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Endorectal MRI of Prostate Cancer: Incremental Prognostic Importance of Gross Locally Advanced Disease

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Abstract

OBJECTIVE—The purpose of this study was to determine the frequency and incremental prognostic importance of gross locally advanced disease seen at endorectal MRI in patients with prostate cancer.

MATERIALS AND METHODS—We retrospectively identified the cases of all patients with biopsy-proven prostate cancer who underwent pretreatment endorectal MRI over a 6-year period ($n = 1777$). Three experienced radiologists identified by consensus patients with gross locally advanced disease, defined as unequivocal extracapsular extension or unequivocal seminal vesicle invasion. Outcome among these patients was compared with that in a control group without gross locally advanced disease matched by D'Amico risk stratification.

RESULTS—Sixty-six of 1777 (3.7%) patients had gross locally advanced disease. One of 1085 (0.1%) patients had low-risk disease, 25 of 489 (5.1%) had intermediate-risk disease, and 40 of 203 (19.7%) had high-risk disease. Follow-up data were available for 44 of these 66 patients. During a median follow-up period of 79 months, biochemical failure and metastasis had developed in 17 and 6 of these 44 patients compared with 9 and none of the 65 patients in the control group ($p < 0.001$).

CONCLUSION—Almost 4% of patients with prostate cancer, particularly those with intermediate- and high-risk disease, have gross locally advanced disease at endorectal MRI and have a significantly worse prognosis than matched controls. These patients may be candidates for more aggressive treatment.

Keywords

MR spectroscopy; MRI; prostate cancer

Prostate cancer is the second most common fatal cancer in American men. In 2010, an estimated 217,730 American men received a new diagnosis of prostate cancer, and 32,050 died of the disease [1]. Despite this sizeable mortality, many cases of prostate cancer are subclinical, and microscopic foci of incidental prostate cancer are detected at autopsy in as many as 40% of men [2]. At pathologic examination after surgery, as many as 29% of

patients undergoing radical prostatectomy for screening-detected prostate cancer are found to have indolent disease according to established characteristics predictive of low risk of progression [3, 4]. That is, many men with prostate cancer have disease that is indolent or incidental. As such, the primary challenge in the fight against prostate cancer is disease characterization—accurately determining who has aggressive disease that merits definitive treatment and its attendant morbidity versus who has indolent disease that may be better managed with active surveillance—rather than diagnosis [5]. Unfortunately, the standard clinical parameters, either alone or in combination, of serum concentration of prostate-specific antigen (PSA), clinical stage at digital rectal examination, biopsy Gleason score, and fraction of biopsy cores positive for cancer are of limited accuracy in predicting prognosis [6–11]. Any parameter that would provide incremental prognostic information would be of practical utility.

Endorectal MRI has emerged as a potentially powerful tool for evaluating the local extent of prostate cancer, and study results have suggested that local staging with MRI may be of incremental prognostic value [12–14]. In such studies, extracapsular extension and seminal vesicle invasion are typically rated on a 5-point scale of definitely absent, probably absent, indeterminate, probably present, and definitely present. Use of this system allows performance of receiver operating characteristic analysis, a sophisticated assessment of aggregate test performance. However, results of some studies have suggested that not only the presence or absence but also the degree of extracapsular extension influences MRI performance and prognostic importance. For example, in one study [15], MRI depicted only one of seven lesions with less than 1-mm extracapsular extension compared with five of seven with more than 1 mm of extracapsular extension. In another study [14], in which the subjects were 80 men treated with radiation therapy, multivariate analysis showed the sole independent predictor of metastatic failure was the mean radial diameter of extracapsular extension. In particular, more than 5 mm of extracapsular extension at pretreatment MRI was associated with increased risk of failure to control early metastasis. In essence, definitely present extracapsular extension or seminal vesicle invasion may be more easily detected and may be more prognostically significant than probably present findings. To our knowledge, the frequency and prognostic importance of such grossly locally advanced disease has not been extensively investigated in patients with prostate cancer. We undertook this study to determine the frequency and incremental prognostic importance of gross locally advanced disease seen at endorectal MRI in patients with prostate cancer.

