

## TRANSRECTAL ULTRASONOGRAM: CLINICAL APPLICATION AND CORRELATION IN CANCER PROSTATE

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### ABSTRACT

**Background:** Aim of this study is to evaluate the efficacy of Trans Rectal UltraSonogram [TRUS] in the diagnosis of cancer prostate in patients who presented with abnormal digital rectal examination [DRE] or high level of Prostatic Specific Antigen [PSA] or both.

**Methods:** A total of 100 patients with the age of 50 to 80 were enrolled in this study. Patients who have abnormal digital rectal examination [DRE] or high PSA level [4ng/ml to 10ng/ml] or both were included in this study. An informed consent was obtained. Trans Rectal Ultra Sonogram [TRUS] was performed for all patients and their prostate echo texture is identified and labeled as hypo echoic, hyper echoic, iso echoic and mixed echoic. Then Trans Rectal Ultra Sonogram guided 12 core biopsy was performed with specific importance to the suspicious lesions. The biopsy results were correlated with the ultrasound findings and the results were analyzed.

**Results:** In our study we observed that 65% of hypo echoic lesions of prostate are malignant, 35% of iso echoic lesions are malignant, 14% of mixed echo texture are malignant. All hyper echoic lesions in our study are found to be benign.

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## INTRODUCTION

### Background

Aim of this study is to evaluate the efficacy of Trans Rectal UltraSonogram [TRUS] in the diagnosis of cancer prostate in patients who presented with abnormal digital rectal examination [DRE] or high level of Prostatic Specific Antigen [PSA] or both. Trans Rectal Ultra Sonogram was performed in all patients and the result of the TRUS is finally correlated with the biopsy report of prostate.

### Methods

A total of 100 patients were enrolled in this study. The period of study was 2 years from September 2014 to August 2016. Inclusion criteria are 1. Age- 50 to 80 years, 2. Abnormal DRE, 3. High level of PSA [4 to 10ng/ml], 4. both the above [2&3] and 5. Informed consent. Exclusion criteria: 1. Rectal pathology, 2. coagulopathy, 3. patient on anti coagulants. Trans Rectal Ultrasound was performed in all patients of the study group. The findings of the echo texture in each patient was observed and labeled as hypo echoic, iso echoic, hyper echoic and mixed echoic. Then TRUS guided biopsy was performed with specific importance to the suspicious lesions using 12 core biopsy technique. The biopsy results were correlated with the echo texture of TRUS and the results were analyzed.

The age of patients included in the study ranges from 50 to 80 years. The mean age of high density distribution was found to be 65 years.

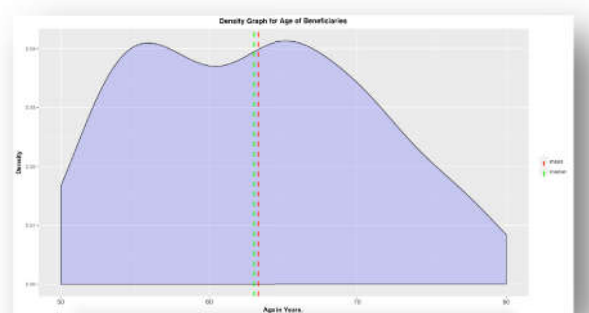


Figure 1 Age Density Distribution in the Study Group

Among the 100 patients in the study group, we observed high Prostatic Specific Antigen [PSA] levels in 71 patients.

65 patients in the study group were found to have abnormal Digital Rectal Examination [DRE].

37 patients had both High PSA level and abnormal Digital rectal examination [DRE].

