ARTICLE

Clinical

MRI lesion size is more important than the number of positive biopsy cores in predicting adverse features and recurrence after radical prostatectomy: implications for active surveillance criteria in intermediate-risk patients

Michael Baboudjian[1,2,3]✉, Alessandro Uleri[4], Jean-Baptiste Beauval[1], Alae Touzani[1], Romain Diamand[5], Jean-Baptiste Roche[6], Vito Lacetera[7], Eric Lechevallier[3], Thierry Roumeguère[5], Giuseppe Simone[8], Daniel Benamran[9], Alexandre Fourcade[10], Gaelle Fiard[11], Alexandre Peltier[5] and Guillaume Ploussard[1]

INTRODUCTION: To determine associations between prostate cancer (PCa) tumor burden measured on biopsy or multiparametric magnetic resonance imaging (mpMRI) and outcomes in intermediate-risk (IR) International Society of Urological Pathology (ISUP) grade 2 men managed with primary radical prostatectomy (RP).

METHODS: This retrospective, multicenter study was conducted in eight referral centers. The cohort included IR PCa patients who had ISUP 2 at biopsy. We defined biopsy tumor burden as low/high based on the absence/presence of more than 25% positive cores. Tumor burden on imaging was defined as low/high based on maximum lesion diameter, <15 mm and ≥15 mm at mpMRI, respectively. The histological endpoint of the study was adverse features at RP, defined as ≥pT3a stage and/or lymph node invasion and/or ISUP ≥3 at final pathology. The clinical endpoint was biochemical recurrence (BCR) after RP.

RESULTS: A total of 698 IR patients was included, of whom 335 (48%) had adverse features. In multivariate logistic regression analysis, there was no statistical association between tumor burden at biopsy and adverse features ($p = 0.7$). Tumor size ≥15 mm at mpMRI was significantly associated with adverse pathology (OR 1.65, 95%CI 1.14–2.39; $p = 0.01$). No significant association was observed between tumor burden at biopsy and BCR ($p = 0.4$). Tumor size ≥15 mm at mpMRI was significantly associated with BCR (HR 1.96, 95% CI 1.01–3.80; $p = 0.04$).

CONCLUSIONS: Our data support extending the inclusion criteria to ISUP 2 men with >25% positive cores, provided they have a low tumor size at mpMRI (<15 mm). Prospective studies should be performed to validate these findings.

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INTRODUCTION

Many newly detected prostate cancers (PCa) are slow growing and generally display indolent clinical behavior with comparatively low risks of metastatic progression [1]. Active surveillance (AS), a protocol of deferred curative treatment until warranted on the basis of defined indicators of disease progression, is therefore increasingly used [2]. Indications for AS have been expanded over time from very low to low-risk PCa, and more recently, to selected intermediate-risk (IR) PCa patients [3–5].

The success of AS depends on the ability to identify clinicopathologic features that distinguish patients with clinically insignificant disease who can be managed appropriately with AS from those who will require definitive treatment. According to the Prostate Cancer Research International Active Surveillance (PRIAS) study results [6], PCa tumor burden on biopsy (i.e., <3 positive cores) have been widely used to identify patients who will benefit from AS. However, recent studies showed that increasing number of biopsy positive cores in International Society of Urological Pathology (ISUP) grade 1 PCa patients was not predictive of adverse pathology at radical prostatectomy (RP), a surrogate marker which is associated with clinically important outcomes such as biochemical recurrence and distant metastasis [7]. In addition, tumor burden biopsy was studied using a standard biopsy scheme based on systematic sampling, without any validation in the era of pre-biopsy mpMRI and image-guided biopsy (i.e., targeted biopsies) [8].

[1]Department of Urology, La Croix du Sud Hôpital, Quint Fonsegrives, France. [2]Department of Urology, North Hospital, Aix-Marseille University, APHM, Marseille, France. [3]Department of Urology, La Conception Hospital, Aix-Marseille University, APHM, Marseille, France. [4]Department of Urology, Fundació Puigvert, Autonoma University of Barcelona, Barcelona, Spain. [5]Department of Urology, Jules Bordet Institute, Université Libre de Bruxelles, Brussels, Belgium. [6]Urology Department, Clinique Saint-Augustin, Bordeaux, France. [7]Azienda Ospedaliera Ospedali Riuniti Marche Nord, Pesaro, Italy. [8]Department of Urology, IRCCS "Regina Elena" National Cancer Institute, Rome, Italy. [9]Division of Urology, Geneva University Hospitals, Geneva, Switzerland. [10]Department of Urology, Hôpital Cavale Blanche, CHRU Brest, Brest, France. [11]Department of Urology, Grenoble Alpes University Hospital, Université Grenoble Alpes, CNRS, Grenoble INP, TIMC, Grenoble, France. ✉email: Michael.BABOUDJIAN@outlook.fr