Material and Methods

Subjects

This study was approved by our institutional committee on human research with waiver of the requirement for written consent and was compliant with HIPAA. Using our departmental prostate cancer imaging database, we retrospectively identified the cases of all patients who underwent baseline endorectal MRI for biopsy-proven cancer between January 1998 and October 2003 ($n = 1777$). This interval was chosen to ensure that patients were examined with relatively contemporary MRI technology and had a reasonably long follow-up period. After review of MR images (see later, Image Interpretation), these patients were divided into those with ($n = 66$) and those without ($n = 1711$) gross locally advanced disease.

The principal investigator reviewed all available medical records to determine the clinical and demographic characteristics of those with gross locally advanced disease, including D'Amico risk classification. D'Amico classification of risk assessment for patients with prostate cancer is based on PSA concentration, Gleason score, and clinical stage. Patients at low risk have a PSA concentration of 10 ng/mL or less, Gleason score up to 6, and a clinical T1–T2a lesion. Intermediate risk is defined as PSA concentration higher than 10 ng/mL but

up to 20 ng/mL, Gleason score of 7, and T2b lesion. High risk is a PSA concentration higher than 20 ng/mL, Gleason score of 8 or higher, and lesion in clinical category T2c or higher [8].

We selected a subset of the 1711 patients without gross locally advanced disease to serve as a control group for comparison with the patients with gross locally advanced disease. The control patients were selected consecutively to identify the chronologically closest patient with the same D'Amico risk class as the index patient and with follow-up information available. To prevent any chronologic bias, the time between MRI examinations of matched patients was set to 60 days or less. According to these criteria, 65 control patients were identified. The demographic and clinical characteristics of the 66 patients with gross locally advanced disease at MRI and the matched control group of 65 patients without gross locally advanced disease at MRI are shown in Table 1.

MRI Technique

All patients were examined in the supine position with a 1.5-T whole-body MRI system (Signa, GE Healthcare). A body coil was used for excitation and a pelvic phased-array coil (GE Health-care) was used in combination with a commercially available balloon-covered expandable endo rectal coil (Medrad) for signal reception. The MRI protocol included the following two sequences: an axial T1-weighted spin-echo sequence through the pelvis (TR/TE, 600/12; slice thickness, 4 mm; interslice gap, 0 mm; FOV, 28–32 cm²; matrix size, 256 × 192; frequency encoding in the transverse direction) and axial and coronal thin-section high-spatial-resolution T2-weighted fast spin-echo sequences of the prostate and seminal vesicles (TR/effective TE, 5000/96; echo-train length, 16; slice thickness, 3 mm; interslice gap, 0 mm; FOV, 14 cm²; matrix size, 256 × 192; anteroposterior frequency encoding to prevent obscuration of the prostate by endorectal coil motion artifact; number of signals acquired, 3).

Image Interpretation

MR images of all 1777 patients were initially reviewed by the principal investigator for preliminary gross identification of possible locally advanced disease. The principal investigator had 5 years of experience in interpretation of endorectal MR images of the prostate. These selected images were then read in consensus by the principal investigator with two coinvestigators, who had 5 and 12 years of experience in interpretation of endorectal MR images of the prostate. Images were reviewed at a PACS workstation (Impax, Agfa). At imaging review, readers knew the patients had biopsy-proven prostate cancer but were unaware of all other clinical and histopathologic findings. Based on their consensus opinion, the readers classified patients as having or not having gross locally advanced disease [16]. Although this designation was ultimately a subjective expert assessment, in general unequivocal extracapsular extension or unequivocal seminal vesicle invasion was considered present when tumor was seen extending more than 5 mm outside the capsular margin of the prostate into the periprostatic fat or seminal vesicles [14]. The principal investigator measured the volume of the prostate using the prolate ellipsoid formula ($\text{length} \times \text{height} \times \text{width} \times \pi/6$) [17].

