"DIAGNOSTIC ACCURACY OF MULTI-PARAMETRIC MAGNETIC RESONANCE IMAGING (mpMRI) OF PROSTATE BASED ON PROSTATE IMAGING REPORTING AND DATA SYSYTEM (PI-RADS) VERSION 2 IN COMPARISION WITH HISTOPATHOLOGY – ONE YEAR HOSPITAL BASED CROSS-SECTIONAL STUDY"

BY

REGISTRATION NO. BS0119006

Dissertation

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfillment

of the requirements for the degree of

M.D.
IN
RADIO-DIAGNOSIS

DEPARTMENT OF RADIO-DIAGNOSIS,
J. N. MEDICAL COLLEGE,
BELAGAVI -590010. KARNATAKA

APRIL 2022

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI, KARNATAKA

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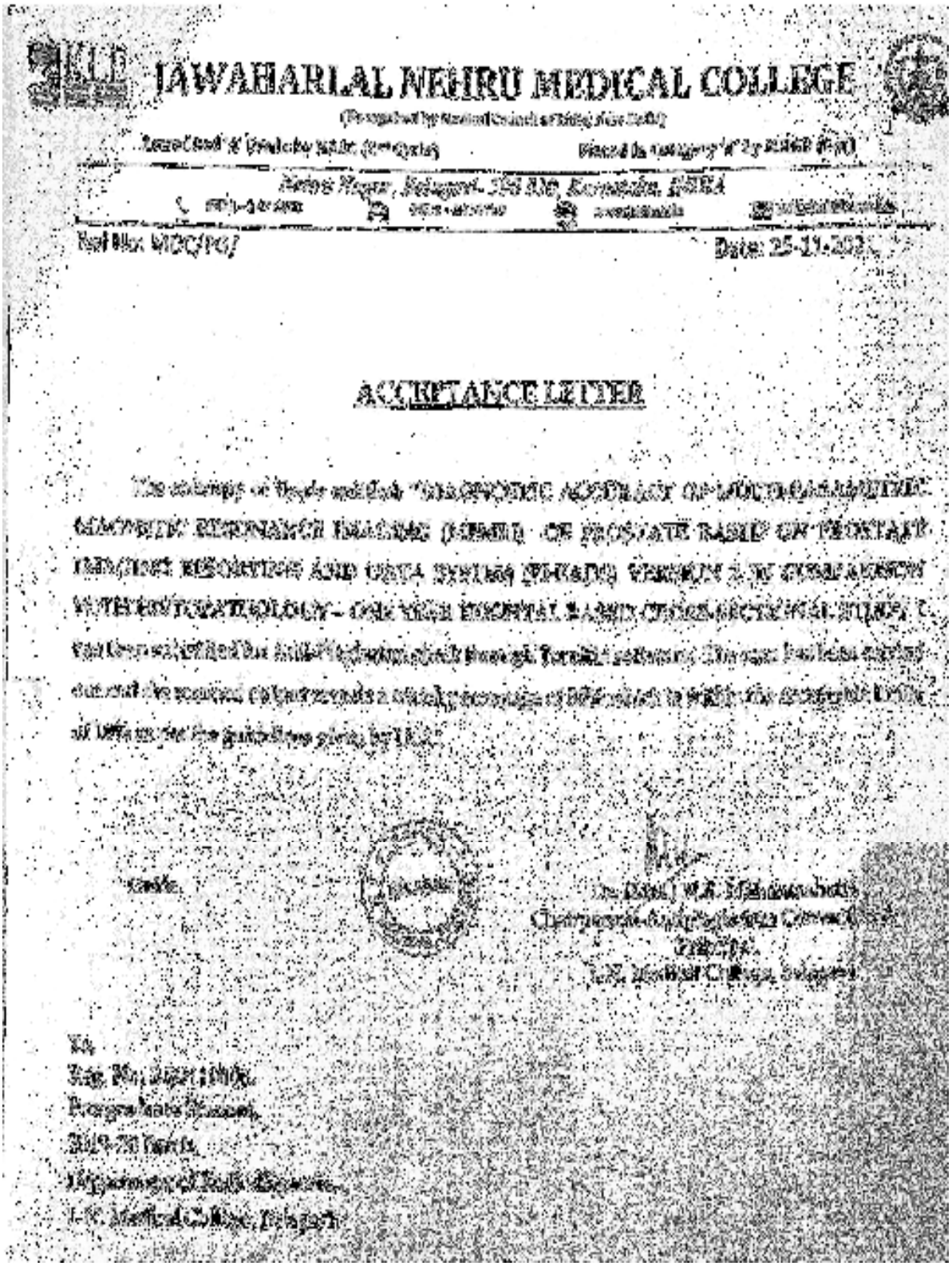
PLAGIARISM ACCEPTANCE LETTER



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ABBREVIATIONS

ADC	**:**	**Apparent Diffusion Co-efficient**
CZ	**:**	**Central zone**
DCE-MRI	**:**	**Dynamic Contrast Enhanced Magnetic Resonance Imaging**
DW-MRI	**:**	**Diffusion Weighted Magnetic Resonance Imaging**
DWI	**:**	**Diffusion Weighted Imaging**
DRE	**:**	**Digital Rectal Examination**
ECE	**:**	**Extracapsular extension**
FLAIR	**:**	**Fluid Attenuation Inversion Recovery**
FOV	**:**	**Field Of View**
GS	**:**	**Gleason's score**
LN	**:**	**Lymphnodes**
mm	**:**	**millimeter**
MRI	**:**	**Magnetic Resonance Imaging**
MRS	**:**	**Magnetic Resonance Spectroscopy**
NPV	**:**	**Negative Predictive Value**
PPV	**:**	**Positive Predictive Value**
PSA	**:**	**Prostate specific antigen**

PIRADS	**:**	**Prostate Imaging - Reporting and Data system**
PZ	**:**	**Peripheral zone**
ROI	**:**	**Region of Interest**
S	**:**	**seconds**
SD	**:**	**Standard Deviation**
sPSA serum	**:**	**Prostate Specific Antigen**
SVI	**:**	**Seminal vesicle invasion**
T2WI	**:**	**T2 Weighted Imaging**
TE	**:**	**Time to Echo**
TR	**:**	**Time to Relax**
TNM	**:**	**Tumor, Nodes and Metastases**
TRUS	**:**	**Trans-rectal Ultrasound TZ Transition zone**

ABSTRACT

BACKGROUND: Recent technological advancements has made multiparametric magnetic resonance imaging (mpMRI) to be a great tool for early detection of clinically significant prostate cancer (PCa) while reducing overdiagnosis of indolent PCa. MRI is an excellent non invasive modality with capabilities of identifying the lesions of prostate based on PIRADS version 2.

OBJECTIVES: To evaluate the recommendations for multi-parametric prostate MRI (mp-MRI) interpretation introduced in the recently updated Prostate Imaging Reporting and Data System version 2 (PI-RADSv2) in correlation with histopathology.

METHODOLOGY: The present study was a prospective study (one year hospital based cross sectional study) was done in Department of Radiology from January 2020 to December 2020 at KLE'S DR PRABHAKAR KORE HOSPITAL, Belagavi, Karnataka. It included 38 patients with raised PSA levels who underwent mpMRI prostate as a routine investigation. PI-RADSv2 was used asses the MRI scans.

RESULTS: Comparing PIRADS over the gold standard histopathology, PIRADSv2 has a sensitivity of 83.33% and the specificity being 96.15%. And the positive predictive value of mpMRI of our study found to be 90.1% with the diagnostic accuracy of 92.1%.

CONCLUSION: From our prospective radiological trial, we can conclude that, prevalence of prostate lesions are most common among elderly male patients with increasing severity as the age progresses. Incidence of transitional zone lesions are more common than the peripheral. Volume of the prostate is positively correlated

with PSA scoring. PSA score and mpMRI itself is enough for diagnosing the lesions below PIRADS III, while the lesions with higher grade might have variation and hence require the biopsy. PIRADS version 2.0 gives us the most reliable findings and avoids the unnecessary biopsy.

KEYWORDS Multiparametric Magnetic resonance Imaging (mpMRI), Carcinoma prostate, PI-RADSv2.

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INTRODUCTION

Recent advancements in the field of radiology and technological profile has made multiparametric magnetic resonance imaging (mpMRI) to be the great tool for the early detection and assessment of clinically significant cancer prostate (prostatic carcinoma). Thus helps in controlling the overdiagnosis of the lesions[1,2]. No matter whichever guidelines we come up with in the field of medicine and radiology, one of major concerns is implementation and acceptance of those particular guidelines. Standardization of image acquisition tools, interpretation and standard reporting guidance differs widely among different epidemiological areas with inter and intra observer variability. This will have a negative impact over the clinical and diagnosing criterias [3]. AdMeTech Foundation's International Prostate MRI Working Group in the mid 2010 explained in detail about all possible appearance of the prostatic lesions and discussed the clinical evaluations of the same. Thereby they recommended a couple of standard guiding models for assessment of prostate lesions, which is now known as Breast Imaging and Reporting Archiving Data System (BI-RADS) [4]

Dickinson with his other clinical research colleagues tried to develop much better criteria for standardizing and improving the interpretation of mpMRI. But it was not as easy as they started with. Henceforth the European Society of Urogenital Radiology (ESUR) came up with development of consensus-based guidelines for the prostate mpMRI, this included all the basic information of the lesion such as clinical indications, minimalistic and optimum method of imaging acquisition protocols. These groups of guidelines are known as Prostate Imaging and Reporting and Data System (PI-RADS).[5] Primary guidelines are considered as version 1 (PI-RADS v1).

There was improvement in those guidelines as the development in imaging progressed, now it has been updated to the version 2.1. [5]

In the recent decade, PIRADS score has been the most reliable diagnosing/ assessment tool in Ca. Prostate. Revised guidelines 2.1 has been set to improve the assessment scoring of indeterminate lesions occupying in the transitional zone (transition zone) and an update to the scoring of lesions on diffusion-weighted sequences (DWI). All these have improved the reporting accuracy of lesions.[6,7] As indeterminate lesions pose a clinically challenging problem regarding managing the patient and further course of action, a dilemma in deciding the need for biopsy, all these can be avoided by this updated version 2.1. A higher accuracy of the PI-RADS 2.1 guidelines have led to a decrease in performing the unnecessary biopsy among many patients.[8,9] Further needs of these diagnostic procedures are to avoid the missing lesions and outcomes, which can also be avoided by improving the resolution of diagnostic imaging. Hence, the present study is taken to evaluate the recommendations for mp-MRI interpretation introduced PI-RADSv2 in correlation with histopathology of prostate.

AIM AND OBJECTIVES

- To evaluate the recommendations for multi-parametric prostate MRI (mp-MRI) interpretation introduced in the recently updated Prostate Imaging Reporting and Data System version 2 (PI-RADSv2) in correlation with histopathology.

REVIEW OF LITERATURE

ANATOMY

John E McNeal in the year 1981, had reviewed more than five hundred evidences and explained the detailed structure of the anatomy of prostate which has made the radiological grading better and comprehensive[10]. He had used the three dimensional model for the explanation of different zones of the prostate. Based on which, the major zones are[11];

- ***Transition zone*** surrounds the prostatic urethra. This zone enlarges in aging men resulting in benign prostatic hyperplasia.
- ***Central zone*** lies in the base of the prostate behind the transition zone and surrounds the left and the right ejaculatory duct.
- ***Anterior fibromuscular stroma*** is a small area of tissue that is situated on the anterior side of the prostate.
- ***Peripheral zone*** is situated on the posterior and lateral side of the prostate.

70-75% of all prostate cancers originate in the peripheral zone (PZ). The posterior aspect of this zone can be examined with a digital rectal exam. 25% of prostate cancers originate in the transition zone (TZ).

HISTORY OF PROSTATE IMAGING[13-21]

The very first study of MRI of the prostate gland was performed almost 40 years ago, in the year 1982 by Steyn and Smith. Most precious advances have occurred after this in the field of MRI technology.(13) Introducing the dynamic contrast-enhanced (DCE), diffusion-weighted sequences (DWI) and also the

spectroscopic MRI are few among them. Image quality has drastically improved with these high-field-strength magnets and phased-array coils, thereby improving the accuracy of clinically significant prostate cancer (prostatic carcinoma).[14]

Clinico-radiological data obtained from the Prostate MRI Imaging Study (PROMIS) and Prostate Evaluation for Clinically Important Disease: Sampling Using Image-guidance Or Not (PRECISION) suggests that MRI always plays an important role in improving the diagnosis of clinically significant Ca prostate. It also has a crucial role in avoiding the overdiagnosis of clinically unimportant disease which is a much needed clinical and surgical factor.[15]

Extensive research literature on diagnostic radiography have explained the diagnosis of Prostatic lesions by using MRI, but many of those reported diagnostic performance of MRI were varied greatly in detection, localization and local staging [16]. This might be partly because of heterogeneity in their diagnostic protocols or the other aspects related to technique of performing MRI.

The very first evidence of prostate transperineal ultrasound examination was first published in 1963. It had very poor quality of image, hence the poor diagnosis. More diagnostic trials went on till the first clinical application of 3.5-MHz transrectal ultrasound (TRUS) of the prostate tried in early 1970s which provided a new hope in the field of diagnostic imaging of the prostate.[17] These primary images also were of comparatively poor quality. Gradually, application of MRI in the radio- diagnosis of cancer was explored by the researcher Damadian et al. Six normal tissue samples and two malignant solid tumours in an animal experiment were observed. Malignant tissues that could be differentiated according to the relaxation times of T1 and T2

were diagnosed and reported. But the parameters observed here were outfitting the range of normal values.[18]

With all the available evidence, Steyn and Smith et al released their initial observations from prostate MRI performed on 25 men by the method of using four-coil, air-cored magnetic rings with a static magnetic field of 0.04 T and a slice thickness of 17.53 mm in the late 80s. Twenty patients who had benign prostatic hyperplasia (BPH) and five others were having postoperative prostate lesions.[19]

Hricak et al. using MRI he investigated both anatomy and pathological features of the pelvic organs in men. They included 10 post operative men. Among them, 9/10 with BPH, 9 Ca prostate and 1 patient had a lymphocele [20]. MRI in them had a better capacity of imaging to provide three planes such as sagittal, axial and coronal images to allow the most accurate volumetric assessment and extension of the lesions[21].

In 1983, Bryan et al. had used either a 0.15T or 0.3T system to obtain the T1, T2-weighted images of four men who were probably diagnosed with Prostatic Cancer and One with BPH. They reported in the imaging that the prostatic carcinoma had an inhomogeneous appearance on MRI. But, MRI was too expensive to be used as a routine screening method [22].

One year later, Buonocore et al [23] performed an MRI of the prostate both clinical and in vitro for 10 men. The results of this study were similar to those of another observation by Hricak et al. that the normal prostate had homogeneous intermediate signal patterns on both T1- and T2-weighted images but the Prostatic carcinoma and the invasion of seminal vesicles were better seen on T2 weighted images.

In 1985, Poon et al [24] conducted a study with an objective of determining the optimal pulse sequence for prostatic imaging and to study the ability of MRI to differentiate BPH from Prostatic Cancer. The MRI system used for the study was a 0.15-T scanner with a body coil.

In 1987, Hricak et al[25] published the first descriptive study describing the appearance of a normal prostate gland and the periprostatic structures on MRI. Fifty-five men with benign and malignant prostate and bladder disorders were reviewed retrospectively. The technical requirements for a scan of diagnostic quality was discussed in this article. The participants underwent MRI scanning which was performed with a 0.35- or 1.5-T system and different body elliptical or quadrate coils. Multiplanar T1- and T2-weighted images with different TR and TE values were performed for most of the men recruited in the study. Different slice thicknesses and gaps were also applied. The authors described how the anatomic structures could be visualised when different planes and MR parameters were applied.

