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Index terms:
Magnetic resonance (MR), comparative studies
Prostate, biopsy, 844.1261
Prostate neoplasms, 844.31, 844.32
Prostate neoplasms, MR, 844.121411, 844.121416
Prostate neoplasms, US, 844.12985, 844.12989

Published online before print
10.1148/radiol.2243011553
Radiology 2002; 224:701–706

Abbreviations:
DRE = digital rectal examination
PSA = prostate-specific antigen

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Guarantors of integrity of entire study, D.B., B.H.; study concepts and design, S.L., S.A.L.; literature research, D.B., B.W.; clinical studies, D.B.; data acquisition, D.B., B.W.; data analysis/interpretation, D.B., M.T.; statistical analysis, D.B., M.T.; manuscript preparation, D.B., T.F.; manuscript definition of intellectual content, D.B., M.T., B.H.; manuscript editing, D.B., T.F.; manuscript revision/review, B.H., M.T.; manuscript final version approval, B.H., D.B.

Patients with a History of Elevated Prostate-Specific Antigen Levels and Negative Transrectal US–guided Quadrant or Sextant Biopsy Results: Value of MR Imaging[1]

PURPOSE: To determine the role of magnetic resonance (MR) imaging performed with a combined endorectal body phased-array coil for patients with elevated prostate-specific antigen (PSA) levels or suspicious free-to-total PSA ratios in whom prior transrectal ultrasonographically (US) guided biopsy findings were negative for prostate cancer.

MATERIALS AND METHODS: Forty-four patients with PSA levels greater than 4 ng/mL or free-to-total PSA ratios lower than 15% but negative biopsy findings were examined with T1- and T2-weighted MR imaging at 1.5 T with a combined endorectal body phased-array coil. All patients underwent digital rectal examination (DRE) and transrectal US. Thirty-eight patients underwent repeat biopsy after MR imaging. The accuracy of MR imaging for detection of prostate cancer was assessed prospectively. Retrospectively, MR imaging findings were correlated with individual biopsy site findings. MR imaging and biopsy results were correlated by using a cross table to calculate sensitivity, specificity, and positive predictive value (PPV). Retrospective analysis results were evaluated with receiver operating characteristic analysis. A *P* value of less than .05 indicated significance (χ^2 test according to Pearson).

RESULTS: At prospective analysis, MR imaging had a sensitivity of 83% and a PPV of 50% for detection of prostate cancer; these values were 33% and 67%, respectively, for DRE and 33% and 57%, respectively, for transrectal US. At retrospective site-by-site analysis, MR imaging results did not correlate significantly with individual biopsy site findings ($P = .126$); sensitivity was 65% and PPV was 12%.

CONCLUSION: In this patient population, MR imaging has higher sensitivity for detection of prostate cancer than DRE or transrectal US.

Prostate cancer is the most common malignancy in men in the United States and second in frequency among the tumors that lead to death in men (1). Prostate cancer typically occurs in older men (2). The concentration of prostate-specific antigen (PSA) in serum is considered to be an important indicator in the early detection of prostate cancer (3). The American Urological Association and the American Cancer Society recommend that men aged 50 years or older undergo an annual digital rectal examination (DRE) combined with PSA level testing. Patients with a PSA level higher than 4 ng/mL at repeat PSA testing should undergo transrectal ultrasonography (US) (4). For histologic confirmation of prostate cancer and planning of therapy, systematic sextant biopsy in addition to targeted removal of tissue from areas that are suspicious at DRE and transrectal US is performed. However, a large number of patients with elevated PSA levels have negative biopsy results (5,6). It has been recommended that these patients undergo repeat biopsy (5,6).

Endorectal magnetic resonance (MR) imaging has widely varying accuracy in the staging

of prostate cancer. Results reported in the literature range from 54% to 87% (7–9). There is as yet no agreement with regard to the value of MR imaging for this indication. In the localization of known lesions of the prostate, endorectal MR imaging has an accuracy of up to 97% (10); however, its performance in the detection of tumor foci smaller than 5 mm in diameter is poor (11). In a study performed by Perrotti et al (12), MR imaging with use of only an endorectal coil had encouraging results in the detection of tumor foci in patients who had elevated PSA levels but negative core-needle biopsy results.

