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Lesion volume on multiparametric magnetic resonance imaging as a non-invasive prognosticator for clinically significant prostate cancer

Manish Kumar Choudhary[1], Kaushik P. Kolanukuduru[1], Neeraja Tillu[1], Ahmed Kotb[2], Zachary Dovey[1], Maurizio Buscarini[1], Osama Zaytoun[1,3]

[1]*Department of Urology, Icahn School of Medicine at Mount Sinai Hospital, New York, United States of America*
[2]*Department of Urology, Northern Ontario School of Medicine University, Thunder Bay, Ontario, Canada*
[3]*Department of Urology, University of Alexandria, Alexandria, Egypt*

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Corresponding author
Manish Kumar Choudhary
Icahn School of Medicine at Mount Sinai Hospital,
1425 Madison Ave,
New York, USA,
manish.choudhary@mountsinai.org

Introduction The association between prostate cancer (PCa) lesion volume on multiparametric magnetic resonance imaging (mpMRI) and clinically significant PCa (csPCa) remains a poorly studied aspect of diagnostic workup in patients with suspicion of PCa. The aim of this study was to assess the diagnostic value of mpMRI lesion volume in detecting csPCa.

Material and methods Patients with an elevated prostate-specific antigen (PSA) and suspicion of PCa underwent mpMRI as part of routine workup. Following this, patients underwent systematic and fusion targeted biopsy of the region of interest (ROI). All target lesions were sampled once in both axial and sagittal planes, with at least 2 cores per target. csPCa was defined as Gleason grade group ≥2, while highly suspicious lesions were considered as those with PI-RADS score ≥4. Multivariate logistic regression was performed for factors predicting csPCa.

Results Fifty men with a total of 108 mpMRI lesions were included, with a mean age of 71 ±6 years. 52% had prior negative biopsies. The mean lesion volume was 0.95 ±0.04 ml. Thirty-two patients (64%) had positive biopsies, among whom 20 had csPCa. Fifteen patients (30%) had highly suspicious PI-RADS lesions. Multivariate analysis demonstrated that capsular bulging, younger age, small prostate, highly suspicious lesions, high PSA density, and lesion volume >1mL were predictive of csPCa.

Conclusions Lesion volume on mpMRI may be used as a non-invasive indicator of csPCa. Future studies exploring the correlation between lesion volume and csPCa may enable patients to be monitored by non-invasive means, while ensuring early intervention when needed.

Key Words: prostatic neoplasms ‹› multiparametric magnetic resonance imaging ‹› magnetic resonance imaging ‹› ultrasonography ‹› biopsy

INTRODUCTION

Multiparametric magnetic resonance imaging (mpMRI) has established itself as a sensitive imaging method for the detection of PCa [1]. It allows for precise localisation of suspicious areas within the prostate and thus plays a major role in guiding decision-making for suspected PCa. Based on the Prostate Imaging-Reporting and Data System (PIRADS) score as per PIRAS v2.1 [2–9]. The integration of mpMRI into TRUS-guided biopsies (MRI/US fusion) has allowed for increased accuracy in lesion sampling, especially in men who are biopsy naïve, had prior negative biopsies, or have large prostates [10, 11]. Unfortunately, despite standardised prostate biopsy (PBx) protocols, the false negative rate remains high [12, 13].

While most of the recent literature is focused on factors predicting the results of mpMRI/US fusion biopsy in terms of the PIRADS score, little

has been done to explore the association between mpMRI lesion volume and clinically significant PCa (csPCa). The current study aimed to assess the diagnostic value of lesion volume on mpMRI and its impact on improving the prediction of csPCa.

MATERIAL AND METHODS

Study setting, design, and population

The present investigation was a retrospective, single-centre study that was performed after institutional review board approval (ID: 346890-2023). Between July 2022 and July 2023 patients who underwent a prostate mpMRI followed by an MRI/US fusion biopsy performed at the same institution were included in this study. All those patients who were detected having lesion on the MRI scan were included in this study. Indications of MRI/US fusion biopsy encompassed 4 different clinical scenarios: persistent clinical suspicion of PCa despite prior negative biopsy (target lesion present but negative for prostate cancer in pathology), initial biopsy to screen for PCa (biopsy naive MRI lesion), confirmation of PCa extent in patients planning on active surveillance (AS) for low-risk disease (confirmatory biopsy of the target lesion), and suspicion of recurrence after previous radiation treatment for PCa (MRI lesion biopsy to rule out recurrence post radiation therapy). All the biopsies were performed by a single practitioner with extensive experience of MRI/US fusion biopsies.

