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Joan C. Vilanova
Josep Comet
Antoni Capdevila
Joaquim Barceló
Josep Ll. Dolz
Marina Huguet
Carles Barceló
Jordi Aldomà
Enric Delgado

The value of endorectal MR imaging to predict positive biopsies in clinically intermediate-risk prostate cancer patients

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J. C. Vilanova (✉) · J. Barceló
Ressonància Girona, Clinica Girona,
Lorenzana 36, 17002 Girona, Catalonia,
Spain
e-mail: rmgirona@comg.es
Tel.: + 34-972410256
Fax: + 34-972221457

J. Comet
Department of Urology,
University Hospital of Girona
Dr. J. Trueta, Crta França s/n,
17007 Girona, Catalonia, Spain

A. Capdevila · J. Ll. Dolz · M. Huguet ·
J. Aldomà · E. Delgado
Centre Diagnòstic Pedralbes,
Cetir Grup Médic, Monestir 3,
08034 Barcelona, Catalonia, Spain

Carles Barceló
Department of Computer Science
and Applied Mathematics,
University of Girona, Campus Montilivi,
17003 Girona, Catalonia, Spain

Abstract The aim of this study was to assess the effectiveness of endorectal MR imaging in predicting the positive biopsy results in patients with clinically intermediate risk for prostate cancer. We performed a prospective endorectal MR imaging study with 81 patients at intermediate risk to detect prostate cancer between January 1997 and December 1998. Intermediate risk was defined as: prostatic specific antigen (PSA) levels between 4 and 10 ng/ml or PSA levels in the range of 10–20 ng/ml but negative digital rectal examination (DRE) or PSA levels progressively higher (0.75 ng/ml $year^{-1}$). A transrectal sextant biopsy was performed after the endorectal MR exam, and also of the area of suspicion detected by MR imaging. The accuracies were measured, both singly for MR imaging and combined for PSA level and DRE, by calculating the area index of the receiver operating characteristics (ROC) curve. Cancer was detected in 23 patients (28 %). Overall sensitivity and specificity of endorectal MRI was 70 and 76 %, respectively. Accuracy was 71 % estimated from the area under the ROC curve for the total patient group and 84 % for the group of patients with PSA level between 10–20 ng/ml. Positive biopsy rate (PBR) was 63 % for the group with PSA 10–20 ng/ml and a positive MR imaging, and 15 % with a negative MR exam. The PBR was 43 % for the group with PSA 4–10 ng/ml and a positive MR study, and 13 % with a negative MR imaging examination. We would have avoided 63 % of negative biopsies, while missing 30 % of cancers for the total group of patients. Endorectal MR imaging was not a sufficient predictor of positive biopsies for patients clinically at intermediate risk for prostate cancer. Although we should not avoid performing systematic biopsies in patients with endorectal MR imaging negative results, as it will miss a significant number of cancers, selected patients with a PSA levels between 10–20 ng/ml or clinical-biopsy disagreement might benefit from endorectal MR imaging.

Key words Prostate · Magnetic resonance · Surface coils · Neoplasms

Introduction

Prostate cancer is a major health concern as its incidence has risen dramatically over the past two decades due to the fact that the population in most western countries is aging and the life expectancy is increasing. In the United States, prostate cancer is the most common malignancy in men, with over 300,000 new cases in 1997 [1]. The increased use of prostatic specific antigen (PSA) as a screening method might explain the aug-

mented incidence and the early diagnosis of prostate cancer. There is currently no consensus on whether or not early detection of prostate cancer is beneficial, as an extensive debate persists on this subject [2, 3]. The available and accepted methods for detecting prostate cancer are a combination of digital rectal examination (DRE) and the PSA. The positive predictive value for prostate cancer for PSA > 4 ng/ml has been reported of 29–31 % and for DRE 25–27 % [3, 4], but the combination of PSA and DRE increases significantly prostate cancer detection [5].

