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Prostate cancer transrectal HIFU ablation: detection of local recurrences using T2-weighted and dynamic contrast-enhanced MRI

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Abstract The objective was to evaluate T2-weighted (T2w) and dynamic contrast-enhanced (DCE) MRI in detecting local cancer recurrences after prostate high-intensity focused ultrasound (HIFU) ablation. Fifty-nine patients with biochemical recurrence after prostate HIFU ablation underwent T2-weighted and DCE MRI before transrectal biopsy. For each patient, biopsies were performed by two operators: operator 1 (blinded to MR results) performed random and colour Doppler-guided biopsies ("routine biopsies"); operator 2 obtained up to three cores per suspicious lesion on MRI ("targeted biopsies"). Seventy-seven suspicious lesions were detected on DCE images (n=52), T2w images (n=2) or both (n=23). Forty patients and 41 MR lesions were positive at biopsy. Of the 36 remaining MR lesions, 20 contained viable benign glands. Targeted biopsy detected more cancers than routine biopsy (36 versus 27 patients, p=0.0523). The mean percentages of positive cores per patient and of tumour invasion of the cores were significantly higher for targeted biopsies (p<0.0001). The odds ratios of the probability of finding viable cancer and viable prostate tissue (benign or malignant) at targeted versus routine biopsy were respectively 3.35 (95% CI 3.05–3.64) and 1.38 (95% CI 1.13–1.63). MRI combining T2-weighted and DCE images is a promising method for guiding post-HIFU biopsy towards areas containing recurrent cancer and viable prostate tissue.

Keywords Prostate cancer · MRI · Dynamic-contrast enhanced MRI · Biochemical recurrence · HIFU

Introduction

Transrectal high-intensity focused ultrasound (HIFU) ablation is a minimally invasive treatment for prostate cancer that has been evaluated since the early 1990s [1–3]. It can be proposed either for patients with clinically localised prostate cancer who are not candidates for surgery [4, 5] or as a salvage treatment of local recurrences of prostate cancer after external-beam radiation therapy (EBRT) [6, 7]. Five-year disease-free survival rates after HIFU ablation of clinically localised prostate cancer fall within the 66–78% range, which challenges the results of radiation therapy [4, 8, 9].

One advantage of the method is that HIFU ablation can be repeated in cases of incomplete cancer destruction, although the risk of complications seems to increase with multiple treatments [10]. Alternatively, efficient treatment of local recurrences after HIFU ablation can also be obtained with radiation therapy, with no increase in complications

compared with first-line EBRT [11]. These efficient treatments make it necessary to diagnose local recurrences early.

To date, most research groups have recommended systematic random sextant biopsy 3–6 months after HIFU ablation. In the case of negative biopsy, the prostate-specific antigen (PSA) level is assessed every 3–6 months after treatment [4, 8, 9]. Prostate biopsy is then repeated on evidence of biochemical failure. However, random biopsy lacks sensitivity in detecting small residual cancer. Transrectal ultrasound (TRUS) is of little help because, after treatment, the gland is diffusely heterogeneous [12]. Colour Doppler can improve residual/recurrent cancer detection by guiding the biopsies towards residual hypervascular foci, but only 38% of sites with residual/recurrent cancer show positive colour Doppler findings [13].

Recently, dynamic contrast-enhanced (DCE) MRI has shown promising results in detecting and localising cancer in untreated prostates [14–17] or in patients with biochemical recurrence after EBRT [18, 19] or radical prostatectomy [20, 21]. Immediately after HIFU ablation, the treated volume appears on nondynamic contrast-enhanced images as a devascularised zone (corresponding to the central core of coagulation necrosis) surrounded by a rim of enhancement (corresponding to inflammation and oedema) [22, 23]. At that time, foci of residual cancer cannot be clearly seen, even with dynamic imaging [23], probably because of their small size and/or because they cannot be distinguished from the inflammatory rim of enhancement that borders the treated volume. During the months following HIFU ablation, the devascularised zone and its peripheral rim of enhancement progressively disappear in a centripetal manner, as coagulation necrosis is replaced by fibrosis [23]. This creates more favourable conditions for distinguishing, using DCE imaging, residual/recurrent cancers (which are usually hypervascular) from post-HIFU fibrosis (which is rather homogeneous and hypovascular). Two recent studies, with small numbers of patients, suggested DCE MRI had a good sensitivity for detecting local recurrences after HIFU ablation [24, 25]. Based on these preliminary findings, DCE MRI has been rapidly accepted at our institution and is now used on a routine basis to localise post-HIFU recurrences before prostate biopsy. However, the clinical usefulness of performing an MR examination before biopsy in patients with biochemical recurrence after prostate HIFU ablation remains to be evaluated. In particular, the proportion of additional local recurrences that can be diagnosed using MRI and biopsy as compared to random and colour Doppler-guided biopsies remains to be determined. We undertook the present study to answer this question.