Imaging and assessment of lesion volume

mpMRI of the prostate including tri-planar T2-weighted (T2W), dynamic contrast-enhanced (DCE) diffusion-weighted (DW) imaging, and MR spectroscopy sequences were performed using a 3.0 Tesla MRI scanner in addition to a 16-channel cardiac surface coil placed over the pelvis with an endorectal coil. These diagnostic mpMRI studies underwent centralised radiological evaluation by a single radiologist to identify the suspicious lesion and to assign the risk scores to individual lesions: low (PIRADS 1, 2), intermediate (PIRADS 3), and high risk (PIRADS 4, 5), as per PIRADS v2.1 guideline [9, 14, 15]. If more than one type of lesion was seen, the index lesion was defined as the lesion with the highest cancer suspicion based on initial mpMRI, irrespective of size. The radiologists worked in consensus to outline index lesions on T2-weighted images, apparent diffusion coefficient (ADC) maps, and early-phase (arterial phase) DCE-MR images. The early-phase DCE-MR image was defined as the DCE-MR image that showed the maximal area of enhancement of the lesion, after the initial arterial enhancement.

DCE-MRI images were evaluated by analysing T1W images, and the diagnostic criteria for PCa included a focus on early enhancement with rapid wash-out compared with the surrounding prostatic tissue. The PCa index lesion volumes were measured as the product of the area of PIRADS lesion in individual sections and the total number of sections with the visible lesion. The largest diameter of each lesion was measured on a picture archiving and communication system workstation, and the lesion was manually segmented on a research software platform. The tumour volume was determined with the same software after manual segmentation on MRI. Kinetic parametric maps were not generated for DCE-MRI. We did not use DCE-MRI maps because PIRADS v.2.1 does not use them to measure the volume. Total prostate volumes were manually obtained for each patient using semi-automated software.

Biopsy protocol and pathological evaluation

All patients with at least one targetable suspicious lesion on mpMRI underwent MR/US fusion biopsy using the Uronav system (Invivo Corporation, Gainesville, Florida, USA). The Uronav system uses a rigid registration interface that allows for fusion of individual mpMRI images at different levels of the prostate with the corresponding US image to generate a combined fused view.

All patients received antibiotic prophylaxis and a cleansing fleet enema before the biopsy as the standard practice protocol of our institution. All biopsies were performed under local anaesthesia. A standard 12-core TRUS-guided biopsy was performed with the transrectal approach along with a fusion biopsy using the mpMRI images, which were segmented (the gland and the lesions were outlined), registered, and fused with the TRUS images. Lesions suspicious for cancer were semi-automatically displayed on the real-time TRUS image. All target lesions were sampled with at least 2 cores per target. After pathological assessment, csPCa were identified. csPCa was defined according to the EAU guidelines: International Society for Urological Pathology (ISUP) grade 2 or higher or the Epstein criteria: Gleason score (GS) >6 or GS 6 with ≥50% of cancer per core involvement or >2 cores with cancer [16, 17]. In the present study we have used the criteria of ISUP grade group 2 or higher.

Statistical analysis

Following the confirmation of the normality of distribution using the Shapiro-Wilk test, continuous and categorical variables were reported as means with standard deviations and absolute numbers with percentages, respectively. Means were compared using the unpaired t-test, while categorical variables were compared using Fisher's exact test. A multivariate logistic regression model was generated considering relevant perioperative variables to assess factors predictive of csPCa. A two-sided p-value of <0.05 was considered statistically significant. The statistical analysis was performed using R programming software 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Bioethical standards

The study was approved by institutional review board (ID: 346890-2023).

RESULTS

Fifty men harbouring 108 lesions on mpMRI were included in the study. Table 1 shows the baseline, imaging, and pathological characteristics of the study population. The mean age of patients in this study was 71 ±6 years. The mean PSA level was 13.3 ±8.5 ng/ml. The indication for mpMRI was prior negative biopsy in 52% of patients, as part of pre-AS workup in 30% of patients, prior to initial biopsy in 12%, and assessment of recurrence and surgical planning in 4% and 2%, respectively. Fourteen per cent of patients were biopsy naïve.