The cancer detection rate for patients with PSA > 10 ng/ml is 58–67 % [6, 7]. Criteria to perform prostate biopsy vary, although patients with PSA values > 10 ng/ml and/or positive DRE are accepted, since their risk of prostate cancer is considered high [8]. It has been described that the volume of prostate cancer and its extension increases with increasing PSA [9, 10]. One of the current controversies is whether patients with PSA values < 10 ng/ml should be submitted to biopsy, because there is a high ratio of the number of biopsies to the number of detected carcinomas [11]. The availability of a reliable, non-invasive and affordable diagnostic method that could detect or select biopsy candidates would facilitate early diagnosis and could reduce the number of false-positive biopsy indications. Precisely, the group of patients with PSA values < 10 ng/ml and prostate cancer are those that tend to have a localized tumor, without extraglandular extension and with the best prognosis [7]. In these cases the possibility of reliable early detection of prostate cancer would be a great aid in handling these patients.

The purpose of this study was to assess the value of endorectal MR imaging in the early diagnosis of prostate cancer in patients with moderate risk, which could avoid unnecessary biopsies in patients with negative MR imaging results.

Material and methods

Between January 1997 and December 1998, 81 consecutive patients at intermediate risk to detect prostate cancer were included for a prospective study by endorectal MR imaging prior to biopsy (age range 47–87 years; mean age 69 years). In all patients, written informed consent was obtained before both endorectal MR and transrectal ultrasound (TRUS)-guided prostate biopsy. Intermediate risk was defined as: PSA levels between 4 and 10 ng/ml with positive or negative DRE; or PSA levels in the range 10–20 ng/ml but negative DRE; or PSA levels progressively higher (0.75 ng/ml $year^{-1}$).

All studies were performed by using a 1.5-T system (Signa, GE Medical Systems, Milwaukee, Wis.), with an endorectal coil (Medrad, Pittsburgh, Pa.). The MR imaging protocol included: acquisition of conventional T1-weighted spin-echo images (TR/TE: 600/20 ms) in the sagittal plane; T2-weighted fast spin-echo images (TR/TE: 5000/144 ms) in the axial, coronal, and sagittal planes; and T2-weighted fast spin-echo fat-suppressed axial images (TR/TE: 4000/150 ms). Field of view was 160 mm, matrix 256 × 192, and section thickness was 5 mm with 0.5 mm intersection gap. All images were interpreted by two radiologists who were blinded for clinical and pathological results and for each other's findings. In any case of disagreement, a final MR evaluation was made by consensus. A consensus interpretation had to be performed in one-third of cases. The diagnostic criteria for prostate cancer was established as a rounded low-signal area within the normal hyperintense peripheral zone on T2-weighted images or a diffuse unilateral hypointensity in the peripheral zone. The presence of a diffuse, peripheral low signal intensity, bilateral and symmetric, was considered due to prostatitis. The MR reports were scored with regard to the presence of the lesion and location (right lobe, left lobe, both lobe, apex, midgland, and bases). A sextant biopsy was performed under TRUS guidance within 3 weeks after endorectal MR. The TRUS was performed using a Kretz Combison 330 scanner with a 7.5-MHz transrectal probe in transverse and sagittal planes. Biopsies were obtained with a Tru-Cut needle biopsy, sampling the bilateral bases as well as the mid and apical portions of the gland. Additional biopsies were also performed on the suspicious areas detected by endorectal MR imaging. When the lesion described by endorectal MR was not seen on TRUS, it was biopsied at the location according to the scheme drawn by the radiologist. The endorectal MR concordance was defined as the proportion of cases where MR indicated the presence of abnormalities, and an abnormality was also determined for the same location by needle biopsy.

Patients

The 81 patients included in this prospective study were divided into two groups. Group A included the 52 patients with PSA levels between 4 and 10 ng/ml and positive or negative DRE. Group B included the 29 patients with PSA levels in the range 10–20 ng/ml but negative DRE.