Materials and methods

Study population

Between September 2006 and July 2008, all patients with biochemical recurrence after prostate cancer HIFU ablation who were referred to our department for prostate MRI followed by transrectal biopsy were offered the opportunity to enter the study, i.e. to have the biopsy performed by two operators. All patients signed appropriate investigational review board forms and gave their consent to participate in the study, the purpose of which was fully explained to them. Patients with contraindication for MRI or who did not want to undergo MRI or to have the biopsy performed by two operators were not included.

A total of 59 patients were included during the study period. Fifty-one of them had been treated for clinically localised prostate cancer in one (n=41) or two (n=10) HIFU sessions. The remaining eight patients had undergone one (n=7) or two (n=1) HIFU sessions for a local recurrence of prostate cancer after EBRT. Table 1 summarises patients' history at inclusion.

MRI technique

All patients were imaged at 1.5 T (Siemens Symphony, Erlangen, Germany) using pelvic phased-array coils only.

First, T2-weighted (T2w) turbo spin echo (TSE) images (TR 6,130 ms, effective TE 109 ms, slice thickness 4 mm, FOV 180×180 mm, matrix 256×192, 3 excitations, echo train length 21) were obtained in the axial, sagittal and coronal planes.

Then, T1-weighted fat-saturated axial fast low-angle shot (FLASH) images (TR 5.38 ms, TE 2.73 ms, flip angle 10°, slice thickness 3 mm, matrix 256×135, FOV 240×204 mm, 1 excitation, acquisition time 15 s) were obtained before injection. Then an intravenous bolus of 0.1 mmol/kg of gadoterate meglumine (Dotarem, Guerbet, Roissy, France) was injected at a rate of 3 cc/s. The arrival of the

Table 1 Patients' history at inclusion

Age (years)	PSA level before HIFU ablation (ng/ml)	Gleason score before treatment	Prostate volume before HIFU ablation (ml)	PSA nadir after last HIFU ablation (ng/ml)	Delay between last HIFU session and MRI (months)	PSA level at inclusion (ng/ml)
72.2±5.6	9.18±4.89	6.4±0.9	27.8±11.6	0.76±1.37	57.2±153.4	2.67±2.05

contrast bolus was monitored using an axial MR fluoroscopic sequence (Care Bolus, Siemens) placed at the level of the common femoral arteries. When the bolus reached the common femoral arteries, the same axial FLASH sequence as the one performed before injection was manually started and repeated 12 times. The total examination time was approximately 30 min.

MR image analysis

For analysis purposes, the prostate was divided into eight sectors (apex, midgland, base and seminal vesicle on the right and on the left).

The diagnostic criteria of cancer recurrence were based on recently published preliminary findings [24]. On T2w images, the prostate was expected to be heterogeneous and diffusely hypointense. Only areas that were homogeneous and clearly more hypointense than the surrounding residual prostate were interpreted as tumoral. Abnormally low signal intensity in the seminal vesicle (SV) lumen or focal thickening of the SV wall was also interpreted as tumour invasion unless the SV content showed high signal intensity on unenhanced FLASH images (possible post-HIFU bleeding or fluid with high protein content that shows low signal intensity on T2w images). On DCE images, all areas showing early and intense enhancement in the prostate or the SV were considered malignant. In the case of SV content with high signal intensity on unenhanced FLASH images, subtracted contrast images were examined to determine whether or not there was an early enhancement of the SV wall.

