DOI: 10.4081/aiua.2022.1.25

ORIGINAL PAPER

The role of MRI in the detection of local recurrence: Added value of multiparametric approach and Signal Intensity/Time Curve analysis

Caterina Gaudiano [1], Federica Ciccarese [1], Lorenzo Bianchi [2], Beniamino Corcioni [1], Antonio De Cinque [1], Francesca Giunchi [3], Riccardo Schiavina [2], Michelangelo Fiorentino [4], Eugenio Brunocilla [2], Rita Golfieri [1]

[1] Department of Radiology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy;
[2] Department of Urology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy;
[3] Department of Pathology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy;
[4] Department of Specialty, Diagnostic and Experimental Medicine, University of Bologna, Bologna, Italy.

Summary

Objective: *The aim of the study was to evaluate the accuracy of multiparametric Magnetic Resonance Imaging (mpMRI) in the detection of local recurrence of prostate cancer (PCa) with the evaluation of the added value of signal Intensity/Time (I/T) curves.*

Materials and methods: *A retrospective analysis of 22 patients undergoing mpMRI from 2015 to 2020 was carried out, with the following inclusion criteria: performing transrectal ultrasound guided biopsy within 3 months in the case of positive or doubtful findings and undergoing biopsy and/or clinical follow-up for 24 months in the case of negative results. The images were reviewed, and the lesions were catalogued according to morphological, diffusion-weighted imaging (DWI) and dynamic contrast-enhanced (DCE) features.*

Results: *The presence of local recurrence was detected in 11/22 patients (50%). Greater diameter, hyperintensity on DWI, positive contrast enhancement and type 2/3 signal I/T curves were more frequently observed in patients with local recurrence (all $p < 0.05$). Of all the sequences, DCE was the most accurate; however, the combination of DCE and DWI showed the best results, with a sensitivity of 100%, a specificity of 82%, a negative predictive value of 100% and a positive predictive value of 85%.*

Conclusions: *The utility of MRI in the detection of local recurrence is tied to the multiparametric approach, with all sequences providing useful information. A combination of DCE and DWI is particularly effective. Moreover, specificity could be additionally improved using analysis of the signal I/T curves.*

KEY WORDS: *Multiparametric magnetic resonance imaging; Prostate cancer; Radical prostatectomy; Prostate cancer recurrence.*

Submitted 14 July 2021; Accepted 25 August 2021

INTRODUCTION

Radical prostatectomy (RP) is a common treatment option in patients with organ confined *prostate cancer* (PCa). However, approximately 10-53% of patients undergoing primary intended curative therapy will develop a *biochemical recurrence* (BCR), depending on their preoperative risk and stage of cancer (1). Measurement of the *prostate specific antigen* (PSA) is a cornerstone of the follow-up after local treatment. In fact, PSA is expected to be undetectable within 6 weeks after a successful RP. A rising serum PSA level is considered to be a BCR (1).
Specifically, a BCR is defined by as a serum PSA measurement ≥ 0.2 ng/mL, followed by a second confirmatory level (1). Once a BCR has been diagnosed, it is important to determine whether the recurrence has developed at local or at distant sites in order to optimise salvage treatment. Although PSA alone does not differentiate local from distant disease, the pattern of its rise has been incorporated into clinical nomograms to predict whether recurrence is more likely to be local or systemic; patients with late BCR (> 24 months after local treatment) and prolonged PSA doubling time (> 6 months) most likely have local recurrent disease (1).
Of the imaging modalities, *multiparametric magnetic resonance imaging* (mpMRI) is the most accurate in the detection of local recurrence, being superior to choline *positron emission tomography/computed tomography* (PET/CT) and to *transrectal ultrasonography* (TRUS) (2-5). *Dynamic Contrast-Enhanced* (DCE) is reported to be the most effective sequence in detecting recurrence while the role of Diffusion Weighted imaging (DWI) is still controversial (2-5).
Thus, the aim of the present study was to evaluate the accuracy of mpMRI in detecting local recurrence by evaluating both the accuracy of each sequence and the combination of DCE-DWI, considering clinical and histopathological data as the reference standard. The value of the signal Intensity/Time (I/T) curves was also assessed.