The mean prostate volume was 64.2 ±40.7 ml, with a range of 29.3–133.5 ml. The mean lesion volume was 0.95 ±0.04 ml, and the mean PSA density was 0.2 ±0.034 ng/ml^2. Seventy-four per cent of patients had more than one lesion on mpMRI. Capsular bulging and extra prostatic extension were noted in 6% and 8% of cases, respectively, on mpMRI. Thirty-two patients (64%) had a positive biopsy. Of these, 37.5% had cancer limited to the targeted lesion, while 43.8% had cancer only in systematic cores. 18.8% of patients had cancer in both the target and in systematic cores.

Table 2 shows the multivariate analysis for factors predicting PCa diagnosis after fusion biopsy. Capsular bulging, age, smaller prostate volume, PSA density, highly suspicious MRI lesions (PIRADS 4, 5), and lesion volume >1 ml on mpMRI were predictive of csPCa.

Low-risk prostate cancer cohort

Low-risk cancer was detected in 12 cases. The mean prostate volume was 87.0 ±16.43 ml, and the mean PSA density was 0.01 ±0.025 ng/ml^2. None of these cases had any high-risk suspicious lesions (PIRAD 4, 5) in the MRI (low- and intermediate-risk suspicious lesions seen in 12 cases).

Table 1. *Baseline, imaging, and pathological characteristics of patients with suspicion of prostate cancer who underwent fusion targeted biopsies*

Parameter	Results
Age (years), mean ±SD	71 ±6
DRE exam findings, n (%)	
Normal	43 (86)
Abnormal	7 (14)
PSA (ng/ml), mean ±SD	13.3 ±8.5
Indication of mpMRI, n (%)	
Active surveillance	15 (30)
Assessment of recurrence	2 (4)
Initial biopsy	6 (12)
Prior negative biopsy	26 (52)
Staging and surgical planning	1 (2)
Number of previous biopsies, n (%)	
0	7 (14)
1	20 (40)
2	10 (20)
3	3 (6)
≥4	10 (20)
5-α reductase inhibitor use, n (%)	4 (8)
MRI prostate volume [ml], mean ±SD	64.2 ±40.7
PSA density (ng/mL^2), mean ± SD	0.20 ±0.034
mpMRI suspicious lesions, no. (%):	
Low (PIRAD <3)	7 (14%)
Intermediate (PIRADS 3)	28 (56%)
High (PIRADS 4 and 5)	15 (30)
MRI lesions per patient, n (%)	
1	13 (26)
2	23 (46)
3	7 (14)
4	7 (14)
Lesion volume [ml], mean ±SD	0.95 ±0.04
Capsular bulging, n (%)	3 (6)
Extracapsular extension, n (%)	4 (8)
Men diagnosed with prostate cancer, n (%)	
On targeted biopsy only	12 (37.5)
On 12-core biopsy only	14 (43.75)
On both targeted and 12-core biopsy	6 (18.75)
Pathological findings, n (%)	
Gleason grade group 1	12 (24)
Gleason grade group ≥2	20 (40)
ASAP	5 (10)
HGPIN	4 (8)
Benign/inflammation	9 (18)

ASAP – atypical small acinar proliferation; DRE – digital rectal exam; HGPIN – high-grade prostatic intraepithelial neoplasia; mpMRI – multiparametric magnetic resonance imaging; PSA – prostate-specific antigen

Table 2. *Multivariate analysis for factors predicting presence of prostate cancer on fusion targeted biopsy*

Parameter		csPCa*	Low-risk PCa*	p-value
Capsular bulging	No bulge	17 (85%)	12 (100%)	0.007
	Bulge	3 (15%)	0 (0%)	
Extracapsular extension	Absent	18 (90%)	10 (83%)	0.704
	Present	2 (10%)	2 (17%)	
mpMRI suspicious lesions	Low (PIRAD <3)	0 (0%)	5 (42%)	0.001
	Intermediate (PIRAD 3)	10 (50%)	7 (58%)	
	High (PIRAD 4,5)	10 (50%)	0 (0%)	
Age in years	Mean ±SD	66.75 ±7.81	66.06 ±4.79	<0.001
Prostate volume [ml]	Mean ±SD	60.97 ±28.52	87.00 ±16.43	<0.001
PSA density [ng/ml^2]	Mean ±SD	0.210 ±0.24	0.01 ±0.025	<0.001
Lesion volume [ml]	Mean ±SD	1.04 ±0.04	0.96 ±0.04	<0.001

* Low-risk PCa was defined as Gleason grade group = 1, while csPCa was defined as Gleason grade group ≥2
mpMRI – multiparametric magnetic resonance imaging; PCa – prostate cancer; PSA – prostate-specific antigen; SD – standard deviation

EPE was documented in 2 cases (17%). The mean lesion volume noted in the MRI was 0.96 ±0.04 ml.

