | -- | -- | -- | -- |
| Total | 86 | 100 | 14 | 100 | 14 | 100 |

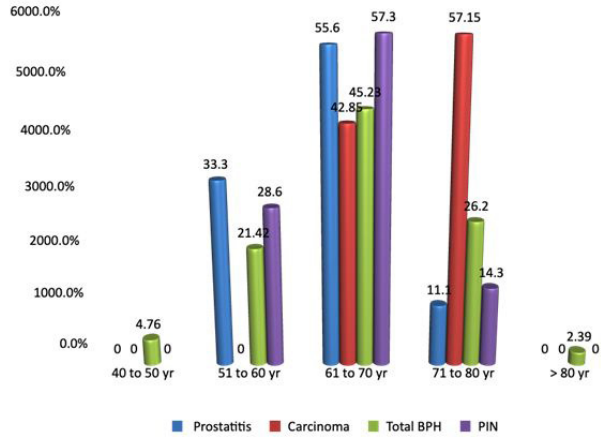


**Figure 1: Age wise distribution of various disease in percentage.**

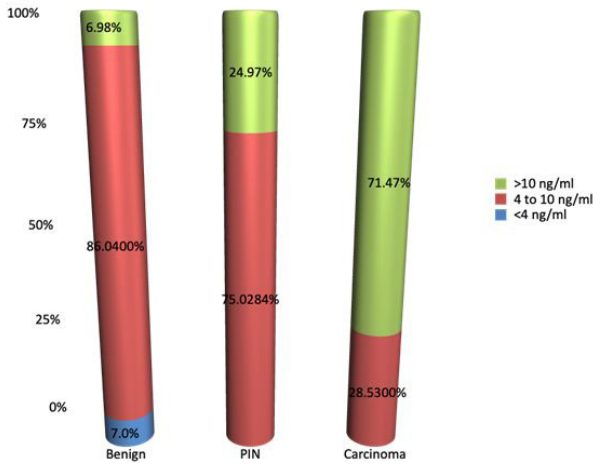


**Figure 2: Serum PSA level in percentage in different conditions.**

was 6th to 7th decade which was in concordance with our study [9.11].

Now considering various proportions of prostatic lesions in the present study, the majority of the cases (73.67%) were benign, of which BPH without prostatitis constituted 56.14% of the cases, followed by 15.78% cases of BPH with prostatitis. A study by Wadgaonkar et al. in Maharashtra in 2013 had a similar finding of the majority of the cases (83.8%) were benign, of which BPH without prostatitis constituted 60% and Abdel-Meguid et al. outside India in their study, found the prevalence of prostatic inflammation with BPH about 20.1% cases which was in accordance to our study [2,12]. In our study PIN(all low grade) with or without BPH was found to be 12.29% so also carcinoma (all were adenocarcinoma) at 12.29% which is resembling a study in 2012 in southern India in which PIN accounted for 9.2% and adenocarcinoma 9.3%. But Wadgaonkar's study had only 1.25% of PIN in their study which according to them was due to not preferring to report PIN, recognizing the difficulty in separating this lesion from the benign epithelium and reactive atypia in TURP specimen [2,3].

Age wise distribution of various prostatic lesions of our study (Table 3) showed that total BPH including prostatitis was maximum (45.23%) in the age group 61 to 70 yrs. followed by 26.2% in 71 to 80 yrs. age group and carcinoma was more prevalent in the age group 71 to 80 yrs. constituting 57.15% followed by 42.85% in the age group 61 to 70 yrs. Wadgaonkar et al. found that BPH was maximum in the age group of 60-69 years having 46.3% of cases and malignant cases showed a peak in two age groups, i.e. in 60-69 years and 70-79 years, each having 41.7% of cases. Anushree et al. of south India had a similar finding of more benign cases in the age group 60 to 69 yrs. and malignant cases in the age group 70 to 79 yrs. But Shakya et al. Nepal, in their study of 106 BPH cases, found 47.16% of cases between 71-80 years followed by 33.96% of cases in 61-70 years.[2,3,13,] Percentage of PIN in the present study was maximum (55.55% ) in 61 to 70 yrs. and the next most prevalent age group was 51 to 60 yrs. having 28.59% cases. A similar study in Gujarat (2012) revealed almost the same finding as our study having most of PIN in the age group 51 to 70 yrs. [14].

Now considering finding suggestive of carcinoma in DRE and USG, the present study showed that 50% of cases suggestive of carcinoma by DRE and 57.14% of cases suggestive of carcinoma by USG were positive for carcinoma in histological findings. A study outside India has a similar finding suggesting 55.8% of cases having abnormal DRE were found to be carcinoma. Another study revealed that 59.7% of cases with abnormal DRE and 59% of cases with hypoechoic lesion on USG were confirmed to be carcinoma by histopathology studies [15,16].

In this study we established cutoff ranges for serum PSA at three levels i.e., less than 4 ng/mL, 4-10 ng/mL and more than 10 ng/mL (Table 6). At less than 4 ng/mL, only three cases were BPH which constituted only 6.98%. No other lesions had a PSA value below 4ng/ml. In the range of 4-10 ng/mL), 74 cases (86.04%) were BPH, four cases (28.53%) were prostatic carcinoma and 12 (85.72%) cases were PIN. 10(71.47%) cases of carcinoma and only two (14.28%) cases of PIN and six( 6.98%) cases of the benign condition were in serum PSA levels more than 10ng/ml. Thus the maximum number of benign and premalignant cases was in 4-10 ng/ml range and the maximum malignant cases were in the range above 10ng/ml. It was also observed that there was a maximum overlap of benign, premalignant and malignant conditions in the range of PSA value 4 -10ng/ml. So this is the 'grey zone' level in our study. A study in Pakistan had almost similar results in which, in the range of 4-10 ng/mL 50% of BPH and 30% of prostatic carcinoma were present. In the higher values of >10 ng/mL, the incidence of carcinoma of the prostate was highest being 50% and 21.9% of BPH were found. Another study also corroborates with our study in which in 4-10 ng/ml PSA concentration, BPH was the predominant contributor (50%). And in the cutoff >10 ng/ml Ca prostate was dominant (50%). A recent study in the western part of India shows a high level of serum PSA is associated with adenocarcinoma with a mean PSA value of 17.6ng/ml [17-19]. Different workers have reported similar ranges of serum PSA for the diagnostic "grey zone", for instance, the study from Pakistan used a cutoff of 4-10 ng/mL and Ortega et al. used 2.5-10 ng/mL which are similar to our study [17,20].

## CONCLUSION

So, in this Eastern part of India prostatic lesions are common in the geriatric age group as in other parts of India and outside. Benign hyperplasia and carcinoma of the prostate are increasingly frequent with advancing age in the 6th to 7th decade and are uncommon before the age of 40. Benign diseases are far more common than malignant ones, BPH being most common followed by prostatitis. The incidence of malignant lesions is near about 10%.

All types of patients have a prostatic enlargement on DRE and USG findings and around 50 to 57% of patients who have a suspicious finding of malignancy on DRE and USG show positivity on histopathology. Higher serum PSA value of more than 10 ng/ml is more associated with carcinoma. Though serum PSA value 4 -10ng/ml is the 'gray zone', but is more commonly associated with benign and premalignant lesions. Normal serum levels less than 4ng/ml may be associated with BPH.

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