Statistical analysis

A binary logistic regression model was used to find the statistical prediction for the positive biopsy results for prostate cancer. The input variables were the numeric PSA level, the binary endorectal MR output (positive/negative), and the binary DRE output (positive/negative). This last variable was used only in the statistical analysis of patients of group A. The output of the logistic regression analysis was the probability of the positive biopsy for prostate cancer.

All receiver operating characteristics (ROC) curves were estimated using the LABROC program (C. Metz, University of Chicago, Chicago, III).

Results

Prostate cancer was detected in 23 patients. Overall, the positive biopsy rate (PBR) was 28 % (23 of 81). The PBR was 21 % (11 of 52) for group A and for group B it was 41 % (12 of 29).

We obtained the following results for tumor detection in the total group of patients for MR alone: 70 % (16 of 23) sensitivity; 76 % (44 of 58) specificity; 53 % (16 of 30) positive predictive value; 86 % (44 of 51)

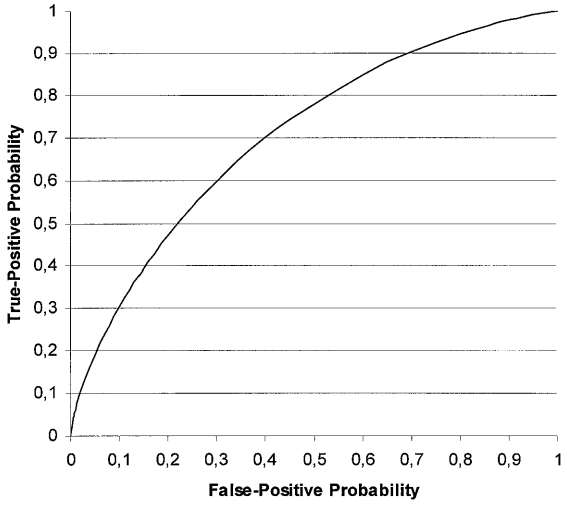

Fig. 1 Receiver operating characteristics (ROC) curve of the predictive model over the general group using MR imaging and PSA level as predictive variables in the logistic regression model (accuracy 70.7 %). General group refers to groups A and B.

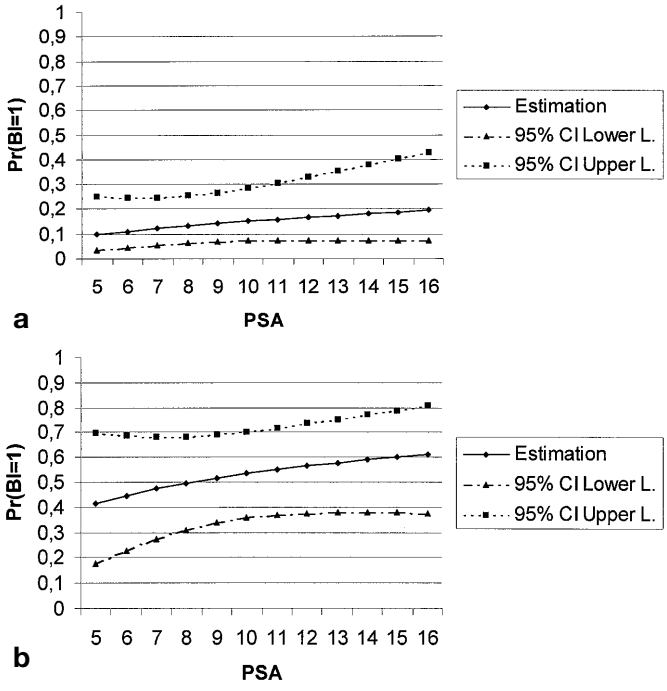

Fig. 2 Estimated probability of positive biopsy when PSA level increases for **a** patients with negative MR imaging, and **b** for patients with positive MR imaging. The probability was estimated over the general group of 81 patients using a logistic regression model with MR imaging and PSA level as predictive variables