Clinical Data and Patient Outcome

After selection of the cases, the principal investigator gathered treatment and outcome data on patients with gross locally advanced disease and the matched control group by reviewing all available clinical notes and laboratory results. For patients with follow-up data, clinical outcome at the most recent contact was categorized as disease free, biochemical recurrence, metastatic recurrence, death of prostate cancer, or death of an unrelated cause. Biochemical recurrence was defined as a serum PSA concentration 2 mg/dL above the nadir value or

three consecutive elevations for patients treated with nonsurgical modalities [18] or any detectable PSA in the serum for patients treated with radical prostatectomy [19]. Metastatic recurrence was defined as the presence of an extraprostatic lesion consistent with metastasis based on histopathologic confirmation or other supportive evidence, such as the development of a new sclerotic bone lesion with increased uptake at bone scintigraphy. Forty-four of the 66 patients with gross locally advanced disease at MRI had follow-up data available. All of the control patients had follow-up data available (having adequate follow-up was one of the criteria for inclusion in the control group).

Statistical Analysis

For statistical analyses, the subjects were divided into those with gross locally advanced disease and the matched control group. The Wilcoxon signed rank test was used to assess distribution with respect to the continuous variables of pre-treatment serum PSA concentration and Gleason score. Gleason score was treated as a categorical variable. The Fisher exact test was used to assess the distribution of patients in the two groups according to the discrete variables clinical staging, presence or absence of biochemical failure, seminal vesicle invasion, percentage of cancer in cores, and extracapsular extension. The Freeman-Halton extension of the Fisher exact test was used for contingency tables larger than 2×2 [20]. Logistic regression was used to test for a difference in outcome for the two groups and to find association between individual clinical and imaging parameters and poor outcome. The logistic regression analysis was performed for all forms of recurrence and for systemic metastasis only. Recurrence events were estimated with the Kaplan-Meier method, and comparisons between groups were done with the log-rank test. Patient data were censored at last follow-up interaction or death if the endpoint of interest had not been attained. Statistical calculations were performed with SAS/STAT software (version 9.1, SAS Institute).

Results

Sixty-six of 1777 (3.7%) patients had gross locally advanced disease. One of 1085 (0.1%) patients had low-risk disease, 25 of 489 (5.1%) had intermediate-risk disease, and 40 of 203 (19.7%) had high-risk disease. Forty-four of the 66 patients with gross locally advanced disease at MRI had follow-up data available. After a median follow-up period of 79 months (range, 49–128 months), 17 of these 44 patients had biochemical failure and six had metastasis, compared with nine and none of the 65 control patients ($p < 0.001$). There was no death in the study sample. The results of univariate analysis of clinical and MRI variables for predicting both biochemical and metastatic recurrence are shown in Table 2. The comparison of outcomes of the two groups by Kaplan-Meier analysis showed a significant difference in outcome for two groups ($p = 0.002$) (Fig. 1). A representative case example is shown in Figure 2.

Discussion

Our data show that almost 4% of patients with prostate cancer have gross locally advanced disease at endorectal MRI and have a significantly worse prognosis than matched controls. Such patients may be candidates for more aggressive treatment, such as whole-pelvis radiation combined with prostatic radiation, adjuvant radiotherapy after surgery, or long-term androgen deprivation therapy [21–23]. Although they could be used to support the routine use of MRI to evaluate all newly diagnosed cases of prostate cancer, these results raise the question whether endorectal MRI should be confined to patients with clinically intermediate and high-risk disease who would be candidates for aggressive therapy; only 1 of 1085 patients with low-risk disease had gross locally advanced disease at MRI. We acknowledge that our approach is based (and focused) on the decision to escalate treatment of patients at higher risk of recurrence, but MRI may add other useful information for

identifying high-yield targets for biopsy and focal therapy and selecting and monitoring patients for active surveillance. Such applications were beyond the scope of our study but have been addressed by others [13–15]. Our finding that patients with gross locally advanced disease at MRI had a significantly worse prognosis than clinically matched patients without gross locally advanced disease is also noteworthy because it implies that these patients would not otherwise be identified on the basis of known risk stratification. This finding also indicates that MRI findings add incremental prognostic information over and above prognostication based on standard established predictors.