The purpose of our prospective study was to determine the role of MR imaging performed with a combined endorectal body phased-array coil for patients with a PSA level greater than 4 ng/mL or suspicious free-to-total PSA ratios (ie, <15%) in whom prior transrectal US–guided biopsy failed to demonstrate a tumor.

MATERIALS AND METHODS

Patients

This prospective MR imaging study included 44 consecutive patients who ranged in age from 46 to 76 years (mean age, 64.6 years; median age, 64.0 years) and met the inclusion criteria. Informed consent was obtained from all patients before MR imaging was performed. Approval from the local ethics committee was obtained for our study. The patients included in the study had a PSA level higher than 4 ng/mL or a suspicious (<15%) free-to-total PSA ratio. All included patients met at least one of these criteria. Six of the included patients had a free-to-total PSA ratio greater than 15%.

These patients' prior transrectal US–guided quadrant or sextant biopsy results were negative. Their PSA levels ranged from 4 to 53 ng/mL (mean, 13.9 ng/mL; median, 12.0 ng/mL). Their free-to-total PSA ratios were 3%–21% (mean, 11.02%; median, 11.0%). The numbers of negative biopsies that the patients had undergone prior to MR imaging were as follows: one in 18 patients, two in 12 patients, three in five patients, four in six patients, five in two patients, and six in one patient. The mean number of negative biopsies was 2.2. The procedures were performed as quadrant or sextant biopsies. The interval between the last biopsy and the MR imaging examination ranged from 6 weeks to 36 months (mean interval, 9.3 months; median interval, 8.0 months). Patient exclusion criteria were contraindications to MR imaging (eg, cardiac pacemaker) or contraindications to the use of an endorectal coil.

DRE results suggested prostate cancer in six patients; in the other 38 patients, rectal palpation results were negative. Transrectal US findings were suspicious areas in the prostate in seven patients and negative for tumor in the other 37 patients. For analysis, the assessment performed by the urologists (B.W., S.L., S.A.L.) at the time of transrectal US–guided repeat biopsy was used. In the patients who did not undergo repeat biopsy, the DRE findings obtained at the last transrectal US examination performed prior to MR imaging were used.

Thirty-eight study patients underwent repeat biopsy after MR imaging. Repeat biopsy was performed 1 day to 3 months after MR imaging. Repeat biopsy results confirmed the presence of prostate cancer in 12 patients. After the results of laparoscopic pelvic lymphadenectomy were found to be negative, six of the 12 patients underwent radical prostatectomy and five were treated with radiation therapy. One patient with proven lymphadenopathy underwent orchiectomy.

MR Imaging Technique

MR imaging was performed with a 1.5-T unit (Magnetom Vision; Siemens, Erlangen, Germany) by using a combined endorectal body phased-array coil (Medrad, Pittsburgh, Pa). The prostate was examined with a T2-weighted turbo spin-echo sequence at angulated transverse- and coronal-section orientations by using 16 × 16-cm and 20 × 20-cm fields of view, respectively, and with an angulated transverse T1-weighted spin-echo sequence by using a 16 × 16-cm field of view. The section thickness was 3.0 mm with an intersection gap of 0.9 mm. An image matrix of 256 × 256 was used in all examinations. We suppressed peristalsis by intravenously administering 40 mg of butyl scopolamine (Buscopan; Boehringer, Ingelheim, Germany) before imaging in 41 patients and by administering 1 mg of glucagon (Glucagen; Novo Nordisk, Mainz, Germany) before imaging in three patients.

Core-Needle Biopsies

Thirty-eight patients underwent repeat systematic transrectal US–guided biopsy after MR imaging. Repeat biopsy was performed with knowledge of the suspicious MR imaging findings. Suspicious MR imaging results were reported by demonstrating the findings on the angulated transverse and coronal MR images. The transrectal US–guided biopsies were performed, with the MR imaging findings taken into account, in 36 patients in the urology department of our hospital (by B.W., S.L., and S.A.L.) and in two patients at another institution. Transrectal US was performed by using a US device (Combison 330; Kretz, Zipf, Austria) with a 7.5-MHz endorectal transducer.