negative predictive value; and 74 % (60 of 81) accuracy. We also combined the positive endorectal MR imaging and the PSA level to predict the biopsy result. Figure 1 shows the associated ROC curve to this predictive model. The accuracy was of 71 %, estimated from the area under the ROC curve of Fig. 1. Figure 2 shows the variation of the estimated probability of positive biopsy when PSA level increases for patients with negative MR imaging (Fig. 2 a), and for patients with positive MR imaging (Fig. 2 b). In this case the fact to know the MR results change the estimated probability significantly. For example, for a PSA of 12 ng/ml the estimated probability is equal to 0.35 [confidence interval (CI): 0.23–0.48]. But if we additionally know that the MR result is positive for prostate cancer, the estimated probability changes to 0.56 (CI: 0.38–0.74). If MR result is negative, the estimated probability changes to 0.17 (CI: 0.08–0.33).

The results for tumor detection in group A ($4 < PSA < 10$) for MR alone were as follows: sensitivity, specificity, and accuracy were 55 % (6 of 11), 81 % (33 of 41), and 75 % (39 of 52), respectively. Combining the DRE and MR outputs, and considering as a suspicious of positive biopsy the patients with DRE and MR positive, simultaneously, the resulting sensitivity, specificity, and accuracy were 36 % (4 of 11), 93 % (38 of 41), and 81 % (42 of 52), respectively. Adding the PSA level as a continuous predictive variable to each one of these regression logistic models, the predictive value does not increase significantly.

The same analysis was performed for the 29 patients of group B ($PSA > 10$). Using only the positive endorectal MR imaging as a predictive variable, the sensitivity, specificity, and accuracy were 84 % (10 of 12), 65 % (11 of 17), and 72 % (21 of 29), respectively. The ROC curve in Fig. 3 shows the sensitivity and specificity when MR imaging is combined with the PSA level to predict the positive biopsy in patients of group B. In this case the accuracy is estimated to be 84 %.

Table 1 Interaction between PSA level and results of MR findings in predicting positive biopsy outcome

	MR	Biopsy positive (%)
Group A	Normal	13 (5 of 38)
(PSA 4–10 ng/ml; $n = 52$)	Abnormal	43 (6 of 14)
Group B	Normal	15 (2 of 13)
(PSA 10–20 ng/ml; $n = 29$)	Abnormal	63 (10 of 16)
Both groups ($n = 81$)	Normal	14 (7 of 51)
	Abnormal	53 (16 of 30)

Table 1 shows the relationship of group A and B to the results of endorectal MR in predicting positive results for prostate cancer. According to a logistic regression model in which biopsy outcome was the response, MR imaging contributed significantly as a predictor of cancer for group A and B, although the CI were large in both groups (CI: 1.20–20.40 for group A and 1.49–56.30 for group B). In this case, the relative risk of positive

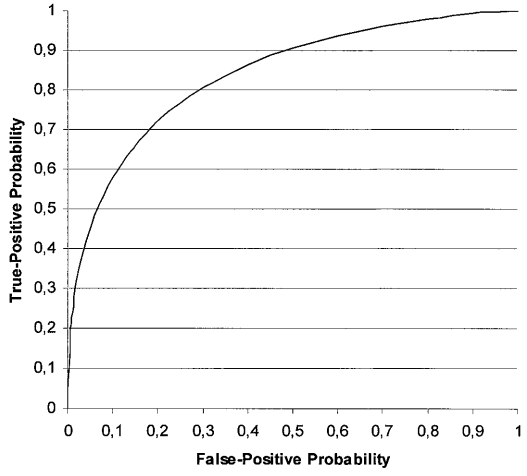

Fig. 3 Estimated ROC curve of the predictive model over group B (PSA > 10) using MR imaging and PSA level as predictive variables in the logistic regression model (accuracy 83.9 %)