Our results are largely concordant with those of similar studies. In a follow-up study of 1025 patients undergoing radical retropubic prostatectomy for prostate cancer, D'Amico et al. [19] found that T3 disease detected at pre-operative MRI was associated with a significantly worse prognosis in patients with intermediate- and high-risk disease but not in those with low-risk disease. In a study of the role of preoperative MRI in the decision to resect or preserve the neurovascular bundle [24], MRI was found most useful in the subset of 36 patients with high-risk disease (defined on the Partin nomogram [7] as 75% or greater probability of extracapsular extension). MRI findings changed the surgical plan for 28 of the 72 neurovascular bundles in these patients. On the basis of pathologic findings, the change was found appropriate in 26 of the 28 cases. The common themes of these studies are that MRI findings related to disease extent are important variables in planning treatment and predicting outcome and that imaging is most useful to patients with higher-risk disease. Even though the prevalence of locally advanced prostate cancer depends on the definition used and on which patients underwent MRI, our fraction of 4% is in accordance with that in a large series in which the fraction of these tumors declined from approximately 11% to 3.8% of all cases of prostate cancer [25].

Our study had limitations. First, the imaging diagnosis of gross locally advanced disease lacked histopathologic verification. Therefore, we cannot be certain that the imaging features of gross extracapsular extension and gross seminal vesicle invasion correspond to the true pathologic status. Although it is always desirable, we believe that in this case the pathologic information may be mitigated in relation to the unequivocal endpoint of outcome. We clearly found that these imaging findings are predictive of a worse prognosis. From the patient's perspective, the correspondence between imaging and pathologic findings is less important than the correspondence between imaging findings and outcome. Patients usually are more concerned with what is going to happen to them than with what is the exact pathologic extent of the tumor.

The second limitation was that evaluation of tumor extent was subjective and based on expert interpretation, so the reproducibility and generalizability of our results are unknown. The terms gross extracapsular extension and gross seminal vesicle invasion lack an objective definition. This problem affects MRI evaluation of the prostate in general because currently available parameters are poorly suited to quantitative assessment. Additional research may help to develop more quantitative and reproducible MRI criteria for prostate cancer. However, most radiologists are familiar with the use of 5-point scales to grade imaging findings [26]. In our study gross extracapsular extension and seminal vesicle invasion would have reflected a rating of 5 on such a scoring system. Although our approach of reaching consensus of three observers was defined to assure that imaging findings were unequivocal, we acknowledge that interobserver agreement could have been evaluated, especially considering that factors such as difficulty of cases and clinical experience of observers can affect the level of agreement.

This study was retrospective and observational and conducted at a single institution. These factors both limit the ability to draw conclusions that can be widely applied and may have

introduced unintended bias. For example, despite our matching system, the patients without gross locally advanced disease at MRI appeared more likely to undergo radical prostatectomy than those with gross locally advanced disease (Table 1), suggesting other factors, conceivably including the availability of MRI results, might have influenced management options. The question of possible bias related to differences in therapy can be raised, but reports in the literature [27, 28] suggest that surgery and radiation therapy have similar results when outcomes are compared. Another potential bias would be loss to follow-up. In our study, 22 of 66 men with locally advanced disease were lost to follow-up. We acknowledge that differential loss of follow-up between outcome groups can bias results, leading to underestimates or overestimates of differences in outcome in the two groups. Even in the unlikely event that all patients with missing follow-up data did not have any of the outcomes, leading to overestimation of estimates, the numbers still suggest a difference between groups. Finally, our suggestion that outcome may be improved by identifying patients with gross locally advanced disease at MRI and offering these patients more aggressive therapy is unproven. All of the limitations emphasize the need for more rigorous prospective multicenter studies.

