# **Original Article**



# An Observational and Cross-sectional Study on Prostate Specific Antigen among Patients with Benign Hypertrophy of Prostate in a Tertiary Care Hospital of Bihar

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## **ABSTRACT**

*Introduction:* PSA, an organ specific single chain glycoprotein released from the epithelial cells located in prostate gland. It is a well-known marker of prostate carcinoma, moreover it is postulated to have role in other prostate pathologies too. These pathologies include prostate inflammation, bacterial prostatitis, Benign Prostate Hyperplasia (BPH) and Urinary Tract Infection (UTI). Out of these, BPH is the commonest benign tumors affecting male population. The estimated prevalence ranges from 50% in the 6th decade of life and 90% for those in the 9th decade.

*Materials and Methods:* The current hospital-based, cross-sectional study was conducted on 148 known cases of BPH visiting the OPD of Darbhanga Medical College & Hospital, Laheriasarai, Bihar and underwent for serum PSA assay. The serum PSA levels was done by ELISA. Routine investigations included CBC, KFT, FBG and USG. All the statistical analysis was plotted using Microsoft Excel 10.0.

**Results:** No significant association was noted between serum PSA and age groups of BPH patients. Though it was noted that serum PSA is strongly correlated with PV and PSA density among patients diagnosed with BPH.

**Conclusion:** We conclude that there was no association between age specific reference range and serum PSA levels. But PV and PSA density must be kept in mind while making interpretation for PSA level so as to improve the diagnostic capability of PSA for any prostate related pathology.

Keywords: Benign prostatic hyperplasia, Prostate specific antigen density, Prostate volume, Urinary tract infection.

#### **INTRODUCTION**

rostate cancer has been reported to be the most common malignancy among the elderly male population. Globally, the proportion of population diagnosed with prostate cancer is rising. <sup>1</sup> This can be attributed to the demographic transition from the adult and the elderly population. Other reasons are improvement in the health services and health seeking behavior. <sup>2</sup> Early detection of the disease is known to cure. To measure the growth of prostate and to detect the presence of malignancy at the earliest, Prostate Specific Antigen (PSA) test is used. Other diagnostic parameter to confirm the diagnosis is USG using International Prostate Symptom Score.

PSA is a 237 amino acid protein of the kallikrein family with a single-chain glycoprotein. The proenzyme (proPSA) is secreted by the secretory cells of the prostate gland which is proteolyzed by removing the pro-peptide group. After that it is released in the blood stream in measurable state. In the situations, PSA can be increased in the conditions like growth of prostatic tissue, inflammation of the prostate, UTI, trauma to the perineal area and male ejaculation. <sup>3</sup> Abnormally higher PSA level can indicate malignant changes development of cancer in the prostate gland. However, high levels of PSA can also be found in other conditions that are noncancerous. One such most

common condition with elevated PSA is BPH that is enlargement of the prostate gland. 4,5

#### **METHODOLOGY**

The current hospital-based, cross-sectional observational study was conducted in the Department of Biochemistry, Darbhanga Medical College & Hospital, Laheriasarai, Bihar, India. The study period was January 2023 to December 2023, during which 148 known cases of BPH visited the OPD and underwent PSA evaluation. Informed consent forms were duly signed by the participants before inclusion in the study. All the patients were explained about the details of the study in the local language. Ethical approval was obtained from the Institutional Ethics Committee. All the patients who were more than 45 years of age and presented with lower urinary tract symptoms were approached for participation. Patients diagnosed with carcinoma of the prostate gland were excluded from the study. Also, any individual on drugs that are known to alter the PSA levels or the history of diabetes, tuberculosis, urinary tract infection and hypertension were also excluded from the study.

Maintaining all sterile precautions, blood samples were obtained from each one of the participants in a fasting state after overnight fasting. After clotting, serum was separated by centrifugation at the rate of 2200-2500 revolution per minute done for 15 minutes at the room



temperature. The serum samples were labeled and sent for PSA estimation that were strictly carried out within 24 hours. Complete Blood Count was done by auto analyzer (Transasia Bio-medicals Ltd.,). <sup>6</sup> Total Serum Protein (TSP) was estimated by the Biuret method, FBG by glucose oxidase method, serum urea by modified Berthelot method, serum creatinine by Brod and Sirota method by using semi-auto analyzer. <sup>7-10</sup> The serum PSA levels of these patients were estimated through Sandwich ELISA (enzyme linked immunosorbent assay) by ELISA PSA kit (Cal Biotech Company, PS235T). <sup>11</sup> Transabdominal USG reports were collected from each patient and then PSA density was calculated by PSA/PV.

