KOELIS
BEST PAPERS

Summary

1.1 MRI/US targeted biopsy

3D versus 2D Systematic Transrectal Ultrasound-Guided Prostate Biopsy: Higher Cancer Detection Rate in Clinical Practice

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Prostate Cancer - 2013

PURPOSE: To compare prostate cancer detection rates of extended 2D versus 3D biopsies and to further assess the clinical impact of this method in day-to-day practice.

MATERIALS AND METHODS: We analyzed the data of a cohort of 220 consecutive patients with no prior history of prostate cancer who underwent an initial prostate biopsy in daily practice due to an abnormal PSA and/or DRE using, respectively, the classical 2D and the new 3D systems. All the biopsies were done by a single experienced operator using the same standardized protocol.

RESULTS: There was no significant difference in terms of age, total PSA, or prostate volume between the two groups. However, cancer detection rate was significantly higher using the 3D versus the 2D system, 50% versus 34% (P < 0.05). There was no statistically significant difference while comparing the 2 groups in term of nonsignificant cancer detection.

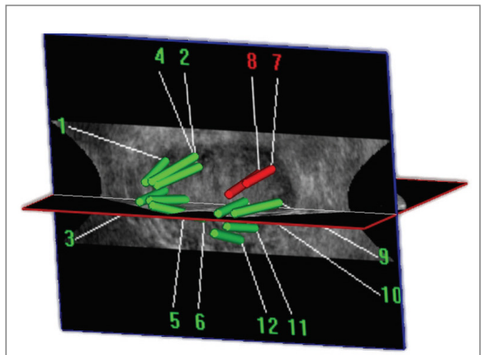

Figure 1. *3D trajectory visualization after biopsy along with mapping and cartography.*

CONCLUSIONS: There is reasonable evidence demonstrating the superiority of the 3D-guided biopsies in detecting prostate cancers that would have been missed using the 2D extended protocoll.

1.1 MRI/US targeted biopsy

First round of targeted biopsies using magnetic resonance imaging/ultrasonography fusion compared with conventional transrectal ultrasonography-guided biopsies for the diagnosis of localised prostate cancer

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BJU Int. - 2015

OBJECTIVE: To assess the accuracy of magnetic resonance imaging (MRI)/transrectal ultrasonography (TRUS) fusion to guide first-round biopsies in the diagnosis of localised prostate cancer (PCa) in men with a prostate-specific antigen (PSA) ≤10 ng/mL.

PATIENTS AND METHODS: A prospective study was conducted on men who met the following criteria: first-round biopsy, multiparametric MRI (mpMRI) showing a lesion with a Likert score ≥2 and a PSA <10 ng/mL. All men underwent a extended 12-core protocol plus a protocol of two or three targeted cores on the mpMRI index lesion. The UroStation (KOELIS®, Grenoble, France) and a V10 ultrasound system with an end-fire three-dimensional TRUS transducer were used for the fusion imaging procedure. Significant PCa was defined as: at least one core with a Gleason score of 3 + 4 or 6 with a maximum cancer core length ≥4 mm.

RESULTS: A total of 152 men, whose median PSA level was 6 ng/mL, were included in the study. The proportion of positive cores was significantly higher with the targeted-core protocol than with the extended 12-core protocol (P < 0.001). The proportion of men with clinically significant PCa was higher with the targeted-core protocol than with the extended 12-core protocol (P = 0.03). The proportion of patients having at least one positive biopsy (targeted-core protocol) was significantly different among the Likert score categories (P < 0.001).

CONCLUSIONS: For the first round of biopsies, MRI/TRUS-fusion targeted biopsies detected more men with clinically significant PCa than did standard extended 12-core biopsy alone.

	EXTENDED 12-CORE PROTOCOL	TARGETED CORE PROTOCOL	P
Cores positive for clinically signifiant PCa, %	7.5	31	<0.001
Men with clinically signifiant PCa detected, %	37	43	0.03
Median number of cores taken per for clinically signifiant PCa	12	2	<0.001
Median (IQR) length of positive cores, mm	4 (2-8)	8 (5-10)	<0.001

PCa, prostate cancer ; IQR, interquartile range

Table 1. *Comparisons of the two biopsy protocols (N = 152).*

Prostate Imaging Reporting and Data System and Likert Scoring System: Multiparametric MR Imaging Validation Study to Screen Patients for Initial Biopsy

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Radiology - 2015

PURPOSE: To compare the diagnostic performance of the magnetic resonance (MR) imaging-based Prostate Imaging Reporting and Data System (PI-RADS) and a Likert scale in the detection of prostate cancer in a cohort of patients undergoing initial prostate biopsy.

MATERIALS AND METHODS: This institutional review board-approved two-center prospective study included 118 patients with normal digital rectal examination (DRE) results but elevated prostate-specific antigen (PSA) levels (4-20 ng/mL) who were referred for initial prostate biopsies and had one suspicious (Likert scale score, ≥3) focus at prebiopsy 1.5-T multiparametric MR imaging performed with T2-weighted, diffusion-weighted [DW], and dynamic contrast material-enhanced imaging. Targeted core biopsies and random systematic core biopsies were performed. The elementary unit for analysis was the core. Relationships were assessed by using the Mann-Whitney U test. Yates corrected and Pearson X(2) tests were used to evaluate categoric variables. A training set was randomly drawn to construct the receiver operating characteristic curves for the summed PI-RADS scores and for the Likert scale scores. The thresholds to recommend biopsy were obtained from the Youden J statistics and were tested in the remaining validation set in terms of predictive characteristics. Interobserver variability was analyzed by using weighed k statistics in a random set of 50 patients.

RESULTS: Higher T2-weighted, DW, and dynamic contrast-enhanced imaging PI-RADS scores were observed in areas that yielded cancer-positive cores. The percentage of positive cores increased with the sum of scores aggregated in five classes as follows: For summed PI-RADS scores of 3-5, the percentage of positive cores was 2.3%; for scores of 6-8, it was 5.8%; for scores of 9 or 10, it was 24.7%; for scores of 11 or 12, it was 51.8%; and for scores of 13-15, it was 72.1% (P for trend, <.0001). For the threshold of summed PI-RADS scores of 9 or greater, sensitivity was 86.6%, specificity was 82.4%, the positive predictive value was 52.4%, the negative predictive value was 96.5%, and accuracy was 83.2%. The respective data for Likert scale scores of 3 or greater were 93.8%, 73.6%, 44.3%, 98.1%, and 73.3%. Good interobserver agreement was observed for the Likert scale (k = 0.80) and the summed PI-RADS (k = 0.73) scoring systems.

CONCLUSIONS: PI-RADS provided the site-specific stratified risk of cancer-positive cores in biopsy-naive men with normal DRE results and elevated PSA levels. There was no significant difference between summed PI-RADS scores of 9 or greater and Likert scale scores of 3 or greater in the detection of cancer in the peripheral zone.

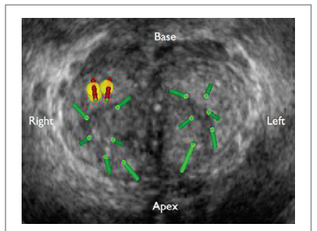

Figure 1. Three-dimensional transrectal US fused image shows the location in the 1o sector of a suspicious focus (yellow; summed PI-RADS score at multiparametric MR imaging, 14) that was targeted by two targeted (red) cores in complement to 12 random (green) systematic cores in a 61-mL prostate.

A Randomized Controlled Trial To Assess and Compare the Outcomes of Two-core Prostate Biopsy Guided by Fused Magnetic Resonance and Transrectal Ultrasound Images and Traditional 12-core Systematic Biopsy

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Eur Urol. - 2016

PURPOSE: Prostate biopsy guided by computer-assisted fusion of magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) images (MRI group) has not yet been compared with 12-core random biopsy (RB; control group) in a randomized controlled trial (RCT).

OBJECTIVE: To compare the rate of detection of clinically significant prostate cancer (csPCa) between the two groups.

DESIGN, SETTING, AND PARTICIPANTS: This RCT included 175 biopsy-naïve patients with suspicion for prostate cancer, randomized to an MRI group (n=86) and a control group (n=89) between September 2011 and June 2013.

INTERVENTION: In the MRI group, two-core targeted biopsy (TB) guided by computer-assisted fusion of MRI/TRUS images of MRI-suspicious lesions was followed by 12-core RB. In the control group, both two-core TB for abnormal digital rectal examination (DRE) and/or TRUS-suspicious lesions and 12-core RB were performed. In patients with normal MRI or DRE/TRUS, only 12-core RB was performed.

OUTCOMES MEASUREMENTS AND STATISTICAL ANALYSIS: The detection rates for any cancer and csPCa were compared between the two groups and between TB and RB.

RESULTS AND LIMITATIONS: Detection rates for any cancer (MRI group 51/86, 59%; control group 48/89, 54%; p=0.4) and csPCa (38/86, 44% vs 44/89, 49%; p=0.5) did not significantly differ between the groups. Detection of csPCa was comparable between two-core MRI/TRUS-TB (33/86, 38%) and 12-core RB in the control group (44/89, 49%; p=0.2). In a subset analysis of patients with normal DRE, csPCa detection was similar between two-core MRI/TRUS-TB (14/66, 21%) and 12-core RB in the control group (15/60, 25%; p=0.7). Among biopsy-proven csPCas in MRI group, 87% (33/38) were detected by MRI/TRUS-TB. The definition of csPCa was only based on biopsy outcomes.

CONCLUSIONS: Overall csPCa detection was similar between the MRI and control groups. Two-core MRI/TRUS-TB was comparable to 12-core RB for csPCa detection.

PATIENT SUMMARY: Our randomized controlled trial revealed a similar rate of prostate cancer detection between targeted biopsy guided by magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) and 12-core random biopsy. The traditional 12-core random biopsy may be replaced by two-core MRI/TRUS targeted biopsy for detection of clinically significant prostate cancer.

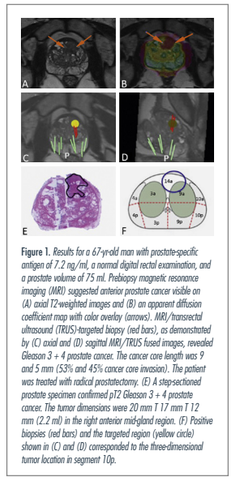

Figure 1. *Results for a 67-yr-old man with prostate-specific antigen of 7.2 ng/ml, a normal digital rectal examination, and a prostate volume of 75 ml. Prebiopsy magnetic resonance imaging (MRI) suggested anterior prostate cancer visible on (A) axial T2-weighted images and (B) an apparent diffusion coefficient map with color overlay (arrows). MRI/transrectal ultrasound (TRUS)-targeted biopsy (red bars), as demonstrated by (C) axial and (D) sagittal MRI/TRUS fused images, revealed Gleason 3 + 4 prostate cancer. The cancer core length was 9 and 5 mm (53% and 45% cancer core invasion). The patient was treated with radical prostatectomy. (E) A step-sectioned prostate specimen confirmed pT2 Gleason 3 + 4 prostate cancer. The tumor dimensions were 20 mm T 17 mm T 12 mm (2.2 ml) in the right anterior mid-gland region. (F) Positive biopsies (red bars) and the targeted region (yellow circle) shown in (C) and (D) corresponded to the three-dimensional tumor location in segment 10p.*

1.1 MRI/US targeted biopsy

Detection of prostate cancer using MRI-Ultrasonography image-fusion targeted biopsy in African-American men

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BJU Int. - 2017

OBJECTIVE: To assess the diagnostic yield of targeted prostate biopsy in African-American (A-A) men using image fusion of multi-parametric magnetic resonance imaging (mpMRI) with real-time transrectal ultrasonography (US).

MATERIALS AND METHODS: We retrospectively analysed 661 patients (117 A-A and 544 Caucasian) who had mpMRI before biopsy and then underwent MRI/US image-fusion targeted biopsy (FTB) between October 2012 and August 2015. The mpMRIs were reported on a 5-point Likert scale of suspicion. Clinically significant prostate cancer (CSPC) was defined as biopsy Gleason score ≥7.

RESULTS: After controlling for age, prostate-specific antigen level and prostate volume, there were no significant differences between A-A and Caucasian men in the detection rate of overall cancer (35.0% vs 34.2%, P = 0.9) and CSPC (18.8% vs 21.7%, P = 0.3) with MRI/US FTB. There were no significant differences between the races in the location of dominant lesions on mpMRI, and in the proportion of 5-point Likert scoring. In A-A men, MRI/US FTB from the grade 4-5 lesions outperformed random biopsy in the detection rate of overall cancer (70.6% vs 37.2%, P = 0.003) and CSPC (52.9% vs 12.4%, P < 0.001). MRI/US FTB outperformed random biopsy in cancer core length (5.0 vs 2.4 mm, P = 0.001), in cancer rate per core (24.9% vs 6.8%, P < 0.001), and in efficiency for detecting one patient with CSPC (mean number of cores needed 13.3 vs 81.9, P < 0.001), respectively.

CONCLUSIONS: Our key finding confirms a lack of racial difference in the detection rate of overall prostate cancers and CSPC with MRI/US FTB between A-A and Caucasian men. MRI/US FTB detected more CSPC using fewer cores compared with random biopsy.

1.1 MRI/US targeted biopsy

Transrectal Ultrasound-Guided Prostate Biopsy for Cancer Detection: Performance of 2D-, 3D- and 3D-MRI Fusion Targeted Techniques

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Urol Int. - 2017

INTRODUCTION: The study aimed to evaluate 3 different modalities of transrectal ultrasound (TRUS)-guided prostate biopsies (PBs; 2D-, 3D- and targeted 3D-TRUS with fusion to MRI – T3D). Primary end point was the detection rate of prostate cancer (PC). Secondary end point was the detection rate of insignificant PC according to the Epstein criteria.

MATERIALS AND METHODS: Inclusion of 284 subsequent patients who underwent 2D-, 3D- or T3D PB from 2011 to 2015. All patients having PB for initial PC detection with a serum prostate-specific antigen value ≤20 ng/ml were included. Patients with T4 and/or clinical and/or radiological metastatic disease, so as these under active surveillance were excluded..

RESULTS: Patients with T3D PB had a significantly higher detection rate of PC (58 vs. 19% for 2D and 38% for 3D biopsies; p = 0.001), with no difference in Gleason score distribution (p = 0.644), as well as detection rate of low-risk cancers (p = 0.914). Main predictive factor for positive biopsies was the technique used, with respectively a 3- and 8-fold higher detection rate in the 3D- and T3D group. For T3D-PB, there was a significant correlation between radiological cancer suspicion (Prostate Imaging Reporting and Data System Score) and cancer detection rate (p = 0.02).

CONCLUSIONS: T3D PB should be preferred over 2D PB and 3D PB in patients with suspected PC as it improves the cancer detection rate.

1.1 MRI/US targeted biopsy

Accuracy of elastic fusion biopsy in daily practice: Results of a multicenter study of 2115 patients

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Int J Urol. - 2018

OBJECTIVES: To assess the accuracy of KOELIS® fusion biopsy for the detection of prostate cancer and clinically significant prostate cancer in the everyday practice.

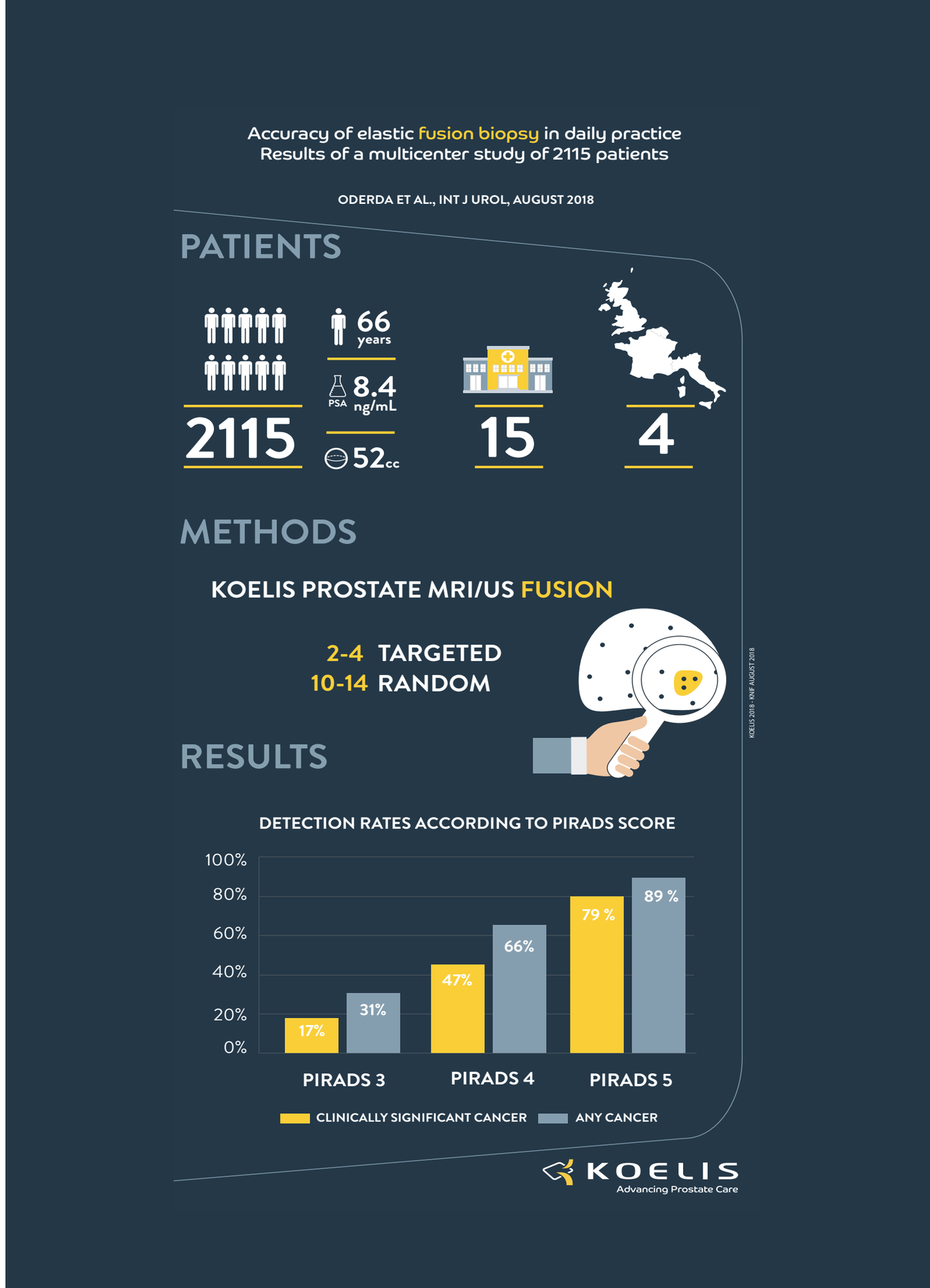
METHODS: We retrospectively enrolled 2115 patients from 15 institutions in four European countries undergoing transrectal KOELIS® fusion biopsy from 2010 to 2017. A variable number of target (usually 2-4) and random cores (usually 10-14) were carried out, depending on the clinical case and institution habits. The overall and clinically significant prostate cancer detection rates were assessed, evaluating the diagnostic role of additional random biopsies. The cancer detection rate was correlated to multiparametric magnetic resonance imaging features and clinical variables.

RESULTS: The mean number of targeted and random cores taken were 3.9 (standard deviation 2.1) and 10.5 (standard deviation 5.0), respectively. The cancer detection rate of KOELIS® biopsies was 58% for all cancers and 43% for clinically significant prostate cancer. The performance of additional, random cores improved the cancer detection rate of 13% for all cancers (P < 0.001) and 9% for clinically significant prostate cancer (P < 0.001). Prostate cancer was detected in 31%, 66% and 89% of patients with lesions scored as Prostate Imaging Reporting and Data System 3, 4 and 5, respectively. Clinical stage and Prostate Imaging Reporting and Data System score were predictors of prostate cancer detection in multivariate analyses. Prostate-specific antigen was associated with prostate cancer detection only for clinically significant prostate cancer.

CONCLUSIONS: KOELIS® fusion biopsy offers a good cancer detection rate, which is increased in patients with a high Prostate Imaging Reporting and Data System score and clinical stage. The performance of additional, random cores seems unavoidable for correct sampling. In our experience, the Prostate Imaging Reporting and Data System score and clinical stage are predictors of prostate cancer and clinically significant prostate cancer detection; prostate-specific antigen is associated only with clinically significant prostate cancer detection, and a higher number of biopsy cores are not associated with a higher cancer detection rate.

	Target biopsies only	Target + random biopsies	*P*
PCa detection on biopsy			
CDR	965 (45.6%)	1230 (58.2%)	<0.001
PCa Gleason score			
GS 6	357 (37.3%)	461 (40.1%)	0.14
GS 7	437 (45.7%)	493 (42.8%)	0.25
GS 8-10	162 (16.9%)	197 (17.1%)	0.86
Missing	9	79	
PCa detection according to DRE			
Negative	494 (65.9%)	664 (69.0%)	0.17
Positive	256 (34.1%)	299 (31.0%)	0.17
Missing	215	266	
PCa detection according to size			
<10 mm	256 (45.6%)	305 (46.7%)	0.70
≥10 mm	305 (54.4%)	348 (53.3%)	0.70
Missing	404	577	
PCa detection according to PI-RADS			
3	144 (15.7%)	208 (17.8%)	0.20
4	450 (49.0%)	595 (51.0%)	0.36
5	325 (35.4%)	363 (31.1%)	0.03
Missing	46	64	
PCa detection according to previous biopsy			
Biopsy naïve	371 (52.9%)	420 (48.6%)	0.08
Previous negative biopsies	299 (42.7%)	393 (45.4%)	0.27
Patients in active surveillance	31 (4.4%)	52 (6%)	0.16
Missing	264	365	
Clinically significant PCa detection on biopsy			
Clinically significant CDR	716 (33.9%)	909 (43.0%)	<0.001
Clinically significant PCa detection according to PI-RADS			
3	77 (11.3%)	114 (13.2%)	0.29
4	334 (48.9%)	426 (49.4%)	0.84
5	272 (39.8%)	323 (37.4%)	0.36
Missing	33	48	

Figure 1. *Biopsy results in terms of PCa and clinically significant PCa detection, comparing target biopsies only with target + random biopsies*



MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis

Kasivisvanathan V, M.R.C.S., Rannikko A.S, Borghi M, Panebianco V, Mynderse L.A,Vaarala M.H, Briganti A, Budäus L, Hellawell G, F.R.C.S.(Urol.), Hindley R.G, F.R.C.S.(Urol.), Monique J. Roobol M.J, Scott Eggener S, et al., for the PRECISION Study Group Collaborators*

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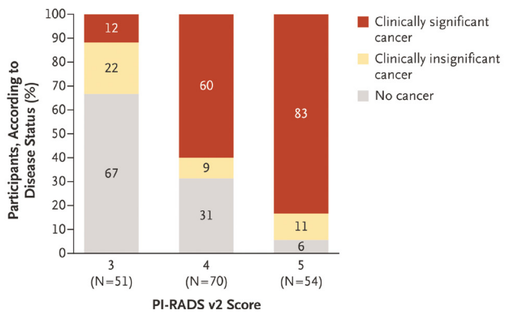
N Engl J Med. - 2018

BACKGROUND: Multiparametric magnetic resonance imaging (MRI), with or without targeted biopsy, is an alternative to standard transrectal ultrasonography–guided biopsy for prostate-cancer detection in men with a raised prostate-specific antigen level who have not undergone biopsy. However, comparative evidence is limited.