Transrectal prostate biopsy

Prostate biopsy procedures were performed using a Kretz Voluson 530 D ultrasound system with a S-IC5–9 end-fire probe (Kretz AG, Zipf, Austria) operating at 7.5 MHz for grey-scale imaging and at 6.5 MHz for colour Doppler. A total of five radiologists with 15, 5, 3, 3 and 1 years' experience in prostate MRI and biopsy participated in this study. For each patient, the biopsy procedure was performed by two of these five radiologists. The first biopsy operator, who was blinded to the MR results, performed random and colour-guided biopsy according to our institutional post-HIFU biopsy procedure. First, a TRUS of the prostate was obtained in transverse and sagittal planes. The prostate volume was determined using the ellipsoid formula: length × width × height × 0.52. Then at least one sample was randomly obtained in every prostate sextant and in every seminal vesicle. Additional colour Doppler-guided biopsies were performed if hypervascular foci were visible in the prostate [13]. These biopsies will be referred to as "routine biopsies" in the rest of this paper.

During this time, the second operator reviewed the MR images and had to precisely identify suspicious areas on T2w or DCE images. When operator 1 was finished performing the routine biopsies, operator 2 obtained biopsies from all areas that were suspicious on MR images (up to three samples from each suspicious area). These biopsies will be referred to as "targeted biopsies" in the rest of this paper.

All biopsy procedures were performed under local anaesthesia. Targeted biopsies were obtained immediately after routine biopsies without removing the TRUS probe. All samples were inked on their capsular extremity and carefully labelled with the site of origin.

Statistical analysis

Per core analysis

A logistic regression model with random intercept was used to quantify the effect of targeted biopsies versus routine biopsies on the probability of finding viable cancer

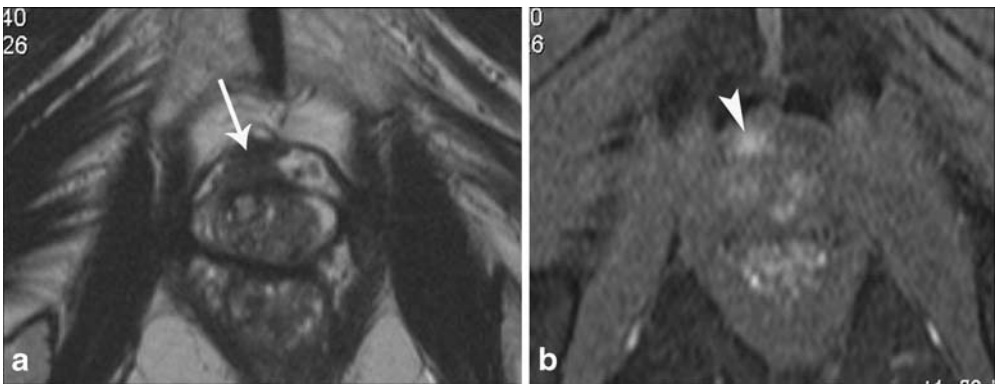

Fig. 1 Patient with an initial PSA level of 14 ng/ml and an initial Gleason score of 6. The post-HIFU PSA nadir was 0.69 ng/ml. The PSA level at inclusion was 4.1 ng/ml. **a** T2w images showed a hypointense suspicious anterior nodule (*arrow*). **b** DCE images were confirmative (*arrowhead*). At routine biopsy (operator 1), 1 sample out of 11 was positive for cancer (left base, Gleason 6, 0.5 mm). At targeted biopsy (operator 2), one sample out of three was positive for cancer (Gleason 6, 1 mm)