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Given that current guidelines recommend offering AS only to patients with low-volume ISUP 2 PCa patients (i.e., ≤3 positive cores), we sought to investigate whether initial tumor burden at biopsy could predict pathological results and clinical outcomes after RP in ISUP 2 patients [9]. Moreover, as multiparametric magnetic resonance imaging (mpMRI) has been incorporated as a stratification tool in AS [10–13], we hypothesized that tumor size (i.e., largest diameter) measured at imaging could be more informative and predictive of post-RP outcomes than tumor burden on biopsy in ISUP 2 patients.

METHODS

Patients

This retrospective, multicenter study was conducted between 2014 and 2021 in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki. Patients were identified retrospectively from a prospectively maintained database that records all RP procedures from eight referral centers in France, Italy, Switzerland and Belgium. The cohort included patients aged ≥18 years with clinically localized IR PCa who had positive mpMRI (Prostate Imaging Reporting and Data System [PI-RADS] ≥3), PSA < 20 ng/mL, ≤cT2b and ISUP 2 at biopsy. All patients underwent MRI-targeted biopsy + systematic biopsies and subsequent RP with or without pelvic lymph node dissection.

During the study period, a total of 1768 PRs were performed at the 8 participating centers. We excluded patients with ISUP ≥ 3 (n = 623), ISUP 1 (n = 310), baseline PSA value > 20 (n = 37), stage ≥T2c (n = 16), non-suspicious mpMRIs (i.e., PI-RADS 2, n = 12), intraductal or cribriform carcinoma (n = 4), unrecorded mpMRI lesion size (n = 21), missing PSA value (n = 5), and missing data on number of cores collected (n = 42)."

Procedures

All prebiopsy mpMRI scans, consisting of multiplanar T2-weighted images, diffusion-weighted imaging, dynamic contrast-enhanced mpMRI, and T1-weighted images with fat suppression [14], were performed using a 1.5- or 3-T scanner and were reported according to the PI-RADS v.1 (until 2015), PI-RADS v.2 (2015–2019) and PI-RADS v.2.1 (since 2020) by dedicated radiologists [15]. The expertise of the radiologists varied by center, but they were generally radiologists experienced in reading prostate mpMRIs (Supplementary Table 1). Tumor dimensions were measured primarily on T2-weighted imaging sequences in the axial plane. The size of the tumor lesion on mpMRI was defined from the largest measured dimension.

Prostate biopsies were performed by either a transrectal or a transperineal route. The biopsy approach used was left to the judgment of each treating physician. Lesions with a PI-RADS score ≥3 on mpMRI underwent targeted biopsy (with a minimum of two cores per lesion) in addition to concomitant systematic biopsies. Targeted biopsies were performed using MRI/US fusion software at all participating centers.

RP ± pelvic lymph node dissection was performed using an open, laparoscopic, or robotic-assisted approach. Surgical specimens were evaluated by pathologists with genitourinary expertise at each institution. Follow-up was per institution, which generally included a PSA level measurement every 3 to 12 months for 5 years and annually thereafter.

Data synthesis and analysis

We defined tumor burden on biopsy as low or high based on the absence/presence of more than 25% positive cores (relative to the total number of cores taken). Imaging tumor size was defined as low or high based on maximum lesion diameter, <15 mm and ≥15 mm at mpMRI, respectively. As there is no consensus definition of high tumor burden on biopsy or imaging, we performed several sensitivity analyses to assess associations between different thresholds on biopsy (biopsy volume ≥20%, ≥33%, ≥50%, and positive cores >3) or mpMRI (> 5 mm and >10 mm) and predefined endpoints.

Descriptive statistics were carried out of the available variables according to tumor burden at biopsy and mpMRI. Categorical variables were reported as frequencies and percentages (%) and compared by Chi-square test, and continuous variables as medians and interquartile ranges (IQR) and compared by Mann-Whitney test.

