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Pathoclinical Correlation of Digital Rectal Examination, Serum Prostate-Specific Antigen & Trans-Rectal Ultrasound-Guided Biopsy in Prostate Cancer – An Institutional Review

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Abstract:
Background*: The incidence of prostate cancer (PCa) is higher in Australia, North America, and European countries and low in Asia.* PCa remains underdiagnosed in the developing world where it often presents late. *Traditionally, abnormal digital rectal examination warrants serum PSA (Prostate-Specific Antigen) levels where a cut-off of 4.0 ng/mL has been used to recommend prostate biopsy that forms the cornerstone in diagnosing and treating this disease. Over the last two decades, TRUS has become the gold standard in performing prostate biopsies although the trend is changing towards transperineal biopsy in recent times. The reported cancer detection rate of Trans-Rectal Ultrasonography (TRUS) guided biopsies ranges between 30- 40 percent in western countries and about 20 percent in Asian countries.*
Materials and Methods*: In this prospective randomized controlled study, 62 male patients seen for 2 years in a single institution with abnormal DRE, serum PSA was subjected to TRUS and TRUS biopsy at our institution during the study period June 2017 to June 2019 and the data were analyzed to correlate clinical, laboratory and pathological findings.*
Results*: In our study, those patients with proven carcinoma prostate on TRUS biopsy, 48 patients had abnormal DRE (Sensitivity- 90.57%, Specificity – 91.67%) and 26 patients had elevated PSA levels (Sensitivity- 72.87%, Specificity- 94.37%). When all three modalities were combined, it further increased the sensitivity to 93.23% and specificity to 97.47% implying combined modality had a better cancer detection rate.*
Conclusion: *Our study concludes that there is a strong correlation between patients with abnormal DRE, elevated PSA, and abnormal TRUS findings. The diagnosis of prostate cancer is most predictable when PSA and DRE together with TRUS yield suspicious findings of malignancy.*
Key Word*: Prostate Cancer; Digital Rectal Examination; Serum PSA; Trans-rectal Ultrasound; Biopsy*

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I. Introduction

Prostate cancer is the commonest malignancy among males in most parts of the world. Although the incidence of prostate cancer is increasing in the developed world, it remains under-diagnosed in the developing world where it often presents late. Biopsy of the prostate forms the cornerstone in diagnosing and treating this disease. Historically, needle biopsies of the prostate have been performed either transrectally or trans-perineally, with digital palpation of the gland and guidance of the biopsy needle per rectum. Three important developments significantly changed the way prostate cancer was diagnosed in the early 1990s. Firstly, the adoption of a systematic rather than random biopsy scheme as described by Hodge et al. Secondly, the use of a biopsy gun as opposed to hand-operated Tru-cut needles and thirdly, the advent of the transrectal ultrasound (TRUS) probe enabling the clinician to visually guide the biopsy needle.

Over the last two decades, TRUS has become the gold standard in performing prostate biopsies. The initial work from Stanford University demonstrated that TRUS biopsies diagnosed cancer in 23 of 43 patients. In a further publication in the same journal, they showed that the yield of prostate cancer was better with six systematic random biopsies of abnormal areas in the prostate. The benefits of ultrasound in guiding biopsy needles became more apparent as the understanding of prostate anatomy and distribution of carcinoma improved, assisted by McNeal's description of the different zones. Since then, much work has been done to determine the optimal sites and numbers of prostate biopsies to maximise cancer detection of what remains a

test with a significant sampling error. The consensus today for initial biopsies is to use a minimum of 10–12 laterally directed biopsies from the peripheral zones with the use of TRUS.

II. Material And Methods

The study population included a total of 62 male patients seen for 2 years in a single institution with abnormal DRE, serum PSA was subjected to TRUS and TRUS biopsy at our institution during the study period June 2017 to June 2019.

Study Design: Prospective open label observational study

Study Location: This was a tertiary care teaching hospital-based study done in Department of Urology, at Stanley Medical College, Chennai, Tamil Nadu, India.

Study Duration: November 2019 to November 2021.

Sample size: 62 patients.

