



Biopsies prostatiques en présence d'une lésion cible à l'IRM : quand peut-on se passer des biopsies randomisées ?

Bastien Nicolan

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UNIVERSITE DE MONTPELLIER
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THESE

Pour obtenir le titre de
DOCTEUR EN MEDECINE

Présentée et soutenue publiquement
Par
Bastien NICOLAN

Le 3 juin 2021

TITRE

Biopsies prostatiques en présence d'une lésion cible à l'IRM : quand peut-on se passer des biopsies randomisées ?

Directeur de thèse : Pr Ingrid MILLET

JURY

Président :

Pr Patrice TAOUREL

Assesseurs :

Pr Ingrid MILLET

Pr Rodolphe THURET

Dr Isabelle SERRE

Membre invité :

Dr Cécile VERHEYDEN

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Remerciements

Aux membres de mon jury,

Monsieur le Professeur Patrice Taourel, vous nous faites l'honneur de présider ce jury de thèse.

Merci de m'avoir accueilli dans votre service et d'avoir accepté de juger ce travail. Veuillez recevoir l'expression de mon plus grand respect.

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Abstract

Objective: To assess the predictive factors (clinical, biological and MRI data) that enable identifying men in which a sole targeted biopsy detects the maximal prostate cancer risk group. We hypothesized that randomized biopsies have little therapeutic impact when they have a lower ISUP than targeted ones.

Material and method: In a cohort of 144 consecutive patients who underwent a combination of targeted biopsies (by MRI/ultrasound fusion technique) and 12 randomized biopsies between June 2017 and March 2020, we retrospectively recorded clinical (age, digital rectal exam, personal history of prostate biopsy, family history of prostate cancer, ERSPC score 3-4 and 6), biological (PSA and PSA density), and MRI parameters (quantitative and qualitative data on the target and on the off-target area). Two groups of patients were defined based on ISUP scores obtained on targeted and randomized biopsies, and on the length of positive biopsy coverage in case of equal ISUP. We performed univariate and bivariate analysis of all the studied variables to predict in which situation randomized biopsies had an ISUP lower than targeted biopsies. Interobserver agreement analyses were performed on each variable.

Results: The mean age of our cohort was 67 years (IQR: 61-72) and the mean PSA level was 9.7 ng/mL (IQR: 5.5 - 11). A total of 30 patients (20.8%) were cancer free. Among the 114 patients with cancer, 85 (74.6%) had a higher ISUP score on targeted biopsies than on randomized ones, while the remaining 29 patients (25.6%) were in the opposite case (ISUP score RB > TB). Of all variables studied, none showed a significant difference between the two groups.

Conclusion: We were not able to show any predictive factors to select patients for whom randomized biopsies could be dropped when there was a target on prostate MRI. The combination of targeted biopsies and randomized biopsies should still be required.

Introduction :

Recently, several studies (1–5) have proven the usefulness of prostate MRI in the diagnostic pathway of prostate cancer. Multiparametric MRI (mpMRI) enables to delineate areas of significant cancer (Prostate Imaging Reporting and Data System - PIRADS) and to target them during biopsies (by fusion of MRI – ultrasound images). Then, it has been recommended since 2019 to perform a prostate mpMRI (6,7) when there is a suspicion of cancer, before any biopsy. If mpMRI detects a 3 to 5 PIRADS lesion, an association of targeted and 12 randomized prostate biopsies is advocated (2,5,7). Treatment will then be based primarily on biopsies results by stratifying men into d'Amico risk groups, leading to curative treatment if a grade 4 is detected by biopsies corresponding to “significant cancer”.

Although targeted biopsies (TB) have been shown to detect significantly more significant cancer than randomized ones (1,3), the role of randomized biopsies (RB) is less clear from a therapeutic point of view. Randomized biopsies allow a complete sample of the prostate but they are more commonly and significantly associated with underdetection of high-grade prostate cancer and overdetection of low-grade (= grade 3, clinically insignificant) cancer (1) generating overtreatment. They are also associated with longer procedures, increasing patient discomfort as described in the Egbers et al study (8) in which targeted biopsies were preferred by 65 % of the patients, with significantly less pain. They would increase theoretically the risk of infection with less sepsis reported in the same study (8) when only targeted biopsies are done, but without statistical difference. Moreover, randomized biopsies increase costs because of the extra time needed for pathologists to analyse these multiples cores (9).

Yet, the detection of prostate cancer should be as minimally invasive as possible by reducing side effects, to identify a high proportion of men who would benefit from treatment,

and to minimize the identification of men with clinically insignificant cancer in order to prevent overtreatment. The benefit/risk balance of performing randomized biopsies should then be a matter of shared decision-making: could there be some situations in which we could drop them when targeted biopsy is done at the same time?

To our knowledge, only a few studies have attempted to answer this question (10–14). Several predictive criteria have been described when the uselessness of RB was defined as detection of ISUP < 2 (10,13) like a PIRADS 5 target and a previous negative biopsy, or when the uselessness of the RB was defined as RB < TB (12), like PSA density ≤ 0.15 .

However, no study has looked at MRI analysis of the off-target prostate and the perfusion parameters. We can suggest that other criteria may be predictive of the usefulness of randomized biopsies, and in particular the analysis of the peripheral off-target zone on MRI. For example, in the event of a very suspicious target (PIRADS 5) and a homogeneous off-target peripheral zone with high ADC values, randomized biopsies are unlikely to be helpful. Conversely, in the case of a PIRADS 3 target, and a heterogeneous off-target peripheral zone with intermediate ADC values, randomized biopsies will probably be more contributory as significant cancer could be hidden by chronic inflammatory findings.

The purpose of the present study is then to identify predictive parameters (clinical, biological and radiological) allowing to select the patients who would benefit from a single targeted biopsy by dropping the randomized ones. We assume that a randomized biopsy with an ISUP score lower than the targeted one or when equal ISUP score, if the length of biopsy involvement is lower, is useless for management decision.

Materials and methods

1. Patients:

This retrospective study was approved by our institutional review board (N°202000698) and written informed consents were waived by this IRB.