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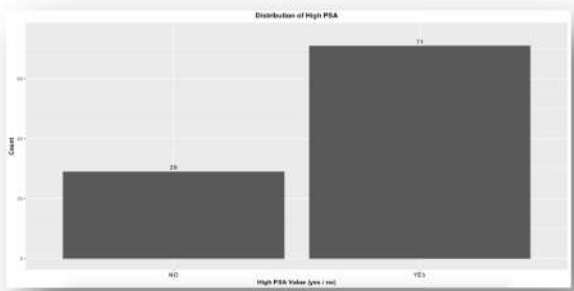


Figure 2 Distribution of High Psa

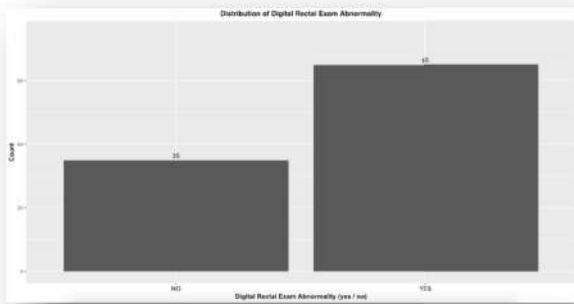


Figure 3 Distribution of Abnormal Digital Rectal Examination

All the patients were subjected to Trans Rectal Ultra sonogram [TRUS] and the echo texture of the prostate was noted in each individual.

Our results in the TRUS are listed below.

Trus report	Total patients [100]
Hypoechoic	69
Isoechoic	20
Hyperechoic	3
Mixed echoic	7

All the patients have undergone TRUS guided Prostate Biopsy. The biopsy confirmed the positive cancer patients.

The results were given below.

Trus report	Total	Biopsy-Cancer Positive	Biopsy-Cancer Negative	Percentage of the cancer
Hypoechoic	69	45	24	65.21%
Isoechoic	20	7	13	35%
Hyperechoic	3	0	3	0%
Mixed echoic	7	1	6	14.28%

In the hypo-echoic group 45 patients among the total of 69 patients were found to be positive for malignancy. The 20 patients who had an iso echoic texture in the TRUS, 7 patients were found to have malignancy. 3 patients with hyper-echoic report none of them found to be malignant. Mixed echoic result was found in 7 patients among which 1 patient was confirmed as malignant in biopsy.

S.NO	Analysis of Transrectal Ultrasonogram	Formula	Value
1	Sensitivity or True positive rate	TP/(TP+FN)	87%
2	Specificity or True negative rate	TN/(TN+FP)	35%
3	Positive Predictive Value (PPV)	TP/(TP+FP)	61%
4	Negative Predictive Value (NPV)	TN/(TN+FN)	70%
5	False Positive Rate	FP/(FP+TN)	65%
6	False Negative Rate	FN/(FN+TP)	13%
7	Accuracy	(TP+TN)/(TP+TN+FP+FN)	63%

In our study the sensitivity, specificity, positive predictive value, negative predictive value and the accuracy of Trans Rectal Ultra Sonogram were analyzed. We found out that the sensitivity is as high as 87% and so it can be used as one of the secondary screening tool with patients having high PSA levels and abnormal Digital Rectal Examination [Abnormal DRE]. But the specificity is low as 35% so TRUS can be used as a diagnostic tool only and the results should be confirmed by prostate biopsy.

**RESULTS**

Thus in our study we observed that 65% of hypoechoic lesions of prostate are malignant, 35% of isoechoic lesions are malignant, 14% of mixed echotexture are malignant. All hyperechoic lesions in our study are found to be benign.

**DISCUSSION**

Prostate cancer is the most commonly diagnosed cancer, making this disease a significant public health issue. Unfortunately, the anatomical location of the prostate does not lend itself to straight forward examination.

TRUS continues to play an important role in the evaluation of the prostate when malignancy is suspected. Although the optimal method of prostate biopsy is controversial, ultrasound is critical in ensuring accurate sampling of the gland. Trans rectal ultrasound with prostate biopsy, a generally well-tolerated outpatient procedure, in conjunction with the development of serum assays for Prostate-Specific Antigen (PSA), has resulted in an impressive change in the manner of diagnosis and stage presentation of men with prostate cancer.

**Digital rectal examination**

Historically, digital rectal examination has been the principal method of examination of the prostate. Digital rectal examination (DRE) is the primary method of examination of the prostate. This technique allows the examiner to appreciate the gland’s morphology like a discrete nodule, focal induration, a diffusely hard prostate and, in some cases, asymmetry. As a subjective examination, however, DRE has limitations. Not all prostatic malignancies are palpable on DRE (1).