MATERIALS AND METHODS

Study population

This study was an observational, retrospective, single centre study; it was approved by the Authors' local institution review board and conducted in accordance with institutional guidelines, including the Declaration of Helsinki. All patients were notified of the investigational nature of this study and gave their written informed consent (*Approval code: STUD-OF, Prot. N. 323*).
Patients with clinical suspicion of local recurrence after

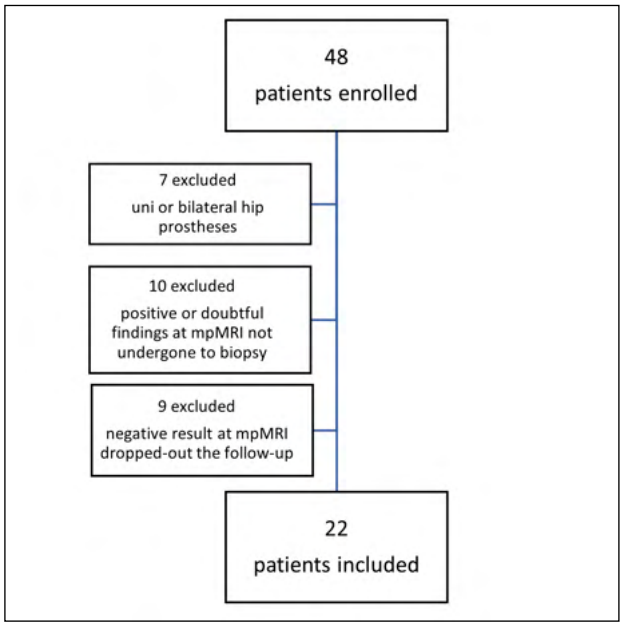
No conflict of interest declared.

RP who had undergone mpMRI at the Authors' Institute from February 2015 to January 2020 and had performed TRUS guided biopsy within 3 months in the case of positive or doubtful findings or had undergone biopsy and/or clinical follow-up (PET/CT with 11C-Choline and PSA) in the case of negative results for up to 24 months, were enrolled. Patients with uni or bilateral hip prostheses causing artefacts in image interpretation were excluded from the analysis. Overall, a total of 48 patients were enrolled, and 22 were included in the final analysis as showed in Figure 1. For each patient, PSA levels as well as *Digital Rectal Examination* (DRE) and TRUS data were recorded.

mpMRI protocol study

The mpMRI examinations were performed using a 1.5T whole-body scanner (*Signa HDxt; GE Healthcare, Milwaukee, WI, USA*) and a standard 8-channel pelvic phased-array surface coil combined with a disposable endorectal coil.
The morphological study was carried out using high-resolution Fast Relaxation Fast Spin Echo *T2-weighted* (T2w) sequences in the sagittal, axial and coronal planes, including the prostate bed. The DWI and DCE acquisition were also carried out in the axial plane, with the same parameters as the T2w axial sequence in order to obtain a match. The DWI was carried out using a single-shot echo-planar imaging sequence with high b-value acquisition (2000 s/mm^2) and another sequence with two b-values (50 and 1000 s/mm^2), useful for the calculation of the *apparent diffusion coefficient* (ADC) map. The DCE acquisition was obtained using *three-dimensional* (3D) T1-weighted Spoiled Gradient Recalled sequences during the intravenous injection of a gadolinium-based contrast agent at a flow rate of 3 ml/sec followed by 15 ml of saline solution. The 3D data sets were acquired with 10 second temporal resolution; the acquisitions before contrast agent administration can be used to detect foci of haemorrhage.

Figure 1.
Flowchart for patient selection.