We reviewed all consecutive patients who had prostate MRI followed by targeted biopsies and 12 randomized biopsies, between June 2017 and March 2020 at CHU Lapeyronie in Montpellier. The indication for pre-biopsy prostate MRI was: a/ before a second set of biopsies when PSA increased with a negative first biopsy; b/ during active surveillance; c/ before any first set of biopsies since 2018.

Patients were included in the study if: a/ they had at least a bi-parametric MRI including T2 and diffusion-weighted images performed in our center; b/with a \geq PIRADS 3 target or a PIRADS 2 target in the case of active surveillance or clinical abnormalities on the digital rectal examination; c/ and a complete biopsy procedure with targeted and 12 randomized ones.

Patients were not included in the study if: a/ the MRI had not been performed in our center, because quantitative parameters (ADC and perfusion) could not be assessed given the different MRI protocols; b/ MRI didn't include diffusion-weighted images or had significant artefacts preventing the visibility of the prostate; c/ they had not had the 12 randomized biopsies.

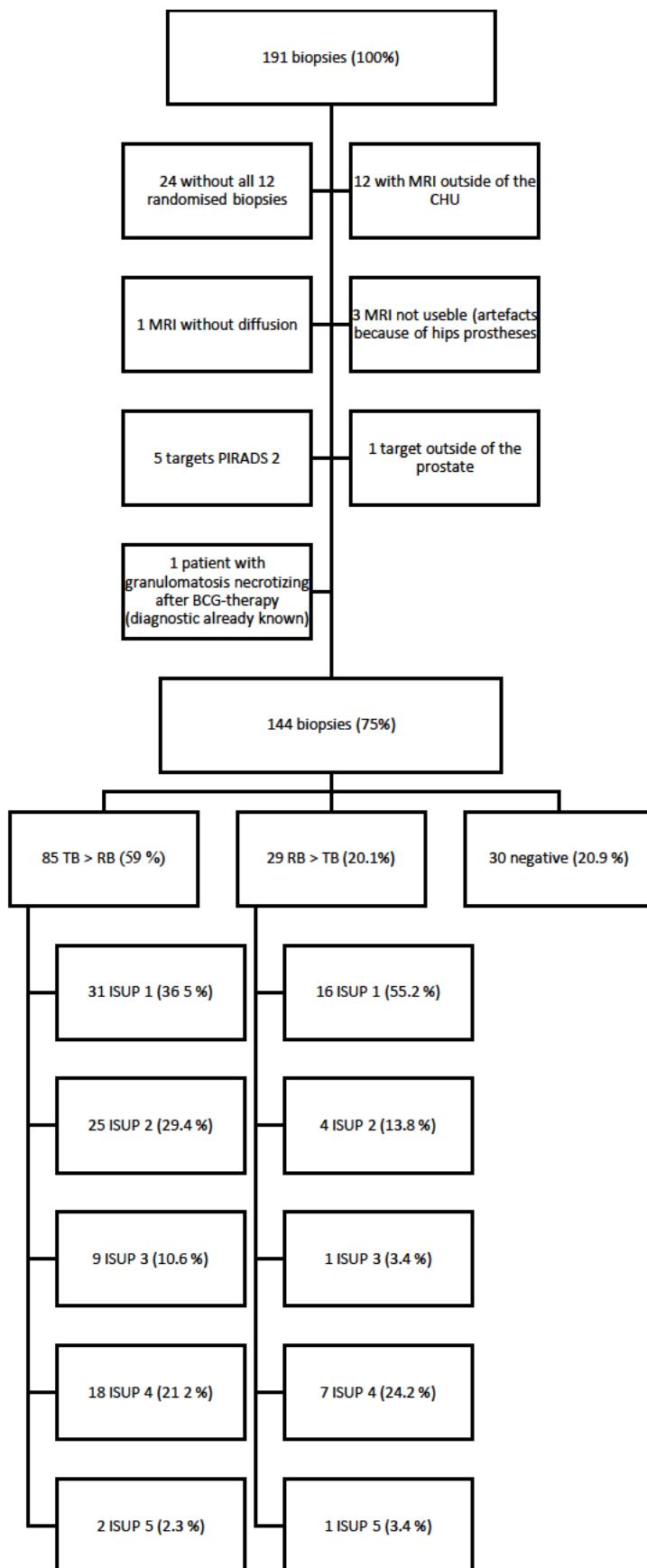


Figure 1- Flow-chart. TB = targeted biopsies / RB = randomised biopsies

For each patient, one author (BN) looked for a family history (first degree) of prostate cancer, a personal history of prostate biopsies (positive or not), digital rectal examinations abnormalities and the PSA value. Thus, we were able to calculate the PSA density (with the prostate volume measured on MRI), and the ERSPC scores 3 and 4 (15), which estimates the risk of having a biopsy detectable (potentially aggressive) prostate cancer according to age, PSA, prostatic volume, digital rectal examination, history of biopsies and the highest PIRADS score, and the ERSPC score 6 (figure 2), which calculates a man's future risk over the next four years, according to age, PSA, prostatic volume, digital rectal examination, history of biopsies and family history. Finally, we collected the treatment for each patient.

Future Risk Calculator*

Time = 0 (Now)

Age (years)

PSA (ng/ml)

DRE Abnormal Normal

Family history * Yes No

DRE volume class (cc) ▾

Previous neg. biopsy Yes No

Time = 4 (4 years later)

Probability of NO Prostate Cancer:
87.7%

Probability of potential LOW RISK
Prostate Cancer: **8.4%**

Probability of potential AGGRESSIVE
Prostate Cancer²: **3.9%**

Figure 2 - Example of ERSPC 6 score calculation (15)

2. IRM

MRIs were all multiparametric and performed using a 1.5-Tesla (MAGNETOM Aera, Siemens Medical Solutions, Erlangen, Germany) with a phased array surface coil. No endorectal coils were used.

The MRI protocol included multiplanar T2-weighted images, axial diffusion weighted images (with b values of 0, 1000 and 2000 s/mm², apparent diffusion coefficient maps were automatically elaborated), and axial T1-weighted images with dynamic injection (temporal resolution of 8 sec lasting for 2 min). Four patients had an MRI without injection (2.8%).