Octant biopsy was performed in 34 patients; sextant biopsy, in three patients; and quadrant biopsy, in one patient. Sextant biopsy specimens were obtained from the basal, intermediate, and apical parts of the prostate on each side. For octant biopsy, two additional specimens were obtained laterally. Quadrant biopsy specimens were obtained from the basal area and from the intermediate to apical area on each side. At least one specimen was obtained from each area that had suspicious changes at MR imaging. All biopsy specimens were obtained by using a biopsy gun (Urotech, Bruckmuehl, Germany) with an 18-gauge needle. The site of removal of each biopsy specimen was documented, and individual histologic examination of the specimens from each removal site was performed. This protocol yielded a total of 294 biopsy specimens (four specimens from one quadrant biopsy, 18 specimens from three sextant biopsies, and 272 specimens from 34 octant biopsies).

Prospective Analysis

The MR imaging findings were analyzed prospectively (D.B., M.T., B.H.) in a patient-by-patient manner. The angulated transverse and coronal T2-weighted images were evaluated for hypointense regions in the peripheral zone. Confluent hypointense areas were classified as suspicious findings. Diffusely and inhomogeneously hypointense areas were classified as inconclusive findings. On the T1-weighted images, regions were classified as suspicious only when they were isointense relative to the surrounding tissue. On the basis of the suspicious areas identified, the entire prostate was classified as suspicious, inconclusive, or negative for cancer. We localized the suspicious lesions by assigning them to the apical, intermediate, lateral, or basal area of the prostate on the right or left side.

Retrospective Analysis

Retrospective analysis was performed only with the 34 patients who under-

TABLE 1
Correlation of MR Imaging and Repeat Biopsy Findings at Prospective Analysis

Repeat Biopsy Findings	MR Imaging Findings		
	Suspicious	Inconclusive	Unlikely*
Positive	10	2	0
Negative	10	9	7
Total	20	11	7

Note.—Data are numbers of patients.
* Finding unlikely to be prostate cancer.

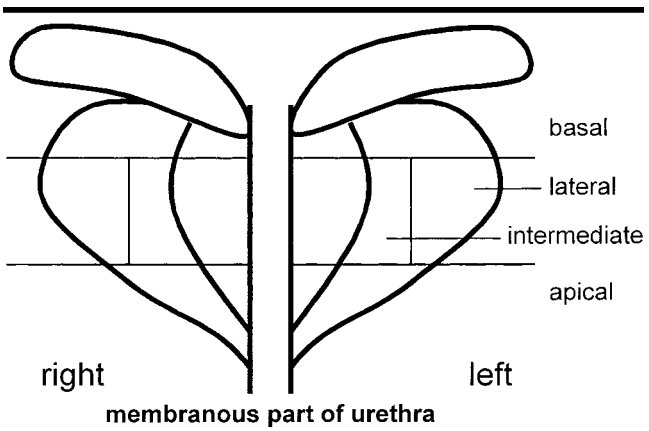


Figure 1. Diagram (coronal view) of MR imaging findings correlated with histologic core-needle biopsy results.

went octant biopsy after MR imaging. We excluded the four patients who underwent quadrant or sextant biopsy from this analysis to avoid bias that could result from the different numbers of biopsy specimens obtained from each patient. For analysis of the suspicious areas on MR images relative to the biopsy sites, the prostate was subdivided, as it was for octant biopsy, into basal, lateral, intermediate, and apical areas on each side (Fig 1). For each of these sites, the probability of prostate cancer on the angulated transverse and coronal T2- and T1-weighted images was recorded on a diagram by using a scale of 1 to 5, on which 1 meant prostate cancer was unlikely; 2, mildly suspicious for prostate cancer; 3, moderately suspicious for prostate cancer; 4, intermediately suspicious for prostate cancer; and 5, highly suspicious for prostate cancer. The MR images were assessed in consensus by two radiologists (D.B., M.T.) who were blinded to the histologic results. For correlation of the site-by-site MR imaging findings with the histologic findings, the histologic results were recorded on a corresponding diagram.

We reassessed the data on the six patients who underwent radical prostatectomy after positive repeat biopsy to correlate the MR imaging and biopsy findings with the results of histologic examinations of the prostatectomy specimens.

Statistical Analyses

The MR imaging findings and repeat biopsy results were correlated by using a cross table, from which sensitivity, specificity, and positive and negative predictive values were calculated. Receiver operating characteristic analysis was performed to evaluate the results of retrospective analysis. Significance was calculated by using the χ^2 test according to Pearson. A P value of less than .05 indicated a significant correlation.

PSA levels were compared with the results of histologic examination of the repeat biopsy specimens obtained from each patient. In addition, to correlate PSA levels with individual biopsy sites, we ranked the PSA levels according to biopsy site.

