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A retrospective study on significance of total and free Prostate specific antigen (PSA) level with their ratio in diagnosis of prostatic lesions at a tertiary care centre

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Abstract

Background: Prostate specific antigen (PSA) is a protein made by prostate and is produced by cancerous as well as non-cancerous cells. PSA is screening test used to detect undiagnosed prostate cancer in men. Normally it is present in small quantity with healthy prostate (<4 ng/ml) but often elevated in other prostatic lesion like BPH, Acute and Chronic prostatitis and prostatic adenocarcinoma.

Materials and Methods: Our study includes total of around 70 patient presented with complaint of dribbling of urine, increased frequency and urge incontinence on digital rectal examination (DRE). Tests were performed on random blood serum by 3rd generation ELISA (immunoassay principle).

Results: 70 patients were involved in our study among which it was found 44 had total PSA moderately elevated (4.0-10.0 ng/ml) suggesting high risk category. 16 Patients with PSA<4.0ng/ml were considered low risk. 10 Patients had low % Free PSA and were referred for biopsy to confirm prostatic malignancy.

Conclusion: PSA in the range of 4 to 10 ng/ml identified men as high risk. Most patients with PSA in this range were observed to have early stage disease, while more than half of the men with PSA levels above 10ng/ml had advanced disease. Thus, the detection of prostate cancer in its potentially curable stages requires the use of % FPSA to group individual men into low risk (high % FPSA & low Total PSA) to high risk (low % FPSA & high total PSA) to help in biopsy decisions.

Keywords: Benign prostatic hyperplasia, prostatic adenocarcinoma, prostatic biopsy

Introduction

PSA- Tumor markers are substances that can be detected in higher than normal amount in the blood, urine or body tissue of some patient with certain type of cancer. A tumor marker may be produced by a tumor itself or by the body in response to the presence of cancer [1].

PSA is synthesized in the prostatic ductal epithelium and prostatic acini. The lumen of the prostatic gland contains the highest concentration of PSA in the body, a number of barriers exist between the glandular lumen and the capillaries. Disease such as infections, inflammations and cancer may produce a breakdown in this barrier allowing more PSA to enter the circulation [2, 3].

PSA is a protein produced by both cancerous as a well as non cancerous cells. The prostate specific antigen (PSA) level in the blood may be elevated in men who have prostatitis, benign prostatic hyperplasia and any kind of malignant growth in the prostate gland. While PSA does not allow to distinguish between benign prostatic condition and cancer, an elevated serum PSA level may indicate that other tests are necessary to determine whether cancer is present or not [1]. Total PSA, free PSA & % free PSA level which is the ratio of free PSA & total PSA is studied here to correlate the significance in the early diagnosis of prostatic cancer.

Aims and Objectives

1. To introduce Prostate Specific Antigen level testing in routine diagnosis as well as a screening procedure.
2. To assess the diagnostic accuracy of Prostate Specific Antigen level in prostatic enlargement such as in various neoplastic and non neoplastic lesions.
3. To correlate the serum Prostate Specific Antigen findings with histopathological study.

Materials and Methods

Type of study: Retrospective study

Duration of study: The present study consists of 70 cases of prostatic enlargement for a period of 2 year between July 2021 to June 2023.

Type of sample: Whole blood was collected in plain vacuette and serum was separated from it and tests were performed.

Inclusion criteria

1. All male patient with urinary symptoms of;
 - a. Increased frequency
 - b. Dribbling of urine
 - c. Urge incontinence
2. Residual urine
3. All male patient with enlarged prostatic gland on DRE (Digital Rectal Examination)

Exclusion criteria

- 1) Men with late stage prostate cancer.
- 2) Men with hormone refractory or recurrent prostate cancer.

Material & Method & Principle of the test [4]

This test is based on automatic ELISA plate analyser assay. QUALISA is a quantitative test kit is a sandwich based enzyme linked immunosorbent assay principle. Tested sample were placed into the microwells coated by specific murine monoclonal to human total/free PSA-antibodies. Antigen from specimen was captured by the antibodies coated onto the microwell surface. Unbound material was removed by washing procedure. Second antibodies-murine monoclonal to human total/free PSA, labelled with peroxidase enzyme was then added into microwells. After washing procedure, the remaining enzymatic activity bound to the microwell surface was detected and quantified by addition of chromogen-substrate mixture, stop solution and photometry at 450 nm. Optical density in microwell was directly related to quantity of the measured analyte in the specimen.

Results

In the present study, the presenting complaints of cases with prostatic disease included dribbling of urine after completing of urination and incomplete emptying sensation. In all the cases a detailed history was taken and physical examination was done which include digital rectal examination. All the cases had suspicious DRE. All the 70 cases were evaluated by serum PSA level. In all cases (70) histopathological examination of prostate biopsy was done in histopathology section of our college.

Table 1: Age wise distribution of 70 patients with prostatic lesions at different cut off level of serum PSA level (n=80)

Age	Serum PSA level (ng/ml)			No. of patients
	<4.0	4 to 10	>10	
40-49	1	2	0	3
50-59	6	8	1	15
60-69	10	22	5	37
70-79	1	15	3	19
>80	0	4	2	6
Total	18	51	11	80

In Table No.1, maximum no. of patients were from 6th decade, 72.97% (27 out of 37) had serum PSA value higher than 4 ng/ml.