METHODS: In a multicenter, randomized, noninferiority trial, we assigned men with a clinical suspicion of prostate cancer who had not undergone biopsy previously to undergo MRI, with or without targeted biopsy, or standard transrectal ultrasonography–guided biopsy. Men in the MRI-targeted biopsy group underwent a targeted biopsy (without standard biopsy cores) if the MRI was suggestive of prostate cancer; men whose MRI results were not suggestive of prostate cancer were not offered biopsy. Standard biopsy was a 10-to-12–core, transrectal ultrasonography–guided biopsy. The primary outcome was the proportion of men who received a diagnosis of clinically significant cancer. Secondary outcomes included the proportion of men who received a diagnosis of clinically insignificant cancer.

RESULTS: A total of 500 men underwent randomization. In the MRI-targeted biopsy group, 71 of 252 men (28%) had MRI results that were not suggestive of prostate cancer, so they did not undergo biopsy. Clinically significant cancer was detected in 95 men (38%) in the MRI-targeted biopsy group, as compared with 64 of 248 (26%) in the standard-biopsy group (adjusted difference, 12 percentage points; 95% confidence interval [CI], 4 to 20; P=0.005). MRI, with or without targeted biopsy, was noninferior to standard biopsy, and the 95% confidence interval indicated the superiority of this strategy over standard biopsy. Fewer men in the MRI-targeted biopsy group than in the standard-biopsy group received a diagnosis of clinically insignificant cancer (adjusted difference, −13 percentage points; 95% CI, −19 to −7; P<0.001).

CONCLUSIONS: The use of risk assessment with MRI before biopsy and MRI-targeted biopsy was superior to standard transrectal ultrasonography–guided biopsy in men at clinical risk for prostate cancer who had not undergone biopsy previously. (Funded by the National Institute for Health Research and the European Association of Urology Research Foundation; PRECISION ClinicalTrials.gov number, NCT02380027.)



Percentages of Men with Clinically Significant, Clinically Insignificant, and No Cancer, Identified According to PI-RADS v2 Score

Use of prostate systematic and targeted biopsy on the basis of multiparametric MRI in biopsy-naive patients (MRI-FIRST): a prospective, multicentre, paired diagnostic study

Rouvière O, Puech P, Renard-Penna R, Claudon M, Roy C, Mège-Lechevallier F, Decaussin-Petrucci M, Dubreuil-Chambardel M, Magaud L, Remontet L, Ruffion A, Colombel M, Crouzet S, Schott A, Lemaitre L, Rabilloud M, Grenier N, for the MRI-FIRST Investigators*

Service d'Imagerie Urinaire et Vasculaire (Prof O Rouvière MD, M Dubreuil-Chambardel PhD), Service d'Anatomo-Pathologie (F Mège-Lechevallier MD), and Service d'Urologie (Prof M Colombel MD, Prof S Crouzet MD), Hôpital Edouard Herriot, Service d'Urologie (Prof A Ruffion MD), Service d'Anatomo-Pathologie (M Decaussin-Petrucci MD), Center Hospitalier Lyon Sud, Pôle de Santé Publique (L Magaud PhD, Prof A-M Schott MD), and Service de Biostatistique et Bioinformatique (L Remontet MD, M Rabilloud MD), Hospices Civils de Lyon, Lyon, France; Faculté de Médecine Lyon Est (Prof O Rouvière, Prof M Colombel, Prof S Crouzet) and Faculté de Médecine Lyon Sud (M Decaussin-Petrucci) Université Lyon 1, Université de Lyon (L Remontet, M Rabilloud), Lyon, France; Service de Radiologie, CHU Lille, INSERM, Université de Lille, Lille, France (Prof P Puech MD, Prof L Lemaitre MD); U1189 - ONCO-THAI - Image Assisted Laser Therapy for Oncology, Lille, France (Prof P Puech, Prof L Lemaitre); Services de Radiologie, Hôpitaux Tenon et Pitié Salpétrière, AP-HP, GRC-UPMC n°5 Oncotype-URO, Sorbonne Universités, Paris, France (Prof R Renard-Penna MD) ; IADI, INSERM, Université de Lorraine, Nancy, France

Lancet Oncol. - 2019

BACKGROUND: Whether multiparametric MRI improves the detection of clinically significant prostate cancer and avoids the need for systematic biopsy in biopsy-naive patients remains controversial. We aimed to investigate whether using this approach before biopsy would improve detection of clinically significant prostate cancer in biopsy-naive patients.

METHODS: In this prospective, multicentre, paired diagnostic study, done at 16 centres in France, we enrolled patients aged 18–75 years with prostate-specific antigen concentrations of 20 ng/mL or less, and with stage T2c or lower prostate cancer. Eligible patients had been referred for prostate multiparametric MRI before a first set of prostate biopsies, with a planned interval of less than 3 months between MRI and biopsies. An operator masked to multiparametric MRI results did a systematic biopsy by obtaining 12 systematic cores and up to two cores targeting hypoechoic lesions. In the same patient, another operator targeted up to two lesions seen on MRI with a Likert score of 3 or higher (three cores per lesion) using targeted biopsy based on multiparametric MRI findings. Patients with negative multiparametric MRI (Likert score ≤2) had systematic biopsy only. The primary outcome was the detection of clinically significant prostate cancer of International Society of Urological Pathology grade group 2 or higher (csPCa-A), analysed in all patients who received both systematic and targeted biopsies and whose results from both were available for pathological central review, including patients who had protocol deviations. This study is registered with ClinicalTrials.gov, number NCT02485379, and is closed to new participants.

FINDINGS: Between July 15, 2015, and Aug 11, 2016, we enrolled 275 patients. 24 (9%) were excluded from the analysis. 53 (21%) of 251 analysed patients had negative (Likert ≤2) multiparametric MRI. csPCa-A was detected in 94 (37%) of 251 patients. 13 (14%) of these 94 patients were diagnosed by systematic biopsy only, 19 (20%) by targeted biopsy only, and 62 (66%) by both techniques. Detection of csPCa-A by systematic biopsy (29·9%, 95% CI 24·3–36·0) and targeted biopsy (32·3%, 26·5–38·4) did not differ significantly (p=0·38). csPCa-A would have been missed in 5·2% (95% CI 2·8–8·7) of patients had systematic biopsy not been done, and in 7·6% (4·6–11·6) of patients had targeted biopsy not been done. Four grade 3 post-biopsy adverse events were reported (3 cases of prostatitis, and 1 case of urinary retention with haematuria).

INTERPRETATION: There was no difference between systematic biopsy and targeted biopsy in the detection of ISUP grade group 2 or higher prostate cancer; however, this detection was improved by combining both techniques and both techniques showed substantial added value. Thus, obtaining a multiparametric MRI before biopsy in biopsy-naive patients can improve the detection of clinically significant prostate cancer but does not seem to avoid the need for systematic biopsy.

1.1 MRI/US targeted biopsy

Improvement of the intermediate risk prostate cancer sub-classification by integrating MRI and fusion biopsy features

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Urol Oncol. - 2020

INTRODUCTION: Treatment decision-making for intermediate-risk prostate cancer (CaP) is mainly based on grade and tumor involvement on systematic biopsy. We aimed to assess the added value of multi-parametric magnetic resonance imaging (mpMRI) and targeted biopsy (TB) features for predicting final pathology and for improving the well-established favourable/unfavourable systematic biopsy-based sub-classification.

MATERIALS AND METHODS: From a prospective database of 377 intermediate risk CaP cases, we evaluated the performance of the standard intermediate risk classification (IRC), and the predictive factors for unfavourable disease on final pathology aiming to build a new model. Overall unfavourable disease (OUD) was defined by any pT3-4 and/or pN1 and/or grade group (GG) ≥ 3.

RESULTS: The standard IRC was found to be predictive for unfavourable disease in this population. However, in multivariable analysis regression, ECE on mpMRI and GG ≥3 on TB remained the 2 independent predictive factors for OUD disease (HR = 2.7, P = 0.032, and HR = 2.41, P = 0.01, respectively). By using the new IRC in which unfavorable risk was defined by ECE on mpMRI and/or GG ≥3 on TB, the proportion of unfavorable cases decreased from 62.3% to 34.1% while better predicting unfavorable disease in RP speciments. The new model displayed a better accuracy than the standard IRC for predicting OUD (AUC: 0.66 vs. 0.55).

CONCLUSIONS: The integration of imaging and TB features drastically improves the intermediate risk sub-classification performance and better discriminates the unfavourable risk group that could benefit from more aggressive therapy such as neo-adjuvant and/or adjuvant treatment, and the favourable group that could avoid over-treatment. External validation in other datasets is needed.

1.1 MRI/US targeted biopsy

Techniques and Outcomes of MRI-TRUS Fusion Prostate Biopsy

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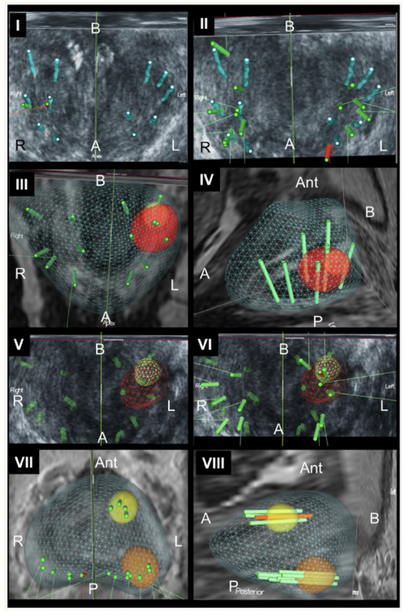
Curr Urol Rep. - 2021

PURPOSE OF REVIEW: The goal of this study is to review recent findings and evaluate the utility of MRI transrectal ultrasound fusion biopsy (FBx) techniques and discuss future directions.

RECENT FINDINGS: FBx detects significantly higher rates of clinically significant prostate cancer (csPCa) than ultrasound-guided systematic prostate biopsy (SBx), particularly in repeat biopsy settings. FBx has also been shown to detect significantly lower rates of clinically insignificant prostate cancer. In addition, a dedicated prostate MRI can assist in more accurately predicting the Gleason score and provide further information regarding the index cancer location, prostate volume, and clinical stage. The ability to accurately evaluate specific lesions is vital to both focal therapy and active surveillance, for treatment selection, planning, and adequate follow-up.

SUMMARY: FBx has been demonstrated in multiple high-quality studies to have improved performance in diagnosis of csPCa compared to SBx. The combination of FBx with novel technologies may have the potential to further enhance this performance.



Techniques and strategies for prostate biopsy.

1.1 MRI/US targeted biopsy

Optimizing MRI-targeted prostate biopsy: the diagnostic benefit of additional targeted biopsy cores

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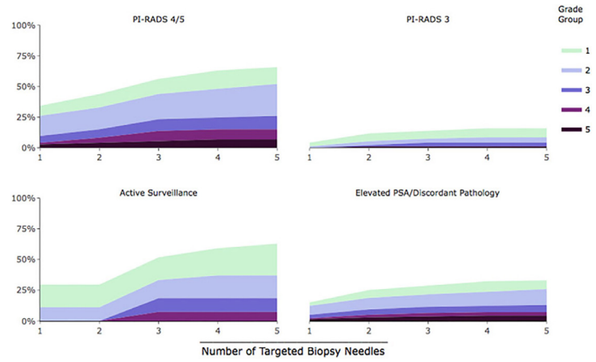
Urol Oncol. - 2021

INTRODUCTION: The optimal number of biopsy cores to obtain during MRI-targeted prostate biopsy remains ill-defined. This study sought to determine the optimal number of targeted biopsy cores to obtain from a region of interest to maximize detection of clinically significant prostate cancer.



MATERIALS AND METHODS: Consecutive patients undergoing MRI-targeted prostate biopsy at a single institution that newly implemented a targeted biopsy pathway from May 2017 to February 2018 were prospectively enrolled. Five biopsy cores were obtained and individually analyzed from each region rated ≥3 on PI-RADS v2.0 to determine the incremental diagnostic benefit of each additional targeted biopsy core. Variables associated with increasing Grade Group from the first to fifth biopsy core were assessed.

RESULTS: One hundred and four patients (79% for elevated PSA) were enrolled, 82% of which had a prior biopsy. Men with a PI-RADS >3 lesion were more likely to have pathologic upgrading with additional targeted biopsy cores (OR:4.76; 95% CI:2.34-9.70; P < 0.0001), particularly to Grade Group ≥2 (OR:5.16; 95% CI:2.17-12.29; P = 0.0002), compared to men with PI-RADS 3 lesions. Detection of clinically significant cancer increased from 26% to 44% to 52% when comparing the first, third, and fifth biopsy cores amongst men with a PI-RADS >3 lesion and from 1% to 4% to 9% for PI-RADS 3 lesions. Urinary retention was the most common complication, occurring in 6 (5.7%) patients.

CONCLUSION: Clinically significant prostate cancer detection is improved with increased number of MRI-targeted biopsy cores, particularly for urologists early in their learning curve.

1.1 MRI/US targeted biopsy

Dynamic evaluation of MRI-targeted, systematic and combined biopsy for prostate cancer diagnosis through 10 years of practice in a single institution.

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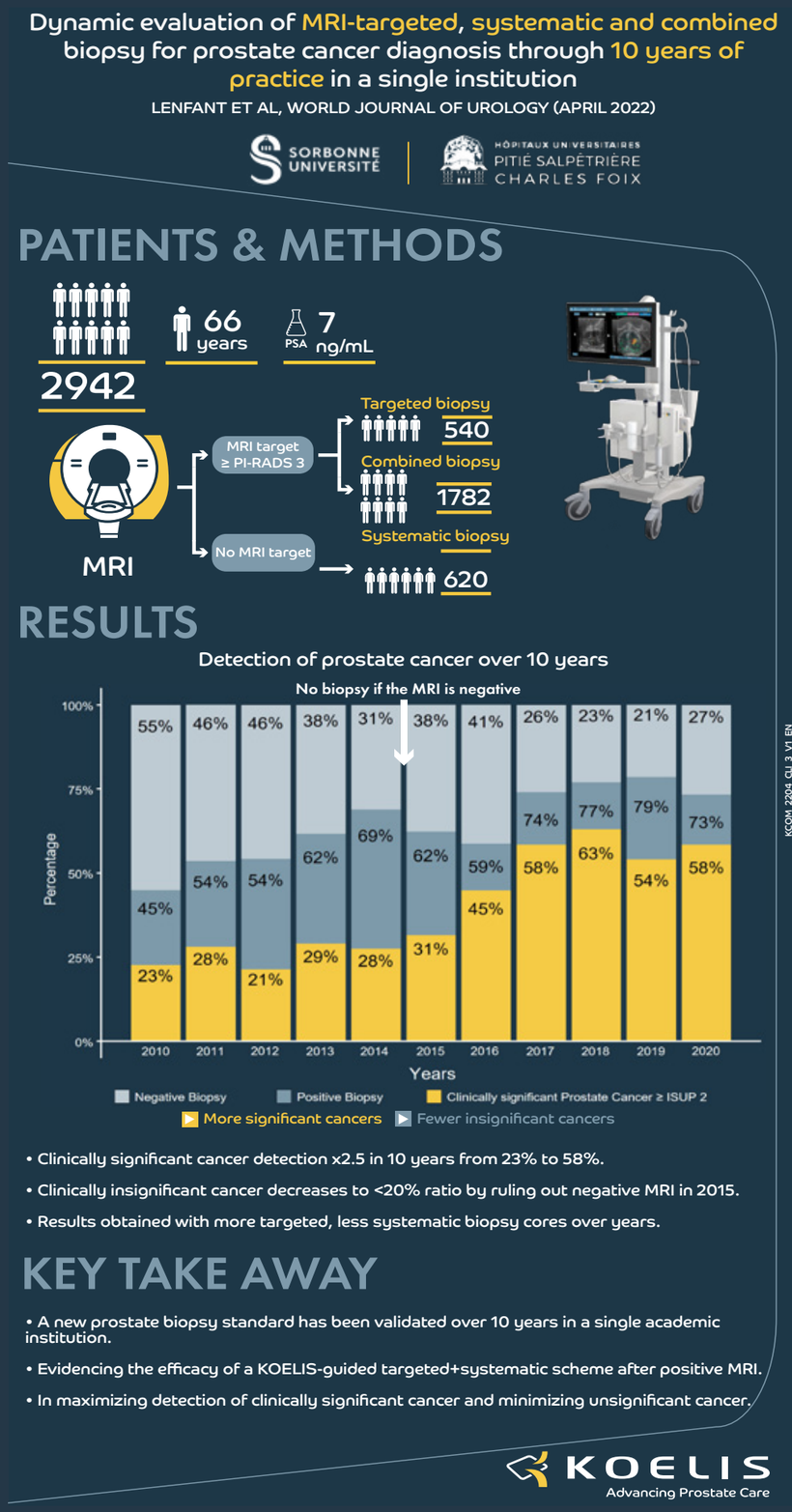
World J Urol - 2022

PURPOSE: To perform a dynamic evaluation of the prostate cancer (PCa) detection rate according to the biopsy strategy over 10 years of practice in a single institution that pioneered MRI-targeted fusion biopsy (MRI-TB).

METHODS: This stage 4 IDEAL study prospectively included all consecutive patients who underwent transrectal prostate biopsy for clinically suspected PCa between January 2010 and November 2020. Patients with positive MRI (PIRADS score ≥ 3) underwent both MRI-TB and systematic biopsy (SB) while those with negative MRI (PIRADS score < 3) underwent SB only. The main outcome was the evolution of the detection rate of clinically relevant PCa (csPCa; grade ≥ 2). The secondary outcome was the change in PCa detection rate according to the biopsy method.

RESULTS: A total of 2942 men underwent prostate MRI and a prostate biopsy: 2322 underwent MRI-TB and 620 had SB only. The detection rate of csPCa increased 2.5-fold from 23 to 58%. The detection rate of PCa and csPCa was significantly higher in patients who underwent MRI-TB compared to those who underwent SB only (67% vs. 52% and 40% vs. 32%, respectively (P < 0.001 for both comparisons)). The number of csPCa diagnosed by MRI-TB increased linearly over the study period and represented the majority of PCa diagnoses after 2016.

CONCLUSIONS: Implementation of MRI-TB in patients with positive MRI led to improved detection of csPCa.



Optimizing multiparametric magnetic resonance imaging-targeted biopsy and detection of clinically significant prostate cancer: the role of perilesional sampling

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Prostate Cancer Prostatic Dis. - 2023

BACKGROUND: The added-value of systematic biopsy (SB) in patients undergoing magnetic resonance imaging (MRI)-targeted biopsy (TB) remains unclear and the spatial distribution of positive cores relative to the MRI lesion has been poorly studied. The aim of this study was to determine the utility of perilesional biopsy in detecting clinically significant prostate cancer (csPCa).

METHODS: We enrolled 505 consecutive patients that underwent SB and TB for suspicious MRI lesions (PI-RADS score 3-5) at Jules Bordet Institute between June 2016 and January 2022. Patient-specific tridimensional prostate maps were reviewed to determine the distance between systematic cores containing csPCa and the MRI index lesion. Primary outcomes were the cancer detection rate (CDR) per patient and the cumulative cancer distribution rate of positive cores for each 5 mm interval from the MRI index lesion. The secondary outcome was the identification of risk groups for the presence of csPCa beyond a 10 mm margin using the chi-square automated interaction detector (CHAID) machine learning algorithm.

RESULTS: Overall, the CDR for csPCa of TB, SB, and combined method were 32%, 25%, and 37%, respectively. While combined method detected more csPCa compared to TB (37% vs. 32%, $p < 0.001$), no difference was found when TB was associated with perilesional sampling within 10 mm (37% vs. 35%, $p = 0.2$). The cumulative cancer distribution rate for csPCa reached 86% for the 10 mm margin. The CHAID algorithm identified three risk groups: (1) PI-RADS3 («low-risk»), (2) PI-RADS4 or PI-RADS5 and PSA density <0.15 ng/ml («intermediate-risk»), and (3) PI-RADS 5 and PSA density ≥0.15 ng/ml («high-risk»). The risk of missing csPCa was 2%, 8%, and 29% for low-, intermediate- and high-risk groups, respectively. Avoiding biopsies beyond a 10 mm margin prevented the detection of 19% of non-csPCa.

CONCLUSIONS: Perilesional biopsy template using a 10 mm margin seems a reasonable alternative to the combined method with a comparable detection of csPCa. Our risk stratification may further enhance the selection of patients.

Predicting contralateral extraprostatic extension in unilateral high-risk prostate cancer: a multicentric external validation study

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Wolrd J Urol. - 2024

PURPOSE: Accurate prediction of extraprostatic extension (EPE) is crucial for decision-making in radical prostatectomy (RP), especially in nerve-sparing strategies. Martini et al. introduced a three-tier algorithm for predicting contralateral EPE in unilateral high-risk prostate cancer (PCa). The aim of the study is to externally validate this model in a multicentric European cohort of patients.