Below are the MRI images of prostate by Steyn JH et al[13]

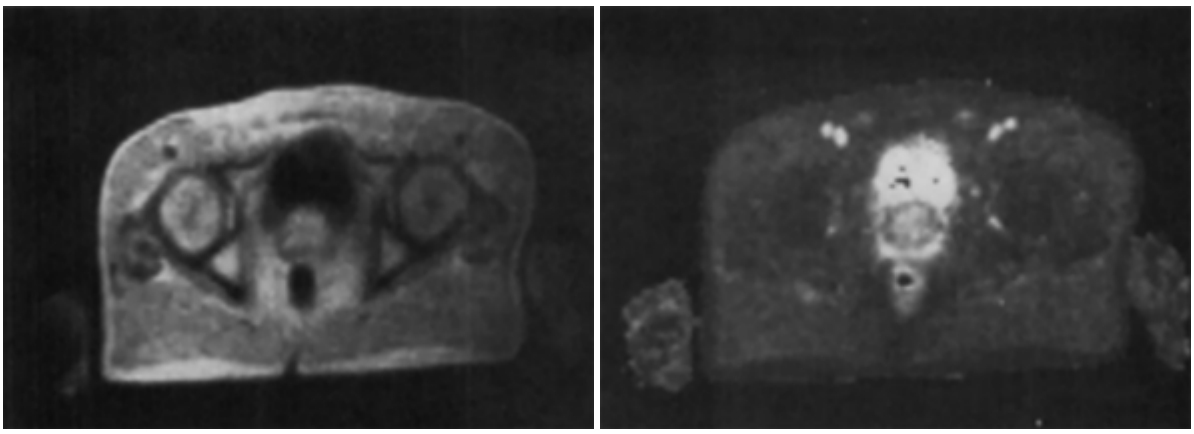


Image 1A[13]: Proton density–weighted MR image shows BPH with prostate outlined between bladder and rectum.

Image 1B[13]: T1W imaging of BPH showing bladder urine with very long T1

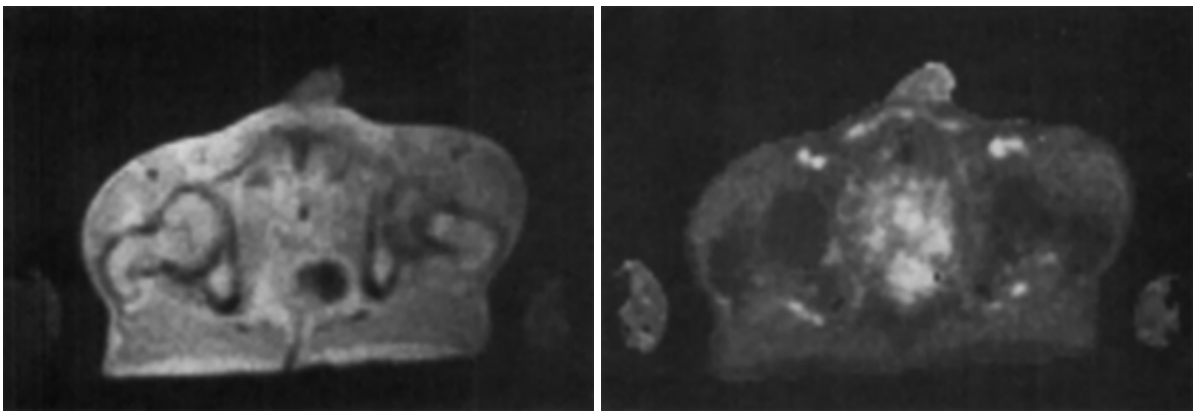


Image 1C: PDW imaging of Ca prostate and T1W MRI image of Ca prostate

Poon PY et al[24], had reported their findings in the study, comparing the MRI imaging of transverse and coronal sections of the prostate using 3D imaging technique. Below are the images discussed in their article.

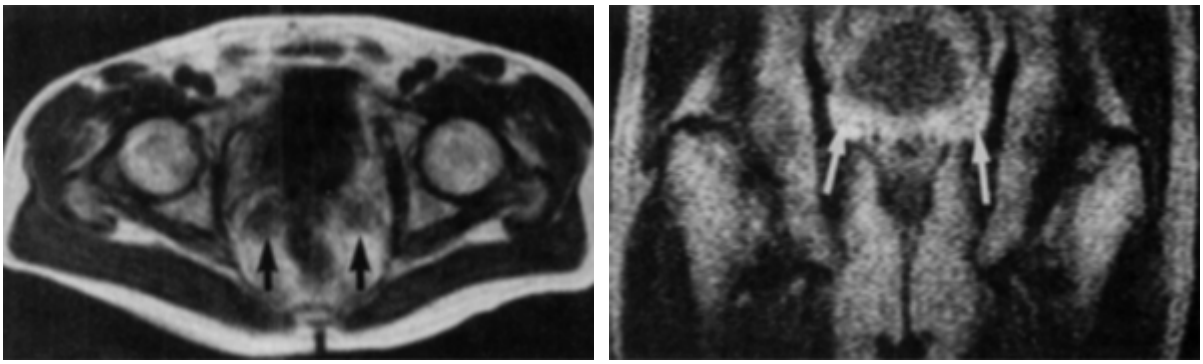


Image 2A: Transverse section of the normal prostate using 3D imaging

Image 2B: Coronal section of the normal prostate using 3D imaging

Another group of clinical radiologists, mirowitz et al[20] had observed and graded the Ca prostate in their study by applying the gadolinium enhanced endo-rectal MR imaging: T2W and T1W images. Following are the few evidences of their imaging from a 63 year old male with cancer prostate.

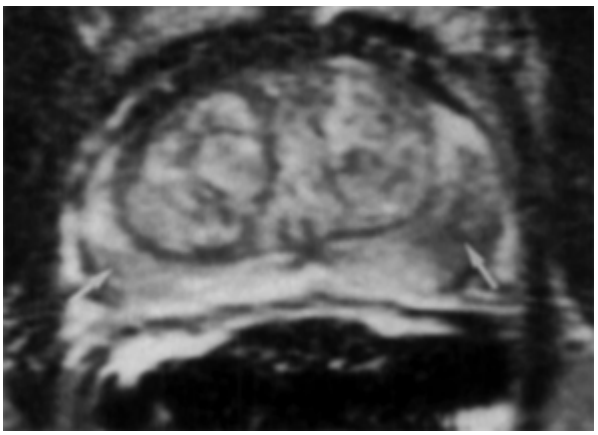


Image 3[20]: Ca prostate as seen with T2W imaging

Multiparametric Imaging

The MRI protocol that is been presently used for prostate imaging is called multiparametric MRI (mpMRI) since it consists of a combination of T2-weighted imaging, DWI, and DCE-MRI. The significance of the MRI sequence DWI is being more widely recognized over time, whereas the popularity of spectroscopic MRI has decreased. The applications of MRI for the prostate gland in the early days were based on T1- and T2-weighted imaging only, however additional sequences, such as DCE-MRI, spectroscopic MRI, and DWI, were later developed in the 1990s[26].

Dynamic contrast-enhanced

In 1993, Mirow et al[27]. Were the first to report the effect of contrast enhancement on prostatic carcinoma staging. They concluded that the use of gadolinium contrast was not indicated for routine staging of prostatic carcinoma but can be useful in assessing invasion of seminal vesicles.

Two years later, Brown et al[28] had reported that the detection of prostatic carcinoma was better after dynamic acquisition. They concluded that dynamic bolus contrast enhancement can be useful in the evaluation of the tumor margins.

After these initial studies on the effect of contrast enhancement, the use of contrast medium in prostate MRI saw some rapid developments in the methods of acquiring the MRI data , with rapid series of images continuously taken after bolus administration of the contrast medium over time.[29]

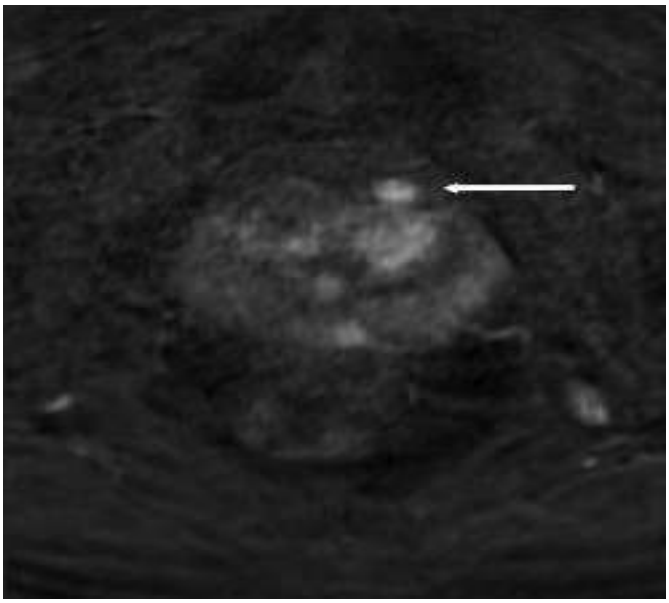


Figure 4[29]: Arrow indicating the residual tumor as seen in DCE imaging

Spectroscopic MRI

The first study of spectroscopic MRI of the prostate was published in 1988 by Sillerud et al.[30-31] These authors detected citrate in the prostate, analyzing citrate signals from normal rat tissue, benign hypertrophic human prostate tissue in vitro and from the normal in vivo prostate tissue of a healthy human volunteer. In 1995, Kurhanewicz Central zone et al[32] studied if citrate levels detected by spectroscopy could reliably differentiate regions of prostatic carcinoma from healthy peripheral zone tissue and BPH. They observed that the citrate levels in patients with prostatic carcinoma were lower than that in patients with BPH or men with normal peripheral zone prostate tissue. The patients with prostatic carcinoma were having a lower ratio of the mean citrate level to peak creatine plus choline levels compared to that of the

patients with BPH and men with normal peripheral zone prostate tissue.[32-35] This variation in ratio of mean citrate level to peak creatinine plus choline levels was statistically significant ($p < 0.05$).

Despite the initial excitement about spectroscopic MRI, this technique has slowly diminished in popularity over time for assessment of prostatic carcinoma. A multicenter study[36] showed no added advantage of spectroscopic MRI over MRI for men with relatively low-volume and low-risk disease who underwent radical prostatectomy. However, spectroscopic MRI has become a superb technique in the identification of aggressive cancers, but DWI can also now give the same information in lesser time and with lesser expertise.[37,38]

DWI—DWI depicts the water molecules' movement in tissues, which indicates the tissue cellularity. Prostatic carcinoma is characterized by larger number of cells and destruction of water-rich glandular tissue, resulting in a lower water diffusivity (and a lower apparent diffusion coefficient [ADC]) compared with that seen in normal tissue. A region of restricted diffusion (e.g., tumor) is hyperin-tense on high-b-value DWI and hypointense on the corresponding ADC map. [39]

In 2002, Issa was the first to report the application of DWI for prostatic carcinoma. The ADC was measured in the transition and peripheral zones of seven healthy men and 19 men with prostatic carcinoma.[40] For men who had prostatic carcinoma, the ADC values were lesser in the malignant tissue than that in noncancerous areas that were found to be having the values 1.38 vs 1.92×10^{-3} mm^2/s with the significant *p value of* < 0.001. Since then, many studies and reviews have investigated the usefulness of prostate DWI, supporting its inclusion in the diagnostic pathway of prostatic carcinoma[41,42].

As far as the magnetic field strength is concerned, in the early 20th century Bloch et al[43]. reported the first comparison of 1.5- and 3-T scanners, T2-weighted imaging and DCE-MRI with pelvic phased-array surface coils combined with an endorectal coil, confirming the higher quality and also the clinical utility of endorectal 3-T scanners. A 3-T MRI examination of the prostate has shown to have a higher signal-to-noise ratio and improved contrast resolution with more detailed images. Unfortunately they found an important drawback is the high sensitivity to artifacts such as the metallic artifacts from hip prostheses. These can degrade the image quality, especially that of DWI[44].

However, in realistic practice, these issues generally outweighed the benefits of using 3 T as outlined in Prostate Imaging Reporting and Data System version 2 (PI-RADSv2) system. Supporting this evidence indicates that the 3-T MRI is able to increase the detection of smaller lesions, but the magnet strength is only one of the factors that influence acquisition of a prostate MR image of adequate image quality, as reported by Dickinson et al[45]. The use of these 1.5- or 3-T systems and an endorectal coil system still varies across centers and also its questionable.

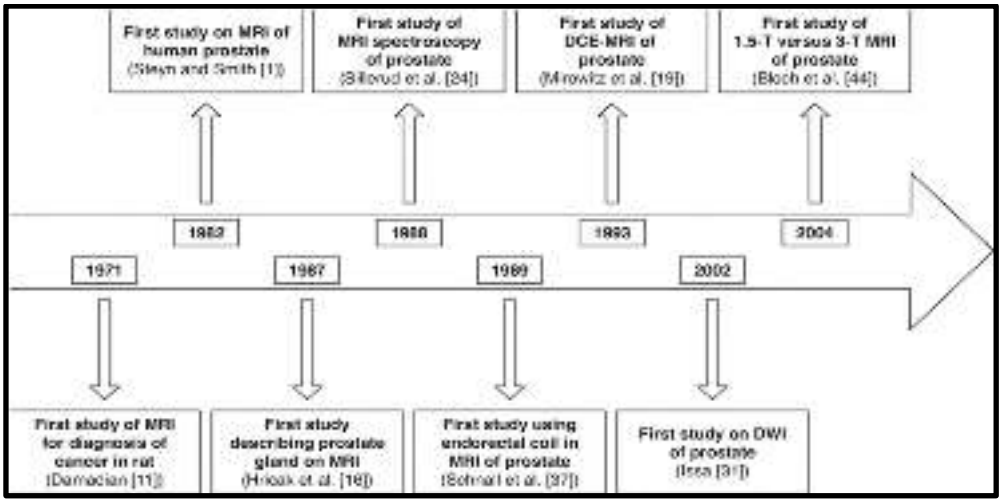


Figure 5[20]: Chronological timeline of major technical developments in MRI of prostate.

PRESENT GUIDELINES AND CLINICAL APPLICATIONS

The multiparametric MRI of the prostate plays an active role in assessing the prostatic carcinoma clinical pathway in many parts of the world, thus influencing the management of several aspects of this disease from initial diagnosis to post recurrence assessment. This growing interest in the field of MRI has led to a lot of variations in imaging protocols, interpretation and also to implement the same into clinical care.[46,47]

About this rapid development of this particular MRI technique, it is of interest to observe how and why this MRI has been advocated as a much valuable tool for evaluation of prostatic carcinoma over the past few decades.[48]

Primarily, it is to be noted that the European Association of Urology[49,50] has developed a series of recommendations for prostatic carcinoma that were published in 2011 and were then revised. According to these developed guidelines, mpMRI of the prostate should be used for local staging, specifically before carrying forward with the repeat biopsy, when the suspicion of prostatic carcinoma persists despite negative biopsy findings, because such a technique can change patient management and may help to trigger MRI-targeted biopsy. Whole-body DWI could be also used to assess bone metastases.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) guidelines[51] supported the use of mpMRI for men with positive biopsy findings for whom the radical treatment or an active surveillance was being considered and for those with negative TRUS biopsy findings, for whom the suspicion of prostatic carcinoma was remaining. The American College of Radiology Appropriateness Criteria (ACRAC) for the pretreatment detection, staging and

surveillance of prostatic carcinoma was released in 2013 supporting the appropriateness of prostate MRI for a range of many clinical scenarios.[52]

The first international consensus meeting on prostate MRI which was published in 2011 by Dickinson et al.[53] It was recommended that the T2-weighted imaging, DWI and also DCE-MRI were the most important sequences for the detection, localization and characterization of prostatic carcinoma. Use of an ordinal 5-point Likert MRI-based scale to score the likelihood of malignancy from being highly unlikely to highly likely and also a pictorial report showing lesion location were recommended[53].

In the year 2012 the European Society of Urogenital Radiology (ESUR) released the first version of the Prostate Imaging Reporting and Data System (PI-RADS). This consisted of basic recommendations for MRI acquisition, interpretation and reporting. All together, three different protocols for the detection, staging and node and bone assessment were developed. A score from 1 to 5 is used to indicate the likelihood of a patient having clinically significant prostatic carcinoma on each MRI sequence, including spectroscopic MRI and the overall score was then assessed[54].