Interpretation was performed independently by two radiologists, a senior radiologist (CV, 8 years of experience) and a junior radiologist (BN, 4 years of experience). A third radiologist (IM, 12 years of experience) made the reading consensus when there were discrepancies. Readers were blinded to the biological and clinical parameters and also to the histological results.

For each MRI, both radiologists independently determined the number of PIRADS ≥ 2 target, according to the Prostate Imaging-Reporting and Data System (PI-RADS) version 2.1. Then, they selected the target with the highest PIRADS (or the largest lesion in case of several targets with equal PIRADS) and reported the image slice number to allow the third reader (IM) to check if both readers had identified the same target.

Both readers assessed for each target : a/ the measure of the target on T2, diffusion and perfusion sequences with the largest transversal size on each sequence reported in mm; b/ the localization of the target in a transversal plane: transitional / peripheral zone, anterior / posterior (the posterior part was located behind the line located at 22 mm and parallel to the tangent of the posterior edge of the prostate, the anterior part was on the anterior side of the line – figure 3); and in a coronal plane: apex / middle zone / base; c/ the measure of the ADC of the lesion in

mm²/sec using a ROI (region of interest) drawn on more than 80% of the target; d/ the ratio between the contrast enhancement of the lesion relative to the adjacent transitional zone (this measurement was made on the 1st sequence where the target appeared enhanced and both measures were done at the same time – figure 4). If the target was not enhanced, no measure was done.

Then, the off-target peripheral zone was analysed: the readers measured a/ the minimum ADC value on the side of the lesion and on the contralateral side (ROI of 10 mm³), and b/ classified the ipsilateral and contralateral zone as homogeneous / moderately heterogeneous / very heterogeneous on T2 sequence (figure 5).

Finally, prostate volume was calculated according to the PIRADS-V2 method by multiplying the 3 largest prostate diameters by 0.52 (figure 6).

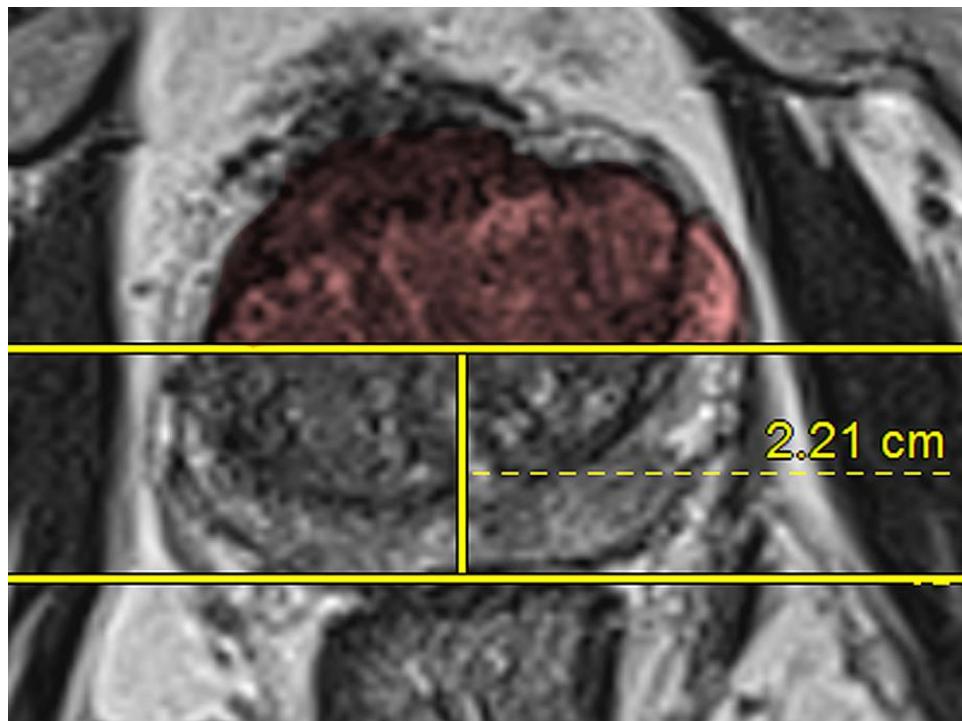


Figure 3 - Axial T2 image. The posterior part of the prostate is between the two yellow horizontal lines, the anterior part (in red) is in front of the most anterior horizontal line.

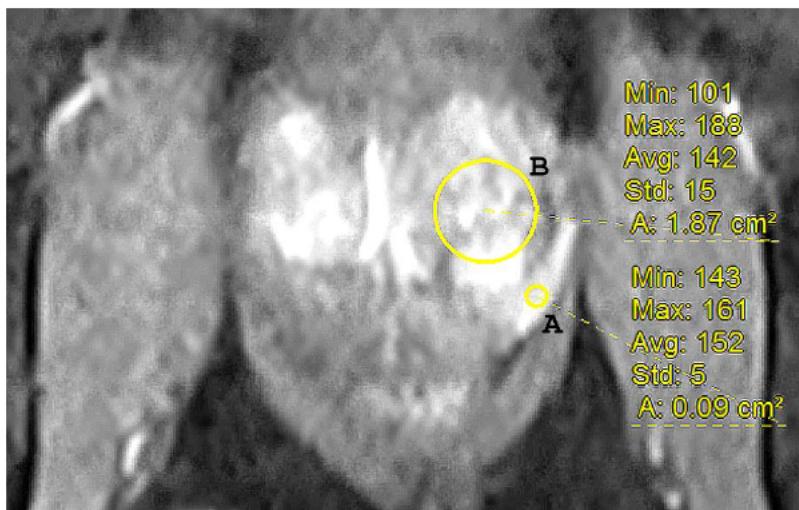


Figure 4 - Axial fat-suppressed T1 enhanced image. Target lesion PIRADS 4 of the left postero-lateral zone. Here, the contrast enhancement of the lesion (A) relative to the adjacent transitional zone (B) was 1.1 (152/142=1.07).