RESULTS

Prospective analysis of the MR images revealed suspicious areas in 21, inconclusive findings in 12, and no suspicious areas in 11 patients. Thirty-eight of the 44 patients who had negative biopsy findings before they underwent MR imaging underwent repeat biopsy after MR imaging. These were 20 of the 21 patients with suspicious MR imaging findings, 11 of the 12 patients with inconclusive MR imaging findings, and seven of the 11 patients with negative MR imaging results (Fig 2).

Repeat biopsy results confirmed prostate cancer in 10 of the 20 patients who had suspicious MR imaging findings. Of these 10 patients, five had undergone one biopsy previously; one, two biopsies; one, three biopsies; one, four biopsies; and one each, five and six biopsies. Two of the 11 patients who had inconclusive MR imaging findings and underwent repeat biopsy had prostate cancer (Fig 3). No tumor was depicted in the seven patients who had negative MR imaging findings and underwent repeat biopsy. Overall, prostate cancer was confirmed in 12 of the 38 patients who underwent repeat biopsy. In the group of patients who underwent repeat biopsy and had suspicious MR imaging findings, MR imaging had a sensitivity of 83% (10 of 12 patients), a specificity of 62% (16 of 26 patients), and a positive predictive value of 50% (10 of 20 patients) for the detection of prostate cancer (Table 1).

DRE results indicated prostate cancer in six of the 44 study patients. All six patients were in the group of 38 patients who underwent repeat biopsy after MR imaging. Repeat biopsy results confirmed prostate cancer in four of the six patients with suspicious findings at palpation and failed to demonstrate cancer in the other two patients. In the group of patients who underwent repeat biopsy, DRE had a sensitivity of 33% (four of 12 patients), a specificity of 92% (24 of 26 patients), and a positive predictive value of 67% (four of six patients) for the detection of prostate cancer (Table 2).

Transrectal US depicted suspicious findings in seven of the 44 patients. All seven patients were in the group of 38 patients who underwent repeat biopsy after MR imaging. Prostate cancer was confirmed at repeat biopsy in four of the seven patients. Thus, transrectal US had a sensitivity of 33% (four of 12 patients), a specificity of 88% (23 of 26 patients), and a positive predictive value of 57% (four of seven patients) for the detection of prostate cancer (Table 2).

Retrospective site-by-site analysis of the 272 specimens from the patients who underwent octant biopsy yielded no sig-

nificant correlation between the finding classifications at MR imaging and the actual presence of prostate cancer (P = .126). After receiver operating characteristic analysis, the categories moderately, intermediately, and highly suspicious were used to define the findings in one group of patients with positive MR imaging findings. The other two categories—prostate cancer unlikely and mildly suspicious for prostate cancer—were used to define the findings in a second group of patients with negative MR imaging findings. Thus, in the patient group with positive MR imaging findings (moderately, intermediately, or highly suspicious), MR imaging had a sensitivity of 65% (15 of 23 specimens), a specificity of 54% (134 of 249 specimens), and a positive predictive value of 12% (15 of 130 specimens).

At the biopsy sites with false-positive MR imaging findings, retrospective analysis revealed prostatitis, fibrosis, or prostatic intraepithelial neoplasia in 75% (86 of 115 sites) of the cases. For the other 25% (29 of 115) of false-positive sites, histologic analysis revealed normal prostate tissue in the biopsy specimens. None of the biopsy sites that were classified as highly suspicious at MR imaging (n = 14) showed normal prostate tissue at histologic analysis, but prostate cancer was demonstrated in only three sites. At the other sites, biopsy revealed prostatitis, fibrosis, or prostatic intraepithelial neoplasia. Biopsy revealed no prostate cancer at those sites that were classified as mildly suspicious at MR imaging (n = 9). The number of cases in this category was too low for site-by-site statistical analysis and thus precluded an assessment of accuracy by site.

The side-based analysis of the MR imaging findings in which the MR imaging findings on one side were assigned the most suspicious rating obtained on that side again revealed no significant correlation with the histologic assessment of that side (P = .167). Again, the findings that were classified as moderately, intermediately, and highly suspicious were summarized as positive MR imaging findings. Under these conditions, MR imaging had a sensitivity of 100% (15 of 15 sides) and a specificity of 19% (10 of 53 sides) for the detection of prostate cancer.