PI-RADSv2 was subsequently released in 2015. This represents a collaborative effort of the ESUR, the American College of Radiology and the AdMeTech Foundation[55]. A recent meta-analysis[56] showed a significantly higher pooled sensitivity of PI-RADSv2 compared with PI-RADS with the significant p value of 0.04. Whereas, statistically significant similar pooled specificity was maintained. There remains a need to improve the standardization of reporting such as Likert scale vs PI-RADS. But PI-RADSv2 provides a good basis from which an inexperienced radiologists can interpret prostate MRI.

In the year 2013, another consensus meeting had taken place in the United Kingdom. Among the presented recommendations from this meeting, a key content was: "Post biopsy staging scans should not be acquired until at least 10 weeks after biopsy to avoid MRI artifacts". Moreover, since the interpretation of prostate MRI can be a challenging task for inexperienced radiologists and because of their steep learning curve, the authors concluded that those who report prostate MRI findings should report at least 50 scans per year and should regularly attend multidisciplinary meetings in order to enhance their appropriateness of reporting MRI.[57]

Moore et al[58] summarised and published a list of recommendations for reporting MRI-targeted biopsy studies in 2013. The panelists highlighted the importance of reporting standard and MRI-targeted biopsies separately and provided a checklist in order to improve the quality of reporting in MRI-targeted biopsy studies by radiologists[59,60]. Upcoming evidence also supports the use of MRI for focal therapy. Two important consensus meetings on this topic have stressed over the importance of mpMRI and have recommended the use of MRI-targeted biopsies can improve the better diagnosis[61].

The importance of mpMRI for men with a clinical suspicion of recurrence of prostatic cancer after receiving the initial treatment of prostatic carcinoma has been proven repeatedly. There is strong evidence on using this technique for detection and localization of recurrence after different forms of treatment, including radical prostatectomy, brachytherapy, external beam radiotherapy, focal ablation and hormone therapy[(62)].

Recurrence in the prostate bed after radical prostatectomy procedure is marked by growth of a soft-tissue nodule which is isointense to muscle on T1-weighted

imaging, is slightly hyperintense to muscle on T2-weighted imaging, shows restricted diffusion, and, unlike postoperative fibrosis and granulation tissue, the nodule enhances avidly after the administration of IV contrast medium[63-65]. Intraprostatic recurrence after radiotherapy and hormonal therapy is seen as T2-hypointense nodular lesions with the bulging of the prostatic capsule with restricted diffusion and early enhancement are also seen[66]. When focal therapy is delivered, the use of IV contrast medium is essential to differentiate viable tumors from necrosis and fibrotic changes[67].

A panel of experts published the Prostate Cancer Radiologic Estimation of Change in Sequential Evaluation (PRECISE) guidelines[68] to enable robust data collection from serial MRI scans of few men undergoing active surveillance. These recommendations were created under an assumption that a systematic approach to reporting findings from baseline and follow-up scans would help in an accurate assessment of the natural history of prostatic carcinoma[69].

The PRECISE recommendations include the scoring system based on score from 1 to 5, for identifying the likelihood of changes occurring between baseline and follow-up scans. This score can facilitate the determination of thresholds for different parameters, specially for tumor size that identify radiologically significant disease and important radiologic changes on mpMRI[70]. If radiological progression is suspected, a targeted biopsy can be performed in order to establish which it is correlated with histologic progression. Once prostatic carcinoma is diagnosed, it is also a critical step to determine whether the cancer has spread beyond the prostate capsule. Also to know whether it is localized or has metastatic lesions as well. In 2016, an international expert panel of oncologic imagers and oncologists drafted the metastasis Reporting

and Data System for Prostate Cancer guidelines. These recommendations were developed to promote standardization and diminish variation in the acquisition, interpretation, and reporting of whole-body MRI scans in advanced prostatic carcinoma and also to provide comprehensive tumour characterization both before treatment and over time.

In 2017, the American Urologic Association issued a statement on the use of mpMRI for prostatic carcinoma endorsed the use of mpMRI for men with abnormal digital rectal examination findings or an elevated prostate-specific antigen level and a previous negative biopsy finding, but it also highlighted that mpMRI cannot yet be recommended for screening or surveillance[71]. The results from a recent consensus meeting to implement mpMRI in the diagnostic pathway of prostatic carcinoma in the United Kingdom has been published, with a set of criteria required for the practical dissemination of high-quality mpMRI as a diagnostic test before biopsy in men at risk for prostatic carcinoma. In this regard, the National Health Service (NHS) of England recommends that all the men with suspected prostatic carcinoma should have prostatic carcinoma diagnosed within 28 days at most, with mpMRI performed before biopsy.(72)

EVALUATION OF PI-RADS SCORE

In order to develop a higher level of standardization and consistency and facilitate multi-center clinical evaluation and implementation of mpMRI for assessment of prostatic carcinoma, the AdMeTech Foundation International Prostate MRI Working Group, recommended the development of a set of consensus guidelines, called Prostate Imaging and Reporting and Data System (PI-RADS), with support of a grant from the U.S. Army Medical Research & Materiel Command

(USAMRMC). This would be based on evidences from published data and consensus expert opinion. The European Society of Urogenital Radiology (ESUR) published the first version of this document, which included clinical indications for prostate mpMRI, minimal and optimal imaging acquisition protocols, and a structured category assessment system now known as PI-RADS version 1. [72]

Since its publication in 2012, the benefits of using a standardized assessment system such as PI-RADS v1 was validated in several clinical and research scenarios and it provided a framework on which less experienced radiologists could base their interpretations. However, it was quickly noticed that it contained many drawbacks, including unclear recommendations for scoring each of the mpMRI parameters. In addition, PI-RADS v1 did not indicate how the scores assigned in each of the pulse sequences would contribute to the determination of the final overall assessment.

Variations and the subjective nature in scoring were causing confusion to the radiologists, referring clinicians, and patients. Since there was a lack of a clearly defined scheme for assigning an overall assessment, PI-RADS v1 had difficulty in achieving consistency in clinical practice, and it was not widely adopted, especially in the United States.[73]

Although PI-RADS v2 is built on the basis of PI-RADS v1, there are many important differences. For PI-RADS v1, the emphasis was on the clinical applications of prostate mpMRI, patient management, and assessment of extraprostatic extension (EPE)/staging. PI-RADS v2 instead focuses on lesion detection and characterization (including benign findings), as well as interpretation and reporting. It consists of detailed explanations, caveats, and detailed instructions on measuring and mapping of

prostatic carcinoma. It also includes many images that illustrate assessment criteria and an extensive lexicon of relevant terminology. [74]

Differences between PI-RADS 1 and PI-RADS 2

Version 1	Version 2
27-sector map	39-sector map
MR spectroscopy may be included	MR spectroscopy is not used
Equal role for DCE (5-point scale)	Minor role for DCE
Lesion size is not a factor (for T2W or DWI)	1.5 cm is used as the cut off between PI-RADS scores 4 and 5 (for T2W and DWI)
No sequence is "dominant"	Concept of "dominant" sequence (DWI for peripheral zone and T2W for transition zone)
Total score of 4–20, consisting of T2W + DWI + DCE + MRS (each graded on a 1–5 scale)	Overall assessment score of 1–5

In PI-RADS v2, prostatic carcinoma is divided into clinically significant and insignificant disease. Clinically significant prostatic carcinoma's are defined as those with a Gleason score ≥7 (including 3+4 with prominent but not predominant Gleason 4 component), and/or volume ≥0.5 cc, and/or EPE.

ASSESSMENT IN PI-RADS Version 2.0

PI-RADS v2 assesses the probability of a patient having clinically significant prostatic carcinoma for each of the lesion using a 5-point scale, which takes into consideration the findings from three pulse sequences that comprise a standard mpMRI exam: T2W, DWI, and DCE.[75]

PI-RADS v2 assesses the likelihood (probability) of clinically significant PCa for each lesion using a 5-point scale, which takes into account findings from three pulse sequences that comprise a standard mpMRI exam: T2W, DWI, and DCE.

The following final Assessment Categories are used:

- PI-RADS 1—Very low: Clinically significant cancer is highly unlikely to be present
- PI-RADS 2—Low: Clinically significant cancer is unlikely to be present
- PI-RADS 3—Intermediate: The presence of clinically significant cancer is equivocal.
- PI-RADS 4—High: Clinically significant cancer is likely to be present
- PI-RADS 5—Very high: Clinically significant cancer is highly likely to be present

DCE is classified as either positive or negative. The corresponding PI-RADS v2 table for either the peripheral zone (PZ) or transition zone (TZ) is then referenced to integrate all three parameters (T2W, DWI, and DCE) and assign a PI-RADS v2 Assessment Category (PI-RADS 1–5) for each lesion, indicating its likelihood of representing clinically significant cancer. One of the key differences between PI-RADS v1 and v2 is that the T2W, DWI, and DCE scores are not summated to assign an overall PI-RADS category.

DWI scoring[76]

A score of 1 to 5 is assigned on DWI by comparing the signal intensity in a lesion to the average signal of "normal" prostate tissue in the histologic zone in which it is located.

These criteria take into consideration: (I) lesion shape and margins; (II) signal intensity; (III) size; and (IV) observations from both the high b-value images and the ADC map.

Below is the criteria for ADC-DWI scoring

Score	**Peripheral zone (PZ) or transition zone (TZ)**
1	No abnormality (i.e., normal) on ADC and high b-value DWI
2	Indistinct hypointense on ADC
3	Focal mildly/moderately hypointense on ADC and isointense/mildly hyperintense on high b-value DWI
4	Focal markedly hypointense on ADC and markedly hyperintense on high b-value DWI; <1.5 cm in greatest dimension
5	Same as 4 but ≥1.5 cm in greatest dimension or definite extraprostatic extension/invasive behaviour

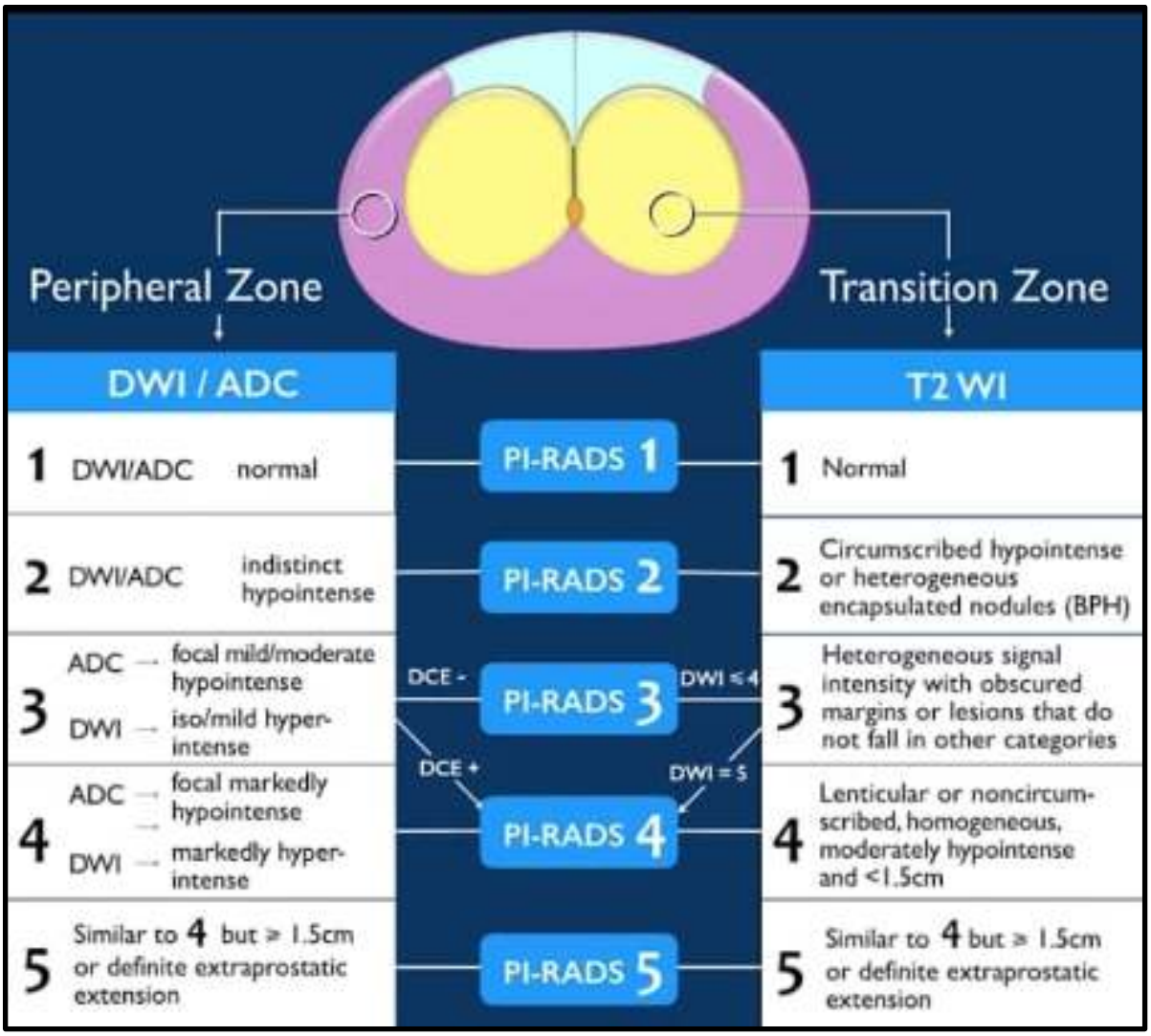


Fig 6a. PIRADS staging of Peripheral Zone and Transition Zone (diagrammatic representation)

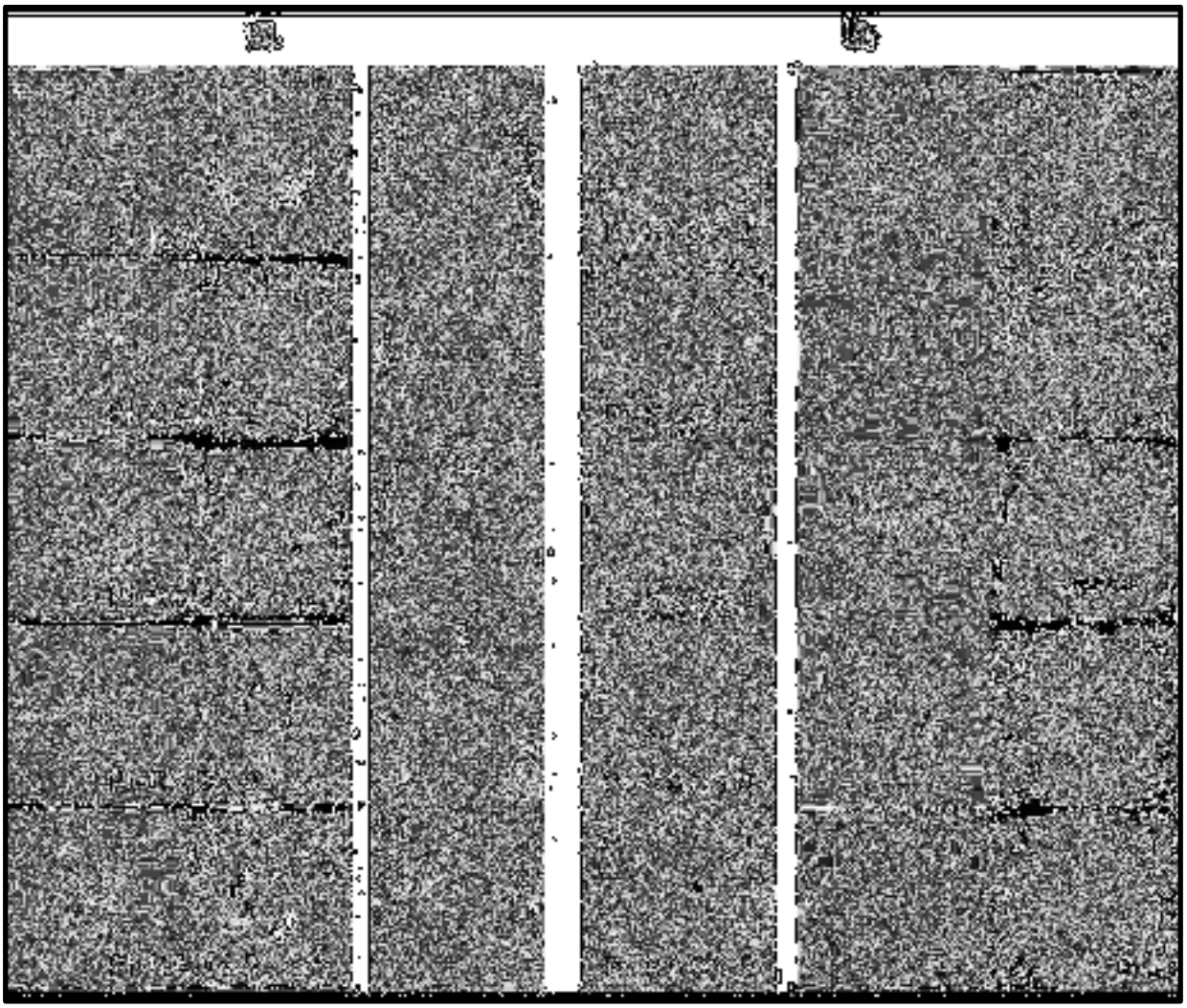


Fig 6b. PIRADS staging of Peripheral Zone and Transition Zone (MRI images)

LIMITATIONS OF PI-RADS VERSION 2.0

- Applying the PI-RADS v2 in certain anatomical zones may also be difficult. [76]
- Central zone displays a level of diffusion restriction that is similar to a significant prostatic carcinoma and other characteristics not delineated in the scoring system play a much more important role in distinguishing central zone from prostatic carcinoma, such as symmetry and location.

