



## RESEARCH ARTICLE

# ASSOCIATION BETWEEN PI-RADS SCALE, HISTOPATHOLOGICAL REPORT AND PSA IN PATIENTS WITH SUSPECTED PROSTATE CANCER AT THE NAVAL MEDICAL CENTER

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### ABSTRACT

**INTRODUCTION:** Prostate Cancer (CaP) rarely produces symptoms at the beginning of disease progression since most tumors originate on the periphery of the gland. To improve early diagnosis and treatment of prostate cancer, the Prostate Imaging and Reporting and Data System, PI-RADS, was created. The system is beneficial in indicating probability and identifying where the biopsy will be directed if necessary, the increasing the chance that the sample will contain tissue with high suspicion of cancer. (4,5) **JUSTIFICATION:** Patients with suspected prostate cancer require an adequate strategy to diagnose the disease early. Multiparametric prostate MRI is a possible method of implementing as part of this screening in our population, and thus complementing the rest of the diagnostic tools. **MATERIAL AND METHODS:** An analytical, observational, transverse and retrospective study was conducted with patients at the Naval Hospital of High Specialty to whom t-tests were applied for independent samples and Mann-Whitney U-test for statistical analysis. Patients with suspected Prostate Cancer were selected who had psa levels, prostate MAGNETIC resonance imaging, and had histopathological reports of transrectal prostate biopsies. **RESULTS:** The sample for convenience was 59 patients, the average age of patients with adenocarcinoma was 65.0 years, without adenocarcinoma 64.4 years. The difference in mean values between the two groups is greater than would be expected by chance; there is a statistically significant difference ( $P < 0.006$ ), in this case we can say that the occurrence of adenocarcinoma is related to the PI-RADS 5 classification, since the value of "P" is less than 0.05, indicating a significant difference. The average pre-MRI PSA value of patients with adenocarcinoma was 8.9 ng/ml, with no adenocarcinoma 4.6 ng/ml, with a value of  $P < 0.928$ , there is no statistically significant difference. **DISCUSSION:** The PI-RADS prostate imaging data reporting and recording system is a tool developed for the timely diagnosis of prostate cancer, however, results in intermediate scores (predictive values) make the diagnosis difficult, so describing the association between these population scores that already has histologically confirmed diagnosis are helpful in clarifying this debate. **CONCLUSION:** Establishing the association between the PI-RADS scale report and the histopathological result of biopsy samples is of great importance, presents benefits for the diagnosis of this disease if supplemented by clinical examination, together it will help to make the appropriate diagnosis.

### INTRODUCTION

The term cancer encompasses a group of more than 100 different types of the disease that has as its main characteristic the rapid and disordered growth of abnormal cells. More common cancers have been identified in women than in men and vice versa, as well as gender-only cancers. Examples of this are malignancies that develop in the reproductive system (1).

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Prostate Cancer (CaP) rarely produces symptoms at the beginning of disease progression since most tumors originate on the periphery of the gland. CaP is a purely manly developmental tumor with clinical onset primarily from the age of 60 (2). It is becoming more frequent in our population in Mexico, accounting for 12% of all deaths (3). Due to the invasion of prostate biopsies and the discomfort of clinical examination, many patients do not perform diagnostic methods for early detection (2) in a form and time. In the vast majority of patients (more than 80%), suspected prostate cancer is based on the detection of a high prostate antigen in the blood and/or a pathological rectal touch and is histologically confirmed by a prostate biopsy.