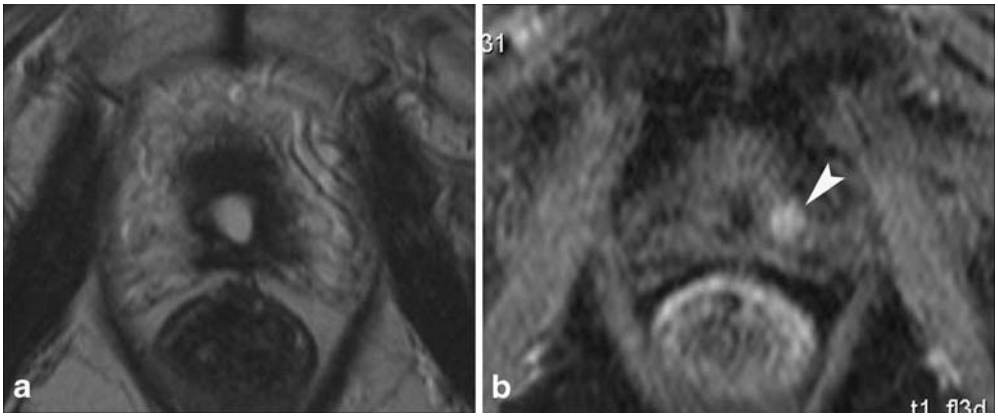

Fig. 2 Patient with an initial PSA level of 6.9 ng/ml and an initial Gleason score of 6. The post-HIFU PSA nadir was 0 ng/ml. The PSA level at inclusion was 3.03 ng/ml. No suspicious lesion was clearly seen on T2w images (**a**). **b** DCE images showed an early enhancing nodule in the left base, just below the bladder neck (*arrowhead*). Routine biopsy (operator 1) did not show recurrent cancer. Targeted biopsy (operator 2) showed cancer in three samples out of three (Gleason 7, 6-mm maximum)

and viable prostate tissue (benign or malignant). This effect was quantified by an odds ratio. The random intercept allowed intrapatient correlation structure to be taken into account.

Per patient analysis

The results of routine and targeted biopsies (positive or negative for cancer) were compared using McNemar's test. The percentage of positive cores and the mean percentage of tumour invasion of the cores obtained in each patient were compared using the paired Student's *t* test.

A *p* value less than 0.05 was considered statistically significant. Throughout this paper, all confidence intervals are 95% confidence intervals.

Results

MRI findings

A total of 77 suspicious areas were seen on MRI in 58 of the 59 patients. Of these 77 suspicious areas, 52 were visible only on DCE images, 2 only on T2w images and 23 on both (Figs. 1, 2, 3). The mean size of the suspicious areas on MRI was 12.8±4.6 mm (range 4–27).

Biopsy findings

Prostate biopsy procedures were performed on average 7.4 days after MRI. The mean prostate volume at TRUS was 9.1±6.6 ml (range 1.5–30).

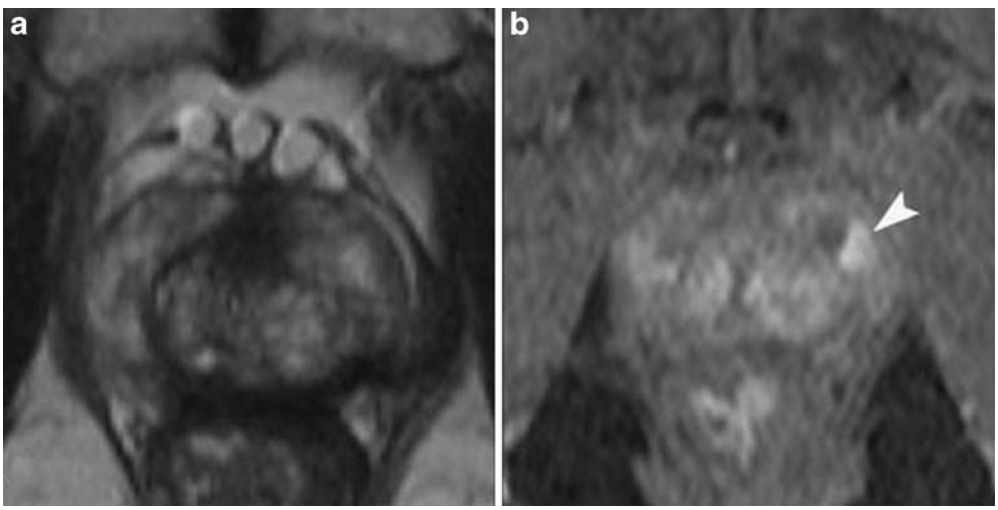

Fig. 3 Patient with an initial PSA level of 5.5 ng/ml and an initial Gleason score of 7. The post-HIFU PSA nadir was 1.84 ng/ml. The PSA level at inclusion was 2.84 ng/ml. No suspicious lesion was clearly seen on T2w images (**a**). **b** DCE images showed an anterior early enhancing nodule in the left lobe (*arrowhead*). Routine biopsy (operator 1) did not show recurrent cancer. Targeted biopsy (operator 2) showed cancer in two samples out of three (Gleason 6, 4-mm maximum)