The DWI and DCE images were processed on an independent workstation with dedicated software (*Functool, 4.5.5, GE Healthcare, Milwaukee, WI, USA*). For the DWI, the high b-value images and the ADC map were evaluated to identify suspected areas. Semiquantitative perfusion was carried out using analysis of the DCE datasets and signal I/T curve generation.

Image analysis

All the mpMRI images were reviewed by two genitourinary radiologists with 10 and 5 years of experience, respectively, in prostate MRI, with a consensus reading blinded to the patients' clinical information.
All the lesions were catalogued according to morphological, DWI and DCE features.
At morphological examination, the presence of soft tissue in the prostate bed slightly hyperintense to muscle was considered suspicious for local recurrence. Location and maximum diameter were also recorded.
At DWI, a suspicious lesion was defined by hyperintensity at high b-value acquisition.
For DCE evaluation, contrast enhancement was evaluated according to a negative/positive binary criterion. A lesion was considered suspicious if characterised by positive contrast enhancement. The signal I/T curve was assessed and classified as type 1 (progressive), type 2 (plateau) or type 3 (wash-in and wash-out).
At the overall evaluation, mpMRI was considered suspicious if all three sequences were in agreement regarding recurrence, negative if all three were in agreement regarding the absence of recurrence and doubtful if agreement existed for 2/3 sequences.

Cognitive fusion biopsy

All patients with suspicious or doubtful lesions at mpMRI underwent a TRUS-guided biopsy by two experienced radiologists, after antibiotic prophylaxis and a cleansing rectal enema, using a non-disposable biopsy gun (*Medgun, Medax, Modena, Italy*) with a disposable 18-gauge needle and an Ultrasound Platform with an end-fire TRUS probe (*Canon-Toshiba Aplio 500™, Japan*). All the biopsies were performed within three months from the mpMRI.
The biopsy procedures were conducted in an outpatient setting, with the patient in a left flank lateral position, after a peri-prostatic nerve blockade with local anaesthesia (lidocaine 2%), using a cognitive approach.
The mean number of samples was 3 (from 2 to 6), depending on lesion size and recognisability; in the case of negative results on mpMRI, the biopsies were carried out around the vesicourethral anastomosis. Each biopsy sample was placed inside a single container with a specific progressive number corresponding to a specific description relating to the site. After the procedure, the patients were observed for 1 hour before discharge.

Pathological analysis

The biopsy samples were analysed by the same dedicated genitourinary pathologist who primarily highlighted the presence or absence of a neoplastic pathology on the samples. Each neoplastic lesion defined as a "*positive result*" was graded according to the *Grade Group System* (GGS) from 1 to 5 and to the *International Society of Urological*

Pathology (ISUP) 2014 classification (6). For each non-neoplastic lesion defined as a "*negative result*", the type of benign finding was reported, including fibrotic tissue or residual benign prostate tissue.

Statistical analysis

The continuous variables were described in terms of medians, with *interquartile range* (IQR), and were compared using the Mann-Whitney test. The categorical variables were described as absolute and relative frequencies and were compared using the Fisher's exact test.

Sensitivity, specificity, *positive predictive value* (PPV) and *negative predictive value* (NPV) were calculated for each sequence (T2w, DWI, DCE). *Receiver operating characteristic* (ROC) analysis and *area under curve* (AUC) were used to assess diagnostic accuracy, using the histopathological and clinical data as the reference standard.

The data were collected and digitised using Microsoft Excel 2016 software; all analyses were carried out using SPSS IBM Statistics® v. 22.0 (*IBM Corp., Armonk, NY, USA*). A P value of < 0.05 was considered statistically significant.

Table 1.

Demographics and clinical characteristics of the overall population and of the two groups of patients stratified according to the pathological or clinical evidence of local recurrence.