Subjects & selection method:

Inclusion criteria:

1. All male patients above 40 years of age with abnormal DRE/ elevated PSA

Exclusion criteria:

1. Patient with bleeding diathesis and abnormal coagulation profile
2. Patients under 40 years of age
3. Patient with LUTS of non-prostatic origin i.e vesical/urethral calculus, elevated bladder neck, bladder malignancy
4. Anterior tumors on MRI Pelvis that cannot be accessed for TRUS guided biopsies

Procedure methodology

After written informed consent was obtained, TRUS guided biopsy data were prospectively collected, on a standardized proforma at the time of biopsy and combined with the histological findings. Only patients with complete data sets were included in the study. Clinical parameters included patient demographics including age, the reason for intervention, PSA value, and clinical findings on DRE. Absolute PSA values were recorded and subsequently subdivided for analyses into five groups: 0–4, 4–9.9, 10–19.9, 20–99.9, and >100 ng/mL.

TRUS was performed using a Mindray DP-50 diagnostic ultrasound machine with a 7.5-MHz transrectal probe. Informed consent was obtained and antibiotic prophylaxis was administered orally 30 min before the procedure. Proctolytic enema was given 4 hours before the procedure. The majority of the patients received local anaesthesia with intrarectal instillation of 20 mL of 2% lignocaine jelly. Few patients received periprostatic needle infiltration of local anaesthesia.

The findings on TRUS were documented for both the right and left lobe as follows: the presence of hypoechoic areas and/or calcifications in the periphery and the centre of the glands as well as the presence of capsular distortion or the visualization of a palpable irregularity. The prostate gland was assessed in the axial plane where the transverse and anteroposterior measurements were taken at the point of maximum diameter, followed by a paramedian longitudinal measurement in the sagittal plane.

The volume was calculated using a standard pre-programmed formula {$\pi/6 \times$ (transverse diameter) $\times$ (anteroposterior diameter) $\times$ (superior-inferior diameter)} based on an ellipsoid shape.

The biopsies were taken with a Bard biopsy gun, 17 mm tip. The number of biopsies taken was documented prospectively in the TRUS group as either the routine 12 cores (2 cores from apex, mid-zone, and base of prostate on the periphery of either lobe) or the routine 12 cores plus additional biopsies of suspicious areas (on ultrasound or digital examination) and sent for histopathological examination.

Statistical analysis

Data were compiled using Microsoft Excel® and statistical analysis was performed by a biostatistician on Stata® software using the Mann–Whitney U test for continuous variables and the Pearson's chi-squared test for categorical variables. A two-tailed p-value <0.05 was accepted as significant with a power of 80%.

III. Result

Over a 24-month period complete data sheets and pathology reports were collected in 62 patients who underwent TRUS, TRUS guided biopsies, and post-operative specimen HPE at our hospital. Predominant iso-echoic prostate glands (53%) on TRUS were of benign origin concurring with the other studies. Of the 4 lesions that were hyper-echoic (7%) on TRUS, 3 were malignant and one was labeled as High-grade PIN [HG PIN}, a premalignant precursor lesion. In the remainder hypo-echoic (40%) lesions, 76% showed malignancy, with 2 lesions labeled as low-grade PIN [LG PIN], essentially a benign condition as proved by many other studies and

one patient had granulomatous prostatitis on TRUS biopsy and post-TURP showed benign adenomatous hypertrophy.