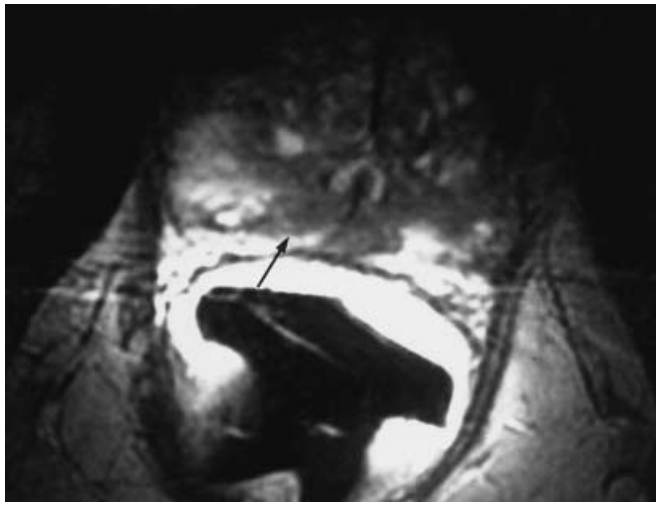

Fig. 4 Prostatic carcinoma. Axial T2-weighted image in an 84-year-old patient with PSA levels progressively higher during the past 10 years (6–11–20 ng/ml). A prostate biopsy performed 15 months previously was negative for neoplasia. Endorectal MR imaging shows a low-signal-intensity lesion *(arrow)* in the peripheral gland indicating tumor. The biopsy guided to the lesion showed adenocarcinoma

biopsy is 4.95 times higher when MR is positive than when the MR result is negative for group A, which is significantly different from 9.17 times for group B.

Table 2 shows the percentage of biopsies that might be avoided for a given sensitivity related to the different groups of patients. From the total seven false-negative lesions, two were located in the bases of the prostate, two in the apex, and the other three in the rest of the peripheral prostate. The 14 false-positive lesions were located four in the bases, four in the apex, and the other six in the rest of the peripheral gland.

There were 3 patients with moderate risk of prostate cancer with PSA levels progressively higher. Two patients had positive biopsy for prostate cancer, with abnormal MR imaging in both cases. One of these patients had previous history of negative biopsy 15 months prior to the study. Magnetic resonance imaging detected a low-signal-intensity lesion in the peripheral zone (Fig. 4). The third case was negative for the biopsy and MR findings.

Discussion

Prostate pathology has been studied extensively since beginning use of MR imaging with body coil [12, 13] and later with endorectal coils [14]. Numerous investigators have studied the accuracy of MR imaging for prostate cancer [15, 16, 17], but there are still disagreements about the ultimate clinical utility of the technique [18]. In any case, this is the only study that reflects the prediction of positive prostate cancer biopsy with MR imaging using endorectal coil, only in the group of patients with intermediate risk, without previous biopsies nor diagnosis of prostate cancer.

The results of the overall sensitivity and specificity are acceptable. However, evaluating the aim of MR imaging in prostate cancer, which is to diagnose the cancer and avoid false biopsies, we find that we would not have diagnosed almost 30 % of the neoplasms, even though we would have saved 63 % of the biopsies. Although there is a certain relationship between pathological MR results and positive biopsy results for prostate cancer, the intervals are too large to make positive considerations of a significant risk between MR imaging and biopsy results.