	Total	Positive biopsy	Negative biopsy/ clinical follow-up	P
Patients, n (%)	22 (100)	11 (50)	11 (50)	-
Age Median (IQR)	69 (64-72)	69 (64.5-72)	69 (63-72.5)	0.29
PSA Median (IQR)	1.16 (0.35-2.32)	1.76 (0.67-2.44)	0.9 (0.32-1.62)	0.002
TRUS, n (%) Positive Negative	 9 (41) 13 (59)	 6 (54) 5 (46)	 3 (27) 8 (73)	0.73
DRE, n (%) Positive Negative	 9 (41) 13 (59)	 5 (46) 6 (54)	 4 (36) 7 (64)	0.91

N: Number; IQR: Interquartile range; PSA: Prostate specific antigen; TRUS: Transrectal ultrasound; DRE: Digital rectal examination.

Table 2.

Histopathological data and clinical outcome of the two groups of patients stratified according to the pathological or clinical evidence of local recurrence.

	Total 22 (100)	Positive biopsy 11 (50)	Negative biopsy/clinical follow-up 11 (50)
Biopsy results, N (%)	18 (82)	11 (100) ISUP 1 - 2 (18) ISUP 2 - 5 (46) ISUP 3 - 0 (0) ISUP 4 - 4 (36) ISUP 5 - 0 (0)	7 (64) Benign prostate tissue 2 (28) Fibrotic tissue 5 (72)
^{11}C-Choline PET/CT Follow-up	11 (50)	-	Local uptake 2 *(18) No local uptake 8 (73) Other side uptake 6 (54)

** Corresponding to benign prostate tissue.*
N: Number; ISUP: International Society of Urologic Pathology; PET/CT: Positron Emission Tomography/Computed Tomography.

Results

The presence of local recurrence was histologically detected in 11/22 patients (50%) while, in the other 11/22 (50%), no local recurrence was assessed by means of biopsy in 7 patients and by means of clinical follow-up and PET/CT in 4 patients.

The demographics and clinical features of the patients are described in Table 1. Patients with evidence of local recurrence at histopathologic analysis had significantly higher PSA levels as compare with patients with no evidence of local recurrence ($p = 0.002$).

Table 2 shows the histopathological findings and clinical outcome in the two groups of patients. In patients with a diagnosis of local recurrence, mpMRI was suspicious in 8/11 (73%) and doubtful in 3/11 (27%) while, in the patients with no evidence of local recurrence, it was suspicious in 3/11 (27%), doubtful in 1/11 (9%) and negative in 7/11 (64%) (Figures 2, 3).

The mpMRI features of all patients are described in Table 3. Regarding the location, local recurrence was found around the vesicourethral anastomosis in 8/11 (73%) and within the retained seminal vesicles in the other 3/11 (27%) patients.

On T2w, there were no statistically significant differences related to morphology or signal intensity while local recurrences were found to present a greater maximum diameter as compared to the benign tissue ($p < 0.001$).

On DWI, hyperintense lesions were more frequently consistent with local recurrence ($p = 0.03$). On DCE, positive contrast enhancement was most frequently detected in patients with local recurrence ($p = 0.008$) as were types 2

Figure 2.

Suspected local recurrence at mpMRI in a 75-year-old man with PSA = 0.91. Axial T2-weighted sequence (a) shows the presence of a hyperintense nodule in the prostate bed behind the vesicourethral anastomosis (arrow), characterised by hyperintensity at Diffusion Weighted Imaging (arrow in b) and hypervascularity at Dynamic Contrast Enhanced evaluation (green circle in c). The signal Intensity/Time curve was classified as type 2 (green line in d). Biopsy sampling documented prostate cancer Gleason Score 3+4 (ISUP 2). CFA = Common femoral artery.