Figure No. 1: Results of TRUS findings

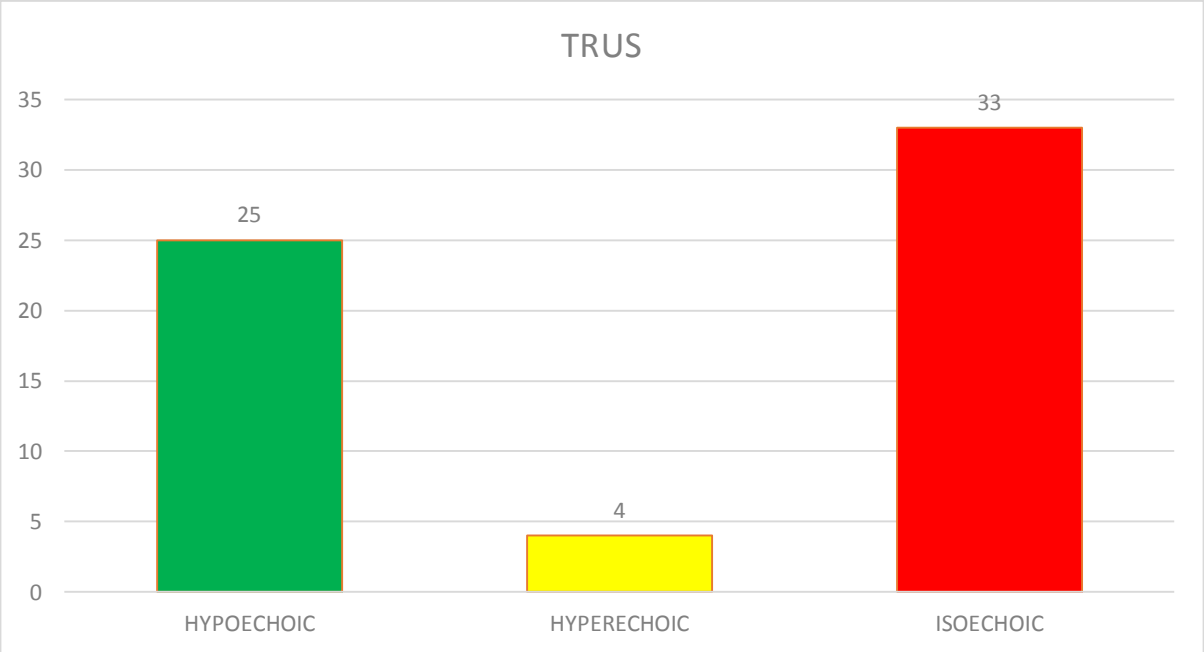

Figure No. 2: Results of TRUS guided biopsy

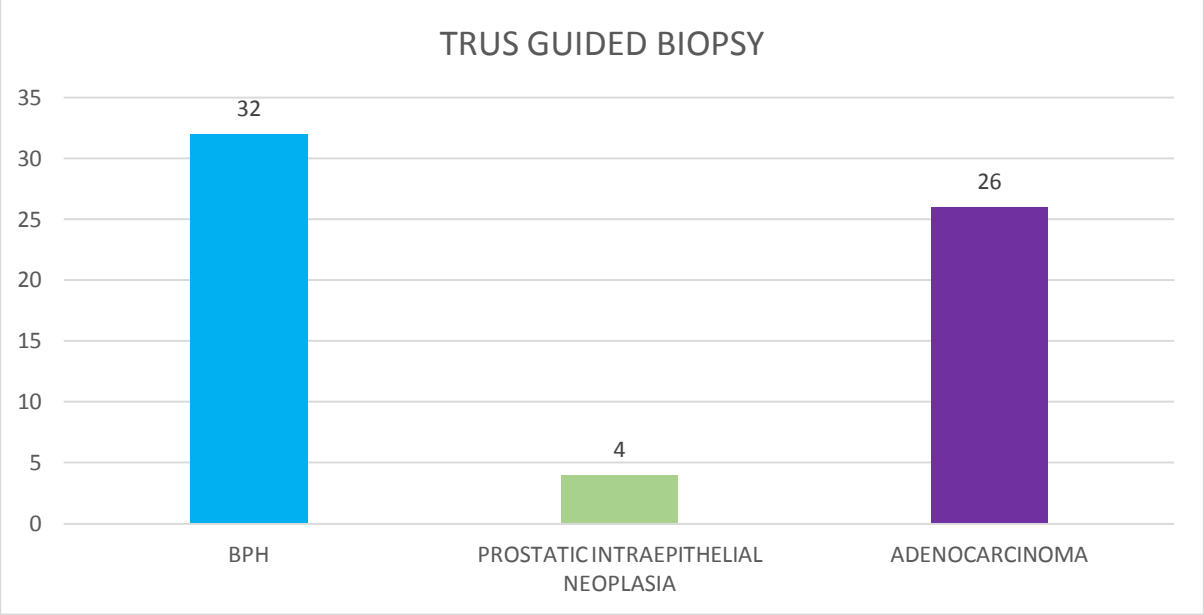

TABLE 1: RESULTS OF TRUS GUIDED BIOPSY

BPH	32
PROSTATIC INTRAEPITHELIAL NEOPLASIA	4
ADENOCARCINOMA	26

TABLE 2: Correlation of TRUS findings and Biopsy

TRUS	**HPE [POST TURP]**		
	BPH	**PIN**	**ADENOCARCINOMA**
HYPO-ECHOIC	4	2	19