The histological endpoint of the study was adverse features at RP, defined as non–organ confined disease (i.e., ≥pT3a) and/or lymph node invasion (i.e., pN +) and/or ISUP ≥ 3 at final pathology. Multivariate logistic regression models were used to evaluate the association between biopsy/imaging tumor burden and risk of pathological upgrading (i.e., ISUP ≥ 3) and adverse pathology (≥pT3a and/or pN+ and/or ISUP ≥ 3). Models were adjusted with baseline PSA value, prostate volume, PSA density, clinical T stage and biopsy access.

The clinical endpoint was biochemical recurrence (BCR), defined as two PSA values of ≥0.2 ng/mL during follow-up. Kaplan-Meier curves were used to illustrate BCR after treatment according to biopsy/imaging tumor burden. Rates of BCR were compared with the log-rank test. Multivariable Cox proportional hazards model was used to evaluate the association between biopsy/imaging tumor burden and hazard of recurrence. The model was adjusted for clinical T stage and positive surgical margins as they were significantly associated with BCR in univariate analysis ($p < 0.05$).

All statistical analyses were performed using R software Version 4.1.3 (R Foundation for Statistical Computing, Vienna, Austria). All tests were two sided with significance level set at $P < 0.05$.

RESULTS

Patient Population

A total of 698 contemporary patients with IR ISUP 2 PCa at biopsy was included. Baseline characteristics are summarized in Table 1. High tumor burden at biopsy (i.e., ≥25% of positive cores) and high tumor size at mpMRI (maximum lesion diameter ≥15 mm) were recorded in 485 (69%) and 187 (27%) cases, respectively.

Risk of adverse features

At final pathology, 169 (24.2%), 266 (38.1%) and 335 (48%) patients had pathological upgrading (i.e., ISUP ≥ 3), pathological upstaging (i.e., ≥pT3a) and adverse features (i.e., ≥pT3a and/or pN+ and/or ISUP ≥ 3), respectively (Table 2). In univariate analysis, high tumor burden at biopsy was associated with pathological upstaging ($p = 0.006$) but not with pathological upgrading ($p = 0.11$) or adverse features ($p = 0.18$). High tumor size at mpMRI was significantly associated with pathological upstaging ($p = 0.006$), pathological upgrading ($p = 0.01$) and adverse features ($p < 0.001$). In multivariate logistic regression analysis (Table 3), there was no statistical association between tumor burden at biopsy and pathological upgrading or adverse features ($p > 0.05$). High tumor size at mpMRI was significantly associated with adverse pathology

Table 1. Patient characteristics.

Variables	Total cohort (n=698)
Age, *years*	65 (61–70)
Preoperative PSA value, *ng/mL*	7 (5.3–9.5)
Prostate volume, *mL*	43 (32–56)
PSA density	0.16 (0.11–0.23)
Clinical T stage	
cT1	71 (33)
cT2	142 (67)
Maximum index lesion diameter	
<15mm	511 (73)
≥15mm	187 (27)
Biopsy access	
Transrectal	649 (93)
Transperineal	49 (7)
Biopsy findings	
No. positive cores per patient	
Tumor burden <25%	213 (31)
Tumor burden ≥25%	485 (69)

PSA Prostate Specific Antigen.
Data are presented as median (interquartile range) or number (percentage).

Table 2. Final pathological results.

Variables	Tumor burden at biopsy <25% (n = 213)	Tumor burden at biopsy ≥25% (n = 485)	P	Maximum lesion diameter <15 mm (n = 511)	Maximum lesion diameter ≥15 mm (n = 187)	P
RP GGG			0.11			0.01
1	12 (5.6)	17 (3.5)		18 (3.5)	11 (5.9)	
2	142 (66.7)	358 (73.8)		381 (74.6)	119 (63.6)	
≥3	59 (27.7)	110 (22.7)		112 (21.9)	57 (30.5)	
pT stage			0.006			0.006
pT2	148 (69.5)	284 (58.6)		332 (65)	100 (53.5)	
≥pT3a	65 (30.5)	201 (41.4)		179 (35)	87 (46.5)	
pN stage			0.8			0.3
pN0-pNx	208 (97.7)	471 (97.1)		499 (97.7)	180 (96.3)	
pN1	5 (2.3)	14 (2.9)		12 (2.3)	7 (3.7)	
Adverse pathology (i.e., GGG≥3 and/or ≥pT3a and/or pN1)	94 (44)	241 (50)	0.18	225 (44)	110 (59)	<0.001

GGG Gleason Grade Group.
Data are presented as median (interquartile range) or number (percentage).