Clinically significant prostate cancer cohort

Clinically significant prostate cancer (CsPCa) was detected in 20 cases. The mean prostate volume in this cohort was 60.97 ±28.52 ml, and the mean PSA density was 0.210 ±0.24 ng/ml^2. Capsular bulge was recorded in 3 (15%) cases. Half of these cases had high-risk (PIRAD 4 or 5) lesions in the MRI, and the rest had PIRAD 3 lesions. EPE was documented in 2 cases (10%). The mean MRI lesion volume noted was 1.04 ±0.04 ml.

DISCUSSION

The MRI/US fusion biopsy has gained momentum in the localisation and management of PCa. Urologists are frequently consulted for the evaluation of the patients having suspicion of PCa despite prior negative PBx. As the biopsy outcomes could vary depending upon the practitioner's experience and the institutional protocols, we cannot assume that the entire gland has been adequately assessed. Studies have demonstrated a higher incidence of false negative biopsies for PCa located in the anterior gland or at the distal apex of the prostate [3, 4]. Based on our favourable experience with mpMRI/fusion biopsy, we performed fusion biopsies for patients with suspicion of PCa, with the hope of providing definitive diagnoses and guiding further management. Candidates of AS represented 30% of our study population. This is consistent with recent data supporting the use of mpMRI/fusion biopsy in AS protocols [4, 18].

We opted to focus on lesion volume as a predictor of PCa, specifically csPCa given that this remains an area of little exploration in the literature. Our results confirmed that lesion volume on mpMRI is a potential predictor for csPCa detection on fusion biopsy, with all men who had lesions >1 ml harbouring csPCa in our study. This could be considered as a cut-off volume for the detection of csPCa, thereby potentially foregoing the need for subsequent biopsy. Taking into consideration that our sample size was too small to draw any definitive MRI lesion size recommendation, further research is needed to study the association between MRI volume and the presence of csPCa in more detail.

Stamatakis et al. [18] showed that the number of suspicious lesions on mpMRI, lesion density, and highest MRI score were associated with AS candidacy. Interestingly, largest lesion volume did not have any statistical significance. It is worth mentioning that we did not include the lesion density as a variable because it depends on prostate volume. We chose to focus on lesion volume to better elucidate its independent impact. Additionally, they used different criteria to define AS candidacy, which included the percentage of tumour in any core [9, 15, 19, 20].

In our study the systematic biopsy cancer detection rate (CDR) was 43%. Bass et al. [21] performed a systematic review and metanalysis to compare the different MRI targeted biopsy approaches and to compare them with TRUS guided systematic biopsies. In this metanalysis, the pooled CDR for TRUS-GB was 0.63 (95% CI: 0.53–0.74). The relatively low systematic biopsy CDR in our study could be explained by the smaller sample size of our dataset [21].

In the multivariate analysis we found significant association between the capsular bulge and the csPCa (p = 0.007), but at the same time it was found to have a low negative predictive value (41%) for ruling out the risk of csPCa. Mehralivand et al. [22] in their prospective study defined an MRI-based EPE grading system. They described a curvilinear contact length of 1.5 cm or capsular bulge and irregularity as grade 1, both features as grade 2, and frank capsular breach as grade 3 MRI-based EPE. On multivariable logistic regression analysis, they found that clinical features plus the MRI-based EPE grading system (prostate-specific antigen, International Society of Urological Pathology stage, MRI grade) predicted pathologic EPE better than did MRI grade alone (AUC, 0.81 vs 0.77, respectively; p = 0.001). In-depth analysis with the extent of capsular bulge is needed to establish the status of this parameter in predicting the risk of having csPCa [22].