**Prostatic specific antigen (psa)**

PSA is a kallikrein like serine protease secreted by epithelial cells in the prostate gland and measured in the blood. Serum levels rise when there is disruption of the basement membrane due to infection, inflammation, malignancy or after prostate manipulation. Therefore PSA is organ specific- but not cancer-specific. An age-specific normal level can be defined. Levels outside this range denote a raised risk of cancer, the risk rising with the level of PSA.

Age in years	Normal range(ng/ml)
40-49	0.0-2.5
50-59	0.0-3.5
60-69	0.0-4.5
70-79	0.0-6.5

**History of transrectal ultrasound**

Trans Rectal Ultra Sonogram (TRUS) was initially described as a technique to evaluate rectal pathology. In 1963, Takahashi and Ouchi were the first to describe the use of TRUS to evaluate the prostate. However, medical ultrasound was rather primitive at this time. The first clinically applicable

images of the prostate obtained with TRUS were described in 1967 by Watanabe *et al* (2). They used a 3.5 MHz transducer, which at that time was considered to be state of the art, to obtain images that were clinically meaningful. As ultrasound technology has become more refined, the use of TRUS in the evaluation of prostatic disease has increased. By the mid 1980s, the 7 MHz ultrasound probe, which more clearly delineated the architecture of the prostate, had become a standard diagnostic instrument of the urologist.

The current state-of-the-art TRUS probe is a 5-8 MHz hand-held, high-resolution probe with multi axial planar imaging capabilities, which has the capacity for both transverse and saggital imaging of the prostate in real time. This probe can be fitted with an adapter that accepts the needle of a spring-loaded biopsy gun, thus allowing multiple cores of tissue to be easily obtained. The visualization provided by the new higher resolution transducers, coupled with the ability to direct the biopsy needle into various regions of interest and to provide uniform spatial separation of the areas to be sampled, has helped to make TRUS-guided prostate biopsy a standard technique in the diagnosis of prostate cancer.

The probe is introduced and the contrast of the console is adjusted to provide a uniform mid-gray image of the normal peripheral zone. The shading of the peripheral zone should be the homogenous gray standard by which other areas of the prostate are classified as hyperechoic, hypoechoic, or isoechoic. Imaging of the gland is then carried out, first in a transverse fashion. The right and left seminal vesicles are viewed, followed by the bladder neck, mid gland, and apex. After complete transverse imaging, the transducer is configured to provide sagittal imaging, and the right, mid, and left aspects of the prostate are visualized. During this part of the examination, particular attention is paid to any regions that are hypo or hyper-echoic when compared to the peripheral zone of the prostate.

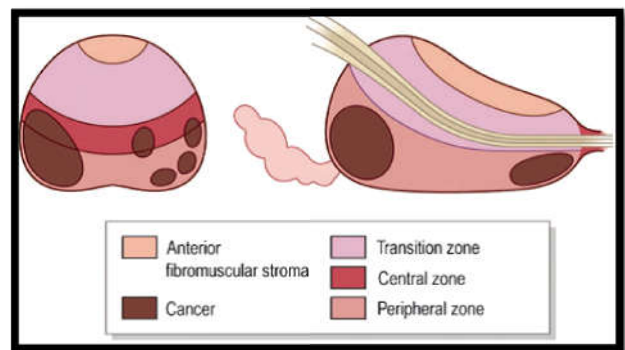
**Transrectal Ultrasonogram and Its Interpretation**

The normal prostate gland has a homogenous, uniform echo pattern. The seminal vesicles are visualized at the base of the bladder and are hypoechoic compared with the remainder of the prostate. In contrast to the homogenous appearance of the normal prostate, a prostatic malignancy may have unique ultrasound findings. Most ultrasound detected lesions found to be carcinoma are described as hypo echoic regions with irregular borders. However, this is not a rule, and the appearance of carcinoma on ultrasound is variable (3).