Our results show lesser effectiveness of endorectal MR imaging in predicting positive biopsy results for prostate cancer than other analytical techniques such as PSA density (PSA-D) and free PSA proportion (fPSA). According to the literature, using a PSA-D threshold

Table 2 Prostate cancer detection: MR imaging–biopsy correlation with percentage of biopsy that might be avoided

	Sensitivity (%)	Specificity (%)	Biopsies spared (%)
Group A (PSA 4–10 ng/ml; $n = 52$)	55 (6 of 11)	81 (33 of 41)	73 (38 of 52)
Group B (PSA 10–20 ng/ml; $n = 29$)	83 (10 of 12)	65 (11 of 17)	45 (13 of 29)
Both groups ($n = 81$)	70 (16 of 23)	76 (44 of 58)	63 (51 of 81)

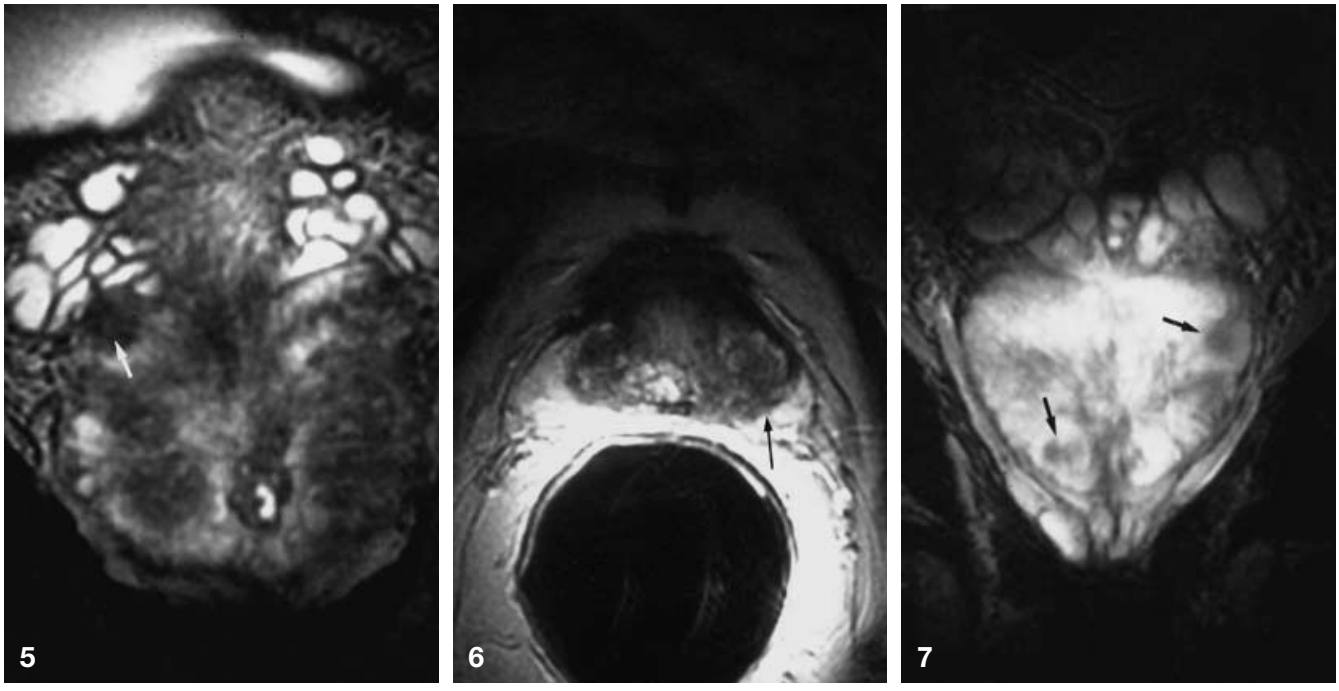

Fig. 5 Prostatic hyperplasia. Coronal T2-weighted image in a 69-year-old patient with a PSA 6 ng/ml, showing a nodular low-signal-intensity lesion *(arrow)* in the right base of the prostate. Malignancy was suspected by endorectal MR imaging and biopsy showed hyperplasia

Fig. 6 Prostatic carcinoma. Axial T2-weighted image shows hypertrophy of the left apex of the prostate *(arrow)*. Adenoma was suspected by endorectal MR imaging and pathology showed carcinoma