- The location of certain lesions may be controversial: Lesions at the apex of the prostate where the differentiation between transition zone and peripheral zone is often difficult. [77]

BIOPSY AND HISTOPATHOLOGY OF PROSTATE LESIONS

Based on the radiological evidence, there are so many controversial reports regarding the grading system and also the inter observer variation of the lesions. Hence the biopsy as a confirmatory procedure is advised in many doubtful conditions. [78]

PROCEDURE OF THE PROSTATE BIOPSY[79,80]

- There are high chances of fecal contamination while taking the rectal biopsy of the prostate. Hence the patient must be given enema prior to the procedure.
- Patients must be usually suggested to be in the left lateral position in order to avoid the risk of air collection in front of the probe. But the lithotomy position is also suggested in many cases.
- Prophylactic single dose antibiotics can be given if needed.
- Before they were using traditional finger guided biopsy under local anaesthetic agents, but recent advances suggested trans urethral or trans rectal ultrasound guided biopsy as the safest.
- Periprostatic nerve block with lignocaine advised in order to reduce the pain and discomfort. Trans urethral ultrasound guided biopsy is the most safest and acceptable procedure.

EVIDENCES SUGGESTIVE OF PI RADS SCORE

Rudolph MM et al,[83] had conducted a retrospective study in the year 2020, with the objective to compare diagnostic performance of PI-RADS version (v) 2.1 and 2.0 for the detection of Gleason Score (GS) ≥ 7 prostate cancer on MRI. In this study, three different experienced radiologists provided a PI-RADS v2.0 score and after at least 12 months later v2.1 scores on lesions among the 333 prostate MRI examinations acquired between the years 2012 to 2015. Diagnostic performance was done by using MRI/transrectal ultrasound fusion biopsy and 10-core systematic biopsy as the reference diagnostic test. Out of 359 lesions, GS ≥ 7 tumour was found in 135 lesions which accounted for 37.60%. Area under the curve (AUC) obtained by the findings had revealed slightly lower values for peripheral zone (peripheral zone) and transition zone (transition zone) scoring in v2.1, with no statistical significance. A significant number of score 2 lesions in the transition zone were downgraded to score 1 in the version 2.1 showing 0% of the GS ≥ 7 tumor. The newly introduced diffusion-weighted imaging (DWI) upgrading rule in v2.1 was applied among 6 lesions from a total of 143 transition zone lesions (4.2%). With all of these above findings, they stated that the PI-RADS v2.1 has no statistically significant differences in overall diagnostic performance of transition zone and peripheral zone scoring compared to that of v2.0. Whereas, downgraded BPH nodules showed favourable cancer frequencies. The new DWI upgrading rule for transition zone lesions was applicable only among a few cases.

Hotker AM et al., was another retrospective study that recruited data from their prospectively maintained institutional database. It was an IRB-approved study in the year 2020 that included 229 patients undergoing a multiparametric prostate MRI

prior to MRI-guided TRUS-based biopsy. This trial had included two readers with high readers with the experience of 6 years and low readers with the experience of 2 years who identified the lesion with the highest PI-RADS score for both version 2.0 and 2.1 for each patient. Inter-reader agreement was also estimated and also the diagnostic accuracy of analysis was performed. Inter-reader agreement on PI-RADS scores was fair for both version 2.0 (kappa: 0.57) and 2.1 (kappa: 0.51). Whereas the detection rates for prostate cancer (Pca) and clinically significant prostate cancer (csPca) were almost identical for both PI-RADS versions and higher for the more experienced reader. According to this new PI-RADS 2.1 scoring system showed comparable diagnostic performance and inter-reader variability compared to version 2.0. These newly introduced diagnostic changes in the version 2.1 seemed to take effect in a very small subset of patients.

Steiger P et al., in the year 2016 they conducted an image analysis based on DWI, DCE-MRI and on T2w sequence guidelines and the pattern recognition on these sequences is primarily defined by the criteria of the PI-RADS™ v2 guidelines. Findings have been described according to the lexicon in appendix III of PI-RADS™ v2 guidelines. Before starting the image interpretation, the quality of the images has to be confirmed. Artefacts like the metal implants like hip prosthesis, air in the rectum and patient movements can compromise the diagnostic value of images. When DWI or DCE-MRI are inadequate, the PI-RADS™ v2 guidelines advise using the substitute sequences as described below.[85]

Predominant sequence is DWI in the peripheral zone and T2w sequence in the transition zone. In case of the assessment of PI-RADS category 3 in the peripheral zone DCE-MRI determines the ultimate PI-RADS assessment category. Whereas, in

PI-RADS assessment category 3 in the transition zone DWI determines the final assessment category of PI-RADS. When the image quality is compromised and DCE-MRI is inadequate for the assessment of the peripheral zone in PI-RADS assessment, category 3 the PI-RADS score is defined by the DWI alone. If DWI is not sufficient, then PI-RAD v2 guidelines advise use of T2w sequence for evaluation of both the peripheral zone and for the transition zone. If both DWI and DCE-MRI are not sufficient or not available then the assessment should be limited to staging for determination of EPE. [86]

Samei and colleagues had recruited 55 patients with suspicious prostatic lesions who underwent PR examination, PSA tests, TRU/S and also Mp-MRI prostate. The average age of the participated men was 62 years and the imaging data were compared with the histopathological data. Histopathology results had revealed 38 malignant and 17 benign lesions. The DWI showed significant restriction with low ADC value of 0.89 ± 0.24 μm2/ms in 30 peripheral zone lesions that diagnosed to be likely malignant with the corresponding score between 3 to 5 and 7 benign lesions had showed no diffusion abnormality with ADC value of 1.34 ± 0.21 μm2/ms which were statistically significant P value of < 0.001. Out of the 18 transition zone lesions, T2 WI diagnosed 7 to be likely malignant with the score of 3 to 5 and 11 were benign with the value of 1–2 score. DCE-MRI revealed the positive results among 28 peripheral zone and 8 transition zone lesions. Adding the DCE-MRI to DWI and T2WI score in equivocal lesions raises its score from 3 to 4 in 6/9 lesions that aids in diagnosis of malignant lesions. Whereas negative enhancement was noted among 9 peripheral zone and 10 transition zone benign lesions. Multi-parametric MRI with PI-RAD V2 scoring system was also proven to be a non-invasive and an accurate tool for

distinguishing between the malignant and benign prostatic lesions.87 Also, their study found the following sensitivity, specificity and accuracy.

Sensitivity	92.11%	Specificity	94.12%
Positive predictive value	97.22%	Accuracy	92.727%

In the year 2020, Kizilay et al[8] had published his radiological trial on correlation of PIRADS imaging with histopathological findings. The mean age of patients participating in their study participants was 65.7 ± 6.31 with the average PSA value 4–10 ng/mL among 59% of their patients. Mean prostate volume was 39.98ml. 53.3% of their samples had 1.1 to 2 mm of the tumour focus at mpMRI. Positivity rate of tumour at mpMRI was detected in two foci in 22 patients among which, 41.7% of them had the lesions belonged to PIRADS 4. Whereas, about 38.5% were having the lesions garding PIRADS 5.

Washino S et al In all, had conducted a retrospective trial among 288 patients, who underwent mpMRI at their hospital between 2010 July to 2014 April. The median patient age, PSA level, prostate volume and PSA density were 69 years, 7.5 ng/mL, 28.7 mL, and 0.26 ng/mL/mL, respectively. The biopsy results were benign, clinically insignificant, and clinically significant prostate cancer in 129 (45%), 18 (6%) and 141 (49%) patients, respectively. The multivariate analysis revealed that PI-RADS v2 score and PSA density were independent predictors for prostate cancer and clinically significant prostate cancer. When PI-RADS v2 score and PSA density were combined, a PI-RADS v2 score of ≥4 and PSA density ≥0.15 ng/mL/mL, or PI-RADS v2 score of 3 and PSA density of ≥0.30 ng/mL/mL, was associated with the highest clinically significant prostate cancer detection rates (76-97%) on the first biopsy. Of the patients in this group with negative biopsy results, 22% were subsequently

diagnosed as prostate cancer. In contrast, a PI-RADS v2 score of ≤3 and PSA density of <0.15 ng/mL/mL yielded no clinically significant prostate cancer and no additional detection of prostate cancer on further biopsies.[88]

Walshe T et al in the year 2014, had published their scientific paper on correlation of PI-RADs score and ADC values of lesions detected on mpMRI at their institute with the grade of cancer which was detected at fusion guided prostate biopsy. The mean patient age was 65±6 years (49-81) and the mean PSA was 13.6±10.6 ng/ml (0.3-62). Any prostatic carcinoma and significant prostatic carcinoma were detected in 77 (28%) and 54 (20%) of lesions, respectively. Any prostatic carcinoma and significant prostatic carcinoma were found in 18% and 7% of PI-RADS-3 lesions, 45% and 35% of PI-RADS-4 lesions, and 71% and 64% of PI-RADS-5 lesions, respectively. There was a correlation between PIRADS score and Gleason score (P=0.01). In univariate analysis, PSA density, smaller prostate volume, lesion size, ADC value, and the PI-RADS score were related to detection of both any prostatic carcinoma and significant prostatic carcinoma. All 16 prostatic carcinoma detected in 31 lesions with ADC<695 were significant. In multivariate analysis, statistically significant determinants of prostatic carcinoma and significant prostatic carcinoma were age (p = 0.04), PSA density (p = 0.007), and PI-RADS score (p = 0.01).[89]

Wang ZB et al have recently published their single centre retrospective study findings. This study was conducted by recruiting the cases from January 2016 to March 2020 with the objective of evaluating the role of prostate-specific antigen density and its correlation with PIRADS version 2 scan to avoid an unnecessary biopsy in transition zone patients with PSA ranging from 4 to 20 ng/mL. 333 biopsy-

naïve patients with transition zone lesions had underwent PI-RADS v2.1 and PSAD were the independent predictors for transition zone cs-prostatic carcinoma in patients with PSA 4-20 ng/mL. 48.0% of them had the grading of 4-5. Very less patients were found to be having Grade 1-2. Among these, the patients with PI-RADS v2.1, the transition zone cs-prostatic carcinoma detection rate significantly varied according to different PSAD stratification. A PI-RADS 4-5 and PSAD <0.15 ng/mL/mL had no cs-prostatic carcinoma (0.0% (0/9)). In contrast, score 4-5 and PSAD 0.15-0.29 and ≥0.30 ng/mL/mL had the highest cs-prostatic carcinoma detection rate. Though these findings were significant radiologically and histopathologically, they did not show any statistical significance. Hence, they concluded that for transition zone patients with PSA 4-20 ng/mL, PI-RADS v2.1 can avoid an unnecessary biopsy regardless of PSAD and the PI-RADS version 2 combined with PSAD could significantly improve diagnostic performance.[90]

Grey et al., in the year 2015 has published their observations found among their prospective single blinded radiological trials among two hundred and one patients. In their study they reported the sensitivity of the study as 97% but the specificity was just 60% at the 95% Confidence interval. [7]

Another study by Westphalen AC and colleagues had conducted a multicentric retrospective cross-sectional study including the patients from 26 centres. They recruited the radiography and demographic details of the biopsy proven patients. More than 3000 patients and overall 5000 and odd lesions were analysed. But the sensitivity and specificity of their PIRADS was not significant enough to consider the reporting. [91]

The present study is taken to substantiate all these above findings.

MATERIAL AND METHODS

Source of data:

Male patients above the age of 40 years with suspected prostate cancer based on prostate specific antigen (PSA) values presenting to Department of Radio-Diagnosis at the KLE'S Dr. Prabhakar Kore Hospital & MRC, Belagavi.

Method of collection of data:

Study design: Hospital based observational study

Sample size:

The minimum sample size formula based on prevalence is

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

Where P is the percentage of prevalence and d is the percentage likely difference in the prevalence.

z_α is linked with the level of significance. For 5% level of the significance $z_\alpha = 1.96$.

Ref: With P = 62% and d = 25% of P = 15.5%, the sample size is 38.[93]

Statistical Analysis:

Since the study is of observational study the plan of analysis will be as follows. For the continuous quantitative variables mean and standard deviation will be calculated. For the purpose of comparison if the data is divided into two groups with respect to certain qualitative characteristic, the continuous variables will be compared

using suitable tools of statistics like unpaired student's t test. The pre and post treatment measures will be compared using student's paired t test. Discrete variables will be represented by median. Suitable graphs will be used to depict the comparison. The categorical data will be expressed in terms of rates, ratios and percentages. The association between the outcome, clinical and demographic characteristics will be tested using Chi-square test, test of proportion or Fisher's exact test. When we compare two independent groups having quantitative values, generally student's unpaired t test is applied. For discrete variables nonparametric tests will be used. Apart from the above suitable tools like ANOVA, correlation, regression etc., will be used according to the need. For all the tests the value of p less than 5% (0.05) will be considered significant.

DURATION: One year – between 1st January 2020 to 31st December 2020

Inclusion criteria:

- Male patients with enlarged prostate above the age of 40 years.
- Patients with suspected PCa based on PSA values (elevated PSA >4.0ng/ml) and suspicious digital rectal examination

Exclusion criteria:

- Patients with known contraindications to MRI.(hip implants, vascular clips)
- Prostate biopsy (within 8 weeks) and any continued post biopsy bleeding.
- Detection of recurrence after Radiotherapy or radical prostatectomy, detection of metastasis outside pelvis.

Institutional Ethical clearance will be taken.

Written informed consent will be taken from all study subjects.

METHODOLOGY:

Study will be done using a 3.0T MRI machine manufactured by siemens. Standard protocol will be followed for all patients undergoing MRI. The patients are undergoing mpMRI as a part of their investigation and further treatment, not for the purpose of my study particularly. Once MRI is done the findings will be noted and analyzed.

EQUIPMENT:

- 3.0T MRI manufactured by Siemens
- Endorectal coil will not be used.