Although PSA rises in various benign entities other than the caP, such as BPH and prostatitis, its use in screening has revolutionized the management of caP in recent years as it increases diagnosis in earlier stages of disease (disease confined to the gland), (Ilic, Neuberger, Djulbegovic, & Dahm, 2013) (Ilic, Neuberger, Djulbegovic, & Dahm, 2013). To improve early diagnosis and treatment of prostate cancer, the American College of Radiology (ACR), the European Society of Urogenital Radiology (ESUR), made a joint effort to develop standards for the Prostate Imaging and Reporting and Data System (PI-RADS) this system was created to assist in the detection, localization and characterization of prostate cancer. Its recommendations for standardizing imaging parameters are intended to decrease variability in the interpretation of prostate MRI studies, which, together with the conduct of a structured report, has the added value of improving communication between radiologists, and between radiologists and urologists (4). The system is beneficial in indicating the likelihood of cancer and is also valuable in identifying where the biopsy will be directed if necessary by increasing the chance that the sample will contain tissue with high suspicion of cancer. (4,5).

**Prostate cancer:** The prostate is a gland that belongs to the male reproductive system, is located just below the bladder (the organ that collects and throws away urine) and in front of the rectum (the lower part of the intestine). Its size is like that of a walnut and surrounds a part of the urethra (the tube that conducts urine to the outside from the bladder). The prostate gland produces a fluid that is part of semen. Prostate cancer is recognized as the most common malignant tumor of the male over 50 years of age. The average lifespan of Mexican in 2008 was 75 years, increasing the incidence and mortality from prostate cancer. It represents the leading cause of death (in man) from cancer in Mexico with a mortality rate of 13 x 100,000 inhabitants (1, 3). As men age, the prostate may enlarge and block the urethra or bladder. This can cause difficulty urinating or interfering with sexual function. This problem is known as benign prostatic hyperplasia that often requires surgery to correct it. Symptoms of benign prostatic hyperplasia or other problems affecting the gland may be similar to symptoms of prostate cancer. The vast majority of cases will be diagnosed in a localized phase from the widespread use of BLOOD determination of PSA (Specific Prostate Antigen). Approximately 30% will develop an advanced disease that will require hormone treatment and most of these will eventually evolve into a castration-resistant disease with a high mortality rate. In developed countries less than 10% of prostate cancers will be diagnosed from metastatic onset.

The presence of comor feasibility, mostly chronodegenerative such as diabetes, hypertension or renal pathology, results in the late detection of this pathology. Risk factors: apart from age, the main risk factors are inheritance, race, diet high in animal fats. It represents the leading cause of death (in man) from cancer in Mexico with a mortality rate of 13 x 100,000 inhabitants (0.0132):

- The most affected age group is those over 65 years of age.
- Seventy percent of patients die at home.
- One of the common complications is bone metastases. • Twenty-five percent of cases are asymptomatic.

- Since the 1980s with the introduction of psanetic antigen, it has been diagnosed earlier.
- Thanks to early diagnosis, potentially curative treatment can be offered.

## Histology

**The prostate gland is anatomically divided into three zones:**

- Central area (25% of the gland) contains the ducts (ejaculatory ducts).
- Transition zone (10%) near the urethra, a region where benign hyperplasia develops.
- Peripheral zone (65%) posterolateral region, more susceptible to cancer development.

Most prostate cancers are adenocarcinomas (70% of the peripheral region, 20% of the transitional zone and 10% of the plant). Other less common tumor types: adenocarcinoma of prostate ducts (often pressing on the urethra), mucinous adenocarcinomas, transitional carcinoma, and small cell or neuroendocrine carcinomas. As for the histological degree, the most commonly used classification is that of Gleason. Gleason's score reaches up to 10 (this would be the most undifferentiated and worst-prognostic grade), the ISUP scale is recently used from 1 to 5, both describing the possibility of the tumor spreading or spreading. The lower the score, the lower the likelihood of tumor spread. Among patients not treated with localized prostate cancer, those with a low Gleason score (2-4) are at very low risk of dying from their cancer in the next 15 years (4-7%) regardless of the patient's age at the time of diagnosis; however, those who have an undifferentiated tumor with Gleason 8-10 have a very high chance of dying from their cancer from other causes even if the diagnosis is in advanced ages (5,6,7)