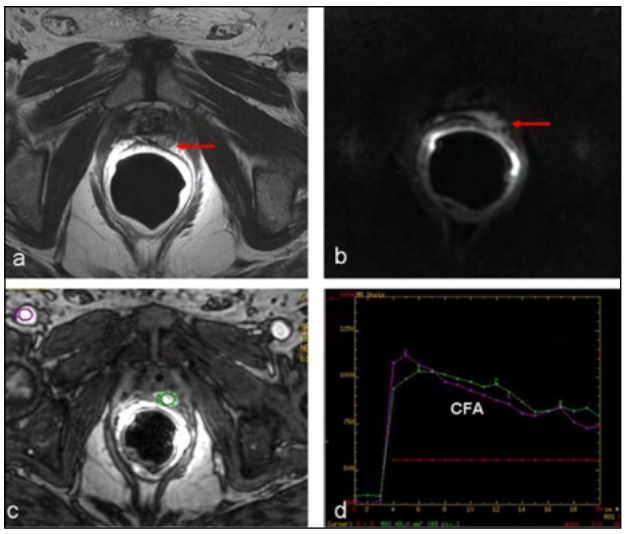


Figure 3.
Doubtful findings at mpMRI in a 73-year-old man with PSA = 0.33. Axial T2-weighted sequence shows the presence of a slightly hyperintense nodule in the prostate bed, adjacent to the vesicourethral anastomosis (arrow in a), characterised by slight hyperintensity at Diffusion Weighted Imaging (arrow in b) and negative contrast-enhancement with a type 1 Signal Intensity/Time curve (green line in c). Biopsy sampling documented fibrotic tissue.

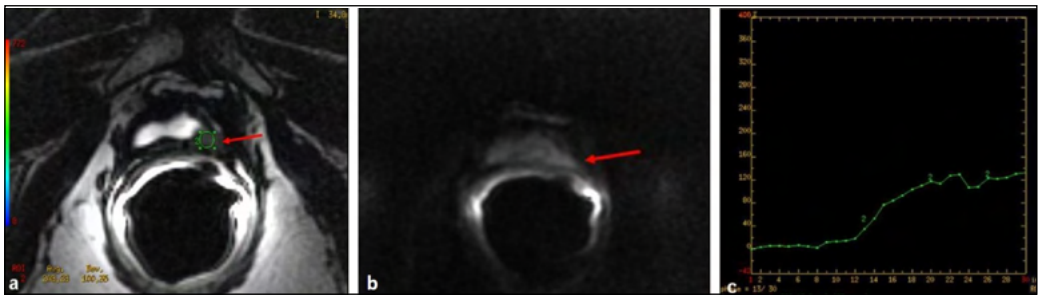


Table 3.
Morphological and functional characteristics of all lesions identified on mpMRI in the two groups of patients stratified according to the pathological evidence of local recurrence.

	Total	Positive biopsy	Negative biopsy/ clinical follow-up	P
N (%)	22 (100)	11 (50)	11 (50)	
T2w				
Maximum diameter (mm) (median; IQR)	10.5 7-14	13 9.5-18	8 6-11.5	< 0.001
Morphology, n (%)				0.6
Nodule	12 (55)	5 (45)	7 (64)	
Amorphous tissue	10 (45)	6 (55)	4 (36)	
Signal intensity, n (%)				0.2
Hypointense	10 (45)	3 (27)	7 (64)	
Hyperintense	12 (55)	8 (73)	4 (36)	
DWI				
Signal intensity, n (%)				0.03
Hypointense	10 (45)	2 (18)	8 (73)	
Hyperintense	12 (55)	9 (82)	3 (27)	
DCE				
Contrast enhancement, n (%)				0.008
Negative	9 (41)	1 (9)	8 (73)	
Positive	13 (59)	10 (91)	3 (27)	
Signal I/T curve, n (%)				0.03
Type 1	9 (41)	1 (9)	8 (73)	
Type 2	10 (45)	7 (64)	3 (27)	
Type 3	3 (14)	3 (27)	0 (0)	

N: Number; T2w: T2-weighted sequence; DWI: Diffusion Weighted Imaging; DCE: Dynamic Contrast-Enhanced; I/T: Intensity/Time.

and 3 at the signal I/T curve while a type 1 curve was most frequent in benign tissue (p = 0.03).
For each sequence, the values of sensitivity, specificity, NPV and PPV obtained using ROC analysis were as follows: 73%, 64%, 70% and 67% for the T2w; 82%, 73%, 80% and 75% for DWI; 91%, 73%, 87% and 71% for DCE, and 100%, 82%, 100% and 85% for the combination DWI+DCE, respectively. Figure 4 shows the ROC curve analysis.