METHODS: The data from 208 unilateral high-risk PCa patients diagnosed through magnetic resonance imaging (MRI)-targeted and systematic biopsies, treated with RP between January 2016 and November 2021 at eight referral centers were collected. The evaluation of model performance involved measures such as discrimination (AUC), calibration, and decision-curve analysis (DCA) following TRIPOD guidelines. In addition, a comparison was made with two established multivariable logistic regression models predicting the risk of side specific EPE for assessment purposes.

RESULTS: Overall, 38%, 48%, and 14% of patients were categorized as low, intermediate, and high-risk groups according to Martini et al.'s model, respectively. At final pathology, EPE on the contralateral prostatic lobe occurred in 6.3%, 12%, and 34% of patients in the respective risk groups. The algorithm demonstrated acceptable discrimination (AUC 0.68), comparable to other multivariable logistic regression models ($p = 0.3$), adequate calibration and the highest net benefit in DCA. The limitations include the modest sample size, retrospective design, and lack of central revision.

CONCLUSION: Our findings endorse the algorithm's commendable performance, supporting its utility in guiding treatment decisions for unilateral high-risk PCa patients.

Magnetic resonance imaging targeted biopsy in biopsy-naïve patients and the risk of overtreatment in prostate cancer: a grading issue

Teddy Jabbour [1] , Alexandre Peltier [1] , Laureen Rocq [2], Nicolas Sirtaine [2], Yolène Lefebvre [3], Henri Bourgeno [1], Arthur Baudewyns [1], Thierry Roumeguère [1], Romain Diamand [1]

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BJU Int. - 2024

OBJECTIVE: To evaluate the impact of applying the 2014 and 2019 International Society of Urological Pathology (ISUP) recommendations on grade group distribution and concordance with radical prostatectomy (RP).

MATERIALS AND METHODS: Overall, 655 biopsy-naïve patients diagnosed by magnetic resonance imaging (MRI) targeted and systematic biopsies for Prostate Imaging Reporting and Data System score ≥3 lesions were identified from a prospectively maintained database from 2016 and 2022. Clinically significant prostate cancer was detected in 249 patients, of whom 69 underwent RP. Wilcoxon signed rank and McNemar's tests were used to compare the ISUP grade group distribution and concordance with RP after applying the 2014 (i.e., highest grade) and 2019 (i.e., global grade) ISUP recommendations, respectively.

RESULTS: Compared to the 2014 ISUP recommendations, the 2019 ISUP recommendations were associated with a significant decrease in ISUP Grade Group 4 (range of difference from -13% to -5%) and an increase in ISUP Grade Group 2 (range of difference from +6% to +11%) in MRI targeted biopsy only, MRI targeted with perilesional biopsies, and MRI targeted with systematic biopsies (all $P < 0.01$). In patients who underwent RP, a significant decrease in downgrading was observed with all biopsy strategies (range of difference from -19% to -12%; $P \leq 0.008$), along with an increase in concordance with RP specimen (range of difference from +12% to +13%; $P \leq 0.02$). The use of the 2019 ISUP recommendation was associated with RP specimen a lower treatment burden.

CONCLUSIONS: The use of the 2019 ISUP recommendations mitigates the grade migration induced by MRI targeted biopsy and improves the concordance with the final RP specimen.

The impact of prostate volume estimation on the risk-adapted biopsy decision based on prostate-specific antigen density and magnetic resonance imaging score

Arthur Baudewyns [1], Karsten Guenzel [2], Adam Halinski [3], Charles Dariane [4], Gina Delavar [5], Julien Anract [5], Nicolas Barry Delongchamps [5], Teddy Jabbour [1], Henri-Alexandre Bourgeno [1], Yolène Lefebvre [6], Mariaconsiglia Ferriero [7], Giuseppe Simone [7], Alexandre Fourcade [8], Georges Fournier [8], Marco Oderda [9], Paolo Gontero [9], Adrian Bernal-Gomez [10], Alessandro Mastrorosa [10], Jean-Baptiste Roche [10], Rawad Abou Zahr [11], Guillaume Ploussard [11], Gaelle Fiard [12], Katerina Rysankova [13], Alexandre Patrick Bui [14], Fayek Taha [14], Olivier Windisch [15], Daniel Benamran [15], Léonidas Vlahopoulos [16], Gregoire Assenmacher [16], Thierry Roumeguère [1], Alexandre Peltier [1], Romain Diamand [1]

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World J Urol. - 2024

PURPOSE: Utility of prostate-specific antigen density (PSAd) for risk-stratification to avoid unnecessary biopsy remains unclear due to the lack of standardization of prostate volume estimation. We evaluated the impact of ellipsoidal formula using multiparametric magnetic resonance (MRI) and semi-automated segmentation using tridimensional ultrasound (3D-US) on prostate volume and PSAd estimations as well as the distribution of patients in a risk-adapted table of clinically significant prostate cancer (csPCa).

METHODS: In a prospectively maintained database of 4841 patients who underwent MRI-targeted and systematic biopsies, 971 met inclusions criteria. Correlation of volume estimation was assessed by Kendall's correlation coefficient and graphically represented by scatter and Bland-Altman plots. Distribution of csPCa was presented using the Schoots risk-adapted table based on PSAd and PI-RADS score. The model was evaluated using discrimination, calibration plots and decision curve analysis (DCA).

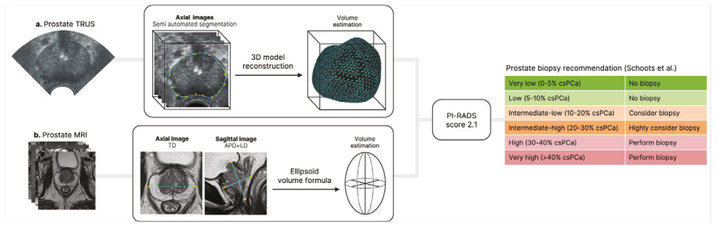

Fig. 1 Prostate volume estimation using **a** semi-automated segmentation using tridimensional ultrasound and **b** ellipsoidal formula using MRI, and prostate biopsy recommendation according to Schoots et al.

RESULTS: Median prostate volume estimation using 3D-US was higher compared to MRI (49cc[IQR 37-68] vs 47cc[IQR 35-66], $p < 0.001$). Significant correlation between imaging modalities was observed ($\tau = 0.73$[CI 0.7-0.75], $p < 0.001$). Bland-Altman plot emphasizes the differences in prostate volume estimation. Using the Schoots risk-adapted table, a high risk of csPCa was observed in PI-RADS 2 combined with high PSAd, and in all PI-RADS 4-5. The risk of csPCa was proportional to the PSAd for PI-RADS 3 patients. Good accuracy (AUC of 0.69 and 0.68 using 3D-US and MRI, respectively), adequate calibration and a higher net benefit when using 3D-US for probability thresholds above 25% on DCA.

CONCLUSIONS: Prostate volume estimation with semi-automated segmentation using 3D-US should be preferred to the ellipsoidal formula (MRI) when evaluating PSAd and the risk of csPCa.

1.1 MRI/US targeted biopsy

The Added Value of Side-specific Systematic Biopsy in Patients Diagnosed by Magnetic Resonance Imaging-targeted Prostate Biopsy

Henri-Alexandre Bourgeno [1], Teddy Jabbour [1], Arthur Baudewyns [1], Yolène Lefebvre [2], Mariaconsiglia Ferriero [3], Giuseppe Simone [3], Alexandre Fourcade [4], Georges Fournier [4], Marco Oderda [5], Paolo Gontero [5], Adrian Bernal-Gomez [6], Alessandro Mastrorosa [6], Jean-Baptiste Roche [6], Rawad Abou Zahr [7], Guillaume Ploussard [7], Gaelle Fiard [8], Adam Halinski [9], Katerina Rysankova [10], Charles Dariane [11], Gina Delavar [12], Julien Anract [12], Nicolas Barry Delongchamps [12], Alexandre Patrick Bui [13], Fayek Taha [13], Olivier Windisch [14], Daniel Benamran [14], Gregoire Assenmacher [15], Léonidas Vlahopoulos [15], Karsten Guenzel [16], Thierry Roumeguère [1], Alexandre Peltier [1], Romain Diamand [17]

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Eur Urol Oncol. - 2024

OBJECTIVE: To evaluate the added value in csPCa detection on side-specific SB relative to MRI lesion and to externally validate the Noujeim risk stratification model that predicts the risk of csPCa on distant SB cores relative to the index MRI lesion.

DESIGN, SETTING, AND PARTICIPANTS: Overall, 4841 consecutive patients diagnosed by MRI-targeted biopsy and SB for Prostate Imaging Reporting and Data System score ≥3 lesions were identified from a prospectively maintained database between January 2016 and April 2023 at 15 European referral centers. A total of 2387 patients met the inclusion criteria and were included in the analysis.

OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS: McNemar's test was used to compare the csPCa detection rate between several biopsy strategies including MRI-targeted biopsy, side-specific SB, and a combination of both. Model performance was evaluated in terms of discrimination using area under the receiver operation characteristic curve (AUC), calibration plots, and decision curve analysis. Clinically significant prostate cancer was defined as International Society of Urological Pathology grade group ≥2.

RESULTS AND LIMITATIONS: Overall, the csPCa detection rate was 49%. Considering MRI-targeted biopsy as reference, the added values in terms of csPCa detection were 5.8% (relative increase of 13%), 4.2% (relative increase of 9.8%), and 2.8% (relative increase of 6.1%) for SB, ipsilateral SB, and contralateral SB, respectively. Only 35 patients (1.5%) exclusively had csPCa on contralateral SB ($p < 0.001$). Considering patients with csPCa on MRI-targeted biopsy and ipsilateral SB, the upgrading rate was 2% (20/961) using contralateral SB ($p < 0.001$). The Noujeim model exhibited modest performance (AUC of 0.63) when tested using our validation set.

CONCLUSIONS: The added value of contralateral SB was negligible in terms of cancer detection and upgrading rates. The Noujeim model could be included in the decision-making process regarding the appropriate prostate biopsy strategy.

1.2 Precision of the OBT Fusion®

TRUS-MRI image registration: a paradigm shift in the diagnosis of significant prostate cancer

Cornud F[1], Brolis L, Delongchamps NB, Portalez D, Malavaud B, Renard-Penna R, Mozer P.

[1]Department of Radiology, Hôpital Cochin, Paris, France

Abdom Imaging. - 2013

ABSTRACT: Accuracy of multiparametric MRI has greatly improved the ability of localizing tumor foci of prostate cancer. This property can be used to perform a TRUS–MR image registration, new technological advance, which allows for an overlay of an MRI onto a TRUS image to target a prostate biopsy toward a suspicious area Three types of registration have been developed: cognitive-based, sensor-based, and organ-based registration. Cognitive registration consists of aiming a suspicious area during biopsy with the knowledge of the lesion location identified on multiparametric MRI. Sensor-based registration consists of tracking in real time the TRUS probe with a magnetic device, achieving a global positioning system which overlays in real-time prostate image on both modalities. Its main limitation is that it does not take into account prostate and patient motion during biopsy. Two systems (Artemis and Uronav) have been developed to partially circumvent this drawback. Organ-based registration (KOELIS®) does not aim to track the TRUS probe, but the prostate itself to compute in a 3D acquisition the TRUS prostate shape, allowing for a registration with the corresponding 3D MRI shape. This system is not limited by prostate/patient motion and allows for a deformation of the organ during registration. Pros and cons of each technique and the rationale for a targeted biopsy only policy are discussed.

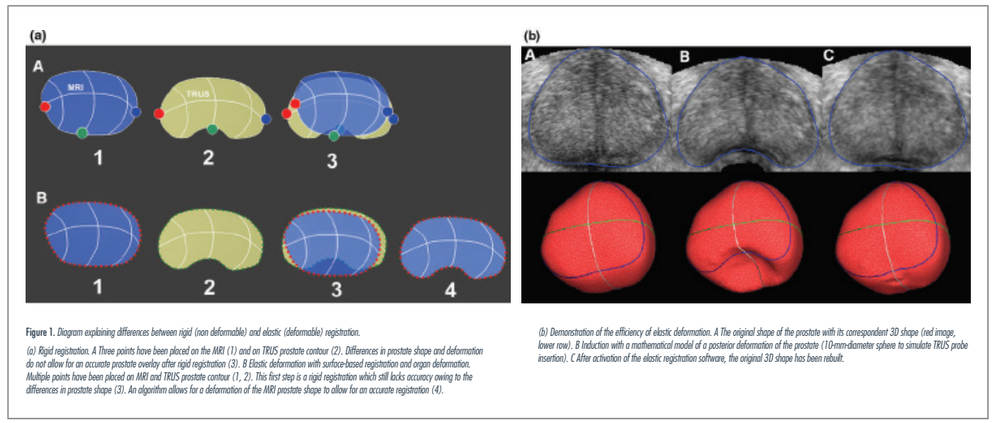

Figure 1. *Diagram explaining differences between rigid (non deformable) and elastic (deformable) registration.*

(a) Rigid registration. A Three points have been placed on the MRI (1) and on TRUS prostate contour (2). Differences in prostate shape and deformation do not allow for an accurate prostate overlay after rigid registration (3). B Elastic deformation with surface-based registration and organ deformation. Multiple points have been placed on MRI and TRUS prostate contour (1, 2). This first step is a rigid registration which still lacks accuracy owing to the differences in prostate shape (3). An algorithm allows for a deformation of the MRI prostate shape to allow for an accurate registration (4).

(b) Demonstration of the efficiency of elastic deformation. A The original shape of the prostate with its correspondent 3D shape (red image, lower row). B Induction with a mathematical model of a posterior deformation of the prostate (10-mm-diameter sphere to simulate TRUS probe insertion). C After activation of the elastic registration software, the original 3D shape has been rebuilt.

1.2 Precision of the OBT Fusion®

Precision Matters in MR Imaging-targeted Prostate Biopsies: Evidence from a Prospective Study of Cognitive and Elastic Fusion Registration Transrectal Biopsies

Cornud F[1], Roumiguié M[1], Barry de Longchamps N[1], Ploussard G[1], Bruguière E[2], Portalez D[2], Malavaud B[2].

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[2] *Institut Universitaire du Cancer, Toulouse*

Radiology - 2018

PURPOSE: To measure the precision in placement of a biopsy needle in a magnetic resonance (MR) imaging–detected target with transrectal ultrasonography (US), to document the clinical relevance of precision, and to report on the precision of cognitive and software-based registrations.

PATIENTS AND METHODS: This prospective study was approved by the institutional review board and performed between June 2013 and September 2013. Patients provided informed verbal consent. Two cores each were obtained with cognitive and fusion techniques in 88 patients with a Prostate Imaging Reporting and Data System version 1 score of at least 3. Precision was measured with Euclidian geometry by using the Digital Imaging and Communications in Medicine archives of the biopsy as the distance from the core to the center (dCC) and the distance from the core to the surface of the target modeled as a sphere. To address clustering of data from multiple cores in the same patients, analyses of precision focused on the best shot for a patient or a technique. The Welch unequal variance t test and Yates corrected x2 test were used as appropriate.

RESULTS: Mean precision was 2.5 mm (95% confidence interval: 1.8 mm, 3.3 mm). Positive cores were closer to the center than were negative cores (dCC: 1.7 mm vs 3.1 mm, respectively; P = .025). More cancers were detected with on-target than off-target cores (33 of 71 cores [46.5%] vs three of 17 cores [17.6%]; P = .03). Cores obtained with the fusion technique achieved a higher precision than did cores obtained with the cognitive technique (dCC: 2.8 mm vs 7.1 mm, respectively; P < .0001). Targeted cores demonstrated cancer in 44 patients. Fewer cancers were detected with the cognitive technique than with the fusion technique (31 of 44 patients [70.5%] vs 40 of 44 patients [90.9%]; P = .03).

CONCLUSIONS: A deformable MR imaging/transrectal US image registration system achieved a higher precision and depicted cancer in more patients than did the cognitive freehand technique. was probably best than PET choline for detecting prostate cancer but it could be complementary.

Precision Matters in MR Imaging–targeted Prostate Biopsies

Cornud F et al. TPrecision Matters in MR Imaging-targeted Prostate Biopsies: Evidence from a Prospective Study of Cognitive and Elastic Fusion Registration Transrectal Biopsies
Radiology - 2018 May;287(2):534-542. doi: 10.1148/radiol.2017162916

DESIGN

PATIENTS **88**

63 yeras

PSA 8.2 ng/mL

40 cc

UROLOGISTS >10 yeras experience

Cognitive MRI Fusion & Elastic Fusion

METHODS

TRANSRECTAL BIOPSY → 2 COGNITIVE CORES → 2 ELASTIC FUSION CORES

ON-TARGET vs OFF-TARGET

CANCER TISSU SAMPLE

CHANCE OF DEMONSTRATING CANCER

46.5% ON-TARGET

17.6% OFF-TARGET

COGNITIVE vs ELASTIC FUSION

LOCATION OF TARGETS	PRECISION Distance from the core to the center of the target: COGNITIVE CORES (n=88)	PRECISION: FUSION CORES (n=88)	INFORMATION Distance from the core to the surface of the target: COGNITIVE CORES (n=88)	INFORMATION: FUSION CORES (n=88)
BASE	8.4mm3	.6mm	4.0mm	-0.8mm
MID	6.6mm2	.5mm	2.6mm-	1.5mm
APEX	6.3mm2	.3mm	1.6mm-	2.4mm

% OF POSITIVE CORES

70.5% COGNITIVE

90.9% ELASTIC FUSION

PUBLICATION CONCLUSION

- **Mean precision was 2.5 mm** (95% confidence interval: 1.8 mm, 3.3 mm)
- **Cores obtained with the fusion technique achieved a higher precision than did cores obtained with the cognitive technique** (dCC: 2.8 mm vs 7.1 mm, respectively; P < .0001)

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1.2 Precision of the OBT Fusion®

A multicentric study on accurate grading of prostate cancer with systematic and MRI/US fusion targeted biopsies: comparison with final histopathology after radical prostatectomy

R Diamand[1], M Oderda[1], W Al Hajj Obeid[3], S Albisinni[4], R Van Velthoven[3], G Fasolis[2], G Simone[5] M Ferriero[5], J-B Roche[6], T Piechaud[6], A Pastore[7], A Carbone[7], G Fiard[8], J-L Descotes[8], G Marra[9], P Gontero[9], E Altobelli[10], R Papalia[10], P Kumar[11], D Eldred-Evans[12], A Giacobbe[13], G Muto[13], V Lacetera[14], V Beatrici[14], T Roumeguere[4], A Peltier[3]

[1]Department of Urology, Jules Bordet Institute, Université Libre de Bruxelles, Boulevard de Waterloo 121, 1000, Brussels, Belgium. rdiamand@ulb.ac.be. [2] Department of Urology, San Lazzaro Hospital, Alba, Italy. [3] Department of Urology, Jules Bordet Institute, Université Libre de Bruxelles, Boulevard de Waterloo 121, 1000, Brussels, Belgium. [4] Department of Urology, Erasme Hospital, Université Libre de Bruxelles, Brussels, Belgium. [5] Department of Urology, Regina Elena National Cancer Institute, Rome, Italy. [6] Department of Urology, Saint Augustin Clinic, Bordeaux, France. [7] Department of Medico-Surgical Sciences and Biotechnologies, Urology Unit, Sapienza University of Rome, Latina, Italy. [8] Department of Urology, Grenoble University Hospital, Grenoble, France. [9] Department of Surgical Sciences, Urology Unit, University of Turin, Turin, Italy. [10] Department of Urology, Campus Bio-medico University, Rome, Italy. [11] Department of Urology, Royal Marsden Hospital, London, UK. [12] Department of Urology, Charing Cross Hospital, London, UK. [13] Department of Urology, Humanitas Gradenigo Hospital, Turin, Italy. [14] Department of Urology, Azienda Ospedaliera Ospedali Riuniti Marche Nord Hospital, Pesaro Fano, Italy.

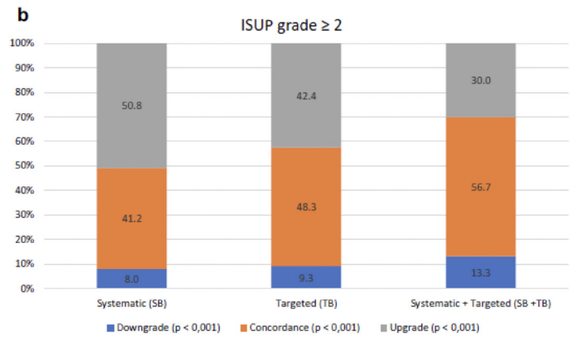
World J Urol. - 2019

OBJECTIVE: To evaluate the accuracy in histologic grading of MRI/US image fusion biopsy by comparing histopathology between systematic biopsies (SB), targeted biopsies (TB) and the combination of both (SB + TB) with the final histopathologic outcomes of radical prostatectomy specimens.

MATERIALS AND METHODS: Retrospective, multicentric study of 443 patients who underwent SB and TB using MRI/US fusion technique (Urostation® and Trinity®) prior to radical prostatectomy between 2010 and 2017. Cochran's Q test and McNemar test were conducted as a post hoc test. Uni-multivariable analyses were performed on several clinic-pathological variables to analyze factors predicting histopathological concordance for targeted biopsies.

RESULTS: Concordance in ISUP (International Society of Urological Pathology) grade between SB, TB and SB + TB with final histopathology was 49.4%, 51.2%, and 63.2% for overall prostate cancer and 41.2%, 48.3%, and 56.7% for significant prostate cancer (ISUP grade ≥ 2), respectively. Significant difference in terms of concordance, downgrading and upgrading was found between SB and TB (ISUP grade ≥ 2 only), SB and SB + TB, TB and SB + TB (overall ISUP grade and ISUP grade ≥ 2) ($p < 0.001$). Total number of cores and previous biopsies were significant independent predictive factors for concordance with TB technique.

CONCLUSION: In this retrospective study, combination of SB and TB significantly increased concordance with final histopathology despite a limited additional number of cores needed.