MRI SEQUENCES THAT WILL BE OBTAINED:

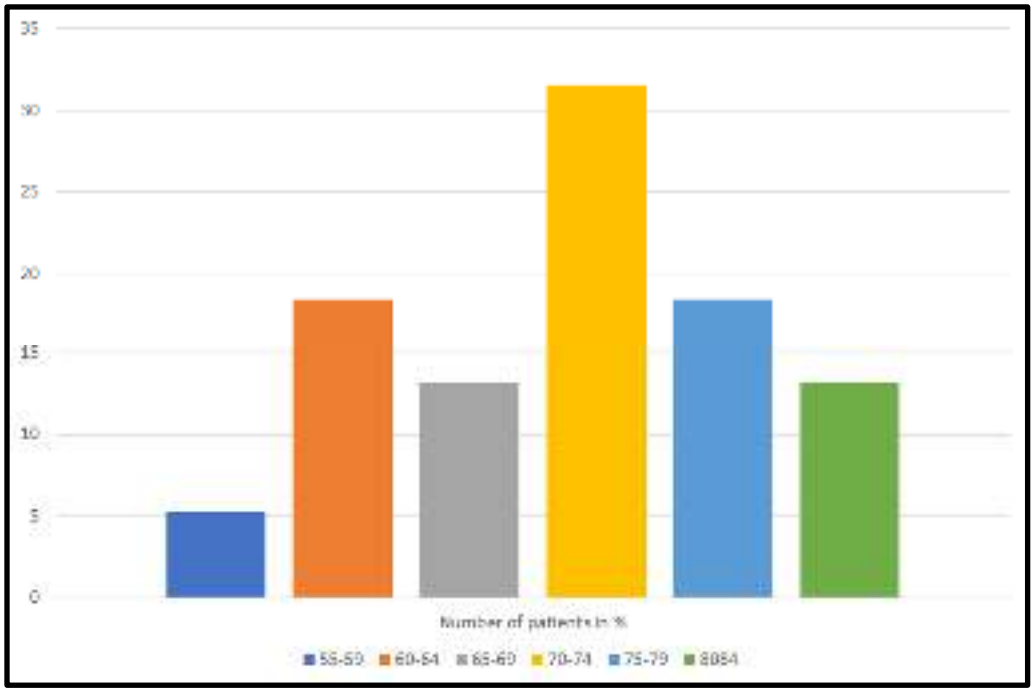
- T2 weighted image
- Diffusion weighted imaging

RESULTS

All the noted epidemiological and radiological findings have been tabulated and analysed using suitable above mentioned statistical methods. Radiological PI RADS 2.0 score and the histopathological grading was correlated. Results are depicted as follows,

Table 1: Distribution of Pattern of Age in Study Population

AGE	NUMBER	PERCENTAGE
55- 59	2	5.26
60 - 64	7	18.42
65 - 69	5	13.16
70 - 74	12	31.58
75 - 79	7	18.42
80 - 84	5	13.16
TOTAL	38	100.00



Graph 1: Distribution of pattern of Age in Study Population

Above table 1 and figure 1 illustrates the distribution of age of the patients in our study.

Out of the total thirty eight patients recruited, two of them i.e. 5.26% of the study population were aged 55-59 years of age, seven of the thirty eight patients i.e. 18.42% of the study population were aged 60-64years, five of them i.e. 13.16% of the study population were aged 65-69 years. The age group of 70-74years had the maximum number of study population i.e. twelve out of thirty eight or 31.58%. Seven of the participants i.e. 18.42% were aged 75-79 years, while the rest of the five participants i.e. 13.16% were aged between 80-84years of age.

Table 2: Pattern of Distribution of Age and PSA levels in the Study Population

	MEAN	S.D.	MINIMUM	MAXIMUM
AGE	70.55	7.32	55	82
PSA LEVEL (ng/ml)	26.29	20.77	8	87

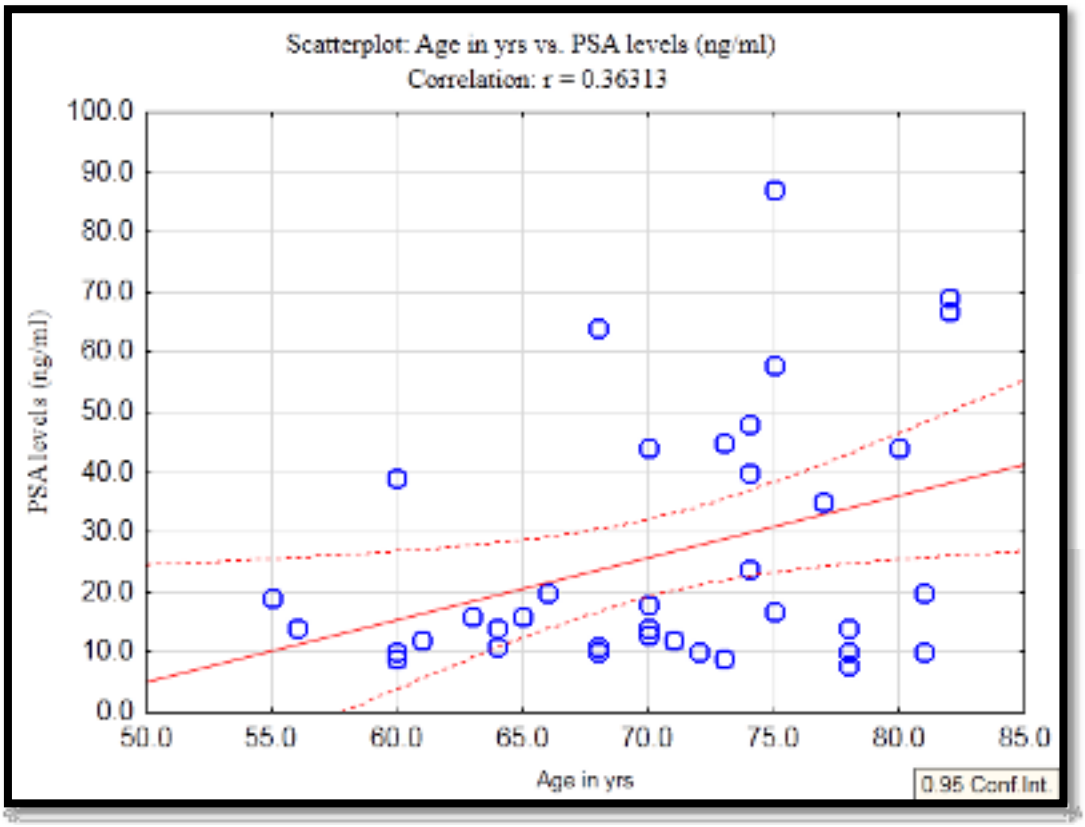
The mean of the study population was 70.55 years with a standard deviation of 7.32, ranging from fifty five to eighty two years. The average PSA level of the study population was 26.29 ng/ml with a standard deviation of 20.77, ranging from eight to eighty seven ng/ml.

Table 3: Correlation between PSA levels (ng/ml) and age in years by Karl Pearson's correlation coefficient

Variables	Correlation between PSA levels (ng/ml) and		
	r-value	t-value	p-value
Age in years	0.3631	2.3384	0.0250*

*p<0.05

As we observed, there is positive correlation between the age of the patient and PSA values but there was no such significance with respect to volume of the prostate. Below figure illustrates the scattered plot of age versus PSA score, which shows the positive correlation.

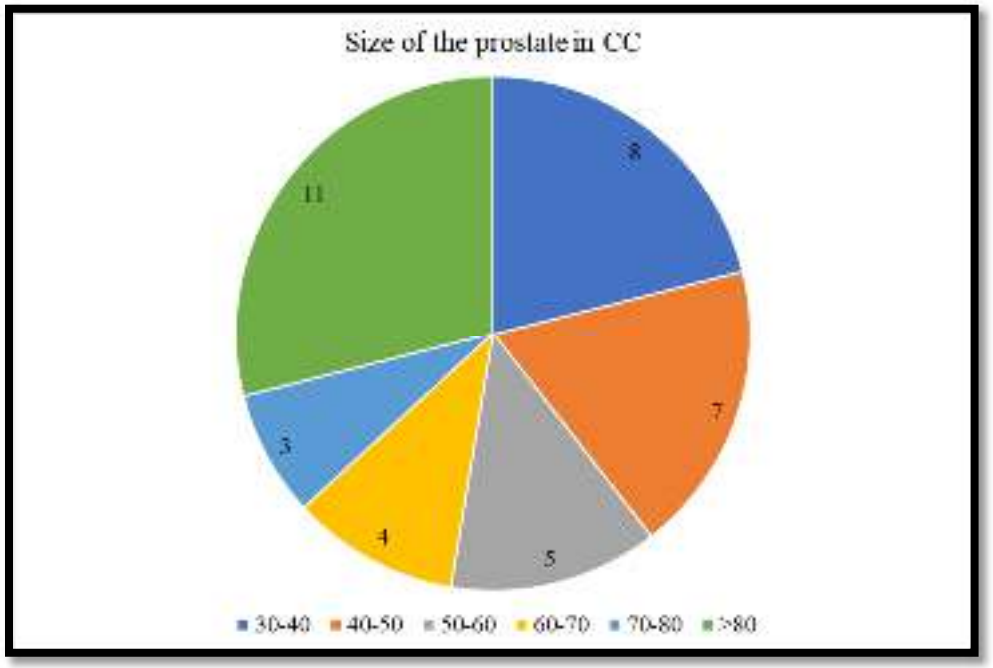


Graph 2: Scatter plot showing the correlation between PSA levels (ng/ml) and age in years

By the above graph we can see the positive r value, indicating the positive correlation.

Table 4: Pattern of Distribution of Prostate Size

SIZE IN CC	NUMBER	PERCENTAGE
30 - 40	8	21.05
40 - 50	7	18.42
50 - 60	5	13.16
60 - 70	4	10.53
70 - 80	3	7.89
> 80	11	28.95
TOTAL	38	100.00



Graph 3: Distribution of Volume of the prostate among study population

The calculated mean prostate size was 70.22cc with a standard deviation of 36.25, ranging from a minimum value of 33cc to a maximum value of 154.8cc. Out of the thirty eight patients in the study population, eight of them i.e. 21.05% had a prostate size of 30-40cc, seven of them or 18.42% had a prostate size of 40-50cc, five of them or 13.16% had a prostate size of 50-60cc, four of them or 10.53% had a prostate size of 60-70cc, three of them or 7.89% had a prostate size of 70-80cc and the rest eleven of them or 28.95% had a prostate size of more than 80cc. These findings are tabulated in table 4 and figure 3 as the pie chart.

Table 5: Distribution Pattern of lesion in Transition Zone in the Study Population

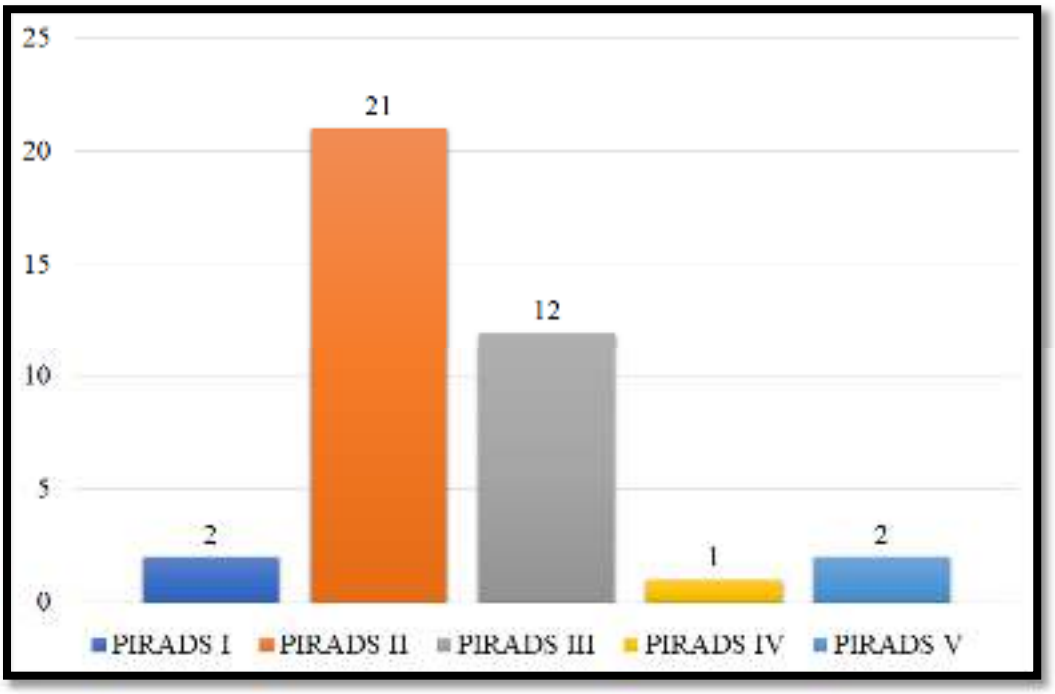
T2	NUMBER	PERCENTAGE
P	36	94.74
A	2	5.26
TOTAL	38	100.00

Table 5 explains the number of patients who showed lesions in the transition zone. Out of the thirty eight patients recruited, thirty six of them i.e. 94.74 percent of them had lesions in the transition zone in MRI while the other two of them i.e. 5.26% of them did not have lesions in the transition zone in MRI. This distribution is also illustrated as a bar diagram in figure 4 below.

Below is table 6 in which we have tabulated the PIRADS grading for the lesions present in the transition zone.

Table 6: Distribution Pattern of PIRADS Grading of transitional zone in the Study Population

PIRADS	NUMBER	PERCENTAGE
I	2	5.26
II	21	55.26
III	12	31.58
IV	1	2.63
V	2	5.26
TOTAL	38	100.00



Graph 4: Distribution of PIRADS grading among the patients having lesions in transition zone

The majority of the study population i.e. twenty five or 55.26% of them had a PIRADS grading of II in the transitional zone. Another twelve of them or 31.58% had a PIRADS grading of III, Two out of the thirty eight or 5.26% had a PIRADS grading of II, one of the Thirty eight or 2.63% had a PIRADS grading of IV in the transitional zone. Rest of the two of the thirty eight or 5.26% had a PIRADS grading of V in the transitional zone.

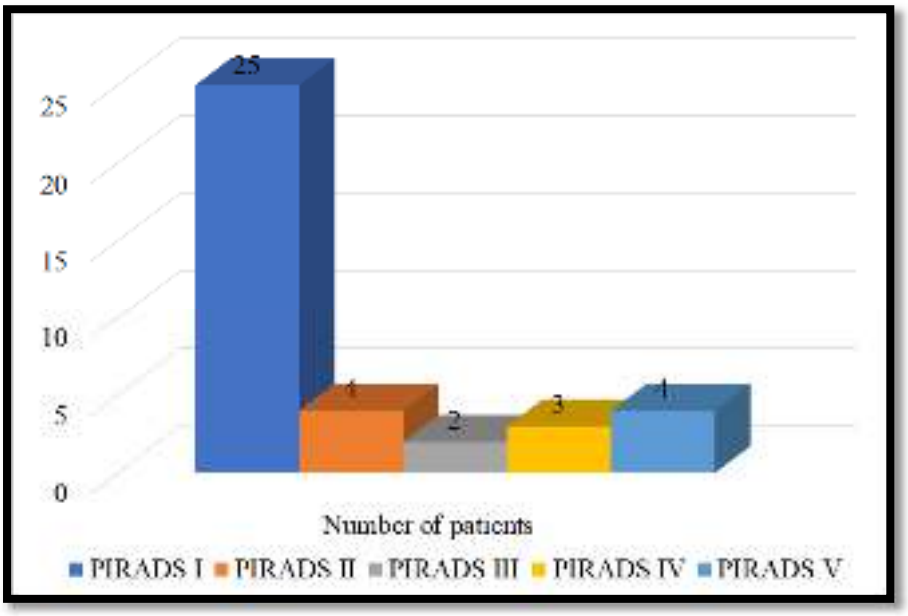
Table 7: Pattern of Distribution of lesion in Peripheral Zone In MRI of the Study Population

DWI/ADC	NUMBER	PERCENTAGE
P	13	34.21
A	25	65.79
TOTAL	38	100.00

Out of the Thirty eight patients recruited in the study, for twenty five of them or 65.79% of the sample size, there were no lesions in the peripheral zone on DWI/ADC sequences. For the rest of thirteen patients or 34.21% of the sample size, there were lesions in the peripheral zone on DWI/ADC sequences.