Side-based analysis involving the six patients who underwent prostatectomy revealed a correlation between the MR imaging findings and the results of biopsy and of histologic assessment of the surgical specimens from 10 of 12 sides. In one case, tumor tissue that was not detected at MR imaging was identified in a lateral lobe, and in another case, tumor portions were demonstrated in a lateral lobe that was classified as suspicious at MR imaging and in which all four biopsy specimens obtained on that side at octant biopsy were negative.

In our study population, the patients who had positive repeat biopsy results had higher PSA levels (mean, 18.75 ng/mL; median, 13.0 ng/mL) than the patients with negative repeat biopsy results (mean, 12.4 ng/mL; median, 11.5 ng/mL). However, site-by-site analysis revealed a negative correlation between PSA levels and positive biopsy sites. We observed a significantly lower mean rank in the distribution of PSA levels for the positive biopsy sites compared with that for the negative sites (P = .001).

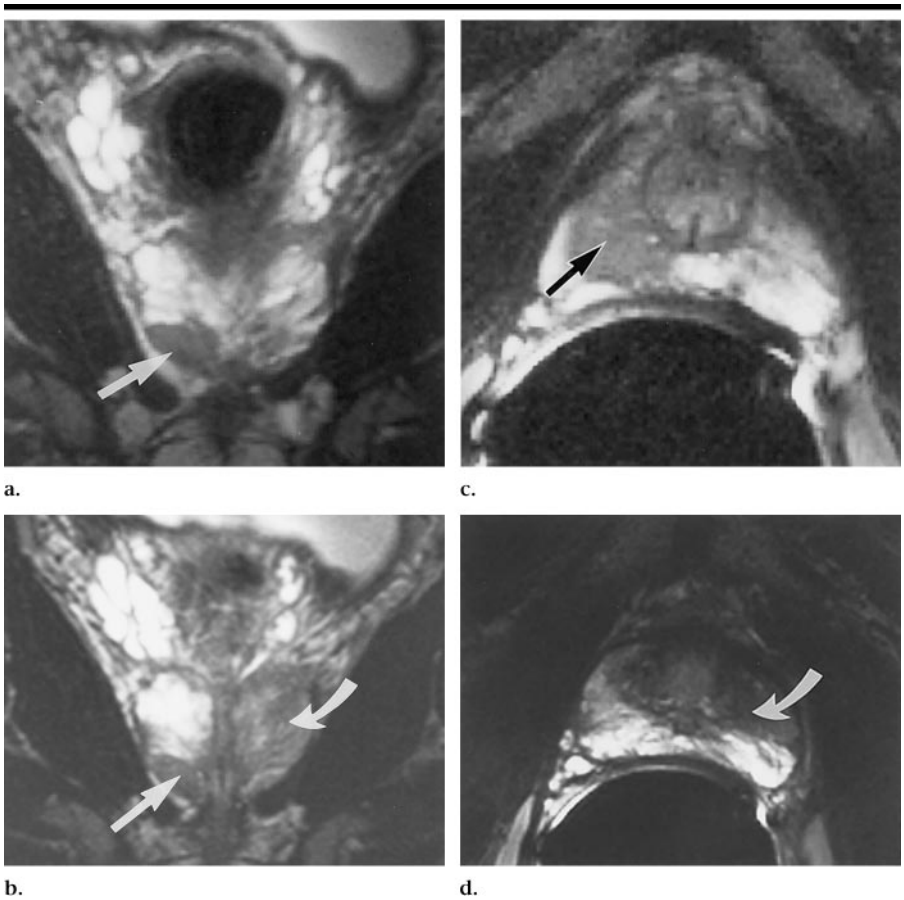
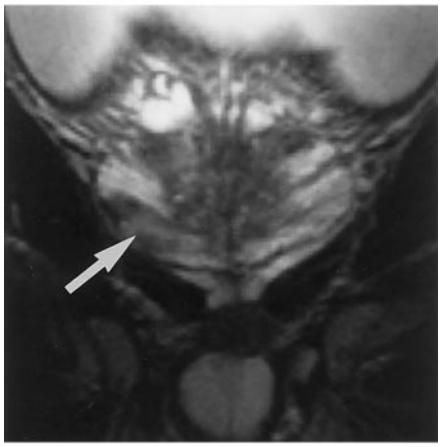