**Diagnosis:** When tumors are locally advanced they are accompanied by clear obstructive symptoms, there may also be hematuria (blood in the urine) or signs of infection (the latter two are rare). When it comes to advanced tumors, edema or swelling of the legs (due to the growth of regional lymph nodes), bone pains (by tumor extension to the bone) and even weakness or loss of strength in the legs (compression of the spinal cord) may occur (7)

- Rectal touch: It consists of an examination of the rectum by which the doctor inserts a finger into a lubricated glove in the rectum and palpates the prostate through the rectal wall for nodules or abnormal areas. The prostate gland is immediately in front of the rectum, and most cancers begin at the back of the gland, which can be felt during a rectum exam. This test is uncomfortable, but it is not painful and takes very little time to perform. The size, consistency and mobility of the prostate should be valued. Usually the cancer is mainly located in the peripheral area of the gland so it can be easily palpable. A suspicious rectal touch is biopsy indication, regardless of PSA levels.
- Determination of PSA blood levels: A laboratory test that measures the concentrations of this blood marker. It is a substance specifically produced by the prostate that can be found in more in the blood of men who have prostate cancer. However, it should be noted that PSA levels can also rise in an infection or inflammation of the prostate

such as benign prostatic hyperplasia (increased prostate size of noncancerous origin). There is much controversy about whether or not to routinely test PSA in the general population for early detection from age 50, however in patients with irrigation criteria to develop the disease (those with family history or carriers of mutation in predisposition genes) if it is advisable to make a periodic determination accompanied by a rectal touch to partri of the 40-45 years (9).

- Transrectal ultrasound-guided prostate biopsy (EcoTR): EcoTR is a procedure that involves inserting a tube about the size of a finger into the rectum to examine the prostate. The probe emits sound waves in the rectum that bounce off the prostate and create echoes that are picked up by the tube. A computer converts the echo pattern into a black and white image of the prostate. The procedure only lasts a few minutes and causes some pressure during the introduction of the tube into the rectum, but usually this procedure does not cause pain. Transrectal ultrasound is not used as an early screening test for prostate cancer, as it often does not show early or incipient cancer. Local anesthesia will be used to perform ecoTR-guided biopsy and will be performed from suspicious areas or in a standardized manner from the base, middle area and apical of both lobes, between 8 and 12 samples (cylinders), especially if the gland is very large in size(5)
- Multiparametric pelvic MRI: A procedure in which a magnet, radio waves and a computer are used to create a series of detailed photographs of internal areas of the body. It can be useful for locating the primary tumor and assessing the locoregional extent (extracapsular involvement and invasion of the seminal vesicles). It will also be used in patients requiring second persistent PSA elevation biopsy.

The process used to define whether the cancer has spread within the prostate or to other parts of the body is called staging. It is important to know the stage or stage of the disease in order to plan treatment.(5,4).

**TNM Tumor characteristics:** The Gleason gradation system is the most common system for prostate adenocarcinoma. Describes the sum of the most common patterns, from 1 to 5 depending on the degree of differentiation. The sum ranges from 2 to 10 representing the latter the most aggressive and worst prognosis.

**PI RADS:** A major objective of a prostate MRI exam is to identify and localize abnormalities that correspond to clinically significant prostate cancer, and mpMRI is able to detect intermediate to high grade cancers with volumes  $\geq 0.5$ cc, depending on the location and background tissue within the prostate gland. However, there is no universal agreement of the definition of clinically significant prostate cancer. In PI-RADS™ v2, the definition of clinically significant cancer is intended to standardize reporting of mpMRI exams and correlation with pathology for clinical and research applications. Based on the current uses and capabilities of mpMRI and MRI-targeted procedures, for PI-RADS™ v2 clinically significant cancer is defined on pathology/histology as Gleason score  $\geq 7$  (including 3+4 with prominent but not predominant Gleason 4 component), and/or volume  $\geq 0.5$ cc, and/or extra prostatic extension (EPE). PI-RADS™ v2 assessment uses a 5-point scale based on the likelihood (probability) that a combination of mpMRI findings on T2W,

DWI, and DCE correlates with the presence of a clinically significant cancer for each lesion in the prostate gland.