Discussion

Prostate cancer is primarily managed by four standard methods, i.e. RP, radiation therapy, androgen deprivation therapy and active surveillance, although new focal therapy methods have rapidly been evolving (1). Treatment choice is based on tumour stage, histology and grade, and is also influenced by patient clinical condition or preference. Of these, RP has been performed for more than a century and remains the most common treatment choice. The procedure involves removing the entire prostate with its capsule intact and the seminal vesicles, followed by carrying out a vesicourethral anastomosis. Surgical techniques have expanded from perineal and retropubic open approaches to laparoscopic and robotic-assisted techniques, with nerve-sparing intent whenever possible (7); the role of *pelvic lymph-node dissection* (PLND) is still controversial and is mainly based on a clinical nomogram. However, the majority of authors have agreed that PLND is

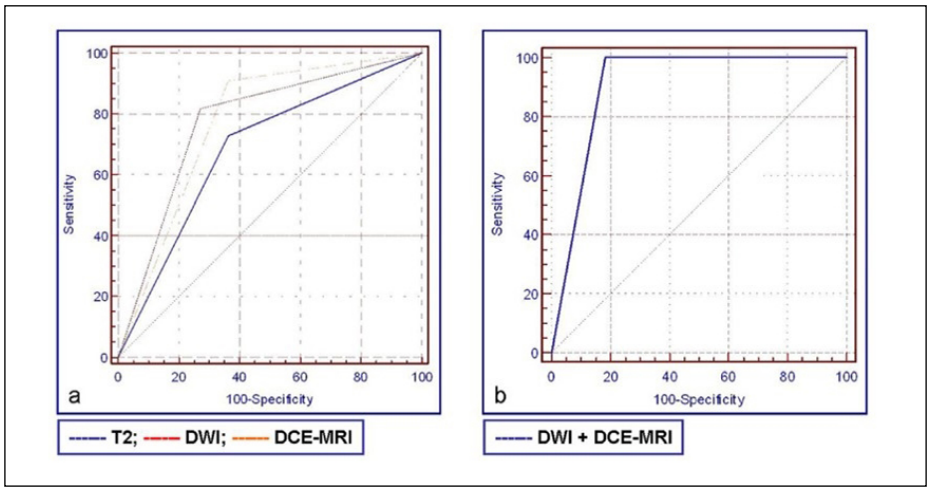


Figure 4.
Receiver operating characteristic (ROC) curves.
a) Comparison between T2 weighted (T2), Diffusion Weighted Imaging (DWI) and Dynamic Contrast Enhanced (DCE); the area under the curve (AUC) was 0.682 for T2; 0.773 for DWI; 0.773 for DCE.
b) Combined DWI+DCE increased the AUC to 0.909.