Conclusion

Almost 4% of patients with prostate cancer, particularly those with intermediate-and high-risk disease, have gross locally advanced disease at endorectal MRI and have a significantly worse prognosis than matched controls. Such patients may benefit from more aggressive treatment.

Acknowledgments

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Fig. 1. Kaplan-Meier curves show recurrence rates in patients free of prostate cancer recurrence (biochemical or metastatic) with (*dashed line*) and without (*solid line*) gross locally advanced disease at MRI. Patients with gross locally advanced disease had significantly poorer ($p < 0.05$) prognosis.

Fig. 2.

58-year old man with newly diagnosed prostate cancer (Gleason score, 6; baseline serum prostate-specific antigen concentration, 6.1 mg/dL; clinical category, T2b; D'Amico classification, intermediate risk).

A, Axial T2-weighted endorectal MR image shows large focus (*asterisk*) of low signal intensity in left peripheral zone consistent with tumor.

B, Axial T2-weighted endorectal MR image superior in relation to **A** shows gross extracapsular extension (*arrow*). Patient was considered to have gross locally advanced disease and was treated with radiation therapy.

C, Axial CT image obtained 46 months after **B** because of increase in prostate-specific antigen concentration shows multiple sclerotic metastatic lesions of bone (*arrows*).

TABLE 1

Distribution of Clinical and Laboratory Variables in Patients With Locally Extensive Disease at Endorectal MRI and a Matched Control Group Without Locally Extensive Disease

Variable	No. of Men With Locally Extensive Disease		No. of Matched Controls (<i>n</i> = 65)	<i>p</i> ^a
	All (<i>n</i> = 66)	With Follow-Up Data (<i>n</i> = 44)		
Mean age (y)	62.2 ± 8.02	61.9 ± 7.7	64.0 ± 7.3	0.16
Mean baseline prostate-specific antigen concentration (ng/mL)	17.1 ± 20.8	14.9 ± 17.3	10.3 ± 6.2	0.10
Gleason score				0.21
6	10 (15.2)	7 (15.9)	16 (24.6)	
7	41 (62.1)	28 (63.7)	26 (40.0)	
8	10 (15.2)	6 (13.6)	21 (32.3)	
9	5 (7.5)	3 (6.8)	2 (3.1)	
D'Amico risk classification				1.00
High	40 (60.6)	26 (59.0)	39 (60.0)	
Intermediate	25 (37.9)	17 (38.6)	24 (36.9)	
Low	1 (1.5)	1 (2.3)	2 (3.1)	
Management				0.02
Prostatectomy		8 (18.2)	19 (29.2)	
Definitive radiation		31 (70.4)	42 (64.6)	
Hormonal therapy alone		5 (11.4)	4 (6.2)	

Note—Values in parentheses are percentages.

^aComparison between patients with locally extensive disease and follow-up data and control group of patients without locally extensive disease.

TABLE 2

Results of Univariate Analysis of Clinical and MRI Predictors of Prostate Cancer Recurrence (Biochemical Failure and Systemic Metastasis) ($n = 109$)

Variable	<i>p</i>	Odds Ratio
Gleason score	0.20	—
Prostate-specific antigen concentration	0.45	—
Clinical T category	0.01	0.28 (0.11–0.68)
MRI T category	0.02	0.35 (0.14–0.89)
Seminal vesicle invasion	0.04	4.17 (1.26–13.73)
Extracapsular extension	0.01	8.59 (1.56–47.21)

Note—Values in parentheses are 95% CI. Dashes (—) indicate that the 95% CI included the value 1.