Contrary to the regular norm, we could not find any significant association between extracapsular extension and the risk of having csPCa. Rooij et al. [7] in their meta-analysis showed that the sensitivity and specificity of MRI to assess EPE was 0.57 (95% CI: 0.49–0.64) and 0.91 (95% CI: 0.88–0.93), respectively. They also concluded that an endorectal coil showed no additional benefit for EPE detection [7].

Cash et al. in their study [23] found that the CDR was strongly correlated with a rising PI-RADS score, values of 4 and 5 increasing the detection of clinically significant tumours and leading to a higher histological stage after RP. CDRs correlated with PI-RADS 2/3/4/5 were 16% (5/32), 26% (29/113), 62% (94/152), and 89% (99/111), respectively. The rates of significant tumours in relation to PI-RADS 2/3/4/5 were 60% (3/5), 66% (19/29), 74% (70/94), and 95% (94/99) [23]. In our study we found similar results showing that the higher PIRAD score was significantly associated with the possibility of having csPCa (p = 0.001).

In our study we took the lesion volume as a continuous variable and found the mean value of the lesion volume to be 0.95 ml. We found lesion volume >1 ml to be significantly associated with csPCa (p <0.001). Scialpi et al. [24] suggested subgrouping the PIRADS 3 lesions based on tumour volume and recommend targeted biopsy for volume >0.5 ml, although this has not been validated [24].

According to the early detection of prostate cancer AUA guideline for the considerations for a prostate biopsy, multiple factors have been shown to contribute to risk calculation for csPCa, including race, age, total PSA, PSA density, percentage of free PSA, and family history of prostate cancer [25]. In our study, on multivariate analysis we found a significant association of age, prostate gland volume, and PSA density with csPCa (p <0.001).

Additionally, we proved that csPCa can be detected in patients with multiple prior negative biopsies. The association of mpMRI suspicion and csPCa is concordant with previous reports that confirmed the prognostic value of this variable [5–8]. There is increasing concern regarding hte over-diagnosis and treatment of men with clinically indolent PCa. Consequently, MRI/US fusion biopsy has evolved from being a tool detecting missed cancer to a modality for better characterisation of clinically significant disease. The mpMRI has been under investigation of low-risk vs high-risk PCa by several investigators [9, 15].

As shown in this study, lesion volume may provide a potential noninvasive indicator of high-grade disease. This can ultimately provide a basis for individualised patient care if data from pre-biopsy MRI can direct management and treatment counselling. Moreover, this can tailor PCa screening protocols as an independent modality to quantify the risk of harbouring csPCa. Given the high fidelity of mpMRI in accurately delineating the size of lesions and current data suggesting that "size matters", it may be possible to monitor patients with mpMRI alone with no need for biopsy in the future. Sidiqqui et al. [19] demonstrated that small index lesions on mpMRI (defined as lesions ≤7 mm) were associated with benign disease, too small to accurately target, or bearing only low-risk PCa. They suggested that patients with small index lesions on mpMRI could forego any additional screening or AS testing [19].

The current study still has some limitations. It is a retrospective single-centre study with a limited sample size that included a heterogeneous group of men. However, this heterogeneity helped us to imply our results on larger categories, not limited to only those with prior negative PBx. Also, this may be related to the referral pattern of our practice. Additionally, we did not use the final prostatectomy pathology as the ideal endpoint in this study because it may have further affected the sample size and the subsequent data interpretation. Data acquisition to address this limitation is underway. However, lesion localisation and size measurements from mpMRI have been reported to be highly correlated with final pathologic findings on radical prostatectomy specimens [16, 20, 26]. Lastly, the inclusion criteria of the study specified patients with mpMRI visible suspicious lesions, thus excluding patients with no lesions seen on mpMRI.

CONCLUSIONS

Lesion volume may be used as a non-invasive indicator of csPCa. Given the high fidelity of mpMRI in accurately delineating the size of lesions, it may be possible to monitor patients with serial mpMRI, thereby limiting the numbers and morbidity of follow-up prostate gland biopsies. However, considering the limited data available, the MRI lesion volume parameter requires further validation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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This research received no external funding.

ETHICS APPROVAL STATEMENT

This project fully considered and protected the rights and interests of the study subjects. This study was approved by the institutional review board (ID: 346890-2023) at the institution where the study took place in accordance with the Declaration of Helsinki.

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