the most accurate staging procedure. Moreover, extensive PLND could also have a therapeutic effect due to removal of micrometastasis, thus reducing the risk of BCR (7).
Several factors could increase the risk of recurrence, such as seminal vesicle invasion, positive surgical margins, extra-prostatic extension, perineural and lymphovascular invasion, tumour volume, ISUP score > 2 and nodal metastasis (8).
However, recurrences in the early setting are extremely difficult to detect with conventional imaging modalities due to low tumour volume. The mean PSA values at the time of imaging have often varied in the literature from 0.2 to 10 or even higher, which is actually far above the level at which the clinician currently wants to know whether the patient suffers from local or distant recurrence (8).
Transrectal ultrasonography can be used in patients with suspected local recurrence, but the reported detection rates at PSA levels < 0.5 ng/ml vary notably from 28.1 to 73.0%; moreover, specificity seems to be lower than DRE for possible false positives due to postoperative fibrosis (1). Although several efforts have been made to improve the accuracy of TRUS, such as the addition of colour Doppler and contrast sonography (9), it is not routinely recommended in the setting of local recurrence (1).
Currently, mpMRI is most frequently used to assess local recurrence and is combined with whole-body choline PET/CT to find regional or distant recurrence (10); in fact, the role of choline PET/CT in the detection of local recurrence is limited because a mild focal uptake of choline in the prostate bed and vesicourethral junction is difficult to differentiate from radioactive urine accumulation (10).
Moreover, detection rates are only 5-24% when the PSA level is < 1 ng/mL but rises to 67-100% when the PSA level is > 5 ng/mL, i.e. when metastatic disease is suspected (1). In this setting, hormone treatment withdrawal may also not be necessary (1). Great interest has recently developed in new prostate-specific tracers, such as *Prostate Specific Membrane Antigen* (PSMA) which seems substantially more sensitive than choline PET/CT, especially for PSA levels < 1 ng/ml, having a detection rate of 34.4% with PSA level < 0.5 ng/ml (11), so that the use of PSMA-PET/CT was introduced by the *European Association of Urology* guidelines. However, the majority of studies are limited by their retrospective design, and whether this approach is really cost-effective remains unknown (1).
Thus, mpMRI, by means of the combination of high resolution morphological T2w images and functional imaging, seems to be particularly accurate in evaluating local recurrence.
At mpMRI, knowledge of the normal post-surgical anatomy is essential for avoiding a misdiagnosis. Normal findings show that the bladder neck is anastomosed to the extraprostatic distal urethra which has a conical shape and falls far more caudally than normal on the sagittal plane; the tissue around the vesicourethral anastomosis is low in signal on T2w, reflecting postoperative scarring and fibrosis. Occasionally, the anastomosis may demonstrate an intermediate T2w signal which mimics recurrence, particularly if there was extensive haemorrhage at the time of surgery. Extensive fat stranding is often encountered surrounding the bladder base. Potential pitfalls could be represented by retained seminal vesicles, residual prostatic tissue or postoperative fibrosis (12).
In the present study, local recurrences were more frequently characterised by a greater diameter, hyperintensity on DWI and positive contrast-enhancement. Of all the sequences, T2w was the least accurate while DCE was the most reliable. These results are in line with what has previously been reported. *Casciani et al.* found that the addition of DCE to T2w increased sensitivity from 48 to 88% and specificity from 52 to 100% (13); similar results have also been reported by others (5, 14, 15). Moreover, DCE was found to increase interobserver agreement and to facilitate the detection of local recurrence, even by relatively inexperienced readers (15).
Sciarra et al. demonstrated that the combination of spectroscopic imaging and DCE could also increase the detection rate (sensitivity of 86% and specificity of 100%); however, spectroscopic imaging is a more complex technique and requires additional expertise and longer acquisition time; therefore, it is less commonly used in clinical practice (16).
The role of DWI is still more controversial as it could be affected by artefacts caused by surgical clips. Panebianco et al. found that the combination of T2w+DWI could produce a detection rate comparable to T2w+DCE (93% sensitivity, 89% specificity, 88% accuracy) (5); however, other studies have reported lower values, with a detection rate of 25-69% depending on tumour size (14) and a sensitivity of 46-49% (16). Our results showed a reduced sensitivity for DWI as compared to DCE sequences (82% vs. 91%, respectively), probably due to artefacts and tumour size affecting the detectability of recurrent lesions.
Therefore, while the general trend in prostate MRI is to develop a "*less is better strategy*", improving the application of biparametric MRI to reduce execution time and improve patient tolerability and safety, this could not be applied in the setting of local recurrence for the well-established additional value of DCE (17). Furthermore, new MRI protocols have been investigated, such as the combination of whole-body and mpMRI in order to assess both local recurrence and metastatic disease (18).
From the results of our study, the combination of DCE+DWI showed better accuracy, having a sensitivity of 100%, a specificity of 82%, an NPV of 100% and a PPV of 85%. Specificity can be additionally improved by the analysis of the signal I/T curve: in fact, while benign tissue most frequently has a type 1 curve, the recurrences generally showed type 2 and 3 curves. This was an interesting observation since the signal I/T curves obtained from the perfusion sequence were not effective in differentiating between benign and neoplastic tissue in the clinical setting of the diagnosis (19).
Even if T2w was the least reliable sequence, it provided important information regarding the postsurgical anatomy and was able to localise the site of recurrence. In this series, the most frequent site of recurrence was the vesicourethral anastomosis as previously reported (3, 10), followed by retained seminal vesicles while recurrences in the retrovesical region were not found, as was frequently observed by *Sella et al.* (20).
The present study had some limitations; first, our results