Table 8: Distribution Pattern of PIRADS Grading of peripheral zone in the Study Population

PIRADS	NUMBER	PERCENTAGE
I	25	65.79
II	4	10.53
III	2	5.26
IV	3	7.89
V	4	10.53
TOTAL	38	100.00

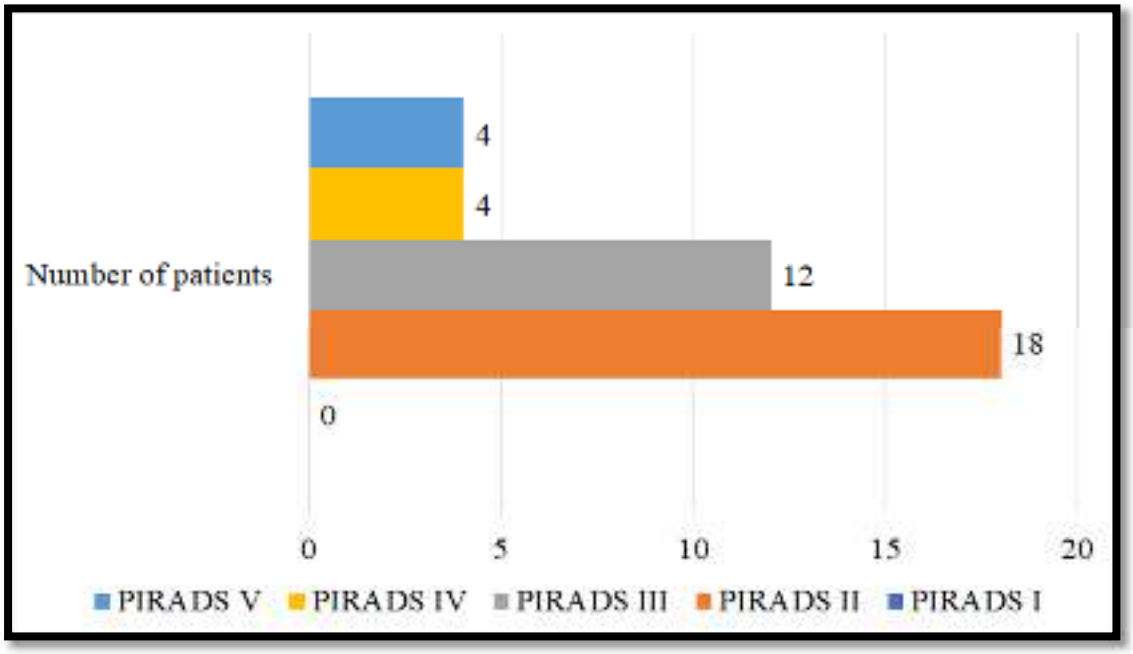


Graph 5: Distribution of PIRADS grading among the patients having lesions in the peripheral zone.

The majority of the study population i.e. twenty five or 65.79% of them had a PIRADS grading of I in the peripheral zone. Another four of them or 10.53% had a PIRADS grading of II, Two out of the thirty eight or 5.26% had a PIRADS grading of III, Three of the Thirty eight or 7.89% had a PIRADS grading of IV in the peripheral zone. Rest of the Four of the thirty eight or 10.53% had a PIRADS grading of V in the peripheral zone.

Table 9: Pattern of Distribution of Final PIRADS Grading

FINAL PIRADS	NUMBER	PERCENTAGE
I	0	0.00
II	18	47.37
III	12	31.58
IV	4	10.53
V	4	10.53
TOTAL	**38**	**100.00**

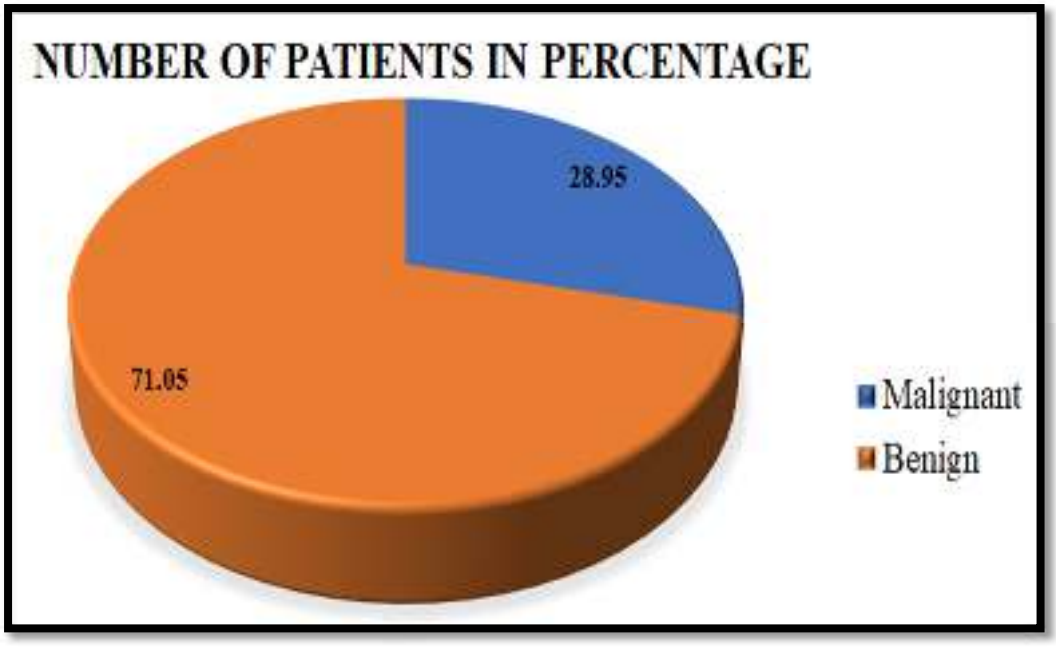


Graph 6: Distribution of final PIRADS grading among the study participants.

Out of the 38 patients recruited, none of the patients had a final PIRADS grading of I, Eighteen of the patients or 47.37% had a final PIRADS grading of II, twelve patients or 31.58 % of them had a final PIRADS grading of III, four patients or 10.53% of them had a final PIRADS grading of IV and the rest of the four patients or 10.53% of them had a final PIRADS grading of V.

Table 10: Pattern of Distribution of Malignancy based on histopathology report in the Study Population

	NUMBER	PERCENTAGE
MALIGNANT	11	28.95
BENIGN	27	71.05
TOTAL	38	100.00



Graph 7: Number of patients with malignant and benign lesions.

Amongst the thirty eight patients recruited in the study, biopsy revealed eleven of them i.e. 28.95% had malignancy. Rest of the twenty seven i.e. 71.05% of the patients' biopsy revealed that the sample was benign.

Table 11: Distribution Pattern of Histopathology Results versus PIRADS

	PIRADS		
HISTOPATHOLOGY	**POSITIVE**	**NEGATIVE**	**TOTAL**
POSITIVE	10	1	11
NEGATIVE	2	25	27
TOTAL	12	26	38

The above table 11, illustrates the correlation between final PI RADS score and the histopathological grading among the patients having both transitional and peripheral lesions. The number of samples which were positive for malignancy in histopathology were eleven. Of these, ten were positive and one was negative according to final PIRADS. Rest of the 27 samples were negative for malignancy in histopathology. Amongst these, twenty five of them were negative and two of them were positive for malignancy according to PIRADS.

Table 12: Accuracy of our mpMRI with respect to PIRADS version 2.0

PARAMETER	%
SENSITIVITY	83.33
SPECIFICITY	96.15
POSITIVE PREDICTIVE VALUE	90.1
NEGATIVE PREDICTIVE VALUE	92.59
DIAGNOSTIC ACCURACY	92.1

Comparing PIRADS over the gold standard histopathology, PIRADS has a sensitivity of 83.33% and the specificity being 96.15%. And the positive predictive value of mp MRI of our study found to be 90.1% with the diagnostic accuracy of 92.1%

Based on the above results, we would like to discuss the study in depth in the discussion part.

DISCUSSION

Cancer Prostate is one of the most common types of cancer among men accounting for almost 20 to 35%. Transitional zone lesions are involved more than peripheral ones. PSA score is used for the screening purpose among the men aged >40 years. Transrectal or transperitoneal ultrasound guided scan and biopsy are used for confirmation. In the year 2015, American college of Radiology introduced the latest version of PIRADS, PIRADS version 2.1 in order to standardize the scoring system globally and to reduce the variability in reporting.

In our study, out of the total thirty eight patients recruited were with mean age of 70.55 +/- 7.32 years (Mean +/- SD) a majority of them were aged between 70 to 74 years of age with the prevalence of 31.58% followed by 65 to 69 and 75 to 79 and 60 to 64 years males with the prevalence of 18.42% and the least prevalence of samples were aged 55 to 59 years. This observation explains the correlation of age with the incidences of carcinoma prostate. Our finding is similar to the study conducted by Stangelberger A et al[92] and also the american cancer society guidelines, in which they had higher prevalence of Ca Prostate is seen among the patients > 65 years. The mean age of the study participants in the study conducted by Kiziley et[8] was 65.7 ± 6.31, which is almost similar to our samples. Also it has been stated that this correlation also has an impact over the treatment.

The average PSA level of our recruited study population was 26.29 ng/ml with a standard deviation of 20.77. This is contrary to Kizilay[8] study finding, in which their patients were having the average PSA score of 4 to 10 ng/ml. The severity was not correlating with the PSA score. But comparatively it was high among the patients aged > 75 years. Washino S et al[88] also reported the same PSA score, but they too had

the higher value among >69 year old patients. Our study has both clinical and statistically significant positive correlation between the PSA value and age with p value < 0.05.

Mean prostate size of the study participants was 70.22cc with a standard deviation of 36.25. Majority of our study samples, 28.95% had a prostate size of more than 80cc. Followed by 21.05% who had prostate size about 30-40cc. 18.42% with 40-50cc volume. 13.16% and 10.35% were presented with 50-60cc and 60-70cc respectively. Least prevalence of about 7.89% found to be 70-80cc. And this volume of prostate size was more among the patients with higher PSA scores. Our observation is similar to Washino et al[88] and also Kizilay et al[8] Even Samei Kareem et al[87]., also had significant correlation between PSA score and the volume of prostate with p value of <0.001.Mean PSA score in a study by Triona M et al was 13.6±10.6 ng/ml, which much high compared to Kareem and Kizilay et al[8,87]. Triona M et al also has reported the radiological as well as statistical significance between PSA and size of the prostate. 33cc and 154.8cc was the minimum and maximum volume of the prostate size reported in our study. We observed the increase in size as the age of samples progressed and also positive correlation with the PSA score. Wang ZB et al[90]., reported the positive correlation between PIRADS version 2.0 and the PSA density and also concluded that benign lesions in the transition zone on mpMRI avoids the unnecessary requirement of biopsy.

36/38 (94.74%) of our samples had lesions in the transition zone. Among which, 5.26% of them had a PI RADS grading of I in the transition zone and also similar prevalence of the patients had grade V. Followed by 55.26% having PIRADS

grading of II in the transition zone. Grade IV and Grade III were found in the transition zone with prevalence of 2.63% and 31.58% respectively.

25/38 (65.79%) of the patients did not have lesions in the peripheral zone on DWI/ADC sequences of the MRI. Of the remaining thirteen patients (34.21%), had lesions in the peripheral zone on DWI/ADC sequences of MRI. The majority of the study population i.e. twenty five or 65.79% of them had a PIRADS grading of I in the peripheral zone. Another four of them or 10.53% had a PIRADS grading of II, Two out of the thirty eight or 5.26% had a PIRADS grading of III, Three of the Thirty eight or 7.89% had a PIRADS grading of IV in the peripheral zone. Rest of the Four of the thirty eight or 10.53% had a PIRADS grading of V in the peripheral zone.

After analysing the final PI RADS, none or 0.00% of patients were found to be having grade I. 18/38 or 47.37 % were found to be having grade II, twelve or 31.58% of them belong to grade III. 4/38 or 10.53% each of the samples belonged to grade IV and grade V. Contrary to our findings, Kareem E et al had reported more cases of lesions on the peripheral zone than the transitional. This finding of them was also proved to be significant on final PI RADS. Washino and Triona et al also had the majority of their study population belong to grade V. And have shown statistically significant correlation with Gleason grading system with p value of 0.01. Whereas, 0.04 of the p value in correlation with age of the study participants.

In our present study, 71.05% of the patients were proved to be benign on histopathology. Whereas 28.95% of our samples were proved to be malignant on the biopsy report. This showed the positive correlation with the final PIRAS score and the correlation of intermittent PIRADS with the histopathological grading. Kareem E radiological findings had the Sensitivity of 92.11%, Specificity 94.12%, positive

predictive value 97.22% and the accuracy of their study was 92.727%. Though our study found a slightly lower sensitivity level with 83.33%, the specificity was 96.15%. 90.1% and 92.1 of the positive predictive value and accuracy respectively. By these above findings, we can report that both the PIRADS and biopsy correlation are important while diagnosing the severity of prostate cancer.

CONCLUSION

From our prospective radiological trial, we can conclude that, prevalence of prostate lesions are most common among elderly male patients with increasing severity as the age progresses. Incidence of transitional zone lesions are more common than the peripheral. Volume of the prostate is positively correlated with PSA scoring. PSA score and mpMRI itself is enough for diagnosing the lesions below PIRADS III, while the lesions with higher grade might have variation and hence require the biopsy. PIRADS version 2.0 gives us the most reliable findings and avoids the unnecessary biopsy.

SUMMARY

A prospective observational study was conducted in the department of Radio-diagnosis of a tertiary care teaching hospital to assess the diagnostic accuracy of multi-parametric magnetic resonance imaging (mMRI) of prostate based on prostate imaging reporting and data system (PI-RADS) version 2 in comparison with histopathology.

MRI turned out as modality of choice in evaluation of prostate in patients with raised PSA levels as it is a non invasive modality. Eventually, final diagnosis is based on histopathology.

In this study we could draw an approach to evaluate the lesions in prostate with MR Imaging using T2WI, DWI and ADC and classify them into benign and carcinoma based on PIRADS v2.

The study has highlighted the features of carcinoma prostate on MRI evaluation in a tertiary care hospital. The study findings can be useful for clinical practitioners dealing with possible cases of carcinoma prostate by providing organized approach in identification and in effective management.