PI-RADS™ v2 Assessment Categories.

PIRADS 1 – Very low (clinically significant cancer is highly unlikely to be present).

PIRADS 2 – Low (clinically significant cancer is unlikely to be present).

PIRADS 3 – Intermediate (the presence of clinically significant cancer is equivocal) PIRADS 4 – High (clinically significant cancer is likely to be present).

PIRADS 5 – Very high (clinically significant cancer is highly likely to be present).

Assignment of a PI-RADS™ v2 Assessment Category should be based on mpMRI findings only and should not incorporate other factors such as serum prostate specific antigen (PSA), digital rectal exam, clinical history, or choice of treatment. Although biopsy should be considered for PIRADS 4 or 5, but not for PIRADS 1 or 2, PI-RADS™ v2 does not include recommendations for management, as these must take into account other factors besides the MRI findings, including laboratory/clinical history and local preferences, expertise and standards of care. Thus, for findings with PIRADS Assessment Category 2 or 3, biopsy may or may not be appropriate, depending on factors other than mpMRI alone. It is anticipated that, as evidence continues to accrue in the field of mpMRI and MRI-targeted biopsies and interventions, specific recommendations and/or algorithms regarding biopsy and management will be included in future versions of PI-RADS™. When T2W and DWI are of diagnostic quality, DCE plays a minor role in determining PIRADS Assessment Category. Absence of early enhancement within a lesion usually adds little information, and diffuse enhancement not localized to a specific T2W or DWI abnormality can be seen in the setting of prostatitis. Moreover, DCE does not contribute to the overall assessment when the finding has a low (PIRADS 1 or 2) or high (PIRADS 4 or 5) likelihood of clinically significant cancer. However, when DWI is PIRADS 3 in the PZ, a positive DCE may increase the likelihood that the finding corresponds to a clinically significant cancer and may upgrade the Assessment Category to PIRADS 4. Our research will not only provide us with the methodological basis of the association of imaging findings and histological behavior of prostate pathology, but also demonstrates the usefulness of MRI to help direct the biopsy to more suspicious anatomical areas, the number of these could be decreased which decreases complications and costs in addition to making a timely diagnosis. The PI-RADS score comprises wide ranges of positive predictive values (PPVs), it is relevant to make the association of the histopathological report and this system in patients who have had endorectal biopsy, if this association is significant, research will provide information to help demonstrate the ability of the test to detect the disease in patients in patients in patients (sensitivity).

## JUSTIFICATION

Patients with suspected prostate cancer require an adequate strategy to diagnose the disease early. Multiparametric prostate MRI is a possible method of implementing as part of

this screening in our population, and thus complementing the rest of the diagnostic tools. Our research will not only provide us with the methodological basis of the association of imaging findings and histological behavior of prostate pathology, but also demonstrates the usefulness of MRI to help direct the biopsy to more suspicious anatomical areas, the number of these could be decreased which decreases complications and costs in addition to making a timely diagnosis. The PI-RADS score comprises wide ranges of positive predictive values (PPVs), it is relevant to make the association of the histopathological report and this system in patients who have had endorectal biopsy, if this association is significant, research will provide information to help demonstrate the ability of the test to detect the disease in patients in patients (sensitivity) (10).