ISO-ECHOIC	26	1	6
HYPER-ECHOIC	0	1	3
TOTAL	30	4	28

Figure No. 3: Finding in TRUS Biopsy

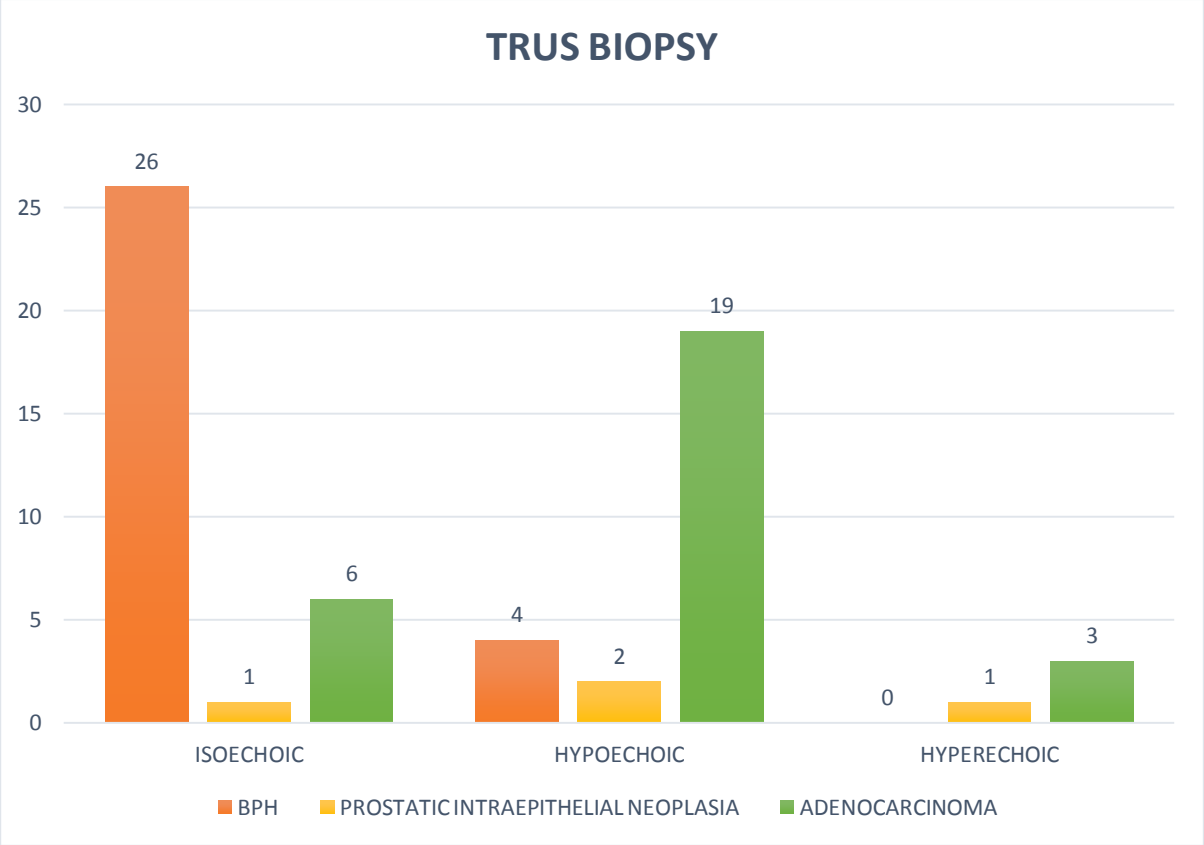

TABLE 4: Correlation of HPE And Serum PSA levels

PSA LEVELS (ng/ml)	**BENIGN**	**PIN**	**MALIGNANT**
0 to 4	5	-	-
4 to 9.9	4	-	2
10 to 19.9	16	3	6
20 to 99.9	6	1	14
More than 100	-	-	5

Figure No. 4: Correlation of DRE, Serum PSA Levels And Histopathological examination reports.