Evaluation of the prostate by TRUS requires a comprehensive knowledge of the anatomy of the prostate, as the current PSA-era phenomenon of stage migration has made most tumors non palpable at diagnosis. The transition zone surrounds the urethra and extends from the ejaculatory ducts proximally. The transition zone is surrounded by a discrete fibro muscular band of tissue, and it is the site of origin of benign prostatic hyperplasia. The peripheral zone encompasses the posterolateral aspect of the prostate from the base (superior) to the apex (inferior), and it accounts for the majority of the volume of the prostate. The majority (70%-80%) of prostate cancers arise from the peripheral zone. The central zone is composed of tissue immediately surrounding the ejaculatory ducts, and it expands inferiorly. The anatomic distinction between the central and peripheral zones is generally not appreciated by ultrasound. In a normal man, these two zones

are seen as a homogenous, iso echoic area in the posterior section of the prostate. Their normal echo pattern is used as a reference for defining other structures as hypo echoic or hyper echoic (4).

The normal transition zone in a young man comprises only a small percentage of the gland and thus is difficult to image. In an older man with benign prostatic hyperplasia, the transition zone expands, compressing its surrounding fibro muscular band of tissue. This compressed tissue gives rise to the “surgical capsule” of the prostate, which is a sonographic landmark of zonal demarcation. Cancer of the prostate was initially thought to have a hyper echoic appearance on ultrasound. However, recent literature confirms that modern ultrasound technique displays prostate cancer as generally a hypo echoic area (5).

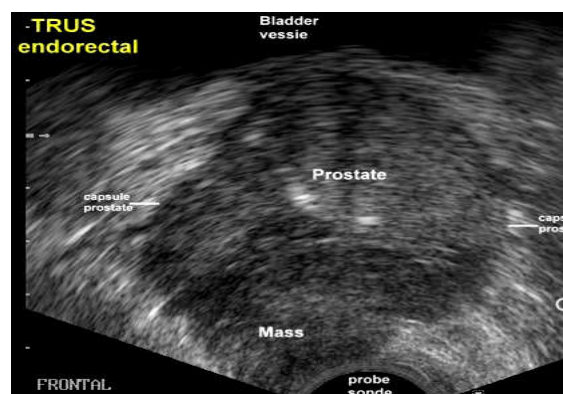


**Figure 4** Common Locations of Prostate Cancer

Lee *et al* reported that the most common sonographic appearance of prostate cancer was a Hypo echoic peripheral-zone lesion. The highest predictive values for prostate cancer are seen in hypo echoic lesions that are well defined and are larger than 1cm.

The etiology of this hypo echoic texture is currently believed to be due to the replacement of the prostatic stroma with infiltrating glandular elements (7). However not all hypo echoic regions in the peripheral zone are prostate cancer. Potential hypo echoic lesions also include prostatitis, prostatic infarction, dilated glands, smooth muscle bundles, scarring, and prostatic intraepithelial neoplasia. Studies following Lee’s work reported that a significant number of prostate carcinomas are isoechoic (8).

The specificity of the classic hypo echoic ultrasound finding of prostate cancer is low; a hypo echoic lesion can reflect anything along the continuum from normal prostate to prostatitis to infarct to prostatic intraepithelial neoplasia (9).





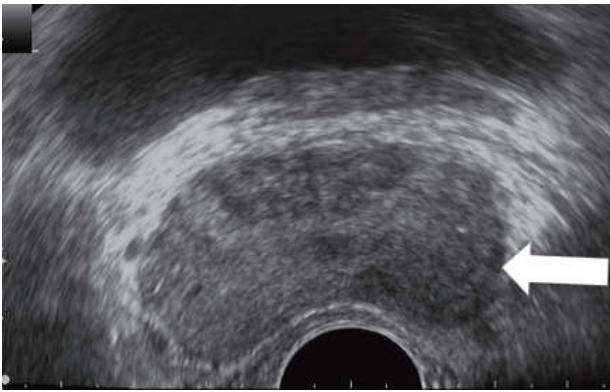


Figure 5 Hypoechoic Lesion in Trus

**Method of Prostate Biopsy**

Full informed consent that outlines alternatives, consequences, and complications of biopsy is obtained prior to the procedure. Patients routinely receive either pre procedural enemas or a formal polyethylene glycol bowel preparation. Administration of prophylactic antibiotics around the time of biopsy has become standard of care. At our institution, we routinely use a 3-day course of a quinolone antibiotic beginning the day before biopsy. Informed consent from the patient is obtained.