Figure 2. **(a, b)** Coronal T2-weighted turbo spin-echo MR images (echo train length, 15; repetition time msec/echo time msec, 4,522/112) obtained in a 62-year-old man with a PSA level of 24 ng/mL and negative results of transrectal US–guided sextant biopsy performed 6 weeks before MR imaging despite suspicious findings at palpation and transrectal US. The images, which were obtained at different positions through the prostate, show hypointense signal in the right apical area of the peripheral zone (straight arrow) and on the left side of the prostate (curved arrow). **(c, d)** Transverse T2-weighted turbo spin-echo MR images (echo train length, seven; 3,500/96) obtained at the **(c)** apical and **(d)** intermediate levels of the prostate in the same patient show corresponding areas of hypointensity (arrow) on the right and left sides. Repeat octant biopsy revealed right apical adenocarcinoma. The four biopsy specimens obtained from the left side showed prostatitis.

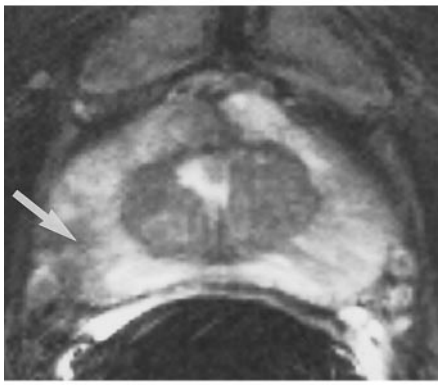
DISCUSSION

Relevant prognosticators of prostate adenocarcinoma are tumor volume (13), TNM stage (14), Gleason score (15,16), and PSA level (17). With PSA screening, it is possible to identify tumors that escape clinical detection (3). Early diagnosis of prostate cancer may lead to an increase in the number of patients with curable disease who can undergo curative radical prostatectomy or curative radiation therapy.

MR imaging study results have shown the combined endorectal body phased-array coil to be superior to the prostate coil alone in prostate cancer staging (7,9). The combined endorectal body phased-array coil was used in our study. In our



a.



b.

Figure 3. T2-weighted turbo spin-echo MR imaging findings in a 76-year-old man with a PSA level of 4.4 ng/mL and negative findings at each of three previous biopsies. There were no suspicious findings at DRE or transrectal US. **(a)** Coronal image (echo train length, 15; 4,522/112) shows inhomogeneous area of hypointensity (arrow) in the right lateral part of the peripheral zone. **(b)** Transverse image (echo train length, seven; 3,500/96) shows corresponding hypointense signal changes (arrow). Repeat octant biopsy revealed adenocarcinoma in one specimen from the right lateral area.

study population of patients with elevated PSA levels but negative transrectal US–guided biopsy results, MR imaging did not have the high accuracy of up to 97% for localization of prostate cancer that is reported in the literature (10).

In a study performed by Perrotti et al (12) with a comparable patient population, MR imaging had a sensitivity of 85%. However, in that study, the endorectal coil was used alone and the results were not analyzed according to individual biopsy sites. Therefore, the findings can, at best, be compared with the results of only our prospective analysis. By defining a negative finding as the absence of suspicious areas at MR imaging, Perrotti et al achieved a high negative predictive value of 94.4% for the presence of prostate cancer in their patient population. In comparison, in our study MR imaging had a negative predictive value of 100% at prospective analysis, and this was probably due to the small number of patients who had negative MR imaging findings and underwent repeat biopsy.

TABLE 2
Comparison of MR Imaging Findings with DRE and Transrectal US Findings in the Detection of Prostate Cancer in 38 Patients with Negative Initial Biopsy Results

Suspicious Findings	Repeat Biopsy Findings: Positive (n = 12)	Repeat Biopsy Findings: Negative (n = 26)
MR imaging	10	10
DRE	4	2
Transrectal US	4	3

Note.—Data are numbers of patients.

Our study consisted of two parts: a prospective analysis and a retrospective analysis. The MR imaging findings observed prior to repeat biopsy were first analyzed prospectively. In this prospective part of the study, it was not possible to analyze the findings according to biopsy site because the MR imaging report primarily described the site with the most suspicious changes. That is why this kind of prospective analysis is useful for determining the positive predictive value of MR imaging performed with a combined endorectal body phased-array coil for demonstration of cancer found at repeat biopsy compared with digital palpation (ie, DRE) or transrectal US.