1.2 Precision of the OBT Fusion®

Accuracy of elastic fusion biopsy: Comparing prostate cancer detection between targeted and systematic biopsy

Marco Oderda [1], Simone Albisinni [2], Daniel Benamran[3], Giorgio Calleris [1], Mauro Ciccariello [4], Alessandro Dematteis[1], Romain Diamand[2], Jean-Luc Descotes[5], Gaelle Fiard[5], Valerio Forte [6], Alessandro Giacobbe [7], Alessandro Marquis [1], Giancarlo Marra [1], Aurel Messas [8], Giovanni Muto [7], Alexandre Peltier [2], Leire Rius [9], Giuseppe Simone [10], Thierry Roumeguere[2], Riccardo Faletti [11], Paolo Gontero [1]

[1] Division of Urology, Department of Surgical Sciences, Molinette Hospital, University of Turin, Turin, Italy. [2] Department of Urology, University Clinics of Brussels, Erasme Hospital and Jules Bordet Institute, Université Libre de Bruxelles, Brussels, Belgium. [3] Department of Urology, Hôpitaux Universitaires Genève, Geneva, Switzerland. [4] Department of Radiological, Oncological, and Anatomo-Pathological Sciences, Sapienza University of Rome, Rome, Italy. [5] Department of Urology, Grenoble Alpes University Hospital, Université Grenoble Alpes, CNRS, Grenoble INP, TIMC-IMAG, Grenoble, France. [6] Department of Radiology, San Carlo di Nancy Hospital, Rome, Italy. [7] Department of Urology, Humanitas Gradenigo Hospital, Turin, Italy. [8] Department of Urology, Hopitaux de Paris, Paris, France. [9] Department of Urology, Galdakao Hospital, Bilbao, Spain.
[10] Department of Urology, Regina Elena National Cancer Institute, Rome, Italy. [11] Division of Radiology, Molinette Hospital, University of Turin, Italy.

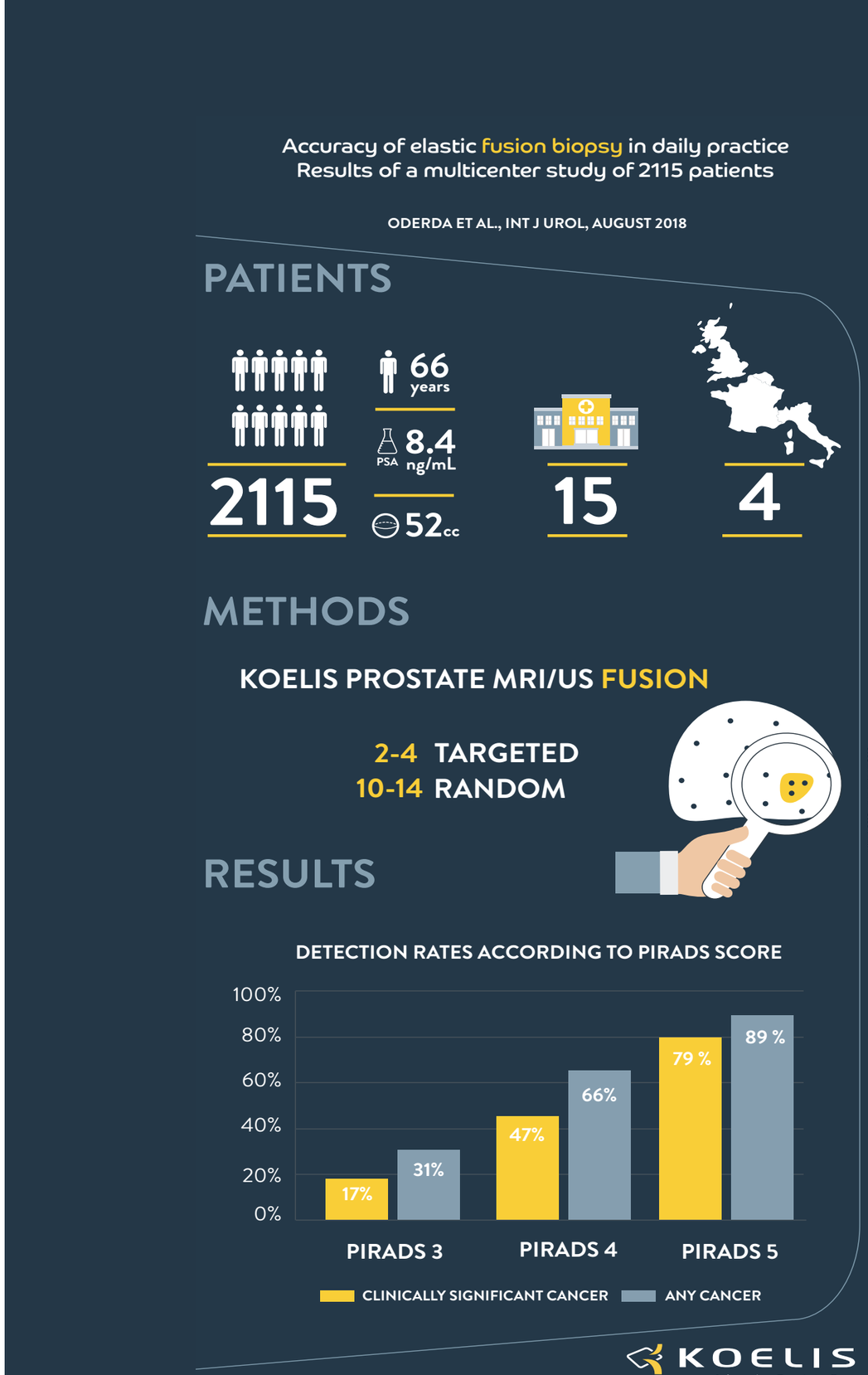
Prostate - 2023

INTRODUCTION: When performing targeted biopsy (TBx), the need to add systematic biopsies (SBx) is often debated. Aim of the study is to evaluate the added value of SBx in addition to TBx in terms of prostate cancer (PCa) detection rates (CDR), and to test the concordance between multiparametric magnetic resonance imaging (mpMRI) findings and fusion biopsy results in terms of cancer location.

METHODS: We performed a retrospective, multicentric study that gathered data on 1992 consecutive patients who underwent elastic fusion biopsy between 2011 and 2020. A standardized approach was used, with TBx (2-4 cores per target) followed by SBx (12-14 cores). We assessed CDR of TBx, of SBx, and TBx+SBx for all cancers and clinically significant PCa (csPCa), defined as ISUP score ≥2. CDR was evaluated according to radiological and clinical parameters, with a particular focus on PI-RADS 3 lesions. In a subgroup of 1254 patients we tested the discordance between mpMRI findings and fusion biopsy results in terms of cancer location. Uni- and multivariable logistic regression analyses were performed to identify predictors of CDR.

RESULTS: CDR of TBx+SBx was 63.0% for all cancers and 38.8% of csPCa. Per-patient analysis showed that SBx in addition to TBx improved CDR by 4.5% for all cancers and 3.4% for csPCa. Patients with lesions scored as PI-RADS 3, 4, and 5 were diagnosed with PCa in 27.9%, 72.8%, and 92.3%, and csPCa in 10.7%, 43.6%, and 69.3%, respectively. When positive, PI-RADS 3 lesions were ISUP grade 1 in 61.1% of cases. Per-lesion analysis showed that discordance between mpMRI and biopsy was found in 56.6% of cases, with 710 patients having positive SBx outside mpMRI targets, of which 414 (58.0%) were clinically significant. PSA density ≥0.15 was a strong predictor of CDR.

CONCLUSIONS: The addition of systematic mapping to TBx contributes to a minority of per-patient diagnoses but detects a high number of PCa foci outside mpMRI targets, increasing biopsy accuracy for the assessment of cancer burden within the prostate. High PSA-density significantly increases the risk of PCa, both in the whole cohort and in PI-RADS 3 cases.



1.2 Precision of the OBT Fusion®

Comparison of MRI-guided Ultrasound Fusion Biopsy and Cognitive Targeted Biopsy in the Diagnosis of Clinically Significant Prostate Cancer: Lesion Size Matters

I-Hung Shao, Fan-Ting Liao, Chun-Bi Chang, Ying-Hsu Chang, Li-Jen Wang, Liang-Kang Huang, Hung-Cheng Kan, Po-Hung Lin, Kai-Jie Yu, Cheng-Keng Chuang, Chun-Te Wu, See-Tong Pang

[1] Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. CA Cancer J Clin. 2022;72:7–33. [2] Ippoliti S, et al. Optimal biopsy approach for detection of clinically significant prostate cancer. Br J Radiol. 2022 Mar 1;95(1131):20210413. [3] Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68:394–424. [4] Yamada Y, et al. Moving away from systematic biopsies: image-guided prostate biopsy (in-bore biopsy, cognitive fusion biopsy, MRUS fusion biopsy) -literature review. World J Urol. 2021 Mar;39(3):677-686. [5] Klotz L, et al. Comparison of Multiparametric Magnetic Resonance Imaging-Targeted Biopsy With Systematic Transrectal Ultrasonography Biopsy for Biopsy-Naive Men at Risk for Prostate Cancer: A Phase 3 Randomized Clinical Trial. JAMA Oncol. 2021 Apr 1;7(4):534-542. doi: 10.1001/jamaoncol.2020.7589. Erratum in: JAMA Oncol. 2021 Apr 1;7(4):639. Erratum in: JAMA Oncol. 2021 Jul 1;7(7):1074. [6] Zattoni F, et al. The Detection of Prostate Cancer with Magnetic Resonance Imaging-Targeted Prostate Biopsies is Superior with the Transperineal vs the Transrectal Approach. A European Association of Urology-Young Academic Urologists Prostate Cancer Working Group Multi-Institutional Study. J Urol. 2022 Oct;208(4):830-837. [7] Wegelin O, et al. The FUTURE Trial: A Multicenter Randomised Controlled Trial on Target Biopsy Techniques Based on Magnetic Resonance Imaging in the Diagnosis of Prostate Cancer in Patients with Prior Negative Biopsies. Eur Urol. 2019 Apr;75(4):582-590. [8] Hamid S, et al. The SmartTarget Biopsy Trial: A Prospective, Within-person Randomised, Blinded Trial Comparing the Accuracy of Visual-registration and Magnetic Resonance Imaging/Ultrasound Imagefusion Targeted Biopsies for Prostate Cancer Risk Stratification. Eur Urol. 2019 May;75(5):733-740. [9] Simmons LAM, et al. Accuracy of Transperineal Targeted Prostate Biopsies, Visual Estimation and Image Fusion in Men Needing Repeat Biopsy in the PICTURE Trial. J Urol. 2018 Dec;200(6):1227-1234. [10] Barrett T, et al. Targeted transperineal biopsy of the prostate has limited additional benefit over background cores for larger MRI-identified tumors. World J Urol. 2016 Apr;34(4):501-8. [11] Marra G, EAU-YAU Prostate Cancer Working Party, et al. Controversies in MR targeted biopsy: alone or combined, cognitive versus software-based fusion, transrectal versus transperineal approach. World J Urol. 2019 Feb;37(2):277-287.

Sci Rep. - 2024

PURPOSE: MRI-guided targeted biopsy (MRGB) was recommended as part of biopsy paradigm of prostate cancers by current guidelines. This study aimed to analyze the diagnostic efficacy of MRGB and systemic biopsy (SB), and to compare diagnostic capabilities within subgroups of MRGB: MRI-cognitive biopsy (MRCB) and MRI-fusion biopsy (MRFB).

MATERIALS AND METHODS: We retrospectively enrolled patients who underwent MRGB for suspicious malignant lesion(s) identified on MRI in a single tertiary center. An mpMRI was performed prior to biopsy and reviewed by an experienced radiologist specialized in prostate cancer. Per-person results of MRGB and each concomitant SB were analyzed as independent biopsies for its positive biopsy rate and positive core percentage. Perlesion results of MRFB and MRCB were compared for the detection rate. Variables of interest were analyzed with t-test, chi-squared test, and logistic regression analysis. Statistical analyses were performed with SPSS software version 23.

RESULTS: Total of 74 patients fulfilled the inclusion criteria and were enrolled. MRFB had higher PCa detection rate comparing to both MRCB and SB (56.1%, 30.3%, and 33.9% respectively, p value = 0.036); csPCa detection rate was also significantly higher in MRFB group (43.9%, 24.2%, and 16.9% in each group respectively, p value = 0.011). In per-lesion analysis, MRCB and MRFB had no significant difference in PCa and csPCa detection rate (41.0% vs. 26.2% and 29.5% vs. 16.7% respectively, p value = 0.090 and 0.103). In the lesion ≤ 1.3 cm group, MRFB could achieve higher PCa detection rate, comparing to MRCB (36.4% vs. 14.3%, p value = 0.047); there were also higher positive rates for PCa and csPCa per biopsied cores (22.1% vs. 6.8% and 15.6% vs. 2.7%, p value = 0.029 and 0.028, respectively). Further logistic regression of multivariate analysis in subgroup of lesion ≤ 1.3 cm revealed that PIRADS score and biopsy method were significant predictors of positive biopsy result for PCa (p value = 0.045 and 0.026, respectively) and for csPCa (p value = 0.043 and 0.025, respectively).

CONCLUSION: In patients receiving trans-perineal prostate biopsy, MRFB had higher cancer detection rate than MRCB and SB. In per lesion comparison, MRFB and MRCB had similar diagnostic accuracy. However, in lesions with diameter less than 1.3 cm, MRFB can provided better diagnose value for PCa and csPCa than MRCB.

1.2 Precision of the OBT Fusion®

Lesion size may affect diagnostic capabilities of MRI-guided ultrasound fusion biopsy and cognitive targeted biopsy for clinically significant prostate cancer

I-Hung Shao # [1 2 3], Fan-Ting Liao # [1], Chun-Bi Chang [4], Ying-Hsu Chang [2 5], Li-Jen Wang [4], Liang-Kang Huang [1 2], Hung-Cheng Kan [1 2], Po-Hung Lin [1], Kai-Jie Yu [1 2], Cheng-Keng Chuang [1 2], Chun-Te Wu [1 2], See-Tong Pang [6 7]

[1] Division of Urology, Department of Surgery, Linkou Chang Gung Memorial Hospital, 5, Fuxing Street, Guishan District, Taoyuan City, Taiwan. [2] College of Medicine, Chang Gung University, Taoyuan, Taiwan. [3] Graduate Institute of Clinical Medical Sciences, College of Medicine, Chang Gung University, Taoyuan, Taiwan. [4] Department of Medical Imaging and Intervention, Linkou Chang Gung Memorial Hospital, Taoyuan, Taiwan. [5] Division of Urology, Department of Surgery, New Taipei Municipal TuCheng Hospital, Chang Gung Memorial Hospital, New Taipei City, Taiwan. [6] Division of Urology, Department of Surgery, Linkou Chang Gung Memorial Hospital, 5, Fuxing Street, Guishan District, Taoyuan City, Taiwan. pst64lab@gmail.com. [7] College of Medicine, Chang Gung University, Taoyuan, Taiwan. pst64lab@gmail.com. # Contributed equally.

Sci Rep. - 2024

MRI-guided targeted biopsy (MRGB) was recommended as part of biopsy paradigm of prostate cancers by current guidelines. This study aimed to analyze the diagnostic efficacy of MRGB and systemic biopsy (SB), and to compare diagnostic capabilities within subgroups of MRGB: MRI-cognitive biopsy (MRCB) and MRI-fusion biopsy (MRFB). We retrospectively enrolled patients who underwent MRGB for suspicious malignant lesion(s) identified on MRI in a single tertiary center, sample size was 74 patients. An mpMRI was performed prior to biopsy and reviewed by an experienced radiologist specialized in prostate cancer. Per-person results of MRGB and each concomitant SB were analyzed as independent biopsies for its positive biopsy rate and positive core percentage. Per-lesion results of MRFB and MRCB were compared for the detection rate.

Variables of interest were analyzed with t-test, chi-squared test, and logistic regression analysis. Statistical analyses were performed with IBM Statistical Product and Service Solutions (SPSS), Version 23 (IBM, Armonk, New York). Total of 74 patients fulfilled the inclusion criteria and were enrolled.

MRFB had higher PCa detection rate comparing to both MRCB and SB (56.1%, 30.3%, and 33.9% respectively, p value = 0.036); clinically significant prostate cancer (csPCa) detection rate was also significantly higher in MRFB group (43.9%, 24.2%, and 16.9% in each group respectively, p value = 0.011). In per-lesion analysis, MRCB and MRFB had no significant difference in PCa and csPCa detection rate (41.0% vs. 26.2% and 29.5% vs. 16.7% respectively, p value = 0.090 and 0.103). In the lesion ≤ 1.3 cm group, MRFB could achieve higher PCa detection rate, comparing to MRCB (36.4% vs. 14.3%, p value = 0.047); there were also higher positive rates for PCa and csPCa per biopsied cores (22.1% vs. 6.8% and 15.6% vs. 2.7%, p value = 0.029 and 0.028, respectively).

Further logistic regression of multi-variate analysis in subgroup of lesion 1.3 cm revealed that PIRADS score and biopsy method were significant predictors of positive biopsy result for PCa (p value = 0.045 and 0.026, respectively) and for csPCa (p value = 0.043 and 0.025, respectively). In patients receiving trans-perineal prostate biopsy, MRFB had higher cancer detection rate than MRCB and SB. In per lesion comparison, MRFB and MRCB had similar diagnostic accuracy. However, in lesions with diameter less than 1.3 cm, MRFB can provided better diagnose value for PCa and csPCa than MRCB.

Lesion size may affect diagnostic capabilities of MRI-guided ultrasound fusion biopsy and cognitive targeted biopsy for clinically significant prostate cancer

Shao IH et al. Lesion size may affect diagnostic capabilities of MRI-guided ultrasound fusion biopsy and cognitive targeted biopsy for clinically significant prostate cancer.
Sci Rep. 2024 Aug;14(1):20173. doi: 10.1038/s41598-024-69661-4

DESIGN

Retrospective, single-institution.

74 patients selected

41 patients in the Fusion Biopsy group

33 patients in the Cognitive Biopsy group

59 patients in the Systematic + Targeted Biopsies group

PRIMARY CRITERIA

PRIMARY OBJECTIVE

PCa detection rate per patient analysis.

SECONDARY OBJECTIVE

CS PCa detection rate, per lesion analysis, analysis according to lesion size (< or > 1.3 cm).

RESULTS

Patients in Fusion group had **significantly higher PCa detection** rate comparing to those in cognitive and systematic Bx group.

CS PCa detection rate: significantly higher in Fusion group
Total Biopsy cores: Significantly higher in Syt + Targeted Bx group.
Patients in Syt + Targeted Bx group had lowest PCa and csPCa positive biopsy core percentage.

	Fusion Bx Group	Cognitive Bx Group	Syst + Targeted Bx group	P value
PCa detection Rate (%)	56.1%	30.3%	33.9%	0.036
CS PCa detection Rate (%)	43.9%	24.2%	16.9%	0.011
Total biopsy cores	6.7	5.9	9.6	<0.001
PCa Positive biopsy core - percentage (%)	31.0%	19.2%	12.0%	0.010
csPCa Positive biopsy core percentage (%)	26.6%	16.1%	7.1%	0.016

THEIR CONCLUSION

In patients receiving trans-perineal prostate biopsy, Fusion had a higher cancer detection rate than cognitive group and than Syst Bx group.
In per lesion comparison, Fusion and cognitive had similar diagnostic accuracy.
However, in lesions with diameter less than 1.3 cm, Fusion can provide a better diagnosis value for PCa and csPCa than Cognitive.

KOELIS
Advancing Prostate Care

KCOM_2412_CLI_3_V1_EN

2.1 Transperineal biopsy under local anesthesia

Multicenter transperineal MRI-TRUS fusion guided outpatient clinic prostate biopsies under local anesthesia

Jacewicz M[1], Günzel K, Rud E, Lauritzen P.M, Galtung K.F, Hinz S, Baco E.

[1]*Department of Urology, Oslo University Hospital, Oslo. Norway*

Urol Oncol. - 2021

INTRODUCTION: Transperineal Prostate biopsies (TPBx) are usually performed under general anesthesia without image fusion. This study aimed to evaluate prostate cancer (Pca) detection rates (CDR), pain, and adverse events using a novel, free-hand TPBx technique, based on elastic fusion of magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) under local anesthesia.

MATERIALS AND METHODS: This multicenter retrospective study included all consecutive patients scheduled for a TPBx. All had clinical suspicion of Pca, active surveillance scheduled for a re-biopsy, or suspicion of local recurrence after previous treatment. Bi-parametric or multiparametric MRI was performed in all patients and classified as positive in the case of Prostate Imaging-Reporting and Data System (PIRADS) suspicion ≥3. At least 1 targeted TPBx was realized from each PIRADS ≥3 index lesion. Six to 12 systematic random TPBx were done in patients with negative MRI. All biopsies were performed under local anesthesia in an outpatient clinic with MRI-TRUS fusion and the 3D navigation system KOELIS TRINITY® PERINE™ (KOELIS®, France). Any- and clinically significant Pca (csPca) (ISUP gr. ≥2) was recorded. Biopsy-related pain and adverse events were reported according to a visual analogue score of 0–10.

RESULTS: In total, 377 patients were included for analyses. The mean age was 67 years (95% Confidence Interval: 66–68) and the median prostate-specific antigen was 7.2 ng/ml (interquartile range [IQR] 4.8–11.0). MRI was negative in 6% and positive in 94%. The median MRI prostate volume was 43 ml (IQR 31–60) and the median MRI index tumor volume was 0.9 ml (IQR 0.5–2.1). The median number of TPBx was 4 (IQR 3–4). The overall detection of any- and csPca was 64% and 52%, respectively. The overall CDR according to PIRADS 3, 4, and 5 was 30%, 70%, and 94%, respectively. In patients with negative MRI, any- and csPca was detected in 23% and 9%, respectively. The median visual analogue score score was 2 (IQR 1–3, range 0–7). Two patients (0.5%) developed postbiopsy infection, of which one developed urosepsis. Treatment requiring haematuria or urinary retention did not occur.

CONCLUSIONS: Free-hand MRI/TRUS fusion-guided and systematic random TPBx in LA is a feasible, safe, and well-tolerated technique for diagnosing Pca.