Table 3. Multivariate logistic regression model for predicting pathological upgrading and adverse pathology after radical prostatectomy.

Variables	Pathological upgrading (GGG ≥ 3)			Adverse pathology (GGG ≥ 3 and/or ≥pT3a and/or pN1)		
	OR	95% CI	P	OR	95% CI	P
Preoperative PSA value	1.05	0.95–1.15	0.3	0.99	0.91–1.09	>0.9
Prostate volume	0.99	0.98–1.01	0.9	0.99	0.98–1.01	0.6
PSA density	1.51	0.08–27	0.8	4.52	0.30–67	0.3
Tumor burden at biopsy ≥25%	0.62	0.39–1.01	0.06	1.08	0.76–1.52	0.7
Maximum lesion diameter ≥15 mm	1.49	0.99–2.26	0.05	1.65	1.14–2.39	0.01
Clinical T stage						
cT1	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
cT2	2.69	1.73–4.18	<0.001	2.32	1.64–3.26	<0.001
Biopsy access						
Transrectal	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
Transperineal	1.52	0.75–3.06	0.24	0.66	0.35–1.24	0.2

OR Odds ratio, *CI* Confident interval, *PSA* Prostate Specific Antigen.

(odds ratio [OR] 1.65, 95% CI 1.14 to 2.39; $p = 0.01$) and there was the suggestion of higher risk of pathological upgrading, but it did not reach the predefined threshold for statistical significance (OR 1.49, 95% CI 0.99 to 2.26; $p = 0.05$).

Biochemical Recurrence

Follow-up data was available in 635 (91%) patients (152 with low tumor burden on biopsy and mpMRI, 37 with high tumor burden on mpMRI only, 310 with high tumor burden on biopsy only, and 136 with high tumor burden on biopsy and mpMRI). After a median follow-up of 21 months, a total of 32 patients experienced BCR. At Kaplan-Meier analysis, the 3-year overall BCR-free survival rate was 89% (95% CI, 0.849 to 0.933). Recurrence-free survival at 3 years was 92.3% and 87.4% in patients with low and high tumor burden at biopsy, respectively (Log-rank $p = 0.18$). Recurrence-free survival at 3 years was 92.7% and 71.2% in patients with low and high tumor size at mpMRI, respectively (Log-rank $p = 0.01$). Recurrence-free survival at 3 years was 96.2%, 95.8%, 92.2% and 76.6% in patients with low tumor burden on biopsy and mpMRI, high tumor burden at biopsy only, high tumor burden on mpMRI only, and high tumor burden on biopsy and mpMRI, respectively (Log-rank $p = 0.07$). The results of the multivariable Cox hazards regression model are summarized in Table 4. No significant association was observed between tumor burden at biopsy and hazard of recurrence after RP ($p = 0.6$). High tumor size at mpMRI was significantly associated with BCR (Hazard ratio 1.96, 95% CI 1.01 to 3.80; $p = 0.04$).

Sensitivity analysis

In sensitivity analysis, tumor burden at biopsy was not associated with the risk of adverse features and BCR, regardless of the definition used (biopsy volume ≥20%, ≥33%, ≥50%, and positive cores >3, all $p > 0.05$, Supplementary Table 2). At mpMRI, only a maximum lesion diameter ≥15 mm was associated with both adverse features and BCR (supplementary Table 3).

DISCUSSION

In this large multicenter study of patients with PCa detected by a mpMRI pathway, we found no association between biopsy tumor

Table 4. Multivariate cox proportional hazards regression model for predicting biochemical recurrence after radical prostatectomy.

Variables	Biochemical recurrence		
	HR	95% CI	P
Tumor burden at biopsy ≥25%	1.26	0.56–2.81	0.6
Maximum lesion diameter ≥15 mm	1.96	1.01–3.80	0.04
Positive surgical margins	5.23	2.61–10.5	<0.001
Clinical T stage			
cT1	Ref.	Ref.	Ref.
cT2	2.47	1.19–5.12	0.02

HR Hazard ratio, *CI* Confident interval, *PSA* Prostate Specific Antigen.

burden and risk of pathological upgrading, adverse features and biochemical recurrence after RP in ISUP 2 PCa patients. In contrast, tumor largest dimension defined on mpMRI was associated with all pathological and clinical endpoints. Our findings challenge current recommendations for AS in IR ISUP 2 patients that are still based on empirical criteria such as the number of positive cores.