## Statistical analysis

Collected data was compiled and entered into Microsoft Excel 10.0. Relevant descriptive statistics was done. Result has been expressed in text, table or figures, as appropriate.

#### **RESULTS**

All the routine investigations were within normal limit in this study. The mean age of the patients was 59.7±12.5 years. The maximum number of patients were in their 7<sup>th</sup> decade of life. The mean PSA was 2.91±3.27 ng/mL and ranged from 0.41-11.6 ng/mL. Levels of PSA varied with the age pf the patients. Though no significant difference was observed between the PSA levels and the age pf the patients. Among BPH patients the mean PSA was 18.65±12.62 ng/mL and the mean PV was 36.4±29.82 mL. Among BPH patients the mean PSA was 18.32±14.63 ng/mL and the mean PSA density was 0.19±0.0 ng/mL. Both these parameters had statistically significant association with the mean PSA. [Table 1]

Table 1: Correlation of PSA among patients with BPH scattered among various age groups

Age (years)	N	PSA (ng/ml)	y/ml) Number of cases based on PSA			Mean±SD	P value
			<4	4-10	>10		
50-59	43	0.4 - 9.2	32	11	0	3.1±2.1	>0.05
60-69	57	0.51 - 11.2	13	39	5	3.3±2.7	
70-79	31	0.62 - 10.3	8	15	8	3.2±2.4	
80-89	15	0.21 - 12.76	4	6	5	4.9±3.2	
90 & above	2	2.7 - 13.6	1	0	1	3.2±1.9	

#### **DISCUSSION**

Based on out finding, we conclude that age is not associated with the PSA levels and PSA does not fluctuate in respect to the age of the BPH patients. In our study highest level of PSA was noted in the 7th decade of life and majority of the patients were from this age group also. The findings in respect to age of the patients is consistent with the study of Deori R et al. <sup>7</sup> In contrast to our study, Mosli HA et al., Casey RG et al., and Deori Ret al., found out that age was significantly correlated with PSA as the levels of PSA increased with advancing age. 6,7,11 As per findings of Casey RG et al., age specific reference ranges are available to increase the specificity and sensitivity of PSA. According to their study, increased PSA may be result of pathology rather than senile changes. <sup>6</sup> Similar results has been given by Deori R et al. 7 It is known that PSA levels more than 10 ng/mL is associated more with the risk to witness malignant changes. Those with PSA levels less than 4 ng/mL are at least risk of malignancy while the range of 4 to 10 ng/mL represents the 'grey zone'. 13 Hence, these age specific range of serum PSA levels makes this parameter a better predicting tumor marker for early detection of malignant changes among the elderly male population.

Among patients with BPH, the volume of prostate glands increases leading to increased PSA. There is a physiological fluctuation in the PV through the life or during the course of different prostate related pathologies. The mean PSA in

the present study was 2.91±3.27 ng/mL and the mean PV was 36.4±29.82 mL. PSA and PV were significantly associated which was almost similar to other studies. Mosli HA et al., concluded that PV and PSA are the key determinants of clinical course, response to treatment and any prostate-related pathology. Levels of PV and PSA were seen to fluctuate hugely with age. PSA and PV showed a significant and strong positive correlation in previous studies. 12, 15 In Indonesian men with BPH, both PV and PSA increased with age and PV was found to be significantly correlated with PSA. 16 In a study by Deori R et al., changes in PV and serum PSA vary with ages. They also reported that PSA and PV have a statistically significant and strong positive correlation. <sup>7</sup> The mean PSA in our study was more than the two studies (Putra IB et al., and Deori R et al.,), this may be because of small sample size or different study population characteristics. They also found that PSA and PSA density were correlated in patients with BPH 17-19 PSA density is known to be an accurate predictor of prostate malignancy. Though this association may be limited by several factors. 17 It is derived by dividing the serum PSA specificity by adjusting for that component of the serum PSA that may arise from benign elements. The largest determinant of prostate size is the transition zone, with expansion resulting from the development of benign prostatic hypertrophy. 18 Kuppusamy S et al., found that PSA density value improves the diagnostic performance of total



PSA level, especially in the range of 4.01 to 30.00 ng/mL as the incidence and cancer detection was quite low.

#### **CONCLUSION**

There was no correlation with age of BPH patients and their PSA levels. PSA did not increase or decrease among different age groups in this study. Hence, age should not be considered with making diagnosis or prognosis based on PSA levels among BPH patients. PSA density is known to increase the diagnostic capability of PSA. Also, PV was significantly correlated in BPH patients as increase in PV is found to be associated with increased serum PSA level.

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