In patients above 7th decade, 96% (24 out of 25) had serum PSA value higher than 4 ng/ml.

In patients below 5th decade, 61.11% (11 out of 18) had serum PSA value higher than 4 ng/ml.

Table 2: Age wise distribution of free PSA value in patients with total serum PSA >4 ng/ml (n=62)

Age (Years)	Mean free PSA value (ng/ml)
<50	0.539 (n=2)
50 to 59	0.765 (n=9)
60 to 69	1.44 (n=27)
70 to 79	1.46 (n=18)
>80	1.63 (n=6)

Table No.2 shows age wise distribution of mean free PSA value, 0.539 ng/ml in <50 years, 0.765 ng/ml in 50 to 59 years, 1.44 ng/ml in 60 to 69 years, 1.46 ng/ml in 70 to 79 years and 1.63 ng/ml in >80 years.

Table 3: Comparison of malignant and non malignant prostatic lesion according to % free PSA value (Serum PSA value >4 ng/ml) (n=62)

% Free PSA	Probability of cancer (%)	No. of Patients	Malignant	Non-Malignant
0-10	56	16	06	10
10-15	28	10	01	09
15-20	20	08	02	06
20-25	16	16	00	16
>25	08	12	00	12

Table No.3 shows out of 16 patients with 0-10% free PSA, 06 patients had a malignant lesion and 10 patients had non malignant lesion.

Out of 10 Patients with 10-15% free PSA, 01 patient had a malignant lesion and 09 patients had non malignant lesion.

Out of 08 Patients with 15-20% free PSA, 02 patients had a malignant lesion and 06 patients had non malignant lesion.

Out of 16 Patients with 20-25% free PSA, all were non malignant on histopathology.

Out of 12 Patients with >25% free PSA, all were non malignant on histopathology.

Discussion

Prostate cancer is very uncommon before the age of 50 years, but its frequency climbs steeply with age to peak in the 9th decade for both incidence and mortality rate [5]. Two of the reasons for the high mortality are that many patients have incurable disease at the time of diagnosis and patients with potentially curable tumors are rarely symptomatic. To reduce mortality from this disease, screening has frequently been recommended for asymptomatic men in the high risk age group [6].

Prostate specific antigen is the initial screening test and most useful marker for early detection of prostate cancer. Although PSA is invaluable marker for screening, it is prostate specific but not cancer specific, since PSA may also be elevated in prostatic hyperplasia. The discrimination between prostate carcinoma and prostatic hyperplasia is potentially more problematic in patients with serum PSA values between 4 to 10 ng/ml. Several other methods have been proposed to identify cancer patients with intermediate serum PSA level [7].

The finding of present study are consistent with other studies when using serum PSA cut off level 10 ng/ml. But the detection rate of other studies is higher when using serum PSA cut off level 4 ng/ml especially in those selected

cases suspicious for malignancy on digital rectal examination or ultrasonography or both. This is because in the present study all cases were selected whether suspicious for malignancy by other parameter or not.

Table 4: Shows comparison of sensitivity, specificity and positive predictive value of serum PSA test at different cut off level to detect prostatic malignancy.

Study	Serum PSA cut off level	Sensitivity%	Specificity%	Positive predictive value%
Roger <i>et al</i> (1997) ^[10]	4 ng/ml	86.7	27.7	43.4
	10 ng/ml	63.9	73.1	60.2
Muhittin <i>et al</i> (2002) ^[11]	4 ng/ml	93.88	21.05	60.53
	10 ng/ml	44.90	68.42	64.71
Amayo <i>et al</i> (2004) ^[12]	4 ng/ml	89.8	37	49
	10 ng/ml	-	-	-
Present study	4 ng/ml	100	25.35	24.51
	10 ng/ml	77.77	94.36	63.63

In table no.4, the present study using cut off value 10 ng/ml, the findings of sensitivity, specificity and positive predictive value were 77.77%, 94.36% and 63.63% respectively which are quite comparable with other authors.

Serum PSA estimation is invaluable test for detection of prostatic malignancy but as it is affected by many factors and also increases in prostatic non malignant lesions, limiting its diagnostic accuracy especially when the values obtained are between 4.0 to 10.0 ng/ml. In such cases it requires help of other parameters also to confirm or rule out the diagnosis.

Conclusion

- The serum PSA levels are a good indicator for the glandular proliferation of the prostate and they can be used as a marker to check for the diagnosis and progression of prostate carcinoma.
- Serum PSA can be used as marker of choice in primary diagnosis of a prostatic enlargement when an early diagnosis is required or when an invasive methods like FNAC/Biopsy is not possible due to patient's condition.
- Percentage of free PSA is more significant than total PSA & free PSA alone.
- Percentage free PSA also helps in selecting the patients who will require prostate biopsy and unnecessary biopsies can thus be prevented.

Conflict of Interest

Not available

Financial Support

Not available

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