Fig. 7 Prostatic hyperplasia. Coronal T2-weighted image in a 62-year-old patient with a PSA 6.7 ng/ml, showing a bilateral nodular low-signal-intensity lesion in the left base and right apex of the peripheral zone *(arrows)*. A malignant lesion was suspected by endorectal MR imaging and biopsy proved a benign hyperplasia in both lesions

value of 0.10 ng/ml cc^{-1} would have obviated 28 % of biopsies at the cost of 10 % of detectable cancer [19]. Using the fPSA proportion in patients with intermediate risk provides even greater predictive value, according to the results of Bangma et al. [19]. In this case, 38 % of biopsies would have been avoided for a cut-off value of 0.20 with 12 % of cancers undetected. According to these statistics, and comparing them with our results, using the clinical parameters of PSA-D and fPSA proportion in patients with moderate risk for prostate cancer would be more justified than performing an endorectal MR prior to biopsy. We would not have diagnosed 17 % of prostate neoplasms, obviating 45 % of biopsies for the group of patients with PSA level 10–20 ng/ml. We found a larger increment in accuracy of this group B (83.9 %), estimated from the area under the ROC curve, compared with the total group (70.7 %). Therefore, in the group of patients with a PSA level between 10 and 20 ng/ml, endorectal MR imaging could be of help in certain selected cases. However, we should consider evaluation first of the other PSA parameters (PSA-D and fPSA) before an endorectal MR is performed in patients with intermediate risk for prostate cancer, because it is more expensive and time-consuming. The potential value of endorectal MR imaging is demonstrated in this study as the knowledge of the PSA level combined with the MR results helps significantly improve the estimated probability of positive biopsy when PSA levels increases.

Although several reports show no significant relation between the results of DRE and biopsy irrespective of PSA level or TRUS findings [6, 20, 21], we have found that the combination of DRE and MR imaging increases the accuracy for the suspicion of positive biopsy.

The rate of positive biopsies with normal endorectal MR imaging found in our study (14 %) is better than the proportion reported for TRUS (28 %) [6, 22]. It showed a sensitivity of 95 % and specificity of 43 % for tumor detection with endorectal MR imaging [16], and sensitivity of 53 % and specificity of 75 % with US [23], although the studies are incomparable due to different patient selection. In any case, results improve when both techniques are performed on the same patient, as has been reported by Werner-Wasik et al. [24], where TRUS and endorectal MR imaging were normal in 12 % of prostate cancer. This proportion is only slightly lower than in our series.

This study by Werner-Wasik [24] is the only one that correlates TRUS and endorectal MR on tumor detec-

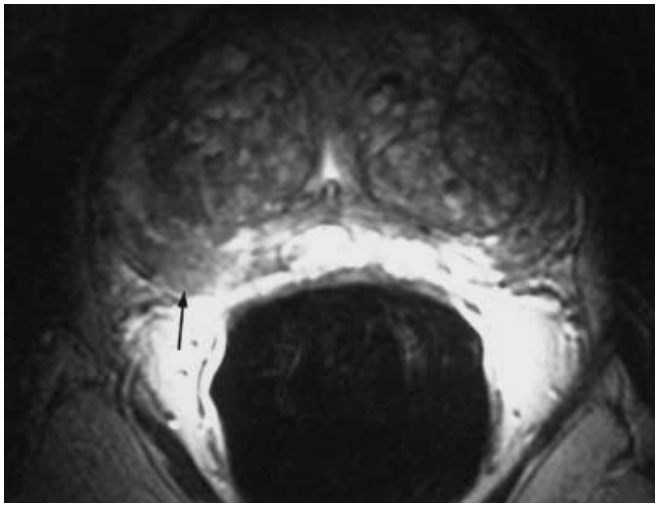

Fig. 8 Prostatic carcinoma. Axial T2-weighted image in a 62-year-old patient shows diffuse low signal intensity in both peripheral zones of the prostate. Although there is flare artifact which degrades the image, there is an asymmetrical low signal intensity in the right peripheral zone bulging the capsule *(arrow)* compatible with neoplasia. Biopsy results demonstrated bilateral prostatitis with adenocarcinoma in the right lobe