Patient comfort is provided by injecting 10 ml of 1% lidocaine along the neurovascular bundles of the prostate, beginning at the seminal vesicles and moving outward to the apex. This is accomplished with a 22-gauge spinal needle, and the injection is performed under TRUS guidance. This procedure is simple and inexpensive, and patients describe good anesthetic results. The three steps of local anaesthesia infiltration of the prostate gland are 1. The needle is positioned just outside the apex of the prostate and the local anaesthetic is injected to create a pool around it, 2. The injection has been made into Denonvilliers' fascia, just beyond the rectal wall, 3.

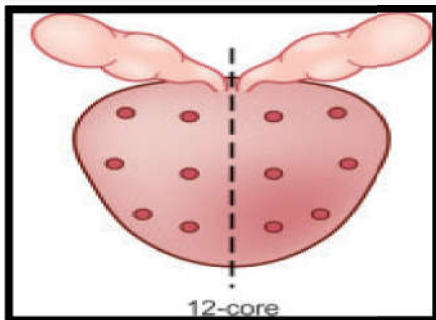
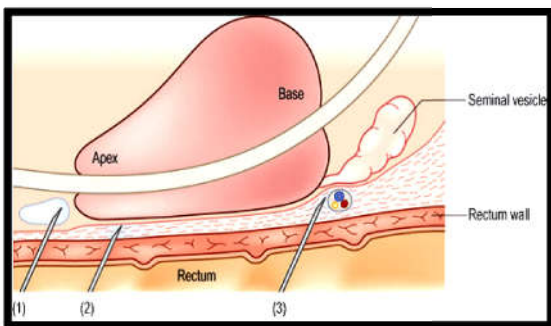


Figure 6 Local Infiltration And Prostatic Biopsy

The local anaesthetic has been introduced around the neurovascular bundle, between the base of the gland and the seminal vesicle.

TRUS-guided biopsies have become established in the acquisition of systematic biopsies from standard locations. The number of systematic biopsies has increased over the years and 12 core biopsy is currently accepted as the minimum standard.

**Analysis of A Diagnostic Test**

**Sensitivity of a test**

It is the ability of the test to find out true positives (patients who truly have the disease].

**Specificity of a test**

It is the ability of the test to find out true negatives ( healthy patients who are correctly identified as not having the disease).

**Positive Predictive Value (PPV)**

It is the probability that subject with positive screening test truly have the disease.

**Negative Predictive Value (NPV)**

It is the probability that subjects with a negative screening test truly not have the disease.

Sensitivity should be very high for a good screening test. Specificity should be high for a good confirmatory test.

**CONCLUSION**

The PSA level is widely used as the screening tool in the detection of prostate cancer. High PSA level with abnormal DRE are the two vital markers of clinical suspicion of prostate malignancy. The patients with high suspicion should be subjected to Trans Rectal Sonogram [TRUS]. TRUS maintains a critical role in the early diagnosis of prostate cancer. Ultrasound is essential in ensuring accurate sampling of the gland. TRUS is an integral facet of prostate biopsy and will continue to contribute to our understanding of the optimum regimen for the diagnosis of prostate cancer. With more patients presenting earlier for biopsy as a result of PSA screening, together with potentially earlier diagnosis resulting from increased gland sampling, prostate cancer may be diagnosed at an earlier stage itself.

In our study most of the hypo echoic lesions are malignant [65%]. Among iso echoic lesions of prostate 35% are malignant. In the mixed echoic lesions 14% of lesions are malignant. All the hyper echoic lesions in our study are benign.

Even though the sensitivity and specificity of the grey scale TRUS is low the combination of the abnormal DRE and High PSA level with the TRUS increases the sensitivity and specificity.

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