To date, the eligibility of IR ISUP 2 PCa patients for AS is limited by very strict consensus-based inclusion criteria proposed by a Canadian consensus [16] which have been endorsed by the American Society of Clinical Oncology [17] and the European Association of Urology [18]. Based on previously published models [13, 19] that aimed to predict the risk of adverse features in low- and intermediate-risk PCa patients treated by RP, the main recommendation is to limit inclusion for AS to men with low ISUP 2 volume (i.e., ≤3 positive cores). However, a recent study showed that performance of available models to predict the risk of adverse features at RP is suboptimal when tested in an external set of contemporary patients diagnosed by mpMRI and image-guided biopsies [20]. Our study corroborates previous findings by showing that biopsy tumor volume alone in ISUP 2 patients may have less impact than previously thought. Although we utilized an alternate different measure of PCa tumor burden that is more applicable in a targeted biopsy era, our data suggests that PCa tumor burden on biopsy may not be as relevant to the most important PCa outcomes, with potential implication for expanding inclusion criteria for AS in IR patients.

The management of localized PCa has changed dramatically since the introduction of mpMRI as a screening tool, which clearly led to a better characterization of IR disease. Recent evidence has shown an association between mpMRI findings and pathological results, lymph node metastasis, and recurrence after surgery [21–24]. In line, we showed that maximum index lesion length at mpMRI was predictive of adverse pathology and hazard of recurrence after RP in ISUP 2 patients. Conversely, our study reinforces previous data by showing that tumor volume/size measured on mpMRI is associated with a higher risk of BCR after RP [25–27] or radiation therapy [28].

By demonstrating that better outcomes can be achieved in patients with low tumor size on mpMRI, our study reveals that mpMRI should play a central role in selecting the best ISUP 2 candidates for AS.

The present study has several limitations that should be acknowledged. First, the main limitation lies in its retrospective design. The lack of a central mpMRI review, the participation of different radiologists, the use of size as a surrogate for volume in mpMRI and the use of different PI-RADS scores during the study period may lead to some heterogeneity in the mpMRI reports. However, it is important to note that all patients were treated at tertiary referral centers and that all physicians adhered to the guidelines and terminology used in current practice, limiting the biases inherent to the multicenter design of this study. Due to the increasing adoption of the transperineal approach to prostate biopsy in our centers, we report data on a mixed cohort of patients biopsied transrectally and transperineally, which may add additional bias. The percentage of pattern 4 has recently been proposed as an important selection criterion for indicating AS in patients with IR [5]. However, this data was gradually included in our dataset during the study period and was only available for a minority of our patients, which prevented us from analyzing it as an independent variable in our multivariate models. We should also recognize that the evaluation of a large cohort of patients undergoing RP and the use of a surrogate endpoint (namely, the risk of adverse features) limit the generalizability of our findings. Prospective investigations addressing the oncological safety of AS in ISUP 2 patients according to our results are needed to validate of our findings as we still do not know whether ISUP 2 patients in the ISUP 2 group can progress during AS. Finally, the short follow-up of this study led to relatively few subjects experiencing BCR, making the model underpowered. Although early BCR, as an intermediate clinical endpoint, is a strong predictor for long-term oncologic outcomes [29], further studies with longer follow-up are warranted to confirm our results.

CONCLUSION

Our data support the extension of inclusion criteria to those with >25% positive cores and confirm the prominent role of mpMRI in improving ISUP 2 patient selection for AS. Prospective studies should be performed to confirm the safety of AS on ISUP 2 men with >25% positive biopsy core, excluding patients with a PIRADS 5 mpMRI lesion.

DATA AVAILABILITY

Data is available on reasonable request from the corresponding author.

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AUTHOR CONTRIBUTIONS

Conceived and designed the analysis: MB, AU, GP; performed the analysis: MB, AU, GP; wrote the manuscript: MB; provided critical feedback in shaping the manuscript: all authors.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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Correspondence and requests for materials should be addressed to Michael Baboudjian.

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Michael Baboudjian (M.D.) works as a urologist in Marseille, France. After completing his residency, he did a one-year fellowship at the Fundacio Puigvert under the mentorship of Dr. Alberto Breda. His research focus on prostate cancer and he is an associate member of the French Prostate Cancer Group (CCAFU). Active surveillance is one of his main research topics, with the aim of expanding its indications. He is also interested in the management of male lower urinary tract symptoms (LUTS) and is an associate member of the EAU Men's LUTS panel. Finally, green urology and sustainability are translational research topics that he hopes to focus on in the coming years.