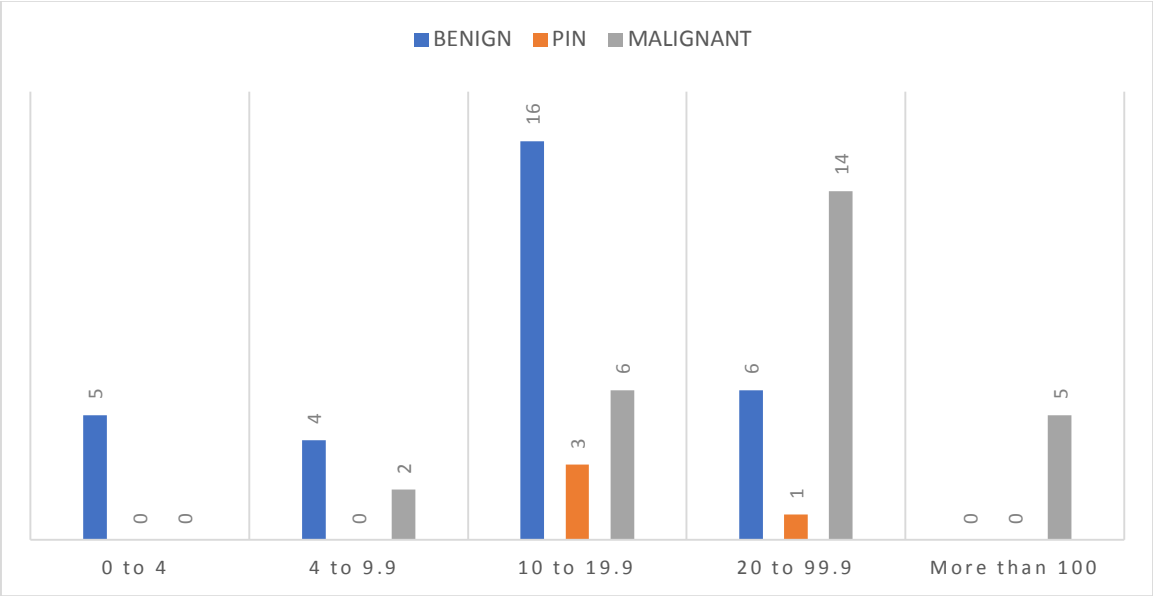

TABLE 5: Correlation of DRE, Serum PSA Levels And Histopathological examination reports.

HPE	PSA > 4	NODULAR DRE	TRUS
BENIGN	25	9	29
PRE-MALIGNANT	4	3	4
MALIGNANT	26	48	27

IV. Discussion

With the description of zonal anatomy by McNeal and the advent of transrectal sonography, the various pathological processes became better defined especially for screening for nonpalpable prostatic carcinoma. The earliest studies in TRUS showed prostatic carcinoma predominantly is an echogenic lesion. Benign lesions like BPH were limited to the transition zone and appeared mostly as a diffuse textural change.

In our series prostate carcinoma appeared mostly hypoechoic focal lesion in the peripheral zone in 19 patients out of which all proved correct on histopathology. Two cases were labeled as BPH and proved to be PIN. 5 of the Iso-echoic prostate on TRUS proved to be malignant. There was a positive correlation between TRUS findings suggestive of carcinoma and PSA levels. Patients with an excess of 10 nmol/ml had predominantly malignancy. JS Wolf demonstrated increased accuracy of the combined staging method using TRUS and PSA. Cooner et al found 45 cases out of 144 screened by TRUS with PSA levels > 10 ng/ml having prostatic carcinoma and concluded that every patient with significantly raised PSA levels should have TRUS examination. Petter Littrays et al suggested a close relationship of prostatic volume to PSA levels. Wolf et al showed that the volume of the hypoechoic lesion is an independent variable for the staging of carcinoma prostate. The use of combined modality screening such as TRUS + PSA showed increased accuracy compared to DRE or TRUS as a stand-alone modality. Thus TRUS + PSA significantly scores over as a screening combination. Wolf et al showed that by combining prospective TRUS evaluation with retrospective PSA analysis, there was increased accuracy of this combined staging/screening method compared to TRUS alone. In our study, those patients with proven carcinoma prostate on TRUS biopsy, 48 patients had abnormal DRE (Sensitivity- 90.57%, Specificity – 91.67%) and 26 patients had elevated PSA levels (Sensitivity- 72.87%, Specificity- 94.37%). When all three modalities were combined, it further increased the sensitivity to 93.23% and specificity to 97.47% implying combined modality had a better cancer detection rate.

V. Conclusion

Our study concludes that there is a strong correlation between patients with abnormal DRE, elevated PSA, and abnormal TRUS findings. The diagnosis of prostate cancer is most predictable when PSA and DRE together with TRUS yield suspicious findings of malignancy. Abnormal PSA is more predictable than abnormal DRE, and abnormal PSA and DRE combined are even more predictable. Nevertheless, TRUS biopsy should be done in the presence of prostate-related voiding symptoms in the presence of abnormality in at least one of those parameters.

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