were obtained at a single high-volume tertiary care centre with significant experience in mpMRI, thus radiologist experience could have influenced the detection rate. Second, it was a retrospective study with a small sample size. Third, the histopathological results were considered to be the reference standard, even if a negative cognitive biopsy could not completely rule out a local recurrence; the anastomotic biopsy, in fact, suffers from low sensitivity such as 40-71% for PSA level > 1 ng/ml and 14-45% for PSA < 1 ng/ml (21). Targeted biopsy, with TRUS fusion software-assisted or MRI in-bore technique, could increase the detection rate of local recurrence, although the procedure may be more complex in this setting and its effectiveness still to be demonstrated. However, the majority of patients included in this population were treated before the fusion software was available in our centre, so each anastomotic biopsy was performed by cognitive technique.

For the reasons described above, in patients with negative anastomotic biopsy it is very important to establish a correct follow-up. First of all, pathologic features (such as pGS, pT and margins and nodal status) should be considered to assess the risk of local recurrence and the kinetics value of PSA (including PSA doubling time and PSA velocity) should be the most important parameters to manage the follow-up. For example, a salvage radiotherapy can be considered or further mpMRI and targeted biopsy may be repeated at 6 months in case of persistent PSA increase with low PSA doubling time, while other examinations (i.e PSMA-PET/CT) should be considered in case of high PSA doubling time due to the increased risk of nodal or systemic recurrence (11). However, in our population a negative clinical follow-up for up 2 years was considered to reduce this bias.

Conclusions

Some important conclusions can be reached. Although mpMRI is rarely used by urologists in the clinical setting of local recurrence (22), many evidences have actually shown its high diagnostic performance. We confirm that DCE is the most accurate sequence in the detection of local recurrence; however, the combination of DWI+DCE was found to be particularly reliable. Moreover, specificity could be further improved by the analysis of the signal I/T curve. T2w imaging provided a morphological evaluation by identifying the site and the dimensions of the recurrences. Thus, the utility of MRI in the detection of local recurrences is tied to the multiparametric technique, with all sequences providing useful information.

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Correspondence
Caterina Gaudiano, MD (Corresponding Author)
caterina.gaudiano@aosp.bo.it
caterina.gaudiano@gmail.com

Federica Ciccarese, MD
Beniamino Corcioni, MD
Antonio De Cinque, MD
Rita Golfieri, MD
Department of Radiology, IRCCS Azienda Ospedaliero-Universitaria di Bologna
Via Albertoni, 15 - 40138 Bologna, Italy

Francesca Giunchi, MD
Department of Pathology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna (Italy)

Michelangelo Fiorentino, MD
Department of Specialty, Diagnostic and Experimental Medicine, University of Bologna,
Via Massarenti 9, Bologna, Italy

Lorenzo Bianchi, MD
Riccardo Schiavina, MD
Eugenio Brunocilla, MD
Department of Urology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna (Italy)