Table 2 Results of routine and targeted biopsy (per patient analysis)

		Routine biopsy		
		Positive	Negative	Total
Targeted biopsy	Positive	23	13	36
	Negative	4	19	23
	Total	27	32	59

Targeted biopsy detected a higher number of recurrent cancers (p=0.0523)

A total of 40 patients (67.8%) had recurrent cancer at routine and/or targeted biopsy. The Gleason score of this recurrent cancer was 6 in 6 patients, 7 in 28 patients, 8 in 3 patients, 9 in 2 patients and indeterminate in 1 patient.

Of the 77 suspicious areas found on MRI, 41 (53.2%) were positive for cancer. In the 36 remaining areas, targeted biopsies showed viable benign prostate glands in 18, prostatic intra-epithelial neoplasia in 2, inflammatory granuloma in 2 and fibrosis or necrosis in 14.

Comparison of routine and targeted biopsies

Per patient analysis

Table 2 shows the separate results of routine and targeted biopsy. Thirteen patients had positive targeted biopsy and negative routine biopsy; four patients had negative targeted biopsy and positive routine biopsy. Targeted biopsies were positive for cancer in a higher number of patients than routine biopsies (36 versus 27 patients, p=0.0523).

The mean percentage of positive cores per patient and the mean percentage of tumour invasion of the cores were significantly higher for targeted biopsies (p<0.0001, Table 3).

Per core analysis

The probability of finding viable cancer on biopsy cores was higher for targeted biopsies (19% vs 7%, p<0.001), with an odds ratio of 3.35 (95% confidence interval 3.05–3.64).

The probability of finding viable prostate tissue (benign or malignant) was also higher in targeted biopsies (47% vs 39%, p=0.012), with an odds ratio of 1.38 (95% confidence interval 1.13–1.63).

Discussion

In the present study, targeted biopsies using MR findings were significantly more likely to contain cancer than routine random and colour Doppler-guided biopsies. If no MRI had been performed, the recurrent cancer would have been missed in 22% (13/59) of the patients. This strongly supports the use of prostate MRI before biopsy in patients with post-HIFU biochemical recurrence.

These good results were mainly obtained using DCE imaging. Recurrences were indeed difficult to detect on T2w images on which the gland appeared heterogeneous and showed diffuse hyposignal. However, in our experience T2w images, which have a higher spatial resolution, remained useful to precisely localise before biopsy a recurrent cancer detected on DCE imaging.

Our study was designed to evaluate the diagnostic yield of targeted biopsies using MR findings (i.e. the proportion of additional local recurrences detected as compared to routine biopsies). However, it cannot assess MR accuracy for post-HIFU residual/recurrent cancer detection. Indeed, some residual/recurrent cancer foci might have remained undetected by targeted and routine biopsies and MR sensitivity might be lower than it appears in this study. Conversely, some suspicious lesions on MR images might have been missed by targeted biopsies and MR specificity might be higher than it appears. The only way to assess MR accuracy would be to obtain prostatectomy specimens, but unfortunately prostatectomy cannot be performed in patients treated by HIFU ablation who usually are nonsurgical candidates. Interestingly, in four patients (6.8%), routine biopsies were positive and targeted biopsies negative. In two of these four patients, routine biopsies were positive in the same sextant as MRI and it is possible that MRI correctly detected the recurrent cancer that was missed by targeted biopsies. In the two other patients, no MR abnormality was seen in the sextants positive at routine biopsy.