To our knowledge, our study is the first that was performed to investigate this type of patient population (ie, with elevated PSA levels but negative initial biopsy results) by means of retrospective correlation of MR imaging findings with histologic results at individual biopsy sites in patients who underwent repeat octant biopsy. The poorer results of the retrospective site-by-site analysis compared with those of the prospective analysis suggest a lower specificity for the detection of malignancy. The retrospective analysis results confirmed that the MR imaging technique that we used does not enable reliable differentiation of prostate cancer from prostatitis, fibrosis, or prostatic intraepithelial neoplasia.

Because there was no significant correlation between the MR imaging findings and the histologic results, an additional more detailed analysis to compare localizations was not performed. Thus, our study results do not enable one to answer the question of whether the location of prostate cancer has any influence on prostate cancer detection at MR imaging (18).

One reason for the poorer results of biopsy site–based retrospective analysis as compared with those of prospective analysis may be limitations in matching the MR imaging findings with the suspicious areas detected at transrectal US and in the biopsy sites. Thus, only a rough correlation between MR imaging findings and histologic results is possible for two reasons: First, a clear-cut spatial assignment of the MR imaging findings to the biopsy sites is difficult because of the angled insertion of the biopsy needle from within the rectum. Second, the biopsy specimen represents only a small part of the area assessed with MR imaging (19). We observed evidence of such limitations in matching MR imaging findings to biopsy sites: The sensitivity of prostate cancer detection improved when the two sides were compared and assignment to adjacent biopsy sites had no effect.

In 16% (21 of 130) of the cases, the suspicious MR imaging findings could be explained by the presence of prostatic intraepithelial neoplasia. Because high-grade prostatic intraepithelial neoplasia is frequently associated with prostate cancer, obtaining a repeat biopsy specimen from the area in which the high-grade prostatic intraepithelial neoplasia was demonstrated is recommended (2). In our patient population, the hypointense changes may have indicated scar formation from a previous biopsy. In our study, hemorrhages in the prostate that occurred early after biopsy were seen in only two patients, who underwent MR imaging as early as 6 weeks after biopsy. In general, the mean interval between initial biopsy and MR imaging was longer in our patient population (20).

The differentiation between regions affected by prostatitis and areas of tumor involvement may be improved with pharmacokinetic MR imaging assessment of other tissue properties, such as perfusion or permeability (21). Another MR imaging technique that may be used to differentiate prostatitis, prostatic intraepithelial neoplasia, and prostate cancer is proton spectroscopy (22,23). The results of a study conducted by Scheidler et al (22) to investigate the localization of prostate cancer showed that specificity

improved to 75% with use of three-dimensional proton MR spectroscopic imaging compared with the specificity of 46%–61% observed with MR imaging alone. However, to our knowledge, no data on the use of this method in the kind of patient population investigated in our study are available in the literature.

Patient-based analysis of our study data revealed increased mean and median PSA levels in patients with prostate cancer. However, site-by-site analysis revealed a significant negative correlation between positive biopsy sites and PSA levels. This finding shows that a patient's PSA level does not enable one to make predictions about each biopsy site. This result, together with the nonsignificant correlation between MR imaging ratings and histologic findings, suggests that at least for the kind of patient population investigated in the present study, biopsy site assessments should not be based on an algorithm that includes the PSA level (24).

The depiction of suspicious areas at MR imaging also offers the opportunity for targeted biopsy of such areas, although MR imaging–guided biopsy has been reported only in individual cases thus far (25). Nevertheless, MR imaging–guided biopsy may improve accuracy because it can be performed directly, without matching MR imaging and transrectal US findings. MR imaging had a positive predictive value of 50% in our prospective analysis involving patients with suspicious MR imaging findings who had undergone repeat biopsy. Considered alone, this value was not high, but the sensitivity of 83% was superior to that of both DRE and transrectal US, each of which had a sensitivity of 40%. The data in our study suggest that MR imaging performed with a combined endorectal body phased-array coil, despite its poorer accuracy for prostate cancer detection at individual sites, can be recommended as a problem-solving modality for patients with elevated PSA levels or suspicious PSA ratios before repeat biopsy.

Acknowledgments: The authors thank Gerda Siebert, Department of Medical Statistics and Biometry, Charité Medical Center, for help with the statistical analysis and Bettina Herwig for translating the manuscript.

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