## MATERIAL AND METHODS

An analytical, observational, transverse and retrospective study was conducted with patients at the Naval Hospital of High Specialty to whom t-tests were applied for independent samples and Mann-Whitney U-test for statistical analysis. Patients with suspected Prostate Cancer were selected who had psa levels, prostate MAGNETIC resonance imaging, and had histopathological reports of transrectal prostate biopsies. The review of the records of the imaging service of patients meeting the inclusion criteria was carried out. Once the final list of dossiers has been obtained, those files that meet the selection criteria will be reviewed. From each of the dossiers, the information established in the variables will be collected to perform the filling of the data collection sheet and subsequent statistical analysis. All patients were given an MRI, with T2 and diffusion (DWI) sequences. The complete study consisted of coronal projections T2, sagittal T2, transverse T2 and transverse DWI, in MagnetomAvanto equipment, Siemens (1.5 Tesla), with pelvic phased array coil. With the images in DWI an ADC map was obtained, in which the apparent coefficients of diffusion of the areas of interest of the prostate gland were measured.

Image protocol. All MRs were made with 1.5 T Machine (MagnetomAvanto, Siemens) with pelvic array phased coil. The pelvic MRI protocol included T2-weighted sagittal, axial, and coronal turbo spin eco images, T1-weighted turbo spin eco coronal images, T1-weighted turbo spin eco axial fat suppression images, diffusion-weighted axial images (b-value 0, 1000, and 2000 s/mm<sup>2</sup>) with ADC map, and T1-weighted images sagittal, coronal.

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## DISCUSSION

The PI-RADS prostate imaging data reporting and recording system is a tool developed for the timely diagnosis of prostate cancer, however, results in intermediate scores (predictive values) make the diagnosis difficult, so describing the association between these population scores that already has histologically confirmed diagnosis are helpful in clarifying this debate. The PI-RADS prostate imaging data reporting and recording system is a tool developed for the timely diagnosis of Prostate Cancer, however, results in intermediate scores (predictive values) make the diagnosis difficult, so describing the association between these population scores that already has histologically confirmed diagnosis are helpful in clarifying this debate. Parameters to be evaluated include determining the location of areas of high suspicion, which helps the biopsy intake be directed and increases the sensitivity and specificity of the histopathological report (5).

The groups studied in this work belonging to the Naval Medical Center indicate association between a high score (PI RADS 5) on the scale and the appearance of prostate adenocarcinoma. This association has a trend directly proportional to the score, because as the patients studied qualify with a higher score on the scale, the probability of developing adenocarcinoma is increased, reaching almost 10 times more in individuals with scores of 5 on the RADS PI scale. It can be said that there is an association between the PI-RADS score and histopathological result for prostate cancer in the studied population and what is mentioned in the literature(20), however, we can only affirm it for individuals with PIRADS ratings of 5, since the significance levels for the minor grades are not statistically significant in this study probably due to the small number of participants counted for the realization of this project.

## CONCLUSION

Establishing the association between the PI-RADS scale report and the histopathological result of biopsy samples is of great importance, presents benefits for the diagnosis of this disease if supplemented by clinical examination, together it will help to make the appropriate diagnosis. The high incidence and prevalence of Prostate Cancer in our environment is a public health problem that requires improvements in diagnostic methods in the health system, not only to detect but to stage confirmed cases. These improvements in the diagnostic method can decrease the time of care in patients with this pathology, which is vital, and reduce the logistical and economic resources necessary for the treatment of the disease and its complications; all these changes will culminate in a reduction in the mortality rate from this pathology. Establishing the relationship between the rating on the PI-RADS scale and the likelihood of developing Prostate Cancer has benefits in these aspects, if clinical examination and histopathological reporting is complemented to help make the timely diagnosis of prostate cancer, this study may be part of the screening of protocol diagnosis in hospital locations that have the necessary resources. This imaging method presents statistically significant differences as a diagnostic tool compared to traditional biomarkers, we highlight the case of the PSA, because despite being considered for a long time a diagnostic method for the detection of this pathology, the levels presented between the groups studied (healthy and sick) did not show a statistically significant difference in this study ,

unlike the PI-RADS rating that is why we consider the pi-RADS scale score as a diagnostic method with a higher predictive value, which must be implemented in all centres that have the necessary resources and which in turn can be used as reference centers for all patients suspected of this pathology.

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