Although some targeting mistakes might have led to erroneous false-positive findings, our data suggest the lack of specificity of MRI: only 53.2% (41/77) of the suspicious areas at MR were positive at targeted biopsy. Similar results were obtained by Kim et al. [25]. We agree with these authors that residual nodules of benign prostate hypertrophy, which can be hypervascular [26], are a potential source of false-positive findings at DCE MRI. In our study, 55.5% (20/36) of the areas suspicious on MRI and negative at targeted biopsy contained viable benign

Table 3 Results of systematic and targeted biopsy (per core analysis)

	Routine biopsy	Targeted biopsy	p
Number of cores per patient	9.05±1.5 (8–15)	3.93±1.5 (2–9)	<0.0001
Percentage of positive cores per patient	10.7±15.2 (0–57.1)	37.6±39.2 (0–100)	<0.0001
Percentage of tumour invasion of the cores	3.5±6.5 (0–31)	13.9±19.8 (0–77.8)	<0.0001

glands. The per core analysis also showed that targeted biopsies had a significantly higher probability of containing cancer and viable normal prostate glands. This suggests that MRI detects not only residual/recurrent cancer but also areas of viable benign residual prostate tissue.

Other MR techniques could be used to improve MR specificity. Spectroscopy has been used to detect locally recurrent cancer after radiation therapy [27–29], cryotherapy [30] or radical prostatectomy [31]. However, spectroscopy specificity seems limited after radiation therapy [29] and its accuracy in detecting recurrences after radical prostatectomy remains controversial [32]. To our knowledge, spectroscopy has never been tested after HIFU ablation. Diffusion-weighted imaging is a promising technique that gave interesting results in localising prostate cancer in untreated prostates [33–35]. Preliminary results suggest it has a higher specificity and a lower sensitivity for detecting residual/recurrent cancer after HIFU ablation [25].

We used only visual criteria for diagnosis of residual/recurrent cancer on DCE images. Kim et al. used dedicated software to generate parametric maps corresponding to the wash-in rate, the wash-out rate, the maximal enhancement, the maximal relative enhancement and the time-to-peak [25]. The differences in the design of the two studies preclude the direct comparison of their results and it remains unclear whether parametric maps are necessary to diagnose prostate cancer or whether simple visual criteria are sufficient. However, our results suggest that accurate diagnosis can be obtained with simple visual criteria.

In this study, we did not use any endorectal coils. The accuracy of prostate cancer staging seems better with an endorectal coil, which provides a higher signal-to-noise ratio [36]. On the other hand, the endorectal coil is expensive and a source of discomfort for the patients. Furthermore, several research groups have shown that tumour detection and localisation (if not tumour staging) could be accurately obtained with DCE imaging using pelvic phased-array coils only [14, 16, 25, 35, 37]. Our results are in line with this finding and suggest that the contrast between the poorly enhancing post-HIFU fibrosis and the early enhancing residual/recurrent cancers is high enough for those residual/recurrent cancers to be easily diagnosed without the need for an endorectal coil.

Our study has several limitations. First, its design does not allow the evaluation of interobserver variability in interpreting MR images. Five radiologists specialized in uroradiology participated in the targeted and routine biopsy procedures and there were not enough patients for each combination of radiologists to draw any solid conclusions concerning interobserver variability. However, previous experience with the visual diagnostic criteria we used for DCE MRI showed that they were robust and easy to learn with excellent interobserver reproducibility [14, 18]. Second, like in other studies [13, 24, 25], the patients were not enrolled on the basis of a clear definition of biochemical recurrence. To date, there is no internationally accepted definition of biochemical recurrence after HIFU ablation. Although there have been some recent propositions for defining post-HIFU biochemical recurrence [38], we tend to adopt at our institution the Phoenix criteria that have been defined for recurrences after EBRT [39]. On average, the patients were enrolled when their PSA level was approximately 2 ng/ml above the PSA nadir value (Table 1).

Conclusion

T2w/DCE MRI is a promising method for guiding post-HIFU biopsy towards areas containing residual (benign or malignant) viable prostate tissue and, thus, to sensitise the detection of locally recurrent cancer in patients with biochemical recurrence. Further research is needed to improve the specificity of the technique and improve the distinction between residual/recurrent cancer and residual benign prostate tissue.

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