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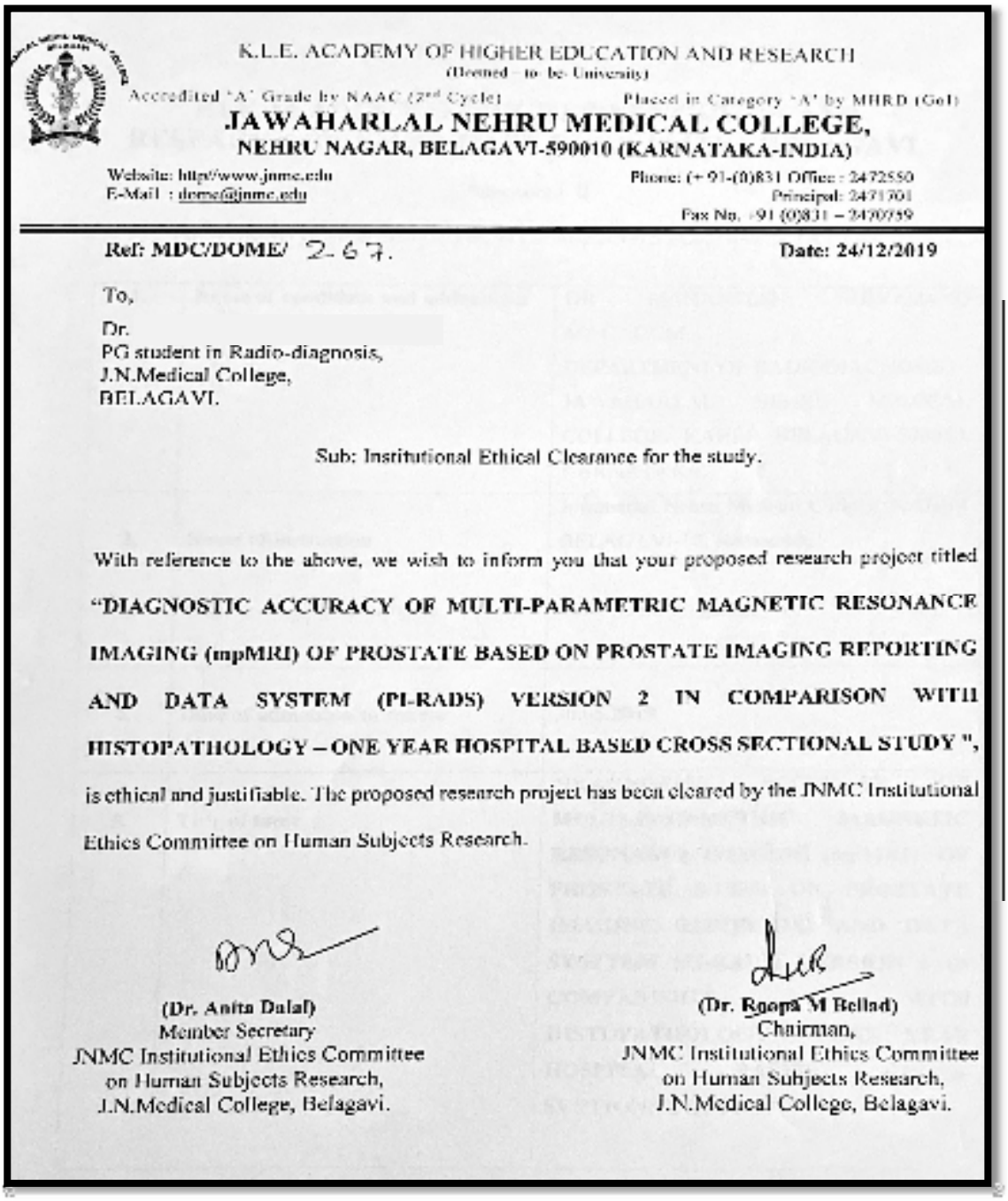
ANNEXURE – I - ETHICAL CLEARANCE LETTER



K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to be University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)

JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2420759

Ref: MDC/DOME/ 2-67. **Date: 24/12/2019**

To,

Dr.
PG student in Radio-diagnosis,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"DIAGNOSTIC ACCURACY OF MULTI-PARAMETRIC MAGNETIC RESONANCE IMAGING (mpMRI) OF PROSTATE BASED ON PROSTATE IMAGING REPORTING AND DATA SYSTEM (PI-RADS) VERSION 2 IN COMPARISON WITH HISTOPATHOLOGY – ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY "**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Anita Dalal)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Rooma M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

ANNEXURE – II - INFORMED CONSENT

TITLE OF THE STUDY: "DIAGNOSTIC ACCURACY OF MULTI-PARAMETRIC MAGNETIC RESONANCE IMAGING (mpMRI) OF PROSTATE BASED ON PROSTATE IMAGING REPORTING AND DATA SYSYTEM (PI-RADS) VERSION 2 IN COMPARISION WITH HISTOPATHOLOGY – ONE YEAR HOSPITAL BASED CROSS-SECTIONAL STUDY"

PRINCIPAL INVESTIGATOR: Dr.

INTRODUCTION AND PURPOSE:

Multi-parametric magnetic resonance imaging (mp-MRI), combining the morphological assessment of T2-weighted imaging (T2WI) with diffusion-weighted imaging (DWI), dynamic contrast-enhanced (DCE) perfusion imaging and spectroscopic imaging (MRSI), has been extensively studied in recent years. In particular, T2WI and DWI have shown considerable promise in the detection, localization, risk stratification and staging of prostate cancer. This review will provide an overview of the different imaging sequences and discuss the current role of mp-MRI in the different aspects of management of prostate cancer.

PROCEDURE:

I request you to kindly participate in the study titled study **"DIAGNOSTIC ACCURACY OF MULTI-PARAMETRIC MAGNETIC RESONANCE IMAGING (mpMRI) OF PROSTATE BASED ON PROSTATE IMAGING REPORTING AND DATA SYSYTEM (PI-RADS) VERSION 2 IN**

COMPARISION WITH HISTOPATHOLOGY – ONE YEAR HOSPITAL BASED CROSS-SECTIONAL STUDY" at Dr. Prabhakar Kore charitable hospital and Medical Research Centre, Belgaum" is being conducted by Dr._____ post graduate in Radio diagnosis at J. N. Medical College Belgaum, Karnataka, under the guidance of Dr._____ Professor, Dept. of Radio diagnosis, J. N. Medical College, KAHER, Belgaum.

We request you to participate in this study as you are eligible to be included. During the study you will be asked questions regarding your present and past medical history and you will be required to answer to the best of your knowledge. U will also be clinically examined as per the protocol drawn.

If you agree to participate in the study, please furnish the details pertaining to the study.

BENEFITS:

Non-invasive modality.

COMPLICATIONS:

No risk to the patient has been documented from multi-parametric MR imaging of the prostate conducted earlier.

ALTERNATIVES:

If patient is not willing to take part in the study, his / her treatment or any other further investigations the patient wants to undergo, in future, in KLE will not be affected by his / her decision.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell if any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study I will receive the standard treatment for patients with my condition.

COSTS:

No additional cost other than MRI which is advised by referring consultant for diagnostic purpose.

PAYMENT FOR PARTICIPATION:

No incentive will be paid to you for participating in this study.

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment whatever available at KLE charitable hospital, Belagavi, will be offered to me. No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in

this research record. Information from this study may be published but my identity will be confidential in any publication.

QUESTION:

If any enquiries in the future or in case of research related injury illness, you may contact following person.

- **Dr. _____**, Department of radio-diagnosis, KLE'S Dr. Prabhakar Kore hospital and MRC, Belagavi.

- **Dr. _____** professor, department of radio-diagnosis, KLE'S Dr. Prabhakar Kore hospital and MRC, Belagavi.

- If you have any queries about the rights as a study subject, you may call **Dr. Dr. ROOPA M BELLAD**, Professor, Department of pediatrics, Chairman of JNMC Institutional Ethical Committee of Human Subjects Research, phone no: 0831-2473777, Ext. 1529 at JNMC Belagavi.

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

"I understand that I am participating in the study, which includes multi-parametric Magnetic Resonance Imaging of prostate. I confirm that I have read and understood the information in the patient information sheet. Procedure is explained to me in detail along with information about the advantages and disadvantages of taking part in the study. I have been given the opportunity to discuss all aspects of the trial, to ask questions and hereby consent to participation in the trial outlined above. I understand that the decision to take part in this study is completely voluntary and I am aware that I can choose to withdraw from the study at any point of time. I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them. I understand that there is no significant risk involved in the test that would be done in this study. No guarantee or assurance has given by anyone as to the results that may be obtained. My signature on this form signifies that I have willingly decided to participate after understanding the above information."

Participant's Name/legally authorized representative:……

Signature/ Left Thumb impression :……....

Name and signature of witness:……..

Date:……..

Place:…….……

ANNEXURE – III - PROFORMA FOR DATA COLLECTION

NAME_____

AGE_____ **OP/IP NO** _____

MOBILE_____

ADDRESS _____

MRI NUMBER: _____

CHIEF COMPLAINTS:

HISTORY OF PRESENTING ILLNESS:

PAST HISTORY:

FAMILY HISTORY:

CLINICAL EXAMINATION

- **Digital rectal examination:**

LAB INVESTIGATIONS

- **PSA Level:**

IMAGING

- **Prostate size:**
- **Prostate volume:**
- **No. of lesions:**

LESION:

- **Location:**
- **Size:**
- **T2WI:**
- **DWI:**
- **ADC:**

PIRADS:

HISTOPATHOLOGY (biopsy):

ANNEXURE – IV - PHOTOGRAPHS OF CASES

Case 1: A 74 year old male patient presented with difficulty in micturition and shows raised PSA level (24 ng/ml) and mild prostatomegaly on ultrasonography.

Fig7.a

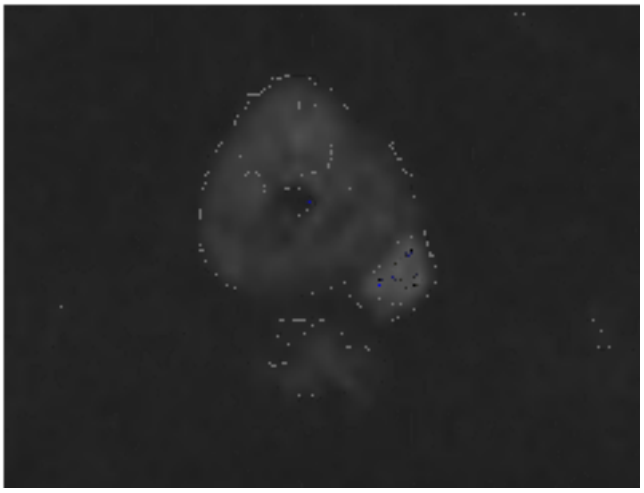


Fig7.b

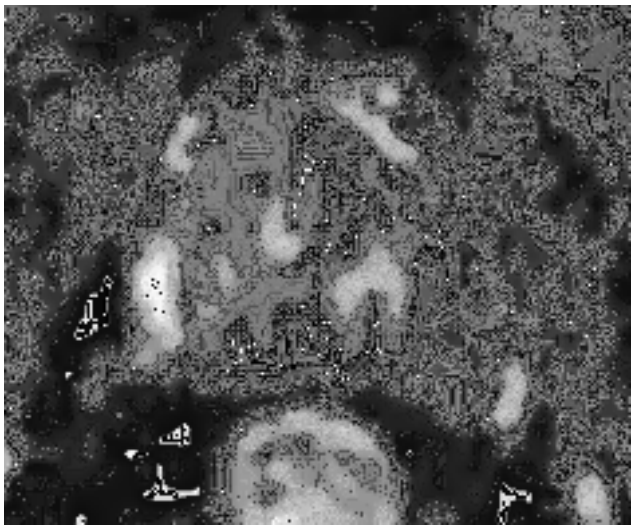


Fig 7.a DWI & 7.b ADC : Focal markedly hypointense area on ADC and hyperintense area on DWI sequence approximately measuring 1.2 cm noted in the peripheral zone on left side categorized PIRADS IV in the peripheral zone.

Case 2: A 68 year old male patient presented with difficulty in micturition and shows raised PSA level (64ng/ml) and mild prostatomegaly on ultrasonography.

Fig 8.a

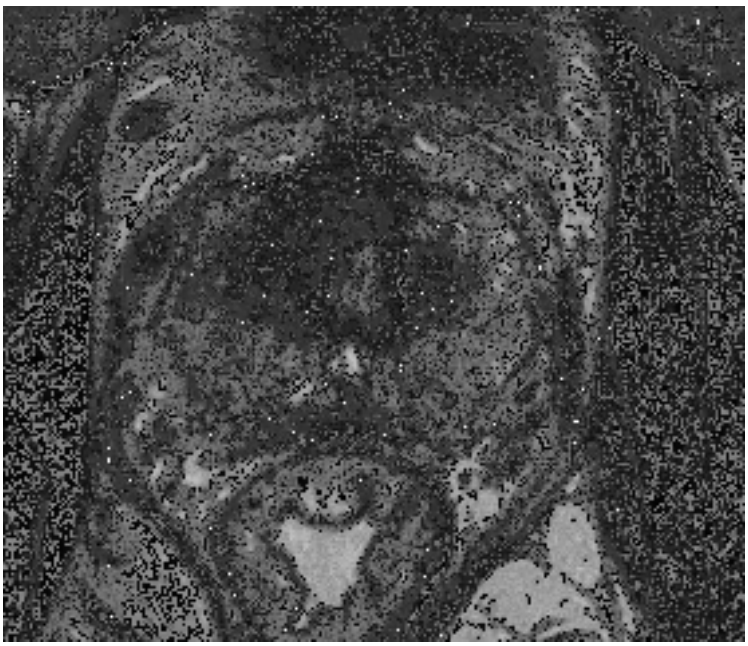


Fig 8.b

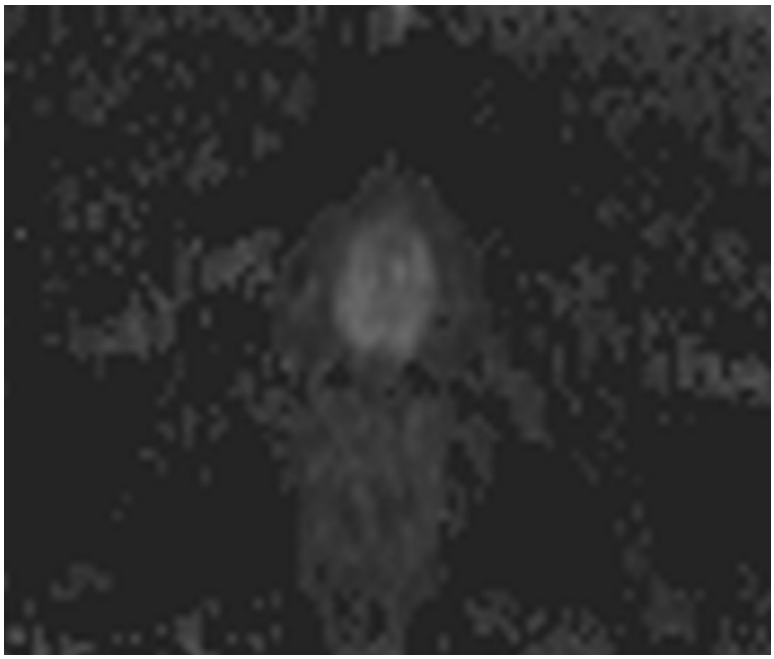


Fig 8.c

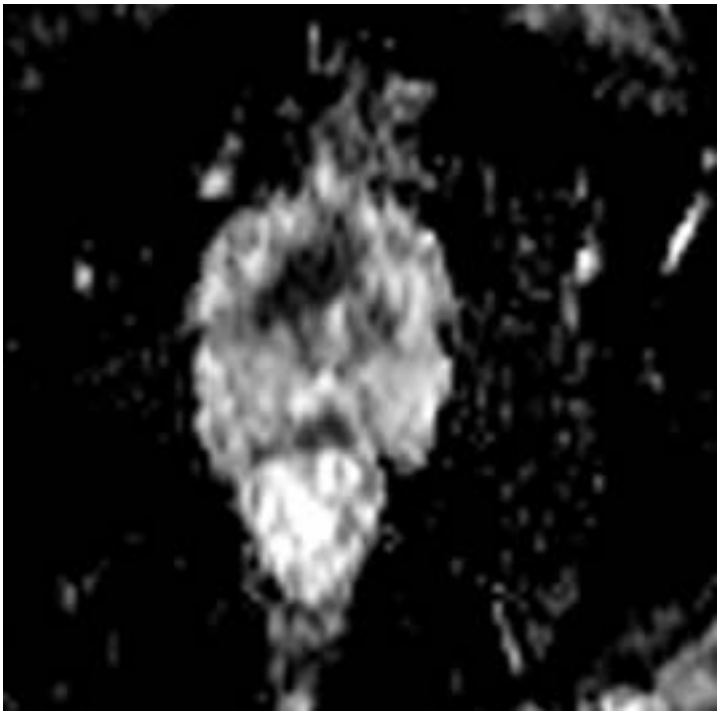


Fig 8.a T2WI, 8.b DWI & 8.c ADC : Large smooth homogeneous hypointense area on T2WI noted in the TZ/AFS. There is high signal on DWI and a decrease in ADC categorized PIRADS V in the transitional zone

Case 3: A 75 year old male patient presented with difficulty in micturition and shows raised PSA level (58ng/ml) and prostatomegaly on ultrasonography.