tion, with higher concordance of MR (39 %) than TRUS (24 %); however, as the authors explain, the predictive value of both techniques cannot be answered on the basis of the information reported. The specificity for detecting prostate cancer with endorectal coil in the present study is better than in other studies [16, 25], although this is at the expense of finding a lower sensitivity, which may be explained by our selection of patients with intermediate risk of prostate cancer. In any case, the results are not comparable, since we analyzed samples of biopsies and other studies analyzed surgical specimens. Moreover, as TRUS is used to localize the biopsy place (e. g. gold standard), the results of the biopsy are influenced by the accuracy of the TRUS. Therefore, comparing endorectal MR and TRUS using biopsy as a gold standard is biased by the fact that the gold standard is not independent.

The variability for the incidence of prostate cancer in the group of patients with intermediate risk is confirmed in our series (28 %). A low incidence of 7 % of cancer [26] has been reported for the group of patients with PSA level of 4–10 ng/ml, to the highest incidence described of 48 % [6] in patients with the same range of PSA level. The wide variability of the incidence of prostate cancer in this group of patients explains why, at this time, the performance of systematic biopsy in patients with PSA values of 4–10 ng/ml is not always indicated because of the great number of negative biopsy results [11]. In these cases, other techniques are used to better predict prostate cancer, such as PSA-D and fPSA proportion, as described previously, and at the moment are more cost-effective than endorectal MR imaging. However, we must consider the role of endorectal MR for certain cases, as demonstrated in this study.

The difficulty of locating prostate cancer by endorectal MR was predominantly at the apex and the bases, especially with adenomatous prostates. In these cases, MR imaging of cancer and hypertrophy were similar; thus it was difficult to differentiate hypertrophy per se from a tumor (Figs. 5, 6). It was in these cases that the greatest percentage of false positives existed. We also found false-positive results for prostate cancer in hypointense lesions within the normal hyperintense signal of the peripheral zone of the gland, as has been described in other series [27], which is attributable to areas of prostatitis or hyperplasia (Fig. 7). These causative factors of hypointense lesions on T2-weighted sequences reduce the specificity of endorectal MR imaging, and significantly reduce the reliability of the test. In cases of prostatitis, MR imaging shows diffuse low signal intensity in the peripheral zone; thus, the presence of prostate cancer is difficult to detect because it shows the similar low signal intensity as in prostatitis. Demonstration of an asymmetrical nodular-like lesion within the diffuse low signal intensity of the peripheral zone (Fig. 8) in cases of prostatitis helps to identify the presence of the tumor.

There were only 3 patients with PSA levels progressively higher in the present study, although in each of them there was a good correlation of MR imaging findings with biopsy results. Endorectal MR imaging was especially useful in the patient with progressively increasing PSA and negative biopsy 15 months before. In these selected cases of disagreement between the biopsy results and the PSA, MR imaging might be effective in localizing the subsequent biopsy; thus, this clinical utility of endorectal MR imaging for the management of patients at intermediate risk should be added to the other indications described in the literature for staging and the prognosis of prostate cancer [28, 29].

In conclusion, the results of this study indicate a lesser prediction of positive biopsy for prostate cancer using the endorectal MR imaging, compared with other analytical techniques, such as PSA-D and fPSA proportion. Although a significant number of unnecessary biopsies would be avoided, endorectal MR exam would not detect a high percentage of neoplasms. At this time, systematic prostate biopsies should not be avoided in patients with normal endorectal MR imaging results. In certain selected cases, endorectal MR imaging may be helpful, especially in patients with clinical-biopsy discrepancy or with PSA range of 10–20 ng/ml.

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