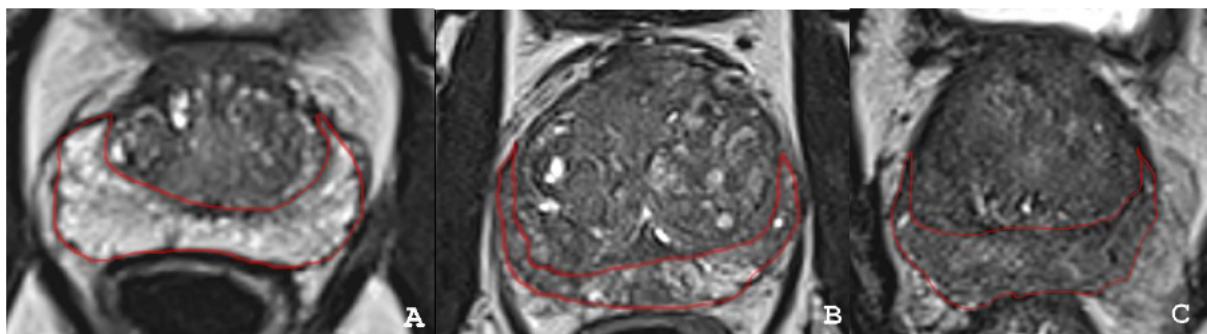


Figure 5 – Axial T2 images in 3 different patients. Peripheral off-target zone on T2 sequence is delimited by the red line: A/homogeneous ; B/moderately heterogeneous ; C/heterogeneous

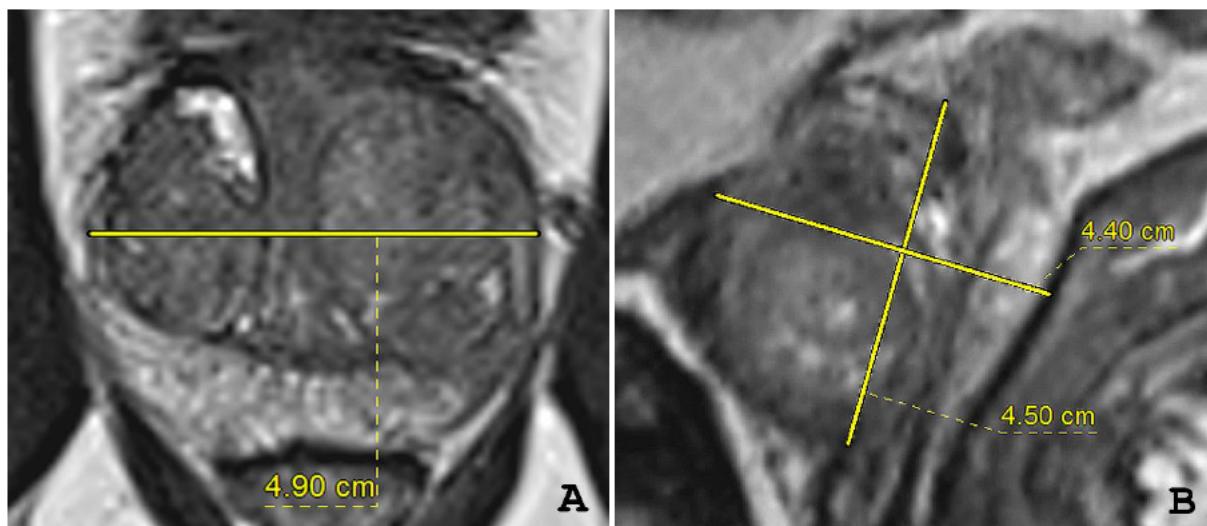


Figure 6 - Axial (A) and sagittal (B) T2 images. Prostate volume measure (PIRADS V2 method). Here, the prostate volume was 50 g ($4.9 \times 4.5 \times 4.4 \times 0.52 = 50.4$).

3. Gold Standard

Randomized biopsies were considered useless if their ISUP score was lower than the targeted one, and when equal ISUP, if the maximum length of tumoral tissue in all the randomized cores were lower than the targeted ones.

We defined then two patient groups according to the biopsies results:

- Group targeted = ISUP TB > RB, or ISUP TB = RB but positive TB length was superior, or negative results for both TB and RB;
- Group randomized = ISUP RB > TB or ISUP RB = TB but RB length was superior.

Biopsies were carried out by 3 radiologists (IM, CV and CF) with the same experience using an Aplio i800 platform (Canon Medical System, Tokyo, Japan) with an endocavity endfire probe (3-11 MHz, Canon Medical Systems, Tokyo, Japan). Isotropic high resolution T2-weighted sequences in axial orientation were imported to the US platform. The intervention was performed with the patient in lateral decubitus position. For all biopsies, a 18G, 30 cm biopsy needle (Achieve, Merit Medical System, USA) was used. The sensor-based, real-time fusion was achieved by the tracking of the US probe in a magnetic field generated by a mini- BIRD receiver. The sensor that was applied to the probe led to a real-time fusion of the TRUS- and MRI-planes. Thanks to this fusion of MRI – ultrasound images (figure 7), a median of 3 targeted biopsies (IQR: 3.00; 4.00) was performed per target. Twelve randomized biopsies were also performed: for each lobe, samples were taken at the mediolobar and lateral level, at the base, in the middle and at the apex (16).

All tissue samples were evaluated by experienced uropathologists. A significant cancer was defined by an ISUP score ≥ 2 .

We gathered the biopsy results, the exact location, ISUP score and length of the positive results.

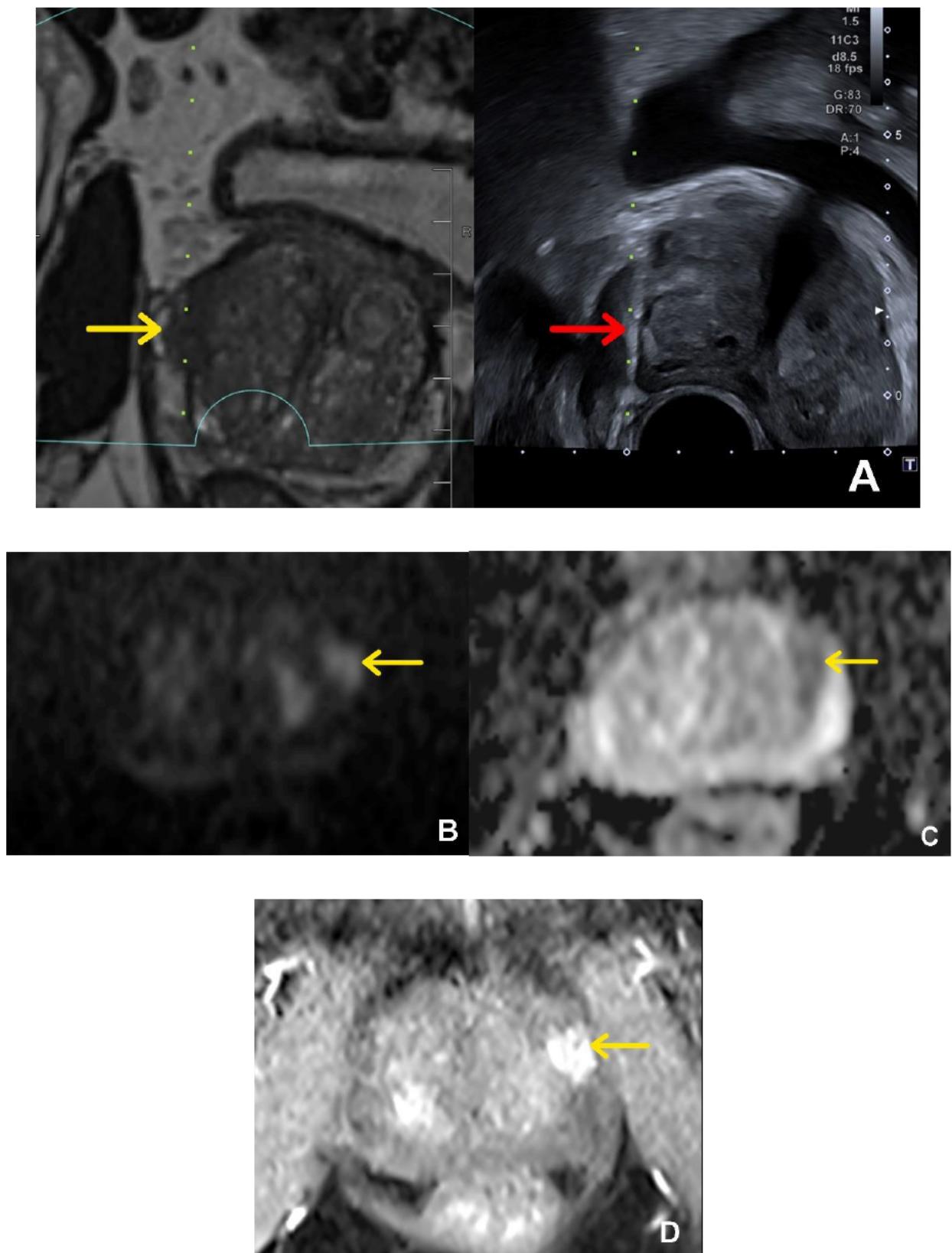


Figure 7 – Example of fusion of MRI and ultrasound (A) with the target on MRI (yellow arrow, T2 sequence) and the biopsy needle on ultrasound (red arrow). B, C and D: MRI before biopsy with the same target (yellow arrow), on diffusion B2000 (B), ADC (C) and T1 with injection (D) sequences.

4. Statistics

Consensual data and average of the measurements for quantitative data were used for final statistics.

Categorical data were presented in terms of absolute and relative frequencies. Continuous variables were presented by means and SD when normal distributed or by medians and quartiles.

We performed the chi-square test, Fisher test, Student's t test and Wilcoxon Mann-Whitney test to calculate differences between the "targeted" and "randomized" groups for numerical and categorical variables. Univariate and multivariate logistic regression analysis were used to evaluate predictors for detection of the patients that would benefit from TB alone.

Interobserver agreement for each CT finding was assessed by computing the kappa coefficient for binary variables and the weighted kappa coefficient for multi-class variables. Results were interpreted as follows: $\kappa=0-0.20$, slight agreement; $\kappa=0.21-0.40$, fair agreement; $\kappa=0.41-0.60$, moderate agreement; $\kappa=0.61-0.80$, substantial agreement; and $\kappa=0.81-1.00$, almost perfect agreement (17). Bland-Altman analysis were used to assess agreement among measurements between observers (18).

All statistical tests were two-sided and P values <0.05 were considered to indicate significant differences. SAS Enterprise Guide, version 8.2 (SAS Institute, Cary, NC, USA) was used for the statistical analyses.

Results

1. Population

A total of 144 targeted and randomized biopsies were included. Table 1 summarises the descriptive characteristics of our cohort. Altogether, the men in the study were on average 67 years old (median: 68.00; Q25-Q75: 61.50-72.00). Among them, 34 (23.6%) had an abnormal DRE. Ten (6.9 %) patients had a first-degree family history. The median PSA level was 7.75 ng/mL (Q25-Q75: 5.47–11.00) and the median PSA density was 0.15 (Q25-Q75: 0.11-0.21). Overall, 66 men (45.8%) were biopsy naïve, while 44 (30.6%) had a history of positive biopsy (patients under active surveillance) and 34 (23.6%) a history of negative biopsy. The median risk of ERSPC 3-4 score was 16 % (Q25-Q75: 9.00-33.50), and the median risk of ERSPC 6 score was 7.85 % (Q25-Q75: 5.10-11.90).

Variables	Overall (n=144)
Age (years)	
Median	68.00
Q25-Q75	61.50-72.00
Family history – 1 st degree, n (%)	
Yes	10 (6.94)
No	134 (93.06)
Previous biopsy, n (%)	
Biopsy naïve	66 (45.83)
Previous negative biopsy	34 (23.61)
Previous positive biopsy	44 (30.56)
PSA value (ng/ml)	
Median	7.75
Q25-Q75	5.47-11.00
PSA density	
Median	0.15
Q25-Q75	0.11-0.21
DRE, n (%)	
Normal	110 (76.39)
Abnormal	34 (23.61)
ERSPC 3-4 (%)	
Median	16.00
Q25-Q75	9.00-33.50
ERSPC 6 (%)	
Median	7.85
Q25-Q75	5.10-11.90

Table 1. Demographic characteristics of men included in our cohort. Data in parenthesis are percentages.

2. Biopsies results

A/ Global results

Overall, 30 patients (20.8 %) were cancer free and 67 (46.5 %) patients had significant cancer. Targeted biopsies were positive in 72.2 % of cases (n=104), and among them 59.6 % found significant cancer (n=62). The distribution of the ISUP was as follow: 42 with ISUP 1 (40.4 %), 28 with ISUP 2 (26.9 %), 12 with ISUP 3 (11.6 %), 20 with ISUP 4 (19.2 %) and 2 with ISUP 5 (1.9 %).

Randomized biopsies were positive in 52.1 % of cases (n=75), and among them 37.3 % found significant cancer (n=28). The distribution of the ISUP was as follow: 47 with ISUP 1 (62.7 %), 13 with ISUP 2 (17.3 %), 2 with ISUP 3 (2.7 %), 12 with ISUP 4 (16 %) and 1 with ISUP 5 (1.3%).

In 45.1 % of cases (n=65), targeted and randomized biopsies were positive, whereas only targeted biopsies were positive in 27.1 % of cases (n=39) and only randomized biopsies were positive in 6.9 % of cases (n=10).

When targeted and randomized biopsies (n=65) were positive, the median length of positivity was 7 mm (Q25-Q75: 4.00-9.00) for targeted one versus 3 mm (Q25-Q75: 2.00-6.50) for randomized one.

Thirty-one (41.4%) randomized biopsies were positive only on the same side as the target, 16 (21.3%) only on the other side, and 28 (37.3%) on both sides.

B/ Specific results

Of the 144 patients included in the study, 20 (13.9 %) had an ISUP score on randomized biopsies higher than the ISUP on targeted biopsies, and 9 (6.25 %) had the same ISUP on targeted and randomized biopsies but a greater maximum positivity length on randomized biopsies. ISUP distribution was reported in figure. 1.

Among the 20 patients for whom ISUP RB > ISUP TB, 10 (50 %) had also positive targeted biopsies. In these 10 patients, the median length of positivity of targeted biopsies was 8.50 mm (7.00-11.00) vs 5.00 mm (2.50-6.50) on randomized biopsies. In 75 % of cases (n=15), the ISUP of randomized biopsies contralateral to the biopsied target was lower than the ISUP of randomized ipsilateral biopsies.

In the 10 patients with negative targeted biopsies, randomized biopsies found ISUP 1 in 90 % of cases and ISUP 2 in 10 % of cases.

Among the 9 patients for whom RB > TB with equal ISUP, mainly ISUP 1 was found (n=7, 78%), whereas ISUP 2 (n=1, 11%) and ISUP 4 (n=1, 11%) were less frequent.

3. Follow-up

Among the 114 patients who had positive biopsies, 32 (28.1 %) were operated. Among them, final histological results mainly found ISUP 2 (n=21, 65.6 %). ISUP 1 (n=3, 9.4 %) and ISUP 3 (n=8, 25 %) were less represented, and no ISUP 4 or 5 was found. The concordance data between the prostatectomy ISUP score and the biopsies one is summarized in Table 2.

Among the 20 patients for whom RB > TB, 5 were operated: 4 with concordant ISUP score between biopsies and final pathology (3 ISUP 2 and 1 ISUP 1), and 1 upgrade to ISUP 2 while the randomized biopsies had only found ISUP 1.

The other patients were treated with radiotherapy-hormonotherapy (n=39, 34.2 %), active surveillance (n=30, 26.3%) or with other treatment (brachytherapy, stereotaxic radiotherapy, abstention, etc. n=10, 8.8%). Three patients (2.6 %) where either lost to follow-up or awaiting a therapeutic decision at the time of writing.

ISUP prostatectomy	Number (n=32)	Randomized biopsies	Targeted biopsies	Randomized + targeted biopsies
1	3	Negative: 0 Concordant: 3 Discordant : 0	Negative: 1 Concordant: 2 Discordant: 0	Concordant: 3 Discordant: 0
2	21	Negative: 6 Concordant: 5 Discordant: 10	Negative: 2 Concordant: 6 Discordant: 13	Concordant: 11 Discordant: 10
3	8	Negative: 4 Concordant: 0 Discordant: 4	Negative: 0 Concordant: 2 Discordant: 6	Concordant: 2 Discordant: 6
Total agreement		25 %	31.25 %	50 %

Table 2. ISUP score comparison between biopsies and prostatectomy.

4. Univariate analysis

Univariate analysis didn't show any significant difference between the "targeted" and the "randomized" groups (Table 3). PIRADS score ($p=0.15$) showed a trend towards significance.

Variable	Overall	TB ≥ RB	RB > TB	Concordance (IC)	p
n	144	115	29		
Age (years)	68.00 (61.50;72.00)	68.00 (61.00 ; 72.00)	70.00 (65.00 ; 73.00)	NA	0.27 '
Family history					
Negative	134 (93.06 %)	107 (93.04)	27 (93.10)	NA	1.00 "
Positive	10 (6.94 %)	8 (6.96)	2 (6.90)		
Biopsy naïve	66 (45.83 %)	57 (49.57)	9 (31.03)	NA	0.07 ""
Biopsy history	78 (54.17 %)	58 (50.43)	20 (68.97)		
Negative biopsy history	34 (23.61 %)	28 (48.28)	6 (30.00)	NA	0.16 ""
Positive biopsy history	44 (30.56 %)	30 (51.72)	14 (70.00)		
No history	66 (45.83 %)				
DRE:					
Negative	110 (76.39 %)	88 (76.52)	22 (75.86)	NA	0.94 ""
Positive	34 (23.61 %)	27 (23.48)	7 (24.14)		
ERSPC					
3-4	16.00 (9.00;33.50)	16.00 (9.00 ; 33.00)	19.00 (7.00 ; 38.00)	NA	0.95 '
6	7.85 (5.10;11.90)	7.50 (4.90 ; 12.50)	8.50 (6.20 ; 10.90)		0.66 '
PSA	7.75 (5.47;11.00)	7.80 (5.43 ; 11.08)	7.50 (5.50 ; 10.00)	NA	0.84 '
PSA density	0.15 (0.11;0.21)	0.15 (0.10 ; 0.21)	0.15 (0.12 ; 0.26)		0.22 '
Volume	53.25 (37.50;71.75)	55.00 (38.00 ; 74.50)	46.00 (37.00 ; 65.50)	0.92 (0.90-0.95) *	0.21 '
Number of target:					
1	106 (73.61 %)	86 (74.78)	20 (68.97)	NA	0.67 "
2	36 (25.00 %)	27 (23.48)	9 (31.03)		
3	2 (1.39 %)	2 (1.74)	0 (0.00)		
PIRADS:					
2	6 (4.17 %)	5 (4.35)	1 (3.45)	0.74 (0.64-0.83) **	0.15 "
3	16 (11.11 %)	10 (8.70)	6 (20.69)		
4	76 (52.78 %)	65 (56.52)	11 (37.93)		
5	46 (31.94 %)	35 (30.43)	11 (37.93)		
Target measure (mm):					
T2	10.75 (8.00;15.25)	11.00 (8.50 ; 15.00)	9.00 (7.00 ; 16.00)	0.85 (0.80-0.89) *	0.66 '
ADC	10.50 (8.00;15.00)	11.00 (8.00 ; 14.00)	10.00 (7.00 ; 15.50)	0.87 (0.82-0.90) *	0.91 '
Perfusion	11.50 (8.50;16.00)	11.75 (8.50 ; 16.00)	10.50 (7.50 ; 15.50)	0.83 (0.76-0.87) *	0.66 '
Target:					
ADC	0.53 (0.46;0.62)	0.53 (0.46 ; 0.63)	0.54 (0.45 ; 0.62)	0.87 (0.82-0.90) *	0.83 '
Enhancement	1.20 (1.05;1.30)	1.20 (1.05 ; 1.30)	1.10 (1.05 ; 1.30)	0.93 (0.90-0.95) *	0.34 '
Target localization:					
1. Transitional zone	28 (19.44 %)	23 (20.00)	5 (17.24)	0.63 (0.46-0.79) ***	0.74 ""
Peripheral zone	116 (80.56 %)	92 (80.00)	24 (82.76)		
2. Anterior	60 (41.67 %)	49 (42.61)	11 (37.93)	0.82 (0.72-0.91) ***	0.65 ""
Posterior	84 (58.33 %)	66 (57.39)	18 (62.07)		
Peripheral zone ADC:					
Ipsilateral	0.86 (0.79;0.95)	0.86 (0.79 ; 0.96)	0.86 (0.81 ; 0.95)	0.58 (0.46-0.68) *	0.59 """
Contralateral	0.87 (0.79;0.96)	0.87 (0.78 ; 0.97)	0.87 (0.82 ; 0.91)	0.68 (0.58-0.76) *	0.94 '
Peripheral zone T2 (ipsilateral):					
1	48 (33.33 %)	38 (33.04)	10 (34.48)	0.49 (0.37-0.61) **	0.85 "
2	75 (52.08 %)	61 (53.04)	14 (48.28)		
3	21 (14.58 %)	16 (13.91)	5 (17.24)		

Peripheral zone T2 (contralateral):					
1	46 (31.94 %)	40 (34.78)	6 (20.69)	0.54 (0.42-0.66) **	0.23 "
2	78 (54.17 %)	58 (50.43)	20 (68.97)		
3	20 (13.89 %)	17 (14.78)	3 (10.34)		

Table 3. Bi-variable analysis for variables predicting prostate cancer missed in targeted biopsies but detected in randomized biopsies. *: Bland-Altman / **: Weighted k / ***: Simple k. ': WMW test / "': FISHER test / "": CHI 2 test / "": STUDENT test

Discussion

In the current study, we postulated that some patients who are candidates for prostate biopsy and who have a positive mpMRI, may sometimes be eligible to a targeted biopsy strategy alone by leaving the randomised biopsies. Unfortunately, we were unable to find some conditions under which systematic biopsy could be safely avoided in men with positive MRI.

The predictive factors most described in the literature such as PIRADS score or PSA density (12,13) did not show a significant association in our study (respectively p=0.15 and p=0.22). This is probably due to 2 main factors. First, we have a limited number of patients. Indeed, the majority of studies with positive results on this subject had larger number of patients (ranging from 251 patients in Günzel's cohort (12) to 441 patients in Dell'Oglio's North American cohort (11), vs 144 in our study). Our data could thus be completed by adding new patients to increase statistical power.

Second, we didn't use the same gold standard to define the usefulness of randomised biopsies. We considered that RB are helpful if the ISUP is greater than targeted ones or if the tumoral length was greater, but in the literature (1,4,5,11,13), RB are considered useful if they detected lesion \geq ISUP 2 whatever the ISUP grade on the target and/or if the positive length of

RB is greater than 5 mm on a core. Even if this strategy looks relevant at first sight, it is not really relevant from a clinical point of view. Indeed, management strategy is mainly based on the higher grade detected by biopsies that determine the prostate cancer risk group according to D'Amico. Then, does the therapeutic strategy will change if RB find ISUP 2 but targeted ones find ISUP 3? The care decision will probably be based on the ISUP 3 grade and the detection of grade 2 in the RB would not change anything as prostate treatment remains to date a global one on the whole prostate. On the other hand, is it totally useless to detect ISUP 1 in RB if the number of positive core exceed half of the biopsies and if the target biopsy is negative? This situation represented 16/144 patients in our cohort (11%), that will indicate at least active surveillance. Does this situation belong to an overtreatment situation? We think that our definition of the usefulness of the RB enables to better integrate the therapeutic impact of biopsies but it explains the discrepancies between our results and the literature. Only Günzel et al. (12) to our knowledge designed their study as ours by assessing the predictors for equal/superior detection of the PCa risk group by TB compared to RB. They found a single predictive factor (free/total PSA ratio \leq 0.15) on multivariate regression analysis of their 251 consecutive patients to select men eligible for a sole MRI/US fusion-guided targeted prostate biopsy.

Anyhow, our population was comparable to those of the main studies conducted on the subject (10–14). In particular, we observed that randomized biopsies found more non-significant cancer than targeted biopsies (62.7 % of positive biopsies for RB vs 40.4 % for TB) which is consistent with the MRI-first cohort (5) and the Ahdoot et al. one (19) that found, respectively, a significant higher rate of non-clinically significant prostate cancer for randomized biopsies (19.5 and 21.6%) than for targeted biopsies (5.6 and 13.7%). Moreover, 29 patients (20.1 %) had theoretical usefulness for the randomized biopsies in our study similar to the 19 % published in Günzel's one, including 13 patients (9 %) showing a significant cancer that is comparable to the

published missed significant cancer by TB ranging from 5.2 to 16% (5,11,13). We also corroborated the Ahdoot et al (19) findings by showing that combined biopsy improves the likelihood that the biopsy findings are predictive of the true pathologic nature of the patient's disease on prostatectomy specimens. Indeed, we showed that 50% of the combined biopsies were concordant with final histopathology, that is close to the 64% reported by Ahdoot et al in their study including 404 patients with prostatectomies.

One could criticise our selection criteria. Indeed, we included some patients with a PIRADS 2 target, and others with a history of biopsy, positive or not, thus including a substantial number of patients on active surveillance ($n = 44$, 30.56%). The presence of patients on active surveillance probably explains the fact that there is a non-significant association ($p=0.07$) between the usefulness of randomized biopsies and a personal history of prostate biopsies. Indeed, in our study, randomized biopsies seemed to be more useful for patients with a previous biopsy history than for naïve ones. This result is surprising especially in comparison with Sathianathan's study (10) which found that patients with a previous negative biopsy being less likely to have clinically significant cancer missed on targeted cores compared to patients undergoing primary biopsy (OR 0.19, 95% IC 0.05-0.52). However, patients on active surveillance had previous positive biopsies, most often including ISUP 1 score, which is usually found incidentally on randomized biopsies when the targeted biopsies are negative. These patients are then more likely to have useful randomized biopsies when biopsies sets are repeated.

Our population was investigated with a rigorous methodology including a same standardised MRI protocol on a single MRI tool, and a standardised prostate biopsies protocol using an elastic MRI-US fusion method. To our knowledge, we are the first to study specifically MRI parameters and in particular the peripheral off-target area, as well as the ERSPC score as

predictors for the usefulness of RB. Our study emphasises the complexity of the peripheral off-target area in prostate imaging, which is often the site of chronic inflammatory findings. Although our readers are trained in prostate imaging, inter-observer agreement is fair to good for ADC measurements (0.58 and 0.68) and for T2 signal analysis (0.49 and 0.54) of the peripheral off-target area. This could be explained by the difference in experience between the two readers, and also by the fact that those findings are quite subjective and are not used in daily practice.

We believe that more advanced techniques especially artificial intelligence with deep-learning should be investigated in the analysis of the off-target peripheral zone in order to find predictive radiomics allowing to better identify areas of aggressive cancer to avoid randomised biopsies. As these techniques are of very recent experimentation, the majority of studies looking for prostate imaging biomarkers has focused on tumor detection. Only few studies have investigated radiomics to predict prostate cancer aggressiveness (20,21) showing promising but still weak results. These new biomarkers should be the aim of further studies by defining the usefulness of the RB from a clinical point of view.

Conclusion

We were not able to show any predictive factors to select patients for whom randomized biopsies could be dropped when there was a target on prostate MRI. The combination of targeted biopsies and randomized biopsies should still be required.

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Biopsies prostatiques en présence d'une lésion cible en IRM : quand peut-on se passer des biopsies non ciblées ?

IRB ID : 202000698

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This notice does not relieve the Study principal Investigator of the obligations under the processing of personal datum

Serment

En présence des Maîtres de cette école, de mes chers condisciples et devant l'effigie d'Hippocrate, je promets et je jure, au nom de l'Etre suprême, d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la médecine.

Je donnerai mes soins gratuits à l'indigent et n'exigerai jamais un salaire au-dessus de mon travail.

Admis dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés, et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.

Respectueux et reconnaissant envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les hommes m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.

Résumé

Objectif : Évaluer dans quelle(s) situation(s) (clinique, biologique et IRM), les biopsies ciblées permettraient à elles seules de sélectionner le plus haut groupe à risque du cancer de la prostate pour un patient donné. Nous estimons que les biopsies randomisées ont peu d'impact thérapeutique lorsqu'elles ont un ISUP plus faible que les biopsies ciblées.

Matériel et méthode : Dans une cohorte de 144 patients consécutifs ayant eu la combinaison de biopsies ciblées (technique de fusion d'images IRM/échographie) et 12 biopsies randomisées entre juin 2017 et mars 2020, nous avons recueilli rétrospectivement les paramètres cliniques (âge, toucher rectal, antécédents personnels de biopsie de la prostate, antécédents familiaux de cancer de la prostate, score ERSPC 3-4 et 6), biologiques (PSA et densité de PSA) et IRM (données quantitatives et qualitatives sur la cible principale et la zone périphérique hors cible). Deux groupes de patients ont été définis en fonction des scores ISUP obtenus sur les biopsies ciblées et randomisées, et de la longueur maximale de positivité des biopsies en cas d'ISUP égal. Nous avons effectué une analyse univariée et bivariée des variables identifiées pour prédire dans quelle situation les biopsies randomisées avaient un score ISUP inférieur aux biopsies ciblées. Des analyses de concordance inter-observateur ont été réalisées pour chaque variable.

Résultats : L'âge moyen de notre cohorte était de 67 ans (IQR : 61-72) et le taux moyen de PSA était de 9,7 ng/mL (IQR : 5,5 - 11). Au total, 30 patients (20.8%) n'avaient pas de cancer. Parmi les 114 patients ayant eu un cancer, 85 (74,6%) avaient un score ISUP plus élevé sur les biopsies ciblées que sur les biopsies randomisées, contre 29 patients (25.6%) dans le cas inverse. De toutes les variables étudiées, aucune n'a montré une différence significative entre les deux groupes.

Conclusion : Notre cohorte ne nous a pas permis de trouver des facteurs prédictifs qui permettrait de sélectionner les patients pour lesquels les biopsies randomisées pourraient être délaissées parmi ceux ayant une cible à l'IRM prostatique. La réalisation d'une combinaison de biopsies ciblées et de biopsies randomisées devrait encore être recommandée.

Mots clés : Cancer de la prostate, IRM multiparamétrique, fusion IRM-échographie, biopsies ciblées, biopsies randomisées, ISUP score.