Fig 9.a

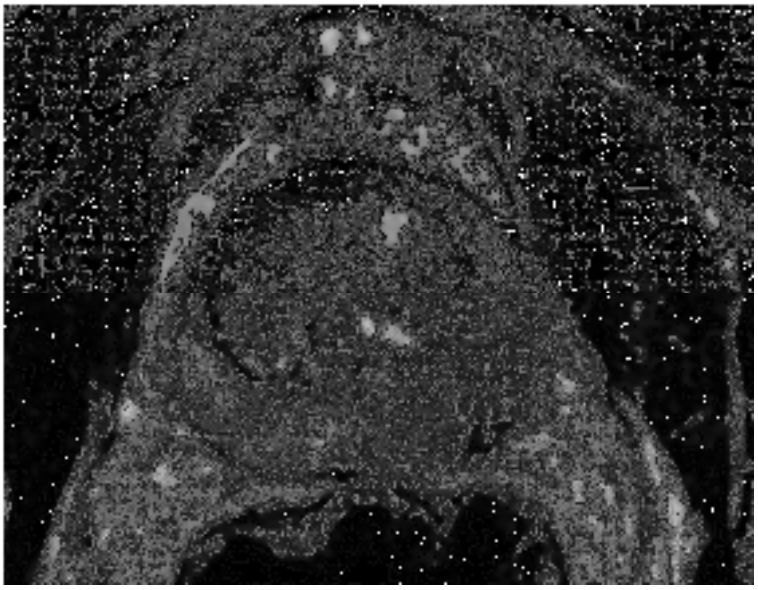


Fig 9.b

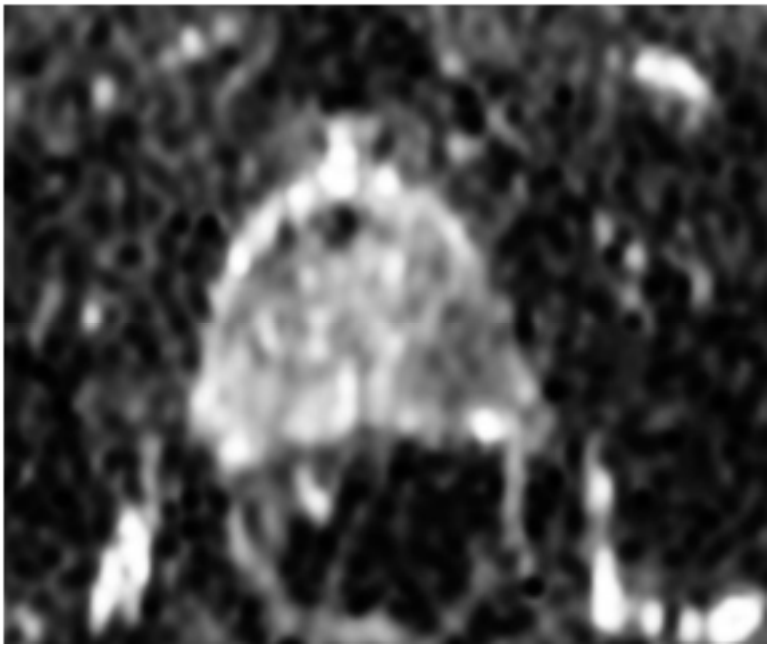
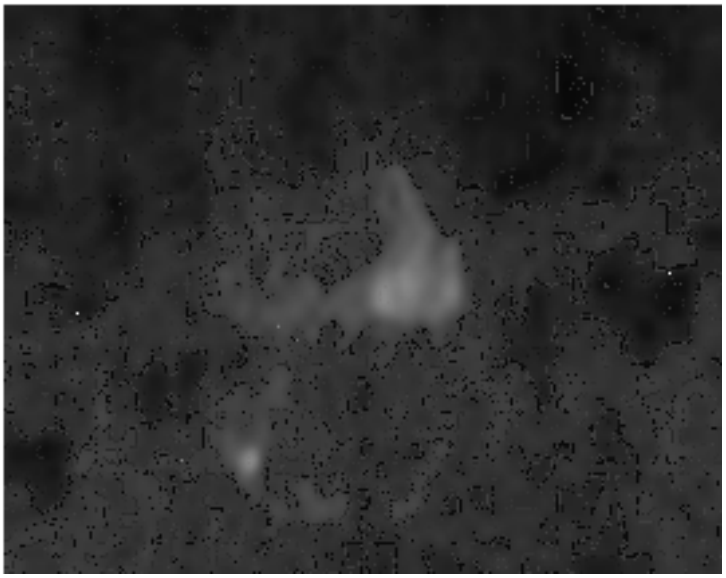


Fig 9.c



<u>Fig 9.a T2WI, 9.b DWI & 9.c ADC</u> : T2 hypointense area approximately measuring 2.0 cm in the posterolateral aspect of the peripheral zone on left side at the level of the mid gland and extending towards the apex. The lesion is markedly hyperintense on DWI and hypointense on ADC categorized PIRADS V in the peripheral zone.

Case 4: A 63 year old male patient presented with difficulty in micturition and shows raised PSA level (16ng/ml) and prostatomegaly on ultrasonography.

Fig 10.a

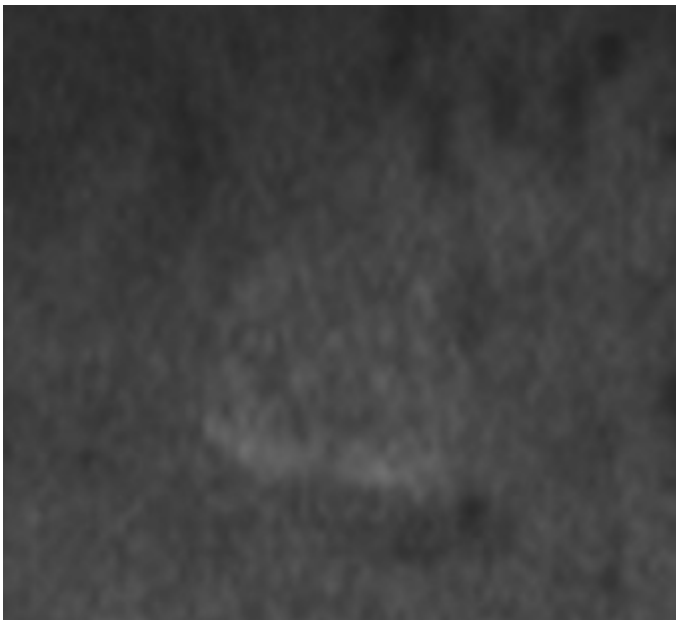


Fig 10.b

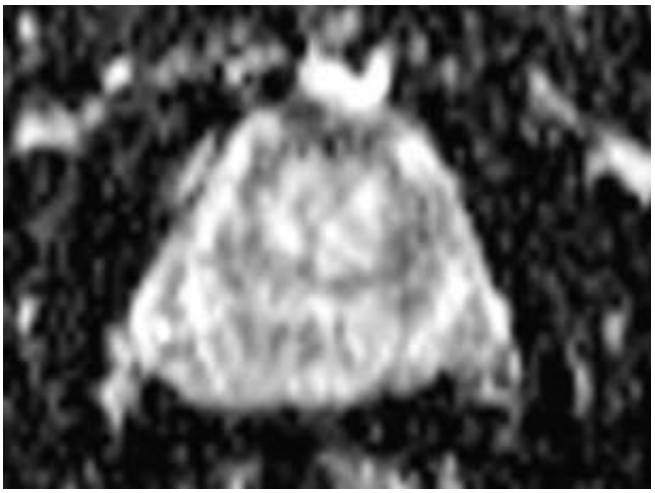


Fig 10.a DWI & 10.b ADC :Patchy moderate hyperintense changes in both peripheral zones (right slightly more than left) on DWI, which are moderately hypointense on ADC categorized as PIRADS III in peripheral zone.

Case 4: A 78 year old male patient presented with difficulty in micturition and shows raised PSA level (14ng/ml) and prostatomegaly on ultrasonography.

Fig 11

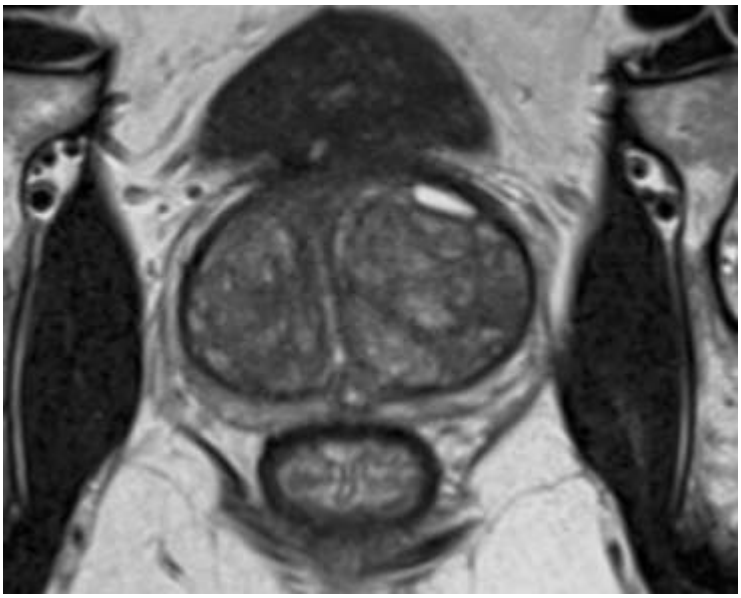


Fig 11.aT2WI: Few well circumscribed T2 hypointense and T2 heterogeneous lesions seen in the transition zone on both sides suggestive of BPH nodules categorized as PIRADS II in transitional zone.

ANNEXURE V: KEY TO MASTERCHART

M	**MALE**
ng/ml	**NANOGRAMS PER MILLILITER**
CC	**CUBIC CENTIMETRE**
PSA	**PROSTATE SPECIFIC ANTIGEN**
MRI	**MAGNETIC RESONANCE IMAGING**
T2WI	**T2 WEIGHTED IMAGING**
DWI	**DIFFUSION WEIGHTED IMAGING**
ADC	**APPARENT DIFFUSION COEFFICIENT**
P	**LESION PRESENT**
A	**NO LESION**
PIRADS	**PROSTATE IMAGING–REPORTING AND DATA SYSTEM**
I	**GRADE I**
II	**GRADE II**
III	**GRADE III**
IV	**GRADE IV**
V	**GRADE V**
BPH	**BENIGN PROSTATIC HYPERPLASIA**
PIN	**PROSTATIC INTRAEPITHELIAL NEOPLASIA**

ANNEXURE VI: MASTERCHART												
SL.NO	**MRI NO**	**NAME**	**AGE**	**SEX**	**PSA LEVEL (ng/ml)**	**MRI FINDINGS**						**HISTOPATHOLOGY IMPRESSION**
						SIZE	**ANSITIONAL ZO**		**PERIPHERAL ZONE**			
						(IN CC)	**T2WI**	**PIRADS**	**DWI/ADC**	**PIRADS**	**FINAL PIRADS**	
1	M7509	BHEEMAGOUDA PATIL	78	M	14	47	P	II	A	I	**II**	**BENIGN WITH CHRONIC INFLAMMATION**
2	M8247	NOORAHAMED TALIKKOTI	75	M	58	48	A	I	P	V	**V**	**PROSTATIC ADENOCARCINOMA**
3	M8621	PRAKASH R M	68	M	10	68	P	II	A	I	**II**	**ACUTE ON CHRONIC PROSTATITIS**
4	M8634	SHANKAR KULKARNI	73	M	45	34	P	II	P	V	**V**	**PROSTATIC ADENOCARCINOMA**
5	M8669	RAJASHEKAR KALBURGI	74	M	40	154.8	P	II	A	I	**II**	**PROSTATIC ADENOCARCINOMA**
6	M8295	DR SHANTEGOUDA PATIL	68	M	11	151.5	P	II	A	I	**II**	**BPH WITH CHRONIC PROSTATITIS**
7	M8867	GURUSIDADAPPA KADAKOL	68	M	64	37	P	V	A	I	**V**	**PROSTATIC ADENOCARCINOMA**
8	M9653	SHIVAJI NARAYANKAR	74	M	24	41.8	P	II	P	IV	**IV**	**BPH WITH ACUTE ON CHRONIC PROSTATITIS**
9	M9654	ERANNA MATAMARI	71	M	12	39.6	P	III	A	I	**III**	**BPH**
10	M10015	BASAVARAJ CHIKKANARGUND	63	M	16	58	P	III	P	III	**III**	**BPH WITH CHRONIC PROSTATITIS**
11	M10288	LINO DOURADO	66	M	20	145	P	II	A	I	**II**	**BPH WITH CHRONIC PROSTATITIS**
12	M12292	SANAGOUDA PATIL	80	M	44	77.2	P	II	A	I	**II**	**BPH WITH CHRONIC PROSTATITIS WITH A FOCUS OF PIN**
13	M12697	ASHOK DADDIKAR	70	M	18	111.3	P	II	A	I	**II**	**ACUTE ON CHRONIC PROSTATITIS**
14	M12832	HUSAINSAB	70	M	14	138	P	II	A	I	**II**	**BPH WITH CHRONIC PROSTATITIS**
15	M12908	GOURIHAR MUTTUR	81	M	20	36	P	II	A	I	**II**	**BPH WITH CHRONIC PROSTATITIS**
16	M13043	HONAPPA PANNALKAR	77	M	35	65	P	IV	A	I	**IV**	**PROSTATIC ADENOCARCINOMA**

SL.NO	MRI NO	NAME	AGE	SEX	PSA LEVEL (ng/ml)	MRI FINDINGS						HISTOPATHOLOGY IMPRESSION
						SIZE	ANSITIONAL ZO		PERIPHERAL ZONE			
						(IN CC)	T2WI	PIRADS	DWI/ADC	PIRADS	FINAL PIRADS	
17	M13085	YAMANAPPA PUJAR	65	M	16	118	P	II	P	II	**II**	**BPH WITH ACUTE PROSTATITIS**
18	M13094	BALVANT KEDARI	70	M	18	40	P	II	A	I	**II**	**BPH**
19	M13683	ADIVEPPA SATYAPPA H	60	M	39	50	P	II	A	I	**II**	**BPH**
20	M14610	VAMAN HARIJAN	60	M	10	52.6	P	II	P	II	**II**	**CHRONIC PROSTATITIS**
21	M14755	MURTUJASAB SHOLAPUR	75	M	87	108	P	III	P	V	**III**	**PROSTATIC ADENOCARCINOMA**
22	M14754	MALLAPPA HONNUTAGI	82	M	69	112	P	III	A	I	**III**	**PROSTATIC ADENOCARCINOMA**
23	M14812	DUNDAPPA MALI	64	M	14	42.8	P	II	A	I	**II**	**ACUTE PROSTATITIS**
24	M14865	UMAKANT SHIVABALAPPA	72	M	10	43	P	III	A	I	**III**	**CHRONIC PROSTATITIS**
25	M14883	BALU BOKE	75	M	17	70	P	III	A	I	**III**	**BPH**
26	M14950	SURESH GHUTE	74	M	48	44	A	I	P	IV	**IV**	**LOW GRADE PIN**
27	M15119	BABU PUJARI	61	M	12	35	P	II	P	III	**III**	**BPH**
28	M15198	YALLAPPA JAKABAL	82	M	67	53.5	P	III	A	I	**III**	**PROSTATIC ADENOCARCINOMA**
29	M15215	KRISHNA DESHINGE	56	M	14	56	P	II	P	II	**II**	**BPH WITH CHRONIC PROSTATITIS**
30	M16764	RICKY FRANCO	55	M	19	65	P	II	A	I	**II**	**BPH**
31	M16764	GURUPADAPPA YALIGAR	78	M	10	39	P	V	P	V	**V**	**PROSTATIC ADENOCARCINOMA**
32	M16853	RAMKRISHNA MENON	60	M	9	33	P	III	A	I	**III**	**BPH WITH CHRONIC PROSTATITIS**
33	M17485	ANIL BANDODKAR	78	M	8	69	P	II	A	I	**II**	**BPH**
34	M21891	BALLAPPA SHIVURUDRA	81	M	10	88	P	III	A	I	**III**	**BPH**
35	M22423	SHANKAREPPA AMMALAGERI	64	M	11	100	P	III	P	II	**III**	**BPH WITH ACUTE ON CHRONIC PROSTATITIS**
36	M22929	NAGAPPA SHIVAPPAGOL	70	M	13	70	P	III	A	I	**III**	**BPH**
37	M23278	VISHWANATH KAKADE	73	M	9	92.9	P	II	A	I	**II**	**ACUTE PROSTATITIS**
38	M23366	SHANKAR NERLI	70	M	44	34.4	P	III	P	IV	**IV**	**PROSTATIC ADENOCARCINOMA**