2.1 Transperineal biopsy under local anesthesia

Infection rate and complications after 621 transperineal MRI-TRUS fusion biopsies in local anesthesia without standard antibiotic prophylaxis

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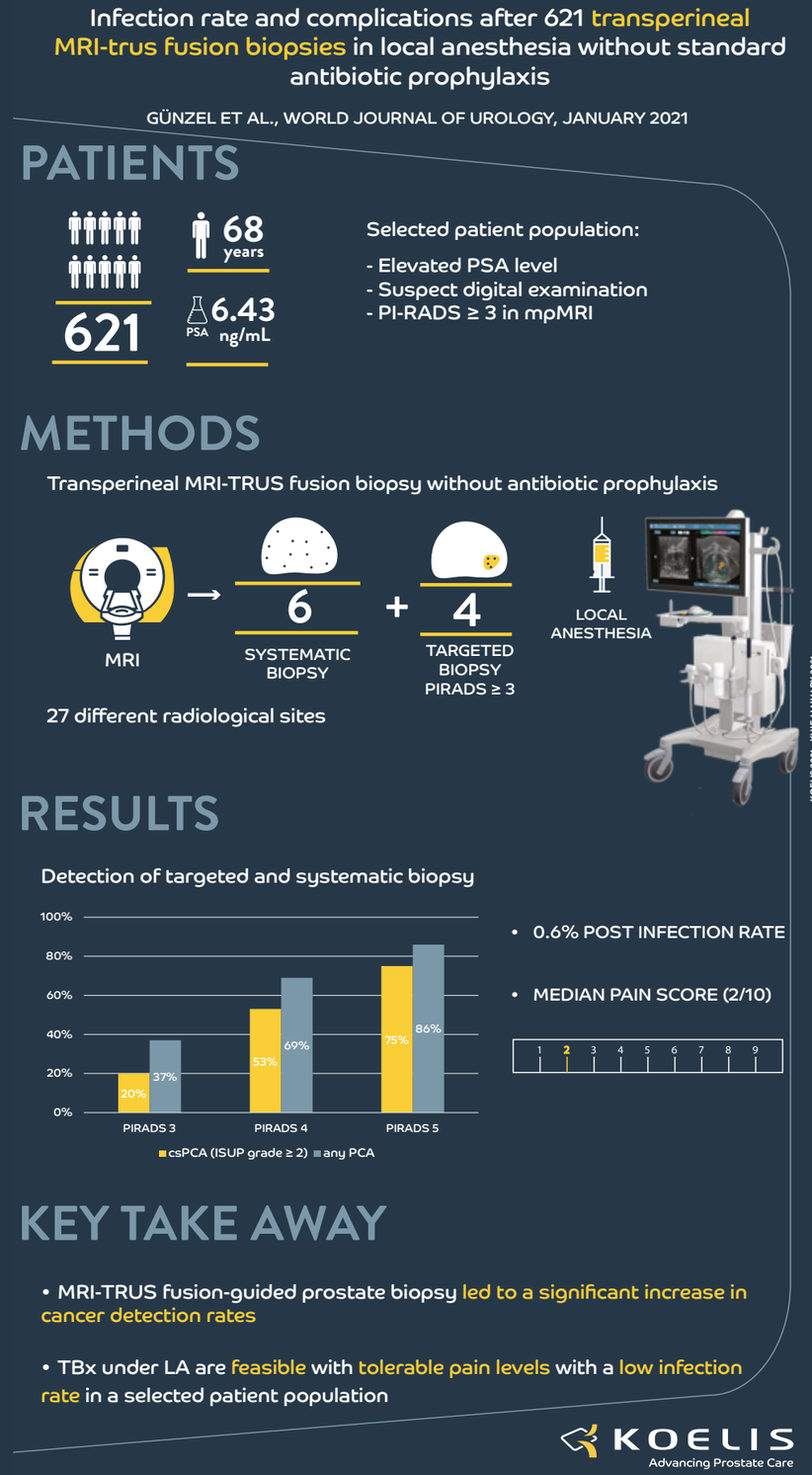
World J Urol. - 2021

PURPOSE: The aim of this study was to assess the post biopsy infection rate, feasibility and prostate cancer (PCa) detection rate (CDR) by performing transperineal MRI-TRUS fusion biopsy of the prostate (TPBx) under local anesthesia (LA) without antibiotic prophylaxis (AP).

METHODS: We prospectively screened 766 men with suspicious lesions on mpMRI, an elevated PSA level or a suspect digital examination undergoing MRI-TRUS-TPBx in LA, from May 2019 to July 2020. Patients with the need for antibiotic prophylaxis or without a PI-RADS target lesion were excluded from final analyses. We reported CDR, perioperative pain (0-10) and postoperative complications. PCa with an ISUP grade ≥ 2 was classified as clinically significant PCa (csPCa).

RESULTS: We included 621 patients with a median age of 68 years (IQR 62-74), a PSA of 6.43 ng/mL (IQR 4.72-9.91) and a prostate volume of 45 cc (IQR 32-64). In median, 4 targeted (TB) (IQR 3-4) and 6 (IQR 5-7) systematic biopsies (SB) detected in combination overall 416 (67%) PCa and 324 (52%) csPCa. Overall CDR of TB for PI-RADS 3, 4 and 5 was 26%, 65% and 84%, respectively. Patients reported a median perioperative pain level of 2 (IQR 1-3). Four patients (0.6%) developed a post biopsy infection, one experienced urosepsis.

CONCLUSIONS: Our results demonstrate that transperineal MRI-TRUS fusion-guided prostate biopsy under LA without AP is feasible, safe and well tolerated.



2.1 Transperineal biopsy under local anesthesia

Antibiotic prophylaxis versus no antibiotic prophylaxis in transperineal prostate biopsies (NORAPP): a randomised, open-label, non-inferiority trial

Maciej Jacewicz [1], Karsten Günzel [2], Erik Rud [3], Gunnar Sandbæk [4], Ahmed Magheli [2], Jonas Busch [2], Stefan Hinz [5], Eduard Baco [6]

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Lancet Infect Dis. - 2022

BACKGROUND: The benefit of antibiotic prophylaxis is uncertain when performing transperineal prostate biopsies. Judicious use of antibiotics is required as antimicrobial resistance increases worldwide. We aimed to assess whether antibiotic prophylaxis can be omitted when performing transperineal prostate biopsies under local anaesthesia as an outpatient procedure.

METHODS: In this randomised, open-label, non-inferiority trial, we aimed to enrol all patients with a suspicion of prostate cancer undergoing transperineal prostate biopsies at two hospitals in Norway and Germany. Patients with a high risk of infection or ongoing infection were excluded. Patients were randomised (1:1) to receive intramuscular (in Norway) or intravenous (in Germany) 1·5 g cefuroxime antibiotic prophylaxis or not. Follow-up assessments were done after 2 weeks and 2 months. The primary outcome was rate of sepsis or urinary tract infections requiring hospitalisation within 2 months. The secondary outcome was the rate of urinary tract infections not requiring hospitalisation. These outcomes were assessed in all eligible randomly allocated participants with a prespecified non-inferiority margin of 4%. Biopsies were performed using an MRI-transrectal ultrasound fusion transperineal technique under local anaesthesia. Patients with a positive MRI underwent 2-4 biopsies per target; in addition, 8-12 systematic biopsies were performed in biopsy naive and MRI-negative patients. This study is registered with ClinicalTrials.gov, NCT04146142.

FINDINGS: Between Nov 11, 2019, and Feb 23, 2021, 792 patients were referred for biopsy, of whom 555 (70%) were randomly allocated to treatment groups. 277 (50%) patients received antibiotic prophylaxis and 276 (50%) did not; two (<1%) patients were excluded after randomisation because of unknown allergy to study drug. Sepsis or urinary tract infections requiring hospitalisation occurred in no patients given antibiotic prophylaxis (0%, 95% CI 0 to 1·37) or not given antibiotic prophylaxis (0%, 0 to 1·37; difference 0% [95% CI -1·37 to 1·37]). Urinary tract infections not requiring hospitalisation occurred in one patient given antibiotic prophylaxis (0·36%, 95% CI 0·01 to 2·00) and three patients not given antibiotic prophylaxis (1·09%, 0·37 to 3·15; difference 0·73% [95% CI -1·08 to 2·81]). The number needed to treat with antibiotic prophylaxis to avoid one infection was 137.

INTERPRETATION: The non-inferiority margin of 4% was not exceeded, suggesting rates of infections were not higher in patients not receiving antibiotic prophylaxis before transperineal prostate biopsy than in those receiving it. Therefore, antibiotic prophylaxis might be omitted in this population.

FUNDING: Oslo University Hospital, Oslo, Norway and Vivantes Klinikum Am Urban, Berlin, Germany.

2.1 Transperineal biopsy under local anesthesia

Managing Discordant Findings Between Multiparametric Magnetic Resonance Imaging and Transrectal Magnetic Resonance Imaging,directed Prostate Biopsy ; The Key Role of Magnetic Resonance Imaging–directed Transperineal Biopsy

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Eur Urol Onco. - 2022

BACKGROUND: Discordant findings between multiparametric magnetic resonance imaging (mpMRI) and transrectal image-guided biopsies of the prostate (TRUS-P) may result in inadequate risk stratification of localized prostate cancer.

OBJECTIVE: To assess transperineal image-guided biopsies of the index target (TPER-IT) in terms of disease reclassification and treatment recommendations.

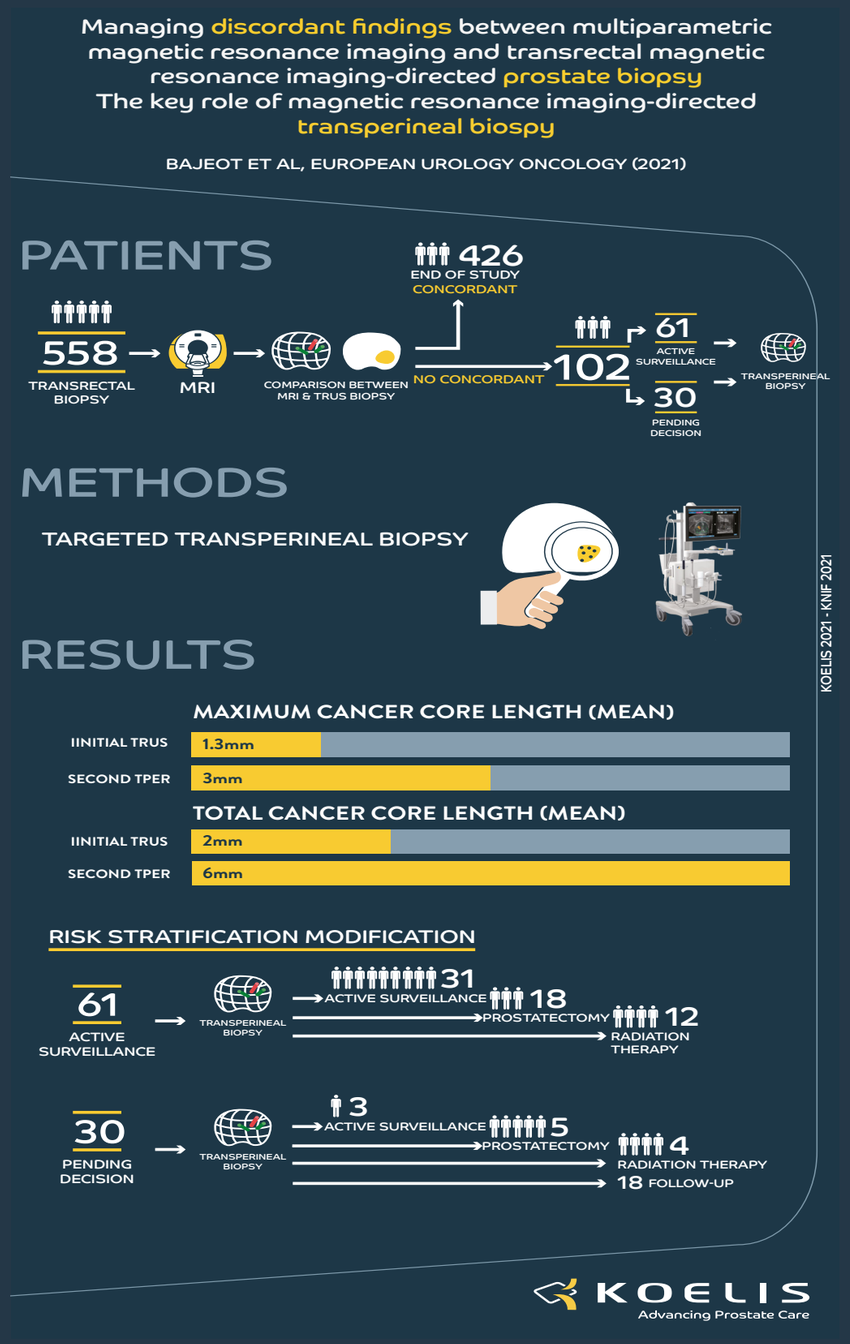
DESIGN, SETTING, AND PARTICIPANTS: Cases referred for suspicion or treatment of localized prostate cancer were reviewed in a multidisciplinary setting, and discordance was characterized into three scenarios: type I—negative biopsies or International Society of Urological Pathology (ISUP) grade 1 cancer in Prostate Imaging Reporting and Data System (PI-RADS) ≥4 index target (IT); type II—negative biopsies or ISUP grade 1 cancer in anterior IT; and type III—<3 mm stretch of cancer in PI-RADS ≥3 IT. Discordant findings were characterized in 132/558 (23.7%) patients after TRUS-P. Of these patients, 102 received reassessment TPER-IT.

OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS: The primary objective was to report changes in treatment recommendations after TPER-IT. Therefore, cores obtained by primary TRUS-P and TPER-IT were analyzed in terms of cancer detection, ISUP grade, and Cambridge Prognostic Group classification using descriptive statistics.

RESULTS AND LIMITATIONS: TPER-IT biopsies that consisted of fewer cores than the initial TRUS-P (seven vs 14, $p < 0.0001$) resulted in more cancer tissue materials for analysis (56 vs 42.5 mm, $p = 0.0003$). As a result, 40% of patients initially considered for follow-up (12/30) and 49% for active surveillance (30/61) were reassigned after TPER-IT to surgery or intensity-modulated radiotherapy.

CONCLUSIONS: Nonconcordance between pathology and imaging was observed in a significant proportion of patients receiving TRUS-P. TPER-IT better informed the presence and grade of cancer, resulting in a significant impact on treatment recommendations. A multidisciplinary review of mpMRI and TRUS-P findings and reassessment TPER-IT in type I–II discordances is recommended.

PATIENT SUMMARY: In this report, patients with suspicious imaging of the prostate, but no or well-differentiated cancer on transrectal image-guided -biopsies, were offered transperineal image-guided biopsies for reassessment. We found that a large share of these had a more aggressive cancer than initially suspected. We conclude that discordant results warrant reassessment transperineal image-guided biopsies as these may impact disease risk classification and treatment recommendations.



2.1 Transperineal biopsy under local anesthesia

Office-based Magnetic Resonance Imaging-guided Transperineal Prostate Biopsy Without Antibiotic Prophylaxis: A Real-world Clinical Utility Study

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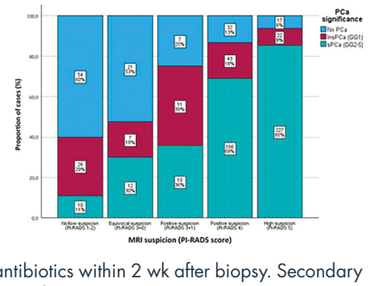
Eur Urol Open Sci. - 2023

BACKGROUND AND OBJECTIVE: Advances in for magnetic resonance imaging (MRI)-guided transperineal biopsy (TPBx) techniques have facilitated outpatient prostate biopsies under local anaesthesia to lower postbiopsy infection rates. However, there is debate regarding antibiotic prophylaxis because of concerns regarding antibiotic resistance and interactions. Our objective was to assess the transition from office-based transrectal biopsy to TPBx performed under local anaesthesia without antibiotic prophylaxis despite potential risk factors for infectious complications.

METHODS: We conducted a prospective assessment of 665 men undergoing office-based MRI-guided TPBx. The primary outcome was the rate of urosepsis or febrile urinary tract infections requiring hospitalisation and/or antibiotics within 2 wk after biopsy. Secondary outcomes included patient-reported procedure tolerability and the prostate cancer detection rate.



KEY FINDINGS AND LIMITATIONS: TPBx using a median of nine cores per patient (range 4-15) detected prostate cancer in 534/665 men (80%). Only four men (0.6%) were hospitalised for suspected postbiopsy infection; no patient experienced urosepsis. The TPBx procedure was well tolerated, with low pain scores (median Visual Analogue Scale score of 2, interquartile range [IQR] 1-3) and positive patient ratings (median rating 1 [no problem], IQR 1-2). Limitations include the single-centre analysis and lack of randomisation for antibiotic prophylaxis.

CONCLUSIONS AND CLINICAL IMPLICATIONS: An office-based TPBx strategy under local anaesthesia without antibiotic prophylaxis is well tolerated and has a very low risk of side effects. This approach should be considered as the standard of care. Further studies may determine if a subgroup of predisposed men could benefit from antibiotic prophylaxis.

2.1 Transperineal biopsy under local anesthesia

Non-infectious adverse events of transperineal prostate biopsies performed under local anaesthesia

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BJU Int. - 2024

OBJECTIVE: To report non-infectious adverse events associated with transperineal prostate biopsy (TPBx) performed under local anaesthesia (LA) in an outpatient setting.

PATIENTS AND METHODS: This study reports secondary outcomes from the Norwegian arm of the prospective NORAPP study (ClinicalTrials.gov identifier NCT04146142) and included all patients referred for prostate biopsy from November 2019 to February 2021. Transperineal magnetic resonance imaging-transrectal ultrasonography fusion TPBx were taken using 40 mL 1% lidocaine with 4 mL of 8.4% sodium bicarbonate placed in the perineal skin, under the prostatic apex, in the m. levator ani bilaterally, and along the path of the needle. Follow-up using patient-reported questionnaires was done immediately after TPBx, and after 2 weeks and 2 months. Pain was reported using a visual analogue scale (VAS) during placement of the LA, and during and after TPBx. Haematuria and acute urinary retention (AUR) rates were recorded.

RESULTS: We included 402 patients, and the response rate was 99.8% (401/402). The median (interquartile range [IQR]) age was 69 (63-74) years, the prostate volume was 40 (27-58) mL, the prostate-specific antigen level was 7.0 (4.5-11) ng/mL, and the number of biopsy cores taken was 8 (6-10). The median (IQR) VAS pain score was 1 (1-2) during placement of LA, 1 (0-2) during TPBx, and 0 (0-0) after TPBx. Haematuria and AUR rates were 64% (95% confidence interval [CI] 60-69%) and 0.5% (95% CI 0.1-1.8%), respectively. No patients were hospitalised or required after the TPBx surgical intervention.

CONCLUSION: Transperineal prostate biopsies can be performed under LA with limited discomfort to the patient and few post-TPBx adverse events.

2.2 Learning curve

Mapping of transrectal ultrasonographic prostate biopsies: quality control and learning curve assessment by image processing

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J Ultrasound Med. - 2009

PURPOSE: Mapping of transrectal ultrasonographic (TRUS) prostate biopsies is of fundamental importance for either diagnostic purposes or the management and treatment of prostate cancer, but the localization of the cores seems inaccurate. Our objective was to evaluate the capacities of an operator to plan transrectal prostate biopsies under 2-dimensional TRUS guidance using a registration algorithm to represent the localization of biopsies in a reference 3-dimensional ultrasonographic volume.
Thirty-two patients underwent a series of 12 prostate biopsies under local anesthesia performed by 1 operator using a TRUS probe combined with specific third-party software to verify that the biopsies were indeed conducted within the planned targets.

RESULTS: The operator reached 71% of the planned targets with substantial variability that depended on their localization (100% success rate for targets in the middle and right parasagittal parts versus 53% for targets in the left lateral base). Feedback from this system after each series of biopsies enabled the operator to significantly improve his dexterity over the course of time (first 16 patients: median score, 7 of 10 and cumulated median biopsy length in targets of 90 mm; last 16 patients, median score, 9 of 10 and a cumulated median length of 121 mm; P = .046).

CONCLUSIONS: In addition to being a useful tool to improve the distribution of prostate biopsies, the potential of this system is above all the preparation of a detailed «map» of each patient showing biopsy zones without substantial changes in routine clinical practices.

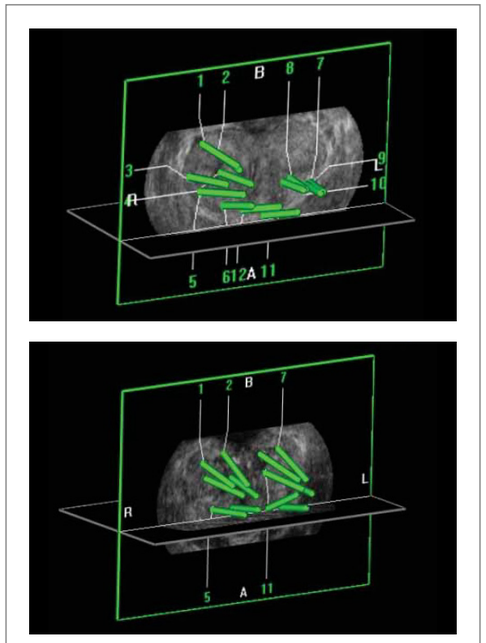

Figure 1. *Examples of biopsy distributions in the coronal plane for 2 different patients. Left, Patient from the first group, left base not sampled. Right, Patient from the second group, good sampling. A indicates apex; B, base; L, left; and R, right.*

2.2 Learning curve

Learning curve for fusion magnetic resonance imaging targeted prostate biopsy and three-dimensional transrectal ultrasonography segmentation

Louis Lenfant [1 2 3], Clément Beitone [3], Jocelyne Troccaz [3], Morgan Rouprêt [1], Thomas Seisen [1], Sandrine Voros [2], Pierre C Mozer [1 2]

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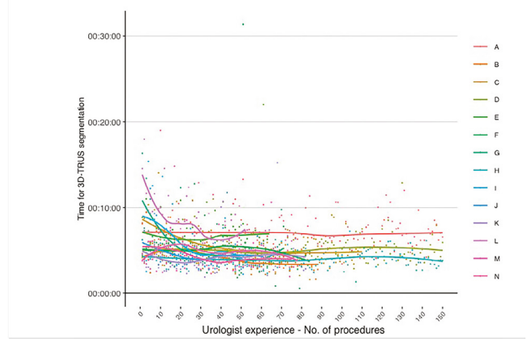
BJU Int. - 2024

OBJECTIVE: To report the learning curve of multiple operators for fusion magnetic resonance imaging (MRI) targeted biopsy and to determine the number of cases needed to achieve proficiency.
Materials and methods: All adult males who underwent fusion MRI targeted biopsy between February 2012 and July 2021 for clinically suspected prostate cancer (PCa) in a single centre were included. Fusion transrectal MRI targeted biopsy was performed under local anaesthesia using the Koelis platform. Learning curves for segmentation of transrectal ultrasonography (TRUS) images and the overall MRI targeted biopsy procedure were estimated with locally weighted scatterplot smoothing by computing each operator's timestamps for consecutive procedures. Non-risk-adjusted cumulative sum (CUSUM) methods were used to create learning curves for clinically significant (i.e., International Society of Urological Pathology grade ≥ 2) PCa detection.

