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ORIGINAL RESEARCH

Association between histopathological results of US-MRI fusion imaging-guided prostate biopsies and systematic ultrasound biopsies for the diagnosis of prostate cancer: A multicenter observational study.

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Abstract

Introduction: The importance of making an early diagnosis of prostate cancer determines the prognosis and survival of patients. This study aimed to determine the associations between histopathological findings and two diagnostic methods for prostate cancer biopsy.

Methods: The present observational study was conducted at the Hospital Naval and Hospital Alcívar in Guayaquil from 2018 to 2023. Patients with a suspected diagnosis of prostate cancer who required transrectal biopsy guided by ultrasound or by US-MRI fusion images were included. The variables were age, PSA level, prostate volume, lesion location, PIRADS 3, PIRADS 4, PIRADS 5, and histopathological diagnosis.

Results: Forty-three patients underwent US-MRI biopsy, and 28 underwent ultrasound biopsy. Patients aged between 60 and 70 were included. In the US-MRI group, 25 patients (58.14%) had positive histology, and in the ultrasound biopsy group, 15 patients (53.57%) had positive histology (OR = 1.2037 [0.4616-3.1390], P = 0.7046). A higher percentage of patients classified as PI-RADS 4 or 5 had cancer, constituting 34% (n=24) of the total patients.

Conclusions: This study found a more significant association between prostate cancer and PI-RADS 4 and 5. The results of this diagnostic method were combined with those of directed and systematic techniques.

Keywords:

Systematic biopsy by magnetic ultrasound; MRI-ultrasound fusion-guided biopsy; Prostate cancer; PIRADS 2.1; Gleason score.

Surgery

Abbreviations

US-MRI: Fusion ultrasound with magnetic resonance imaging.

Supplementary information

No supplementary materials are declared.

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Authors' contributions

Andrés Valle: Conceptualización, curación de datos, Adquisición de fondos, Administración del proyecto, Supervisión.
Carlos Valle Ochoa: Conceptualización, Análisis formal, Metodología.
Carmen Navas: Conceptualización, Curación de datos, Análisis formal
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Paola Gonzále: Análisis formal, Adquisición de fondos, Validación.
Santiago Celi: Conceptualización, curación de datos, análisis formal, adquisición de fondos, investigación, redacción - borrador original.
All the authors have read and approved the final version of the manuscript.

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Availability of data and materials

The datasets used and analyzed during the present study are available from the corresponding author upon reasonable request.

Introduction

Prostate cancer is the second leading cause of death in US men. In Ecuador, the incidence is 38.8 cases per 100,000 inhabitants, with a record of 28,058 new cases of prostate cancer in 2018. The average mortality rate was 11.32 deaths per 100,000 men in 2019; the highest mortality rate occurred in individuals aged 75 to 89 years, followed by those aged 60 to 74 years and, finally, those aged 45 to 50 years [1].

The later the diagnosis is made, the more palliative the treatment is, as it is not possible to perform a prostatectomy, either because of advanced metastasis or because age and comorbidities, together with the risk of intraoperative mortality, outweigh the long-term benefit of surgery [2].

The importance of making an early diagnosis of prostate cancer will determine the prognosis and survival of patients. Initially, most of these patients are asymptomatic or have obstructive urinary symptoms; they are usually associated with locally advanced disease, the same disease that has spread to the urethra or bladder neck. Likewise, they can cause hematospermia or hematuria, and if they affect regional pelvic nodes, they can cause edema in the lower limbs or pain at the pelvic or perineal level. The most common metastases are found in bone and are very often asymptomatic, or they can also cause pathological fractures or spinal or root compression. Other common sites of metastasis are the pulmonary, peritoneal, pleural, hepatic, and central nervous systems [3].

More than 60% of cases are diagnosed, mainly by an increase in PSA in asymptomatic patients and the presence of a palpable nodule on digital rectal examination that requires a biopsy. The digital rectal examination has greater sensitivity than specificity, and the biopsies performed in these patients were positive in 50% of the patients, which is why a positive rectal examination is suggested for this procedure [4].

Concerning laboratory tests, the concentration of prostate-specific antigen has an identical drawback, with high sensitivity but low specificity, since disorders such as prostatitis or benign prostate hypertrophy can result in high false-positive results. However, a 4 ng/ml threshold is still used to detect 70% to 80% of tumors. Diagnostic precision can be improved by establishing age ranges; for example, PSA greater than 2.5 ng/ml in men aged 40 to 49 years, PSA greater than 3.5 ng/ml between 50 and 59 years, and PSA greater than 4.5 ng/ml between 60 and 69 years and between 70 and 79 years. These values make it necessary to carry out other tests to rule out pathology. To make the diagnosis much more precise, free PSA is indicated since it allows us to distinguish between benign processes and prostate cancer.

Although elevated PSA levels are related to the risk of metastasis (greater than 20 ng/ml, with a 50% correlation in patients aged 70 to 80 years with histology reported as malignant and greater than 100 ng/ml, in the majority of metastatic or locally advanced cases), it cannot be established as a conditioning condition since there are cases in which the prostate is above 400 grams. The PSA is above 100 ng/ml, so metastasis is not evident [5].

In the study of images, transrectal ultrasound is a low-cost and accessible technique that allows for the evaluation of prostate anatomy, the description of suspicious lesions, and guided biopsy if required since prostate cancer commonly originates within 3.3 mm of the capsule, with thickening and infiltration of the underlying tissue extending toward the central area [6]. The ultrasound suspicion is given by the visualization of a hypoechoic nodule, which is usually unique but can also be scattered in the gland. However, this is not definitive since other benign etiologies can cause the visualization of the said lesion, such as inflammatory processes, infarction, prostatic hyperplasia, glandular atrophy, and typical vascular structures; therefore, the direct relationship between a hypoechoic nodule and cancer cannot be ascertained. However, we can observe indirect signs that raise diagnostic suspicion, such as mottled ultrasound, contour deformities, asymmetry of the peripheral area, and distortion of the internal anatomy of the gland [7].

Prostate fusion biopsy is a procedure for obtaining prostate samples that combines prostate magnetic resonance and ultrasound (US-MRI) images. In this way, three-dimensional images of the prostate can be created. Devices that perform prostate fusion biopsies include a program to incorporate previously obtained nuclear magnetic resonance images and be able to superimpose them with real-time transrectal ultrasound images [8].

The purpose of this study was to categorize the variables that were studied in individuals with prostate cancer who underwent ultrasound biopsy and US-MRI fusion within the period from January 2018 to April 2023.

Materials and methods

Study design

The present study is observational and cross-sectional. The source is retrospective.

Stage

This study was conducted in the Urology Service at the Guayaquil Naval Hospital and the Alcívar Hospital in Guayaquil, Ecuador. The study period was from January 1, 2018, to December 31, 2023.

Participants

Patients older than 18 years of age with a suspected diagnosis of prostate cancer who required transrectal biopsy guided by ultrasound or by US-MRI fusion images and who subsequently underwent radical prostatectomy and had a histopathological report of the sample were included. The diagnostic suspicion was established with high levels of PSA and free PSA and a positive digital rectal examination. Patients with incomplete data were excluded from the analysis.

Variables

The variables were age, PSA level, prostate volume, history of previous biopsy, lesion location, PIRADS 3, PIRADS 4, PI-RADS 5 score, and histopathological diagnosis.

Data sources/measurements

The source was indirect; an electronic form was filled out from the history data. The multiparametric resonance protocol of the prostate was carried out institutionally, following the guidelines of the European Society of Urogenital Radiology (ESUR) and the American College of Radiology (ACR), in which T2W axial images are requested for the evaluation of the transitional zone, diffusion with an apparent diffusion coefficient (ADC) map to assess the peripheral area, postcontrast T1 with gadolinium to assess early enhancement, and sagittal T2W to complement the assessment of prostate volume and characterization of the lesion. Suspicious lesions were defined according to the PI-RADS score version 2.1 (Prostate Imaging - Reporting and Data System 2019) in 71 patients. Philips MRI and ultrasound equipment were used to create a detailed 3D map of the prostate by combining resonance-ultrasound fusion imaging and organ-specific 3D ultrasound technology. These biopsies were performed entirely transrectally by a team of two experienced specialists (more than 100 biopsies performed) who interpreted the same images before performing the procedure. All patients underwent the preparations before the procedure, beginning with the correct provision of informed consent for both the procedure and for sedation, following the European Guidelines of Urology, triple antibiotic prophylaxis with quinolones, aminoglycosides, and 24-hour tinidazole. Before the procedure, the animals were fed a low-fiber diet for 48 hours before the administration of liquid for 24 hours before the procedure, after which they were fasted for 8 hours before the procedure and placed in a fleet enema. Twelve samples corresponding to systemic biopsies and four samples corresponding to targeted biopsies were taken, depending on the size of the lesion and the anatomy of the prostate. Routine biopsies were performed with an extended pattern of 12 nuclei in the same way for all samples, regardless of the location of the targeted area.

Each prostate biopsy sample was individualized, labeled, and placed in formaldehyde. In the histopathological evaluation, almost all the patients at the Alcívar Hospital were evaluated by the same specialist, while one patient was referred for study in Miami, USA. Different pathologists reviewed the other public insurance patients according to the governing agreement at the time of the biopsy.

The indications for radical prostatectomy were made according to the guidelines of the European guidelines of the Society of Urology. Most of the radical prostatectomies were performed laparoscopically, although 30% were performed open according to the experience of the specialists and according to institutional policy. The inclusion criteria were patients who had undergone a randomized and fusion biopsy procedure in our hospital unit, complete variables, PI-RADS 3 to 5, and clinical imaging suspicion of prostate cancer. The exclusion criteria were PIRADS 2 and incomplete clinical history data. The information was confidential; no personal data were included to identify the study subjects.

Biases

To avoid interviewer, information, and memory biases, the principal investigator always maintained the data with a guide and records approved in the research protocol. Observation and selection bias were avoided by applying the participant selection criteria. Two researchers independently analyzed each record in duplicate, and the variables were recorded in the database once their agreement was verified.

Study size

In Guayaquil, according to the population census, 924069 people between 30 and 59 years old were registered, 49.27% of whom were men, which is the target population of 455,288 men at risk of prostate cancer. The global incidence rate of prostate cancer is 442.4 per 100,000 men, which represents 2012 cases in the city of Guayaquil. Using Epi Info ™ (CDC Atlanta, USA, 2017) for sample calculations with a confidence level of 95%, an expected frequency of 5.0%, and a confidence limit of 5%, the sample size was 70 patients.

Quantitative variables

Descriptive statistics were used. The results are expressed as frequencies and percentages.

Statistical analysis

Inferential statistics were used. For descriptive analysis, frequencies and percentages are presented. Risk associations are

presented as odds ratios (ORs), 95% confidence intervals (CIs), and chi-square *P* values. The statistical package used was IBM Corp., Released in 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.

Results

Participants

Seventy-one patients were included in the study.

Main characteristics of the study group

The most prevalent ages were 60 and 70 years (Figure 1). The free PSA concentration ranged from 0.4-1 ng/dl. The total PSA was 6-7.5 ng/dl. The prostate volume was 40-50 ml. The digital rectal examination revealed alterations in 27 patients (38%), but changes did not occur in 21 (29%). In 23 patients (33%), no records were found. Eighteen (25%) patients had previous biopsies. Of the 71 patients, 43 (60.6%) underwent a US-MRI fusion biopsy. The most frequent location was transition zone n (37, 52%), followed by a mixed location in 26 cases (36%) (Figure 2).

PI-RADS and its association with prostate cancer

Regarding the PI-RADS, it was observed that the patients classified as PI-RADS 4 or 5 had a more significant association with cancer, constituting 34% (n=24) (Figure 3). Table 1. The histological results are presented according to the type of biopsy. No significant differences were found. Of the 40 positive patients, 12 prostatectomies were performed, of which ten were consistent with the previous histopathological results. In contrast, two were performed due to persistent obstructive symptoms despite treatment and knowledge of the last benign histopathological results (Figure 4). The different characteristics of the patients made them not candidates for surgical resolution; therefore, despite the positive biopsy result for prostate cancer, this procedure was not performed, and thus, no histopathological results were obtained from the surgical specimens.

Figure 1. Histogram of the age of the participants.

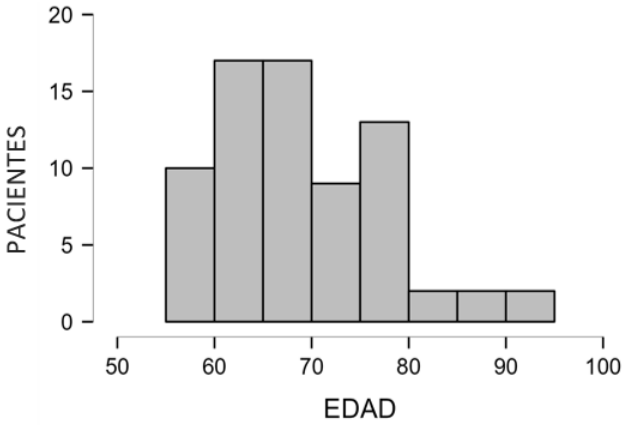

Figure 2. Location of injuries.

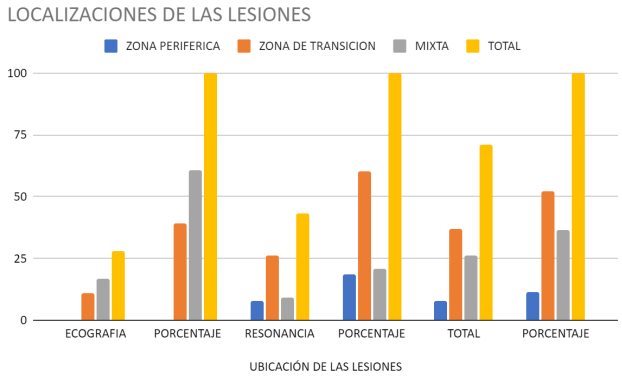

Figure 3. The PI-RADS score and its association with prostate cancer.

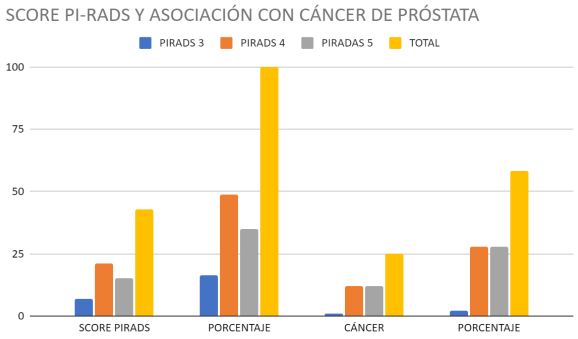

Figure 4. Histopathological results are classified by the biopsy method.

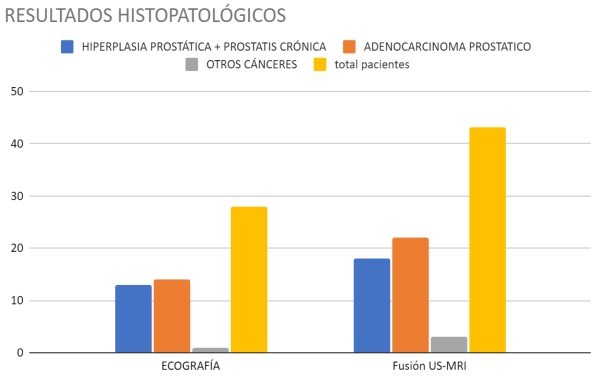

Table 1 . Association of the diagnosis of prostate cancer with the biopsy method.

	US-MRI fusion biopsy N = 43	**Ultrasound biopsy** N=28	**OR (IC95%) *P***
Positive histology for prostate Ca	25 (58.14%)	15 (53.57%)	OR=1.2037 (0.4616-3.1390) *P*=0.7046

Discussion

According to what has been observed in recent years, there have been significant advances in the early diagnosis of prostate cancer with the introduction of multiparametric resonance, which allows better identification of cancers that have a greater probability of survival, as well as aggressive cancers that require radical therapy. The objective should be to reduce the risk of overtreatment in young patients and undertreatment in older patients. The purpose of multiparametric MRI is to help better characterize suspicious lesions and delineate clinically significant cancers to be biopsied later, taking into account challenging locations such as the apex and anterior area of the prostate, and thus reduce the number of biopsies in indolent cancers.

Among the variables included in the analysis was PSA, which is a sensitive but not specific marker for the detection of prostate cancer. Multiple factors can cause increased PSA, such as prostatitis, benign prostatic hypertrophy, perineal trauma, and increased sexual activity. Therefore, to reduce the chances of an overdiagnosis of prostate cancer, these factors, including the general condition of the patient, should be ruled out. In addition to requesting specific PSAs, the older the patient is, the greater the PSA value that results in being in the normal range without the need for prostate cancer. Additionally, an expert urologist should continuously monitor this marker, associated with an elevation greater than or equal to 0.75 ng/dl within a year. However, the PSA is not greater than the corresponding age range [9].

Another parameter that is taken into account to differentiate prostate cancer from other benign prostate diseases is PSA density, which compares PSA levels with prostate volume measured with transrectal ultrasound or multiparametric prostate resonance imaging. PSA can be elevated in both benign and malignant pathologies; therefore, if a patient presents with elevated PSA and digital rectal examination, a small and indurated prostate would be more problematic than a large prostate [10].

In this retrospective study, we found that US/MRI fusion-guided biopsy increased the percentage of prostate cancer-positive patients by 58% compared with that of systematic biopsy by 53%, establishing a percentage comparison between the same methods since the sample size differed significantly between the two procedures. A published meta-analysis reported a slight 1.20-fold increase in the sensitivity of the fusion method [11]. In patients with a previous negative biopsy,

there was no significant difference since the results agreed with the benign histopathological results. Still, differences could be found in those in which the biopsy was de novo, with a more significant percentage of positive results than the systematic results alone [12]. For the groups classified with PI-RADS 4 and 5, fusion biopsy detected more positive lesions than routine biopsy. In contrast, in the PI-RADS 3 group, a fusion-guided biopsy had a lower detection rate of malignant lesions than a randomized biopsy.

It should be taken into account that, with the advent of MRI-directed biopsy, the rates of cancer detection were significantly greater than those in previous years, as indicated by similar studies, such as that of Valerio Forte et al., with rates of 50.5% vs. 43.4%, respectively [13]. Systematic biopsies are superior to PI-RADS 3 for detecting cancer, as indicated by studies by Ahdoot et al. [14]. With 51% fusion biopsies vs. 52% for systematic biopsies and 30.9% vs. 37.8% for the detection of clinically significant cancer, other study results also presented similar results without substantial differences [15, 16].

Previously, the European Association of Urology guidelines indicated fusion biopsy after a negative systematic biopsy. However, in recent updates, multiparametric resonance has been recommended even before the initial biopsy. In our study, we included both groups in the analysis, where only two patients with previously negative biopsy results were observed; these patients had prostate cancer. It should be emphasized that the number of patients who had a previous biopsy compared to the entire sample could have been higher, so the differences were not statistically significant. The parameters chosen to perform the biopsy were a persistently elevated PSA, a suspicious rectal examination, and, in a few cases, persistent urinary obstructive symptoms; these patients were diagnosed by multiparametric resonance and transrectal ultrasound.

Similarly, there was a correlation between a persistently elevated total PSA greater than 20 ng/ml and a positive histopathological result for prostate adenocarcinoma. It is necessary to mention that only six patients were previously described, while most of them presented with a PSA concentration of less than 10 mg/dl, for a total of 45 patients. Specific PSA elevations ranged from 0.4 to 1 in the most significant proportion of patients, constituting approximately 6% (low) of the total population, according to the Rotterdam Prostate Cancer Risk Calculator (RPCRC). An association was not established in our study of the elevation of this marker. Still, it is correlated with the calculation of risk and allows us to use one more tool to reduce the risk of false positives and unnecessary biopsies [11].

Regarding the PIRADS classification system, it was possible to ensure a greater relationship between the detection of clinically significant cancer and PI-RADS 4 and 5 lesions than between clinically significant cancer and PIRADS 3 lesions, with results of 27%, 27%, and 2%, respectively. The population was studied using US-MRI fusion. Similarly, Bae et al. (2019) reported a higher cancer detection rate with PI-RADS scores of 4 and 5 (58.2%) than with PI-RADS 3 [16].

Comparing both methods (systematic alone and combined in fusion biopsy), it was found that the second method detected more cancer in PI-RADS 4 and 5 than the first method. The limitations of the study were varied, including the nonhomogeneity of the sample, the need to obtain more patients who underwent fusion or randomized biopsy, the lack of execution of both procedures in the same patients to establish the effectiveness of the method and the fact that the preselected patients had suspicious lesions with multiparametric resonance (PI-RADS 3 or higher), leaving aside the PI-RADS 2, of which certain cases could have been underdiagnosed. It should be noted that although the patients with PI-RADS 2 were omitted, all of them were under follow-up by their different specialists, and they did not experience significant changes over time during the subsequent controls. However, only two patients with this score underwent prostatectomy due to the persistence of obstructive urinary symptoms, with a definitive diagnosis of prostatic hyperplasia and chronic prostatitis.

One of our strengths was that the biopsies were performed by the same specialists throughout the study, in addition to the interpretation of the multiparametric resonances, taking into account the same criteria. However, the histopathological studies were carried out by specialists whose training and experience we have yet to learn, which is why this is considered a limitation in the results. This variation is attributed to the policy of the public service and the purchasing power of the patient to take the sample to the pathologist, which is economically feasible. This is the reality in daily clinical practice in our country due to the lack of unification of services or the poor distribution of the national health system.

Excluding these limitations, we achieved results compatible with studies carried out in first-world countries, which allows us to recognize the reproducibility and association between prostate cancer and high PIRADS scores, which results in the detection of cancer in early stages and, as a result, the possibility of receiving timely treatment with favorable prognoses.

Conclusions

In this study, we found a more significant association between prostate cancer and PI-RADS 4 and 5. The results of this diagnostic method were combined with those of directed and systematic techniques.

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Declarations

Ethics committee approval and consent to participate

The ethics committee of the International University of Ecuador approved this study.

Publication consent

It is not required when images, radiographs, and specific studies of patients are not published.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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