RESULTS: Overall, 1721 patients underwent MRI targeted biopsy in our centre during the study period. The median (interquartile range) times for TRUS segmentation and for the MRI targeted biopsy procedure were 4.5 (3.5, 6.0) min and 13.2 (10.6, 16.9) min, respectively. Among the 14 operators with experience of more than 50 cases, a plateau was reached after 40 cases for TRUS segmentation time and 50 cases for overall MRI targeted biopsy procedure time. CUSUM analysis showed that the learning curve for clinically significant PCa detection required 25 to 45 procedures to achieve clinical proficiency. Pain scores ranged between 0 and 1 for 84% of patients, and a plateau phase was reached after 20 to 100 cases.

Fig. 1 Learning curves for three-dimensional (3D) TRUS segmentation.



CONCLUSIONS: A minimum of 50 cases of MRI targeted biopsy are necessary to achieve clinical and technical proficiency and to reach reproducibility in terms of timing, clinically significant PCa detection, and pain.

2.3 3D Transperineal versus Transrectal biopsy

Transperineal or Transrectal Magnetic Resonance Imaging-targeted Biopsy for Prostate Cancer Detection

Romain Diamand [1], Karsten Guenzel [2], Georges Mjaess [3], Yolène Lefebvre [4], Mariaconsiglia Ferriero [5], Giuseppe Simone [5], Alexandre Fourcade [6], Georges Fournier [6], Alexandre-Patrick Bui [7], Fayek Taha [7], Marco Oderda [8], Paolo Gontero [8], Katerina Rysankova [9], Adrian Bernal-Gomez [10], Alessandro Mastrorosa [10], Jean-Baptiste Roche [10], Gaelle Fiard [11], Rawad Abou Zahr [12], Guillaume Ploussard [12], Olivier Windisch [13], Quentin Novello [13], Daniel Benamran [13], Gina Delavar [14], Julien Anract [14], Nicolas Barry Delongchamps [14], Adam Halinski [15], Charles Dariane [16], Jan Benijts [17], Gregoire Assenmacher [17], Thierry Roumeguère [3], Alexandre Peltier [3]

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Eur Urol Focus. - 2024

BACKGROUND AND OBJECTIVE: A notable paradigm shift has emerged in the choice of prostate biopsy approach, with a transition from transrectal biopsy (TRBx) to transperineal biopsy (TPBx) driven by the lower risk of severe urinary tract infections. The impact of this change on detection of clinically significant prostate cancer (csPCa) remains a subject of debate. Our aim was to compare the csPCa detection rate of TRBx and TPBx.

METHODS: Patients who underwent magnetic resonance imaging (MRI)-targeted and systematic biopsies for clinically localized PCa at 15 European referral centers from 2016 to 2023 were included. A propensity score matching (PSM) analysis was performed to minimize selection biases. Logistic regression models were used to estimate adjusted odds ratios (ORs) and 95% confidence intervals (CIs).

KEY FINDINGS AND LIMITATIONS: Of 3949 patients who met the study criteria, 2187 underwent TRBx and 1762 underwent TPBx. PSM resulted in 1301 matched pairs for analysis. Patient demographics and tumor characteristics were comparable in the matched cohorts. TPBx versus TRBx was associated with greater detection of csPCa, whether defined as International Society of Urological Pathology grade group ≥2 (51% vs 45%; OR 1.37, 95% CI 1.15-1.63; p = 0.001) or grade group ≥3 (29% vs 23%; OR 1.38, 95% CI 1.13-1.67; p = 0.001). Similar results were found when considering MRI-targeted biopsy alone and after stratifying patients according to tumor location, Prostate Imaging-Reporting and Data System score, and clinical features. Limitations include the retrospective nature of the study and the absence of centralized MRI review.

CONCLUSIONS: Our findings bolster existing understanding of the additional advantages offered by TPBx. Further randomized trials to fully validate these findings are awaited.

2.3 3D Transperineal versus Transrectal biopsy

Transperineal versus Transrectal MRI/TRUS fusion-guided prostate biopsy in a large, ethnically diverse, and multiracial cohort

Lorenzo Storino Ramacciotti [1 2], David Strauss [1 2], Francesco Cei [1], Masatomo Kaneko [1 2], Daniel Mokhtar [1], Jie Cai [1], Delara Jadvar [1 2], Giovanni E Cacciamani [1 3], Manju Aron [1 4], Pierre B Halteh [3], Vinay Duddalwar [1 3], Inderbir Gill [1], Andre Luis Abreu [1 2 3]

[1]USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles, California, USA. [2] Center for Image-Guided Surgery, Focal Therapy and Artificial Intelligence for Prostate Cancer, Keck School of Medicine, University of Southern California, Los Angeles, California, USA. [3] Department of Radiology Keck School of Medicine, University of Southern California, Los Angeles, California, USA. [4] Department of Pathology Keck School of Medicine, University of Southern California, Los Angeles, California, USA.

Int Braz J Urol. - 2024

PURPOSE: To compare transperineal (TP) vs transrectal (TR) magnetic resonance imaging (MRI) and transrectal ultrasound (TRUS) fusion-guided prostate biopsy (PBx) in a large, ethnically diverse and multiracial cohort.

MATERIALS AND METHODS: Consecutive patients who underwent multiparametric (mp) MRI followed by TP or TR TRUS-fusion guided PBx, were identified from a prospective database (IRB #HS-13-00663). All patients underwent mpMRI followed by 12-14 core systematic PBx. A minimum of two additional target-biopsy cores were taken per PIRADS≥3 lesion. The endpoint was the detection of clinically significant prostate cancer (CSPCa; Grade Group, GG≥2). Statistical significance was defined as p<0.05.

RESULTS: A total of 1491 patients met inclusion criteria, with 480 undergoing TP and 1011 TR PBx. Overall, 11% of patients were Asians, 5% African Americans, 14% Hispanic, 14% Others, and 56% White, similar between TP and TR (p=0.4). For PIRADS 3-5, the TP PBx CSPCa detection was significantly higher (61% vs 54%, p=0.03) than TR PBx, but not for PIRADS 1-2 (13% vs 13%, p=1.0). After adjusting for confounders on multivariable analysis, Black race, but not the PBx approach (TP vs TR), was an independent predictor of CSPCa detection. The median maximum cancer core length (11 vs 8mm; p<0.001) and percent (80% vs 60%; p<0.001) were greater for TP PBx even after adjusting for confounders.

CONCLUSIONS: In a large and diverse cohort, Black race, but not the biopsy approach, was an independent predictor for CSPCa detection. TP and TR PBx yielded similar CSPCa detection rates; however the TP PBx was histologically more informative.

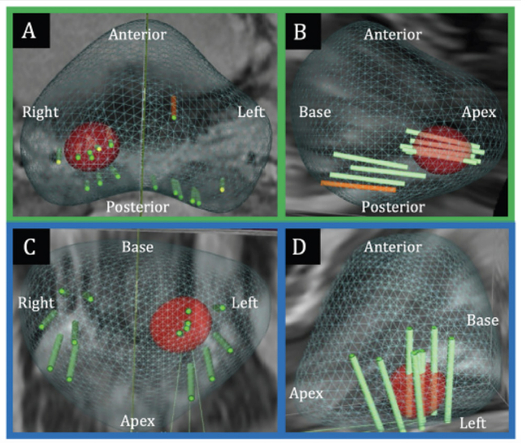

Figure 2. *Prostate biopsy templates.*

2.3 3D Transperineal versus Transrectal biopsy

Transrectal versus transperineal prostate fusion biopsy: a pair-matched analysis to evaluate accuracy and complications

Marco Oderda [1], Romain Diamand [2], Rawad Abou Zahr [3], Julien Anract [4], Gregoire Assenmacher [5], Nicolas Barry Delongchamps [4], Alexandre Patrick Bui [6], Daniel Benamran [7], Giorgio Calleris [8], Charles Dariane [9], Mariaconsiglia Ferriero [10], Gaelle Fiard [11], Fayek Taha [6], Alexandre Fourcade [12], Georges Fournier [12], Karsten Guenzel [13], Adam Halinski [14], Giancarlo Marra [8], Guillaume Ploussard [15], Katerina Rysankova [16], Jean-Baptiste Roche [17], Giuseppe Simone [10], Olivier Windisch [7], Paolo Gontero [8]

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World J Urol. - 2024

PURPOSE: To evaluate biopsy-related complications and detection rates of any PCa and clinically significant PCa (csPCa, intended as grade group ≥ 2) between MRI-targeted TP fusion biopsies (TPBx) and TR ones (TRBx).

METHODS: We performed a multicentric study on 4841 patients who underwent fusion biopsy between 2016 and 2023. A case-control matching was performed to find comparable cohorts of 646 TPBx and 646 TRBx. Mean T test and Pearson chi-square tests were used to compare continuous and categorical variables.

RESULTS: Baseline characteristics were comparable between the cohorts, except for target location with a higher rate of anterior lesions in TPBx group. Complications were rare and no difference was found between the groups, with similar rates of infections after TRBx and TPBx (N = 5 (0.8%) vs N = 2 (0.3%), p 0.45). All patients in TRBx and 90.1% in TPBx group received antibiotic prophylaxis. A higher csPCa detection rate was found in TPBx over the group (50.5% vs 36.2%, p < 0.001). On average, positive targeted cores were increased in TPBx group, for any PCa (1.6 vs 1.4, p 0.04) and csPCa (1.0 vs 0.8, p 0.02). Among the limitations of study, we acknowledge the retrospective design and the possible under-reporting of complications.

CONCLUSIONS: MRI-targeted fusion TPBx achieves a significantly higher csPCa detection than TRBx, with a diagnostic advantage for apical and anterior lesions. No significant differences were found in terms of complications that were rare in both groups, considering a widespread adoption of antibiotic prophylaxis.

Transrectal versus transperineal prostate fusion biopsy a pair-matched analysis to evaluate accuracy and complications

Oderda M et al. Transrectal versus transperineal prostate fusion biopsy: a pair-matched analysis to evaluate accuracy and complications. World J Urol. 2024 Sep;42(1):535. doi: 10.1007/s00345-024-05245-1

DESIGN

Retrospective, international multicenter study.

15

4841

PRIMARY CRITERIA

PRIMARY OBJECTIVE

Biopsies complication, detection of PCa and csPCa.

RESULTS

From a database of 4841 patients, the case-control analysis found
2 comparable cohorts of 646 TP VS 646 TR.
Complications were rare and no difference was found between the groups.
All patients in TRBx and 90.1% in TPBx group received antibiotic prophylaxis.

	TP	TR	Significant ?
csPCA detection rate	50.5%	36.2%	Yes (ρ<0.01)
positive targeted cores for all PCa	1.6	1.4	Yes (ρ=0.04)
positive targeted cores for csPCa	1.0	0.8	Yes (ρ=0.02)

- **A higher** csPCa detection rate forTP Biopsies
- **A higher** positive targeted cores in TPBx group for any PCa
- **A higher** positive targeted cores in TPBx group csPCa

	TP	TR	Significant ?
csPCA detection rate by location :			
Anterior lesion	39.5%	24.5%	Yes (ρ=0.002)
Posterior lesion	43.1%	33.1%	Yes (ρ=0.002)
Apex lesion	44.8%	34.9%	Yes (ρ=0.05)
Base lesion	40.3%	19.4%	Yes (ρ<0.001)

- **Higher** csPCa detection rate forTP Biopsies for all localizations

PUBLICATION CONCLUSION

MRI-targeted fusion TPBx achieves a significantly higher csPCa detection than TRBx, with a diagnostic advantage for apical and anterior lesions. No significant differences were found in terms of complications that were rare in both groups, considering a widespread adoption of antibiotic prophylaxis

KOELIS
Advancing Prostate Care

KCOM_2411_CtI_3_V1_EN

3.1 Diagnostic accuracy : PET/US targeted biopsy

Trimodal (18) F-choline-PET/mpMRI/TRUS targeted prostate biopsies: First clinical experience

J.L. Bonnal[1], A. Marien, A. Rock, K. El Maadarani, C. Francois, A. Delebarre, D. Berssard, B. Mauroy, P. Gosset, T. Blaire

[1] *Hôpital Saint Philibert, Lomme, Groupement des Hôpitaux de l'Institut Catolique de Lille*

EAU 2017

PURPOSE: In this preliminary study ,the feasibility of PET choline compared mpMRI was studied, to define target prostate biopsy. The fusion of these two modalities with 3D echography was to compare the diagnostic performance for primary localization of PCa with mpMRI and the latest generation of PET.

PATIENTS AND METHODS: In a prospective single-center study, fromDecember 2014 to October 2016, all patients with PSA above 10ng/ml or patient with medical history of negative prostate biopsy were included. 3D biopsy with KOELIS® system, mpMRI and PET scan Choline were done for each patients. The biopsy targets were defined with both modalities and merging was done in real time during prostate biopsy sessions with the 3D echography. A review has been done to exclude patients with missed targets.The results were compared to anatomopathological outcome of the biopies.Biopsy was done twice for each target at least and randomized biopsy was done outside the target.

RESULTS: 31 patients were included, mean PSA was 13.01 (5.32-73). Mean number of biopsy was 16 (13-21) and mean prostate volume was 63.41 cc (25-169). During our learning curve, 4 patients with several negative targets but 1 missed target were excluded for global analysis.However,3 patients were detected as positive while all targets were not biopsied. Furthermore, the PET fusion analysis failed for one patient. The cancer detection rate was 69%. If the biopsy came back positive for cancer, the PET,th mpMRI or both targets were respectively positive in 72%, 94%, 100%. On average in this population the number of biopsies by target with TEP or mpMRI were respectively 1.77 (1-7) ,2.74 (3-11).The TEP and IRM by target were associated with positives biopsies respectively in 43% and 62% .Compared to mpMRI ,for one patient only TEP gave a positive target but fail with four other patients. mpMRI was probably best than PET choline for detecting prostate cancer but it could be complementary.

CONCLUSIONS: We demonstrate the feasibility of multiple imagery fusion with echography 3D to define localization of prostate cancer. It was very interesting to observe sometimes a great difference in the distribution of PET choline target and mpMRI target in prostate. A new study with the novel ligands targeting prostate specific membrane antigen (PSMA) could improve our clinical results.

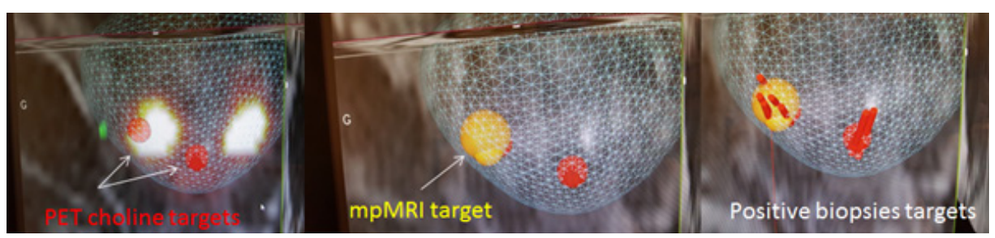

Figure 1. *The biopsy procedure was performed after registration of real-time TRUS with mpMRI and choline-PET by the same operator, using 3D TRUS-tracking system. At the time of biopsy, volume data of the mpMRI and PET 18-ch was elastically fused with TRUS. Each target was biopsied twice.*

3.1 Diagnostic accuracy : PET/US targeted biopsy

Incidentally Detected 18 F-FDG-Avid Prostate Cancer Diagnoseda Using a Novel Fusion Biopsy Platform

Meyer A.R[1], Leroy A[2], Allaf M.E, Rowe S.P, Gorin M.A.

[1] *The James Buchanan Brady Urological Institute and Department of Urology,Johns Hopkins University School of Medicine, Baltimore, Maryland*
[2] *KOELIS®, Inc., Cambridge, Massachusetts*

J Endourol Case Rep. - 2019

BACKGROUND: Localized prostate cancer rarely undergoes a shift in metabolism towards aerobic glycolysis, a process known as the Warburg Effect. Because of this, positron emission tomography (PET)/CT imaging using 2-deoxy-2-[18F]fluoro-d-glucose (18F-FDG) is uncommonly used to evaluate patients with early-stage prostate cancer. However, men undergoing an 18F-FDG PET/CT for unrelated reasons will on occasion be found to have radiotracer uptake within the prostate gland. The appropriate work-up of these patients is poorly defined

CASE PRESENTATION: We present the case of a 61-year-old man with a history of tonsillar squamous cell carcinoma who was incidentally found on 18F-FDG PET/CT to have a hypermetabolic nodule within the prostate. The patient's prostate-specific antigen level was 2.1 ng/cc and digital rectal examination revealed no abnormalities. The patient underwent a targeted prostate biopsy of the lesion using the KOELIS TRINITY® biopsy platform, which uniquely allows for the real-time overlay of transrectal ultrasonography and PET/CT images. Targeted biopsy revealed Gleason score 4 + 3 = 7 (grade group 3) prostate cancer.

CONCLUSIONS: Although the incidental detection of 18F-FDG uptake within the prostate is uncommon, more than half of all patients will be found to have prostate cancer. Based on this case and our review of the available medical literature, it is our belief that men with incidentally detected uptake of 18F-FDG within the prostate should undergo further evaluation with a prostate biopsy. This recommendation is supported by data suggesting that 18F-FDG-avid prostate cancer represents a more aggressive clinical phenotype.

3.1 Diagnostic accuracy : PET/US targeted biopsy

Fusion Targeted Biopsy Using PSMA-PET/CT For Prostate Cancer Diagnosis In Patients With A Previous Negative Biopsy

Olivares R[1], Jofre B[2], González P[2], Velasco A, Franco C, Román C.

[1]Urology Department of Clínica Santa María, Santiago, Chili. [2]Imaging Department of Clínica Santa María, Santiago

CAU 2019

INTRODUCTION: For patients with a previous negative biopsy but with maintained clinical suspicion for prostate cancer, Multiparametric Magnetic Resonance (MRI)-guided biopsy has demonstrated its usefulness and efficiency, especially, for the diagnosis of a clinically significant disease. Approximately 20% of patients have lesions that are "invisible" to resonance. In these cases, PET-CT could have diagnostic usefulness with the definition of limits and guidance of the sampling during the medical procedure.

METHODS:
A 57-year-old patient
PSA level of 10ng/ml
Non suspicious DRE
Biopsy: Two previous negative biopsies
PET/CT PSMA: Two lesions with increased uptake

RESULTS:
45-minute procedure
US/PET-CT Elastic Fusion using KOELIS TRINITY® cartographer
5 targeted core samples obtained from the suspect lesions
18 additional, random cores using sextant scheme as the reference
Anatomical Pathology confirmed a Gleason score of 3+4 in 3/5 of targeted biopsy cores and in 1 among the aleatory sextant biopsy sampling.

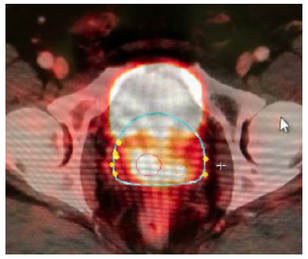

Figure 1. *Two radiotracer uptakes on PSMA-PET/CT*

CONCLUSIONS: First report in Latin America about the usefulness of US/PET-CT PSMA Fusion Biopsy for diagnosis of prostate cancer in a patient with previous negative biopsy and no evidence of malignancy in MRI Series involving a higher number of patients will make possible to evaluate the usefulness and the cost-effectiveness in clinical practice.

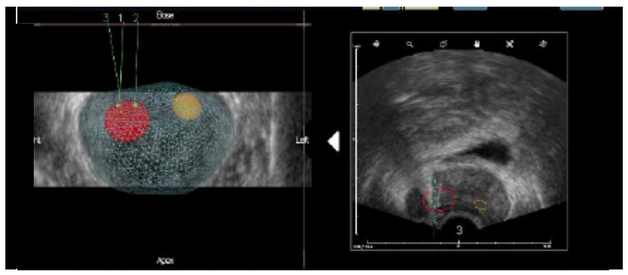

Figure 2. *Targets' contour for the targeted biopsy on the US/PET-CR Fusion*

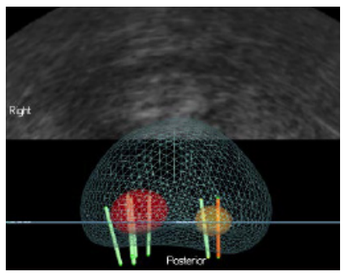

Figure 3. *3D map displaying sample cores*

3.2 Repeat biopsy for active surveillance strategy

Multiparametric magnetic resonance imaging facilitates reclassification during active surveillance for prostate cancer

Fujihara A[1,2], Iwata T, Shakir A, Tafuri A, Cacciamani G, Gill K, Ashrafi A, Ukimura O, Desai M, Duddalwar V, Stern M, Aron M, Palmer S, Gill I, Abreu A.L.

[1] USC Institute of Urology and Catherine & Joseph Aresty Department of Urology, University of Southern California, Los Angeles, California USA
[2] Department of Urology, Graduate School of Medical Science, Kyoto Prefectural University of Medicine, Kyoto, Japan

BJU Int. - 2021

OBJECTIVE: To investigate the utility of multiparametric magnetic resonance imaging (mpMRI) in the reassessment and monitoring of patients on active surveillance (AS) for Grade Group (GG) 1 prostate cancer (PCa).

PATIENTS AND METHODS: We identified, from our prospectively maintained institutional review board-approved database, 181 consecutive men enrolled on AS for GG 1 PCa who underwent at least one surveillance mpMRI followed by MRI/prostate biopsy (PBx). A subset analysis was performed among 68 patients who underwent serial (at least two) mpMRI/PBx during AS. Pathological progression (PP) was defined as upgrade to GG ≥2 on follow up biopsy.

RESULTS: Baseline MRI was performed in 34 patients (19%). At a median follow-up of 2.2 years for the overall cohort, the PP was 12% (6/49) for Prostate Imaging Reporting and Data System (PI-RADS) 1–2 lesions and 37% (48/129) for the PI-RADS ≥3 lesions. The 2-year PP-free survival rate was 84%. Surveillance prostate-specific antigen density ($P < 0.001$) and surveillance PI-RADS ≥3 ($P = 0.002$) were independent predictors of PP on reassessment MRI/PBx. In the serial MRI cohort, the 2-year PP-free survival was 95% for the No-MRI-progression group vs 85% for the MRI-progression group ($P = 0.02$). MRI progression was significantly higher in the PP (62%) than in the No-PP (31%) group ($P = 0.04$). If serial MRI were used for PCa surveillance and biopsy were triggered based only on MRI progression, 63% of PBx might be postponed at the cost of missing 12% of GG ≥2 PCa in those with stable MRI. Conversely, this strategy would miss 38% of those with upgrading to GG ≥2 PCa on biopsy. Stable serial mpMRI correlates with no reclassification to GG ≥3 PCa during AS.

CONCLUSIONS: On surveillance mpMRI, PI-RADS ≥3 was associated with increased risk of PCa reclassification. Surveillance biopsy based only on MRI progression may avoid a large number of biopsies at the cost of missing many PCa reclassifications.

3.2 Repeat biopsy for active surveillance strategy

Validation of the European Society of Urogenital Radiology scoring system for prostate cancer diagnosis on multiparametric magnetic resonance imaging in a cohort of repeat biopsy patients

Daniel Portalez [1], Pierre Mozer, François Cornud, Raphaëlle Renard-Penna, Vincent Misrai, Matthieu Thoulouzan, Bernard Malavaud

[1] *Department of Radiology, Clinique Pasteur, Toulouse, France.*

Eur Urol. - 2012

BACKGROUND: Wide variations in acquisition protocols and the lack of robust diagnostic criteria make magnetic resonance imaging (MRI) detection of prostate cancer (PCa) one of the most challenging fields in radiology and urology.

DESIGN, SETTING, AND PARTICIPANTS: An institutional review board-approved multicentric prospective study; 129 consecutive patients (1514 cores) referred for mpMRI after at least one set of negative biopsies.

INTERVENTION: Transfer of mpMRI-suspicious areas on three-dimensional (3D) transrectal ultrasound images by 3D elastic surface registration; random systematic and targeted cores followed by core-by-core analysis of pathology and mpMRI characteristics of the core locations. The ESUR scores were assigned after the procedure on annotated Digital Imaging and Communications in Medicine archives.

OUTCOME MEASUREMENTS AND STATISTICAL ANALYSIS: Relationships between ESUR scores and biopsy results were assessed by the Mann-Whitney U test. The Yates correction and Pearson x(2) tests evaluated the association between categorical variables. A teaching set was randomly drawn to construct the receiver operating characteristic curve of the ESUR score sum (ESUR-S). The threshold to recommend biopsy was obtained from the Youden J statistics and tested in the remaining validation set in terms of sensitivity, specificity, positive predictive value, negative predictive value, and accuracy.

RESULTS AND LIMITATIONS: Higher T2-weighted, dynamic weighted imaging and dynamic contrast-enhanced ESUR scores were observed in areas yielding cancer-positive cores. The proportion of positive cores increased with the ESUR-S aggregated in five increments (ESUR-S 3-5: 2.9%; ESUR-S 6-8: 11.1%; ESUR-S 9-10: 38.2%; ESUR-S 11-12: 63.4%; and ESUR-S 13-15: 83.3%; $p<0.0001$). A threshold of ESUR-S ≥ 9 exhibited the following characteristics: sensitivity: 73.5%; specificity: 81.5%; positive predictive value: 38.2%; negative predictive value: 95.2%; and accuracy: 80.4%. Although the study was not designed to compare repeat biopsy strategies, more targeted cores than random systematic cores were found to be positive for cancer (36.3% compared with 4.9%, $p<0.00001$).

CONCLUSIONS: In the challenging situation of repeat biopsies, the ESUR scoring system was shown to provide clinically relevant stratification of the risk of showing PCa in a given location.

3.2 Repeat biopsy for active surveillance strategy

A novel technique using three-dimensionally documented biopsy mapping allows precise re-visiting of prostate cancer foci with serial surveillance of cell cycle progression gene panel

Ukimura O[1], Gross ME, de Castro Abreu AL, Azhar RA, Matsugasumi T, Ushijima S, Kanazawa M, Aron M, Gill IS.

[1]*USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles, California.*

Prostate - 2015

BACKGROUND: Conventional systematic biopsy has the shortcoming of sampling error and reveals «no evidence of cancer» with a rate of >50% on active surveillance (AS). The objective of this study is to report our initial experience of applying a 3D-documented biopsy-mapping technology to precisely re-visit geographically documented low-risk prostate cancer and to perform serial analysis of cell-cycle-progression (CCP) gene-panel.

METHODS: Over a period of 40 months (1/2010-4/2013), the 3D-biopsy-mapping technique, in which the spatial location of biopsy-trajectory was digitally recorded (KOELIS®), was carried out. A pair of diagnostic (1st-look) and surveillance (2nd-look) biopsy were performed per subject (n=25), with median interval of 12 months. The documented biopsy-trajectory was used as a target to guide the re-visiting biopsy from the documented cancer focus, as well as the targeted field-biopsy from the un-sampled prostatic field adjacent to negative diagnostic biopsies. The accuracy of re-visiting biopsy and biopsy-derived CCP signatures were evaluated in the pair of the serial biopsy-cores.

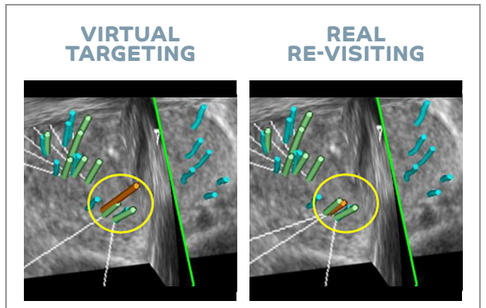

Figure 1. *The re-visiting biopsy technique using the pair of "virtual" and "real" targeting. The re-visiting biopsy technique is demonstrated in Figure 2 by the pair of "virtual" (long orange trajectory, circled in yellow in the left of Fig. 3) and "real" biopsies (short orange trajectory, circled in yellow in the right of Fig. 2), intentionally sampling from the previously positive targets in the location of the right-apex-medial. Because the virtual targeting seemed 3–4 mm too lateral to reach the target, the direction of the real biopsy was further corrected to bring it closer to the target. Note that one core (green trajectory) had already been sampled during the current 2nd look biopsy from the same positive target with the same re-visiting technique. These two re-visiting cores in the 2nd look biopsy were positive for cancer. The overlaid image demonstrates that the pair of green and orange trajectories of the re-visiting technique almost corresponded (or were located within 1–2 mm) with the blue trajectory of the positive core at the right-apex-medial on the 1st-look biopsy.*

RESULTS: The 1st-look-biopsy revealed a total of 43 cancer lesions (1.7 per patient). The accuracy of re-visiting cancer was 86% (37/43) per lesion, 76% (65/86) per core, and 80% (20/25) per patient. This technology also provided an opportunity for 3D-targeted field-biopsy in order to potentially minimize sampling errors. The CCP gene-panel of the 1st-look (-0.59) versus 2nd-look (-0.37) samples had no significant difference (P=0.4); which suggested consistency in the molecular signature of the known cancer foci during the short-time interval of median 12 months. Any change in CCP of the same cancer foci would be likely due to change in sampling location from the less to more significant portion in the cancer foci rather than true molecular progression. The study limitations include a small number of the patients.

CONCLUSIONS: The 3D-documented biopsy-mapping technology achieved an encouraging re-sampling accuracy of 86% from the known prostate cancer foci, allowing the serial analysis of biopsy-derived CCP signatures.

3.2 Repeat biopsy for active surveillance strategy

Performance of systematic, MRI-targeted biopsies alone or in combination for the prediction of unfavourable disease in MRI-positive low-risk prostate cancer patients eligible for active surveillance

Ploussard G[1], Beauval J-B, Lesourd M, Almeras C, Assoun J, Aziza R, Gautier J-R, Loison G, Portalez D, Salin A, Tollon C, Soulié M, Malavaud B, Roumiguié M.

[1]*Department of Urology, La Croix du Sud Hospital, IUCT-O, Toulouse, France*

World J Urol. - 2020

PURPOSE: To assess the upstaging/upgrading rates of low-risk prostate cancer (PCa) according to the biopsy scheme used (systematic (SB), targeted biopsies (TB), or both) in the setting of positive pre-biopsy MRI.

PATIENTS AND METHODS: We included 143 consecutive men fulfilling the Toronto University active surveillance (AS) criteria who underwent a pre-biopsy positive MRI, a combination of SB and software-based fusion TB, and a radical prostatectomy, in two expert centres. The primary endpoints were the pathological upgrading and upstaging rates. Overall unfavourable disease (OUD) was defined by any pT3-4 and/or pN1 and/or ≥ GG 3.

RESULTS: Using TB alone would have missed 21.7% of cancers including 16.7% of ≥ GG 3. The use of TB was significantly associated with a lower risk of ≥ Grade Group (GG) 3 disease ($p < 0.006$) in RP specimens. Combination of SB and TB lowered this risk by 39%, compared with TB alone. The biopsy scheme did not affect the upstaging rates which were substantial even in case of combination scheme (from 37 to 46%). OUD was detected in approximately 50% of cases. The presence of high grade on TB was the only independent predictive factor for both ≥ GG 2 ($p = 0.015$) and ≥ GG 3 ($p = 0.023$) in RP specimens.

CONCLUSIONS: High grade on TB biopsies represented the major predictor of upgrading. Combination of SB and TB better defined the sub-group of patients having the lowest risk of reclassification, compared with TB or SB alone. The risk of non-organ-confined disease remained high, and could not be accurately predicted by MRI or systematic/targeted biopsy features.

3.3 Focal treatment

3D targeted focal cryotherapy treatment: case report of the first procedure at our institution

S. Crouzet[1], P. Moldovan[2]

[1] Department of Urology, Radiology. [2]Hôpital Edouard Herriot, Lyon, France

Poster FTI 2019

INTRODUCTION: Focal treatment is an emerging solution, which yields high interest as an optimal compromise between radical treatment and active surveillance. Nevertheless, this approach requires, in addition to a focally applied energy, an adequate targeting to properly place the energy. The feasibility of focal targeted cryotherapy using a fusion and mapping platform is here investigated on a patient.

METHODS AND MATERIALS: A 71-years-old patient with a chemical recurrence following external beam radiotherapy for prostate cancer, with suspicious foci identified on Choline-PET scan and confirmed by transrectal-targeted biopsy gave consent to receive a targeted and focal cryotherapy treatment. No other tumor site demonstrated on complete workup. The patient was contraindicated for HiFu treatment (rectal stenosis following the initial treatment).A 3D multimodal cartographer (KOELIS TRINITY®, KOELIS®, Meylan, France) and associated accessories (PERINE™ 3D motorized ultrasound probe, STEADYPRO™ mechanical probe holder and needle guides) were used to delineate the region to be treated (MRI/PET-CT/transrectal ultrasound fusion), to guide the cryoprobes implantation and to monitor the focal treatment performed under transperineal access. The cryotherapy system (Visuallce system and IceSphere cryoprobes, GALIL, Arden Hills ,USA) delivered the cryotherapy treatment. Two cryoprobes were placed in the region of interest to be treated under 3D guidance, as well as one thermosensor in the recto-prostatic fascia.

RESULTS: Planning, targeting, and monitoring have been done successfully. The targeting procedure, from the beginning of the fusion to the end of the implantation, lasted 27 minutes and the treatment 33 minutes. 3D ultrasound imaging was used during the procedure to confirm treatment delivery in the targeted area. No pain or adverse effects have been reported. The real-time mapping capacities of the cartography system allowed to guide the cryoprobes in the anatomical volume, improving accuracy and speeding up the procedure. All the treatment information has been gathered in a 3D prostate map which will allow an effective follow-up of the patient.

CONCLUSIONS: Targeted focal cryotherapy using 3D cartography is feasible and allows to plan, guide, monitor and record such a treatment with precision and safety. This tool will be used in clinical routine at our institution.

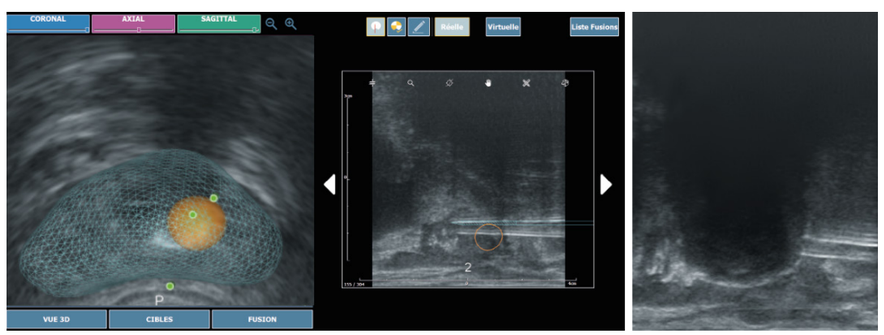

Figure 1: *The real-time mapping capacities of the cartography system allowed to guide the cryoprobes in the anatomical volume.*

3.3 Focal treatment

Value of magnetic resonance imaging/ultrasound fusion prostate biopsy to select patients for focal therapy

Roman Ganzer # [1], Alexander Mangold # [2], Fiona Sofia Siokou [2], Christian Brinkschmidt [3], Wolfgang Brummeisl [2]

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World J Urol. - 2022

PURPOSE: To investigate the role of transrectal MRI fusion biopsy to select patients for prostate cancer focal therapy.

METHODS: Patients with suspected prostate cancer underwent transrectal MRI fusion biopsy with the Koelis trinity device. Two focal therapy eligibility criteria were subsequently defined: Group 1: PSA ≤ 15 ng/ml, unilateral csPCa, ISUP grade ≤ 2, no contralateral PIRADS 3-5 lesion; Group 2: same criteria but ISUP grade 3. These subgroups were correlated with histopathological post-prostatectomy parameters for stage pT2, unilateral csPCa, no ISUP upgrading. In addition, parameters of csPCa detection were analyzed for patients undergoing primary and re-biopsy.

RESULTS: Four hundred fourteen consecutive patients were analyzed (314 for primary biopsy, 100 for re-biopsy). Post-prostatectomy whole mount section analysis was available from 155 patients. 39 and 62 of these patients met focal therapy inclusion criteria for group 1 and group 2, respectively. A correlation with final pathology parameters following radical prostatectomy (stage pT2, unilateral csPCa, no ISUP upgrading) revealed a positive predictive value of only 53.8% and 64.5% for Group 1 and 2, respectively. The overall csPCa detection rate was 73.7%. In the re-biopsy group 20% additional patients with csPCa were detected by targeted biopsy.

CONCLUSION: Despite high csPCa detection rates following MRI fusion biopsy our study demonstrated that, using final pathology to confirm locally advanced tumor stage, presence of bilateral csPCa and ISUP upgrading, between 35.5 and 46.2% of patients would have been incorrectly selected for focal therapy.

Focal Therapy of Prostate Cancer Index Lesion With Irreversible Electroporation. A Prospective Study With a Median Follow-up of 3 Years

Bernardino Miñana López [1], Guillermo Andrés Boville [1], Guillermo Barbas Bernardos [1], Xabier Ancizu Marckert [1], Marcos Torres Roca [1], Luis Labairu Huerta [1], Felipe Villacampa Aubá [1], Fernando Ramón de Fata Chillón [1], Julian Sanz Ortega [2], Marta Abengózar Muela [2], Guillermo Gallardo Madueño [3], Alberto Benito Boillos [3], Andrés Alcázar Peral [3], Fernando Díez-Caballero Alonso [1]

[1] Urology Department, CUN Prostate Center, Clínica Universidad de Navarra, Madrid, Spain. [2] Pathology Department, CUN Prostate Center, Clínica Universidad de Navarra, Madrid, Spain. [3] Radiology Department, CUN Prostate Center, Clínica Universidad de Navarra, Madrid, Spain.

J Urol. - 2023

PURPOSE: Our aim was to assess oncologic, safety, and quality of life-related outcomes of focal therapy with irreversible electroporation in men with localized prostate cancer.

MATERIALS AND METHODS: This was a single-center, phase II study.

INCLUSION CRITERIA: prostate cancer International Society of Urological Pathology grade 1-2, prostate specific antigen ≤15 ng/ml, ≤cT2b. Patients were selected based on multiparametric magnetic resonance imaging and transperineal systematic and targeted magnetic resonance imaging-ultrasound fusion-guided biopsy. Ablation of index lesions with safety margin was performed. Primary end point was cancer control, defined as the absence of any biopsy-proven tumor. A control transperineal biopsy was planned at 12 months and when suspected based on prostate specific antigen and/or multiparametric magnetic resonance imaging information. Quality of life was assessed using Expanded Prostate Cancer Index Composite Urinary Continence domain, International Index of Erectile Function, and International Prostate Symptom Score.

RESULTS: From November 2014 to July 2021, 41 consecutive patients were included with a median follow-up of 36 months. Thirty patients (73%) had International Society of Urological Pathology grade 1 tumors, 10 (24%) grade 2, and 1 (2.4%) grade 3. Recurrence was observed in 16 of 41 (39%) of the whole cohort, and 16 of 33 (48.4%) who underwent biopsy. In-field recurrence was detected in 5 (15%) and out-of-field in 11 (33.3%). Ten of 41 (24.6%) including 3 of 5 (60%) with in-field recurrences had significant tumors (Gleason pattern 4-5; more than 1 core or any >5 mm involved). Median recurrence-free survival was 32 months (95% CI 6.7-57.2). Twenty-six patients (63.4%) were free from salvage treatment. All patients preserved urinary continence. Potency was maintained in 91.8%.

CONCLUSIONS: Irreversible electroporation can achieve satisfactory 3-year in-field tumor control with excellent quality of life results in selected patients.

"Super-active surveillance": MRI ultrasound fusion biopsy and ablation for less invasive management of prostate cancer

Jonathan B Bloom [1], Samuel A Gold [1], Graham R Hale [1], Kareem N Rayn [1], Vikram K Sabarwal [2], Ivane Bakhutashvili [3], Vladimir Valera [1], Baris Turkbey [4], Peter A Pinto [1], Bradford J Wood [3]

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J Urol. - 2023

Multiparametric magnetic resonance imaging (mpMRI) of the prostate has allowed clinicians to better visualize and target suspicious lesions during biopsy. Targeted prostate biopsies give a more accurate representation of the true cancer volume and stage so that appropriate treatment or active surveillance can be selected. Advances in technology have led to the development of MRI and ultrasound fusion platforms used for targeted biopsies, monitoring cancer progression, and more recently for the application of focal therapy. Lesions visualized on mpMRI can be targeted for ablation with a variety of energy sources employed under both local and general anesthesia.

Focal ablation may offer an alternative option for treating prostate cancer as compared to the well-established interventions of whole-gland radiation or prostatectomy. Focal ablation may also be an option for patients on active surveillance who wish to be even more "active" in their surveillance. In this review, we describe the advancements and development of fusion biopsies, the rationale behind focal therapy, and introduce focal ablative techniques for indolent prostate cancers ("super-active surveillance"), including cryoablation and focal laser ablation (FLA) and the subsequent MRI/biopsy surveillance.

3.4 Targeted Microwave Ablation Therapy

Traitement focal transrectal par micro-onde du cancer de la prostate localisé de risque faible et intermédiaire : résultats préliminaires

N. Barry Delongchamps [1], A. Schull [1], D. Saighi [1], M. Zerbib [1], M. Peyromaure [1]

[1] *Hôpital Cochin, Paris, France*

Prostate International - 2025

OBJECTIFS : L'objectif de cette étude était de tester la faisabilité, la précision et la sécurité d'un traitement transrectal de la tumeur index par micro-onde, guidée par fusion d'image élastique IRM-échographie, chez 10 patients ayant un cancer de la prostate de risque faible ou intermédiaire.

MÉTHODES : Les patients éligibles devaient avoir un PSA < 15 ng/mL, une tumeur index à plus de 5 mm du rectum, et ayant un score de Gleason ≤ 3 + 4. Le système de guidage par cartographie 3D KOELIS TRINITY® (KOELIS®) était utilisé pour le diagnostic, le traitement et le suivi. Un applicateur de 18G délivrait les micro-ondes par voie transrectale sous anesthésie générale. Le critère d'évaluation principal était la nécrose complète du volume cible sur l'IRM à j7. Les critères d'évaluation secondaire étaient la tolérance urinaire et sexuelle. Des biopsies ciblées étaient réalisées dans la zone traitée à 6 mois.

RÉSULTATS : Les caractéristiques cliniques et carcinologiques sont résumées dans les Tableau 1, Tableau 2. La totalité des patients ont pu être traités selon le protocole. La durée moyenne de l'anesthésie générale était de 82 (44–170) minutes. Aucune douleur ni aucun autre effet indésirable n'a été observé en postopératoire immédiat et pendant la durée de l'étude. Les mictions ont repris de manière spontanée dans les deux heures suivant l'intervention. À j7, le volume de nécrose recouvrait totalement le volume cible chez 8 (80 %) patients. Après un suivi de 6 mois, aucune modification des scores IPSS et IIEF5 n'a été observée (Tableau 3). Les biopsies réalisées dans la zone présumée traitée montraient la persistance de cancer de Gleason 3 + 3 et 3 + 4 chez 3 (30 %) et 2 (20 %) patients, respectivement.

CONCLUSIONS : Ces résultats suggèrent que le traitement transrectal par micro-onde guidé par fusion d'image IRM-échographie est faisable, précis et bien toléré. Plus de patients sont nécessaires pour mieux évaluer le résultat carcinologique à long terme.

3.4 Targeted Microwave Ablation Therapy

A novel focal therapy – microwave ablation under Organ-Based Tracking (OBT) fusion in patients with localized prostate cancer: Preliminary results of FOSTINE 01b pilot study

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Eur Urol Open Sci. 2020

INTRODUCTION ET OBJECTIVES: Through an ablate-and-resect study, we evaluated the feasibility, safety and histological effects of very low loss (VLL) microwave ablation, performed transrectally under real-time MRI/TRUS image registration and 3D mapping, in patients with localized prostate cancer (PCa).

MATERIALS AND METHODS: Patients with a detectable index lesion on mpMRI, PSA level <20 ng/mL and wishing to undergo a prostatectomy in case of significant PCa on biopsy were eligible for this study approved by Ethics Committee. Targeted biopsies of the index lesion were performed by using an ultrasound-MRI image fusion system with OBT-registration (KOELIS TRINITY®, KOELIS®, France) to provide quality control. Targeted cores were analyzed intraoperatively with an extemporaneous analysis. If positive, the patients were treated during the same session by a targeted focal microwave ablation using a single 18G needle inserted transrectally under sedation. Predictive ablation charts obtained with the microwave generator (TATO, Biomedical Srl, Italy) through in vitro experiments were used to choose the duration and power of the treatment. Treated patients were followed-up for 4 to 6 weeks and the planned radical prostatectomy was performed. All patients underwent uroflowmetry test and filled the self-administered questionnaires (IPSS, IPSS-QOL, IIEF-5, and MSHQ-EjD-SF) before the intervention, at 7 days and 1 month after the procedure. A mpMRI of the treated prostate was performed at 7 days. After radical prostatectomy, whole-mount histology served to define the ablation boundaries and dimensions in the prostate. A total of 10 patients will be operated.

RESULTS: From January to June 2019, 5 patients participated in this ablate-and-resect study without therapeutic intent. Microwave ablation was performed on 4 patients. One patient did not receive the treatment due to negative targeted biopsies and was exited from the study. Another one withdrew his consent after microwave ablation and thus did not undergo radical prostatectomy. He is now under active surveillance. All procedures were performed under sedation in an outpatient setting, with a median intervention time of 81.5 min [63.75-96.5]. After 4 interventions, no patient reported any pain and no serious adverse event was observed. The early postoperative mpMRI showed consistent devascularization on the T1 DCE MRI at the treatment site. A sharp necrosis was also observed on the whole-mount sections. Further interventions will allow to compare clinical observations with the predictive charts.

CONCLUSIONS: Our pilot study demonstrated that microwave ablation guided by OBT-fusion in patients with localized PCa is safe, feasible and easily deliverable in an outpatient setting. Histopathological analyses confirm a well-delimited ablation shape.

3.4 Targeted Microwave Ablation Therapy

Feasibility and safety of targeted focal microwave ablation of the index tumor in patients with low to intermediate risk prostate cancer: Results of the FOSTINE trial

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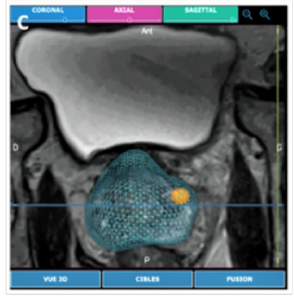
PLoS One. 2021

OBJECTIVE: To assess the feasibility, safety and precision of organ-based tracking (OBT)-fusion targeted focal microwave ablation (FMA), in patients with low to intermediate risk prostate cancer.

PATIENTS AND METHOD: Ten patients with a visible index tumor of Gleason score ≤3+4, largest diameter <20mm were included. Transrectal OBT-fusion targeted FMA was performed using an 18G needle. Primary endpoint was the evidence of complete overlap of the index tumor by ablation zone necrosis on MRI 7 days after ablation. Urinary and sexual function were assessed with IPSS, IIEF5 and MSHQ-EjD-SF. Oncological outcomes were assessed with PSA at 2 and 6 months, and re-biopsy at 6 months.

RESULTS: Median [IQR] age was 64.5 [61-72] years and baseline PSA was 5 [4.3-8.1] ng/mL. Seven (70%) and 3 (30%) patients had a low and intermediate risk cancer, respectively. Median largest tumor axis was of 11 [9.0-15.0] mm. Median duration of procedure was of 82 [44-170] min. No patient reported any pain or rectal bleeding, and all 10 patients were discharged the next day. Seven days after ablation, total necrosis of the index tumor on MRI was obtained in eight (80% [95%CI 55%-100%]) patients. One patient was treated with radical prostatectomy. Re-biopsy at 6 months in the other 9 did not show evidence of cancer in 4 patients. IPSS, IIEF-5 and MSHQ-EjD-SF were not statistically different between baseline and 6 months follow up.

CONCLUSIONS: OBT-fusion targeted FMA was feasible, precise, and safe in patients with low to intermediate risk localized prostate cancer.



OBT-Fusion registration of the microwave applicator and measurement on ultrasound of the expected ablation

3.4 Targeted Microwave Ablation Therapy

Safety and Feasibility of Transperineal Targeted Microwave Ablation for Low- to Intermediate-risk Prostate Cancer

Marco Oderda [1], Alessandro Marquis [1], Giorgio Calleris [1], Daniele D'Agate [1], Riccardo Faletti [2], Marco Gatti [2], Giancarlo Marra [1], Paolo Gontero [1]

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Eur Urol Open Sci. - 2022

OBJECTIVE: To describe the step-by-step procedure for TMA and report early functional outcomes.

DESIGN SETTING AND PARTICIPANTS: This was an experimental phase 1-2 trial in 11 patients diagnosed with a single, MRI-visible PCa lesion of up to 12 mm, scored as International Society of Urological Pathology grade group (GG) 1 or 2.

SURGICAL PROCEDURE: Transperineal TMA under MRI/ultrasound image fusion guidance.

MEASUREMENTS: We recorded patient and PCa features; intraoperative and postoperative parameters; pain (Visual Analog Scale [VAS]) and adverse events (Common Terminology Criteria for Adverse Events v5.0); and prostate-specific antigen (PSA), International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF-5) scores at 1 wk and 1, 3, and 6 mo.

RESULTS AND LIMITATIONS: The median patient age was 67 yr (interquartile range [IQR] 18). Median PSA was 5.4 ng/ml (IQR 1.8), median prostate volume was 51 cm3 (IQR 35), and median lesion size on MRI was 10 mm (IQR 4). Ten patients had GG 2 PCa and one had GG 1 disease. The median procedure time was 40 min (IQR 30). No intraoperative complications were reported. All treatments were performed on a day-case basis and no patients were discharged with a urinary catheter. Postoperatively, no grade ≥2 complications were reported. No significant changes in PSA ($p = 0.46$), IPSS ($p = 0.39$), or IIEF-5 scores ($p = 0.18$) scores were reported. The postoperative VAS score at 24 h was 0 for all patients.

CONCLUSIONS: TMA is safe, feasible, and well tolerated in patients with low- to intermediate-risk PCa. Oncological outcomes are still awaited.

3.4 Targeted Microwave Ablation Therapy

Transperineal Targeted Microwave Ablation (TMA) of localized prostate cancer guided by MRI-Ultrasound fusion and organ-based tracking: a pilot study

Peter Ka-Fung Chiu [1], Chun-Hong Chan [2], Chi-Hang Yee [2], Sui-Yan Lau [2], Jeremy Yuen-Chun Teoh [2], Ho-Fai Wong [2], Ka-Lun Lo [2], Tsz-Yau Yuen [3], Hiu-Yee Hung [3], Carmen Chi-Min Cho [3], Chi-Fai Ng [4]

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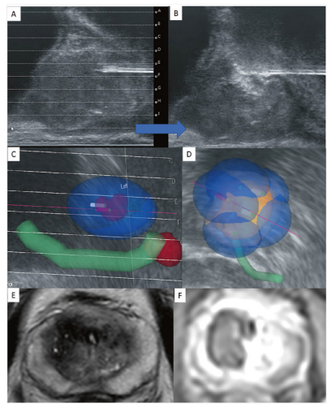
Prostate Cancer Prostatic Dis. - 2023

BACKGROUND: To investigate the efficacy of transperineal targeted microwave ablation (TMA) in treating localized prostate cancer (PCa).

METHODS: This is a single-centre prospective phase 2 trial recruiting men with low to intermediate-risk localized PCa to undergo transperineal TMA. TMA was performed with MRI-Ultrasound fusion guidance and organ-based tracking. A per-protocol 6-month MRI and biopsy were performed for all patients. The primary outcome was any cancer detected on biopsy of each ablated area. Secondary outcomes included per-patient analysis of positive biopsy, complications, urinary symptom score, erectile function and quality of life (QOL) scores.



Targeted microwave ablation (TMA) treatment

RESULTS: In the first 15 men, 23 areas were being treated. The median age was 70 years, number of TMA ablations were 5 (range 2-8), and the total ablation time and operating time was 22 (IQR 14-28) and 75 (IQR 65-85) minutes, respectively. PSA level dropped from a median of 7.7 to 2.4 ng/mL. For the primary outcome, 91.3% (21/23) ablated area had no cancer in 6-month biopsy. In per-patient analysis, 33.3% (5/15) had in or out-of-field positive biopsy at 6 months. Among these five cases, four of them were amenable to active surveillance and 1 (6.7%) case with out-of-field ISUP grade group 2 cancer received radiotherapy. The urinary symptoms, uroflowmetry, erectile function, and QOL scores had no significant difference at 6 months. One patient (out of five patients with normal erection) in the cohort complained of significant worsening of erectile function after TMA. Grade 1 complications including hematuria (33.3%), dysuria (6.7%), and perineal discomfort (13.4%) were observed.

CONCLUSIONS: In this first pilot study, transperineal TMA guided by MRI-Ultrasound fusion guidance and organ-based tracking was shown to be effective, safe, and easily applicable in men with localized PCa.

3.4 Targeted Microwave Ablation Therapy

Transperineal 3D fusion imaging-guided targeted microwaves ablation for low to intermediate-risk prostate cancer: results of a phase I-II study

Marco Oderda, Alessandro Marquis, Giorgio Calleris, Daniele D'Agate, Luisa Delsedime, Elena Vissio, Alessandro Dematteis, Marco Gatti, Riccardo Faletti, Giancarlo Marra, Gabriele Montefusco & Paolo Gontero

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Minim Invasive Ther Allied Technol. - 2024

BACKGROUND: Targeted microwave ablation (TMA) is a novel modality of focal therapy to treat localized prostate cancer (PCa). We evaluated its short-term functional and oncologic outcomes.

METHOD: We performed a single-center, prospective, interventional phase I-II pilot trial (NCT04627896). TMA was performed in 11 patients with a single intracapsular MRI-visible lesion ≤12 mm, International Society of Urological Pathology (ISUP) grade ≤ 2, Prostate Specific Antigen (PSA) < 20 ng/mL, and a 5-mm safety distance from apex and rectum. Patients were treated with a 12 W very low-loss microwaves ablation system, guided by 3D ultrasound/MRI fusion imaging. Follow-up consisted in clinical visits, PSA and validated questionnaires. MRI was scheduled at five months and rebiopsy at six months. The primary endpoints of study were safety and efficacy (absence of tumour in the treated area).

RESULTS: No severe complications were reported. All patients were discharged the same day of treatment without bladder catheter. No significant changes in PSA or questionnaires scores were reported. At rebiopsy, no cancer was found in five patients (45%); eight patients (73%) had an absence of in-field PCa and nine patients (82%) had an absence of in-field ISUP ≥ 2 PCa. New cancer foci outside the treated area were found in three patients (27%). Limitations of this study were the very limited sample size, the short follow-up, and the lack of a comparator.

CONCLUSIONS: TMA guided by fusion imaging is a safe modality with good ablative efficacy.

3.4 Targeted Microwave Ablation Therapy

Targeted Microwave Ablation for Prostate Cancer Under Magnetic Resonance Imaging-Ultrasound Fusion and Organ-based Tracking: Final Results from the First Phase 2 Trial (TMA-HK)

Peter Ka-Fung Chiu [1], Alex Qinyang Liu [2], Chi-Hang Yee [2], Ho-Fai Wong [2], Chun-Hong Chan [2], Angel Kong [2], Sui-Yan Lau [2], Jeremy Yuen-Chun Teoh [2], Ka-Lun Lo [2], Tsz-Yau Yuen [3], Kin-Hoi Wong [4], Cheuk-Man Chu [3], Hiu-Yee Hung [3], Carmen Chi-Min Cho [3], Chi-Fai Ng [5]

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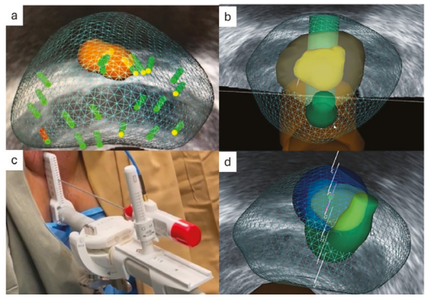
Eur Urol Oncol. - 2024

Targeted microwave ablation (TMA) is a novel focal therapy modality for prostate cancer (PC). TMA-HK is the first phase 2 trial investigating the efficacy and functional outcomes of transperineal TMA (NCT04113811) in 30 men with low- or intermediate-risk PC. TMA was performed transperineally with magnetic resonance imaging (MRI)-ultrasound fusion guidance and organ-based tracking.

All participants underwent prostate MRI at 6 mo after TMA, followed by targeted and 18-core systematic prostate biopsy. The primary outcome was cancer detection on biopsy in each ablated area at 6 mo. Secondary outcomes included per-patient analysis of positive biopsy results, complications, and functional outcomes at 12 mo. A total of 42 areas were treated in 30 patients (seven low-risk and 23 intermediate-risk PC), with no cancer detected in 90.5% (38/42) of the treated areas. Per-patient analysis revealed in-field recurrence in 10.0% (three of 30) of patients, of whom two had grade group 1 and one had grade group 2 disease.

At 12 mo, out-of-field biopsies were positive in 40.0% (12/30) of the patients (ten grade group 1, two grade group 2 disease). Only self-limiting grade 1 and 2 complications were reported. Three patients (10.0%) reported de novo failure to achieve penetrative sexual intercourse. The results demonstrate that TMA for PC resulted in effective ablation, with good cancer control up to 12 mo. PATIENT SUMMARY: We performed the first efficacy trial of targeted microwave treatment for prostate cancer in 30 patients with low- or intermediate-risk disease. Our results show that this treatment achieved excellent local control of the cancer up to 12 months, with a low rate of complications. More research in larger patient groups and over longer follow-up is needed to confirm these findings..



Targeted microwave ablation (TMA) treatment

Targeted Microwave Ablation for Prostate Cancer Under Magnetic Resonance Imaging-Ultrasound Fusion and Organ-based Tracking: Final Results from the First Phase 2 Trial (TMA-HK)

PETER KA-FUNG CHIU ET AL., EUR URO ONCOL, DEC 2024,
PRINCE OF WALES HOSPITAL - HONG KONG

PATIENTS

lesions to be treated
42

patients
30

- Age : 70 [70-74] years old
- Low to intermediate-risk PCa: ISUP 1 - 2
- PSA < 20ng/mL
- Lesion size ≤ 15 mm

METHODS

17G Needle / VLL Microwave Energy: 12W / 2-5 min

Dedicated TMA software to plan and guide transperineal ablations

Koelis Trinity® with OBT Fusion® guidance

MRI and "2nd Look" follow-up fusion biopsy at 6 months post-treatment

Koelis Trinity® System

KOELIS
Advancing Prostate Care

3.4 Targeted Microwave Ablation Therapy

Targeted microwave ablation for prostate cancer (FOSTINE1b): a prospective 'ablate-and-resect' study

Alexandre Peltier [1], Roland van Velthoven [1], Arthur Baudewyns [1], Grégoire Assenmacher [1], Marc Lemort [2], Yolene Lefebvre [2], Nicolas Sirtaine [3], Romain Diamand [1]

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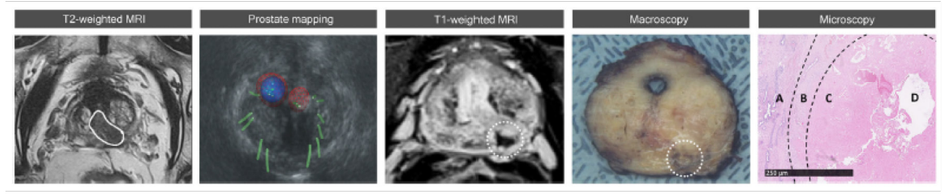
BJU Int. - 2024

OBJECTIVE: To assess histopathological outcomes, as well as feasibility and safety of targeted microwave ablation (TMA) via the Trinity® system (KOELIS, La Tronche, France).

PATIENTS AND METHODS: Prospective, single-institution, interventional Phase IIa study with an 'ablate-and-resect' design. In all, 11 patients diagnosed with localised prostate cancer (PCa) underwent TMA via the Trinity system under conscious sedation in an outpatient setting using a single transrectal TATO® 18-G antenna with different treatment regimens. Magnetic resonance imaging (MRI) and robot-assisted radical prostatectomy (RARP) were conducted at 7 days and 1 month after TMA, respectively. Nine patients received RARP, and two patients chose to withdraw their consent following TMA. These men chose an active surveillance protocol upon confirmation of a low-risk prostate cancer diagnosis. Functional outcomes and adverse events were evaluated at baseline and follow-up visits using validated questionnaires. Prostate volumetry and confirmation of necrosis were carried out through MRI and whole-mount histopathological examination.

RESULTS: The TMA was successfully executed, and all patients were discharged on the same day. No severe adverse events (Common Terminology Criteria for Adverse Events Grade ≥3) were reported at the 7-day and 1-month follow-up visits. Additionally, no declines were observed in urinary, sexual and ejaculation functional outcomes. T1-weighted MRI revealed clear and well-defined ablation zones. The RARP was executed without difficulty, particularly during the dissection of the posterior plane. As a result, no intraoperative complications were encountered. Histopathological assessment on surgical specimens confirmed the absence of viable cells, indicating complete necrosis of the ablative zone if a power intensity >10 W was used during TMA. Ablation zone volumetry revealed no notable distinctions between the three-dimensional segmentation of the virtual ablation zone at TMA (median volume: 2 mL) and MRI (median volume: 1.923 mL). Conversely, a significant reduction was noted in the surgical specimen (median volume: 0.221 mL).

CONCLUSIONS: Targeted microwave ablation via the Trinity system for localised PCa treatment proves to be a secure and feasible procedure, with complete necrosis evidence within the ablation zone on surgical specimens.



Overview of axial imaging sequences and histology after RP in a patient treated by TMA.

3.4 Targeted Microwave Ablation Therapy

Transperineal 3D fusion imaging-guided targeted microwaves ablation for low to intermediate-risk prostate cancer: results of a phase I-II study

Nicolas Barry Delongchamps [1], Alexandre Peltier[2], Eric Potiron[3], Franck Bladou [4], Julien Anract [5], Romain Diamand [6], Grégoire Robert [7], Aurel Messas [8], Roland Van Velthoven [9]

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BJU Compass 08/2024

OBJECTIVE: The aim of this study was to assess the precision and safety of targeted microwave ablation (TMA) using organ-based tracking (OBT) fusion, in patients with intermediate risk prostate cancer.

PATIENTS AND METHOD: We conducted a prospective, multicentric trial. Eligible patients had a prostate-specific antigen (PSA) < 20 ng/mL, a magnetic resonance imaging (MRI)-visible index tumour of Gleason score 3 + 4, with largest axis ≤15 mm and distant of at least 5 mm from the rectum and apex. TMA was performed with microwave needle applicator using OBT fusion, with a transperineal or a transrectal approach. In this interim analysis, we evaluated precision, safety, urinary and sexual outcomes, and PSA density kinetics.

RESULTS: At this point, 37 patients were treated in five centres. Median (interquartile range) age is 68 (63–72) years. Baseline median prostate volume and PSA are of 45 (34–57) mL and 8 (6.2–10.8) ng/mL, respectively. Median largest tumour axis on T2W MRI is of 11 mm (10–13). Patients were treated under general anaesthesia or conscious IV sedation in an outpatient setting. Anaesthesia had a median duration of 78 (66–90) min. A median number of 3 (2–4) 12-W ablations of 2 to 5 min were performed per patient. After a median follow-up of 6 (2.4–10) months, we observed 58 adverse events (AE) in 22 patients. These were of Common Terminology Criteria for Adverse Events (CTCAE) grade 1, 2 and 3 in 43 (74%), 13 (22%) and 2 (4%) cases. Six (15%) patients had an acute urinary retention, five of which considered as severe AE because of rehospitalisation. We did not observe any significant difference in International Prostate Symptom Score (IPSS), Male Sexual Health Questionnaire-ejaculatory dysfunction (MSHQ-EjD) and International Index of Erectile Function (IIEF5) from baseline to last follow-up. Median PSA density evolved from 0.2 (0.1–0.3) at baseline to 0.1 (0.07–0.16) at 12 months.

CONCLUSIONS: These preliminary results suggest that TMA using OBT fusion is precise and safe in patients with intermediate risk localised prostate cancer. Further inclusions and follow-up are needed to assess oncological outcome.

3.4 Targeted Microwave Ablation Therapy

Multi-modality focal therapy for prostate cancer: outcome of the à la carte approach in clinical practice

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BACKGROUND: Our study reported the outcome of a multi-modality focal therapy (FT) cohort for localized primary prostate cancer.

PATIENTS AND METHODS: In a prospective registry all patients underwent MRI and biopsy (fusion targeted or template biopsy) before FT. Modalities included focal HIFU, focal cryotherapy or targeted microwave ablation (TMA). Post-operatively PSA and functional outcome assessment with validated questionnaires were checked 3-monthly. MRI was performed at 1 week, 6 months and 12 months. Elective prostate biopsy was performed between 6 to 12 months.

RESULTS: A total of 102 patients underwent FT between 2019 to 2024. The cohort consisted of 44 (43.1%) patients for focal HIFU, 18 (17.6%) patients for focal cryotherapy and 40 (39.2%) patients for TMA. D'Amico low-, intermediate- and high-risk patients accounted for 31 (30.4%), 66 (64.7%) and 5 (4.9%) patients respectively. Referring to tumor location, focal HIFU had 38 (86.4%) posterior tumors, focal cryotherapy had 12 (72.2%) anterior tumors and TMA had 31 (77.5%) anterior tumors. Biopsy data was available for 63 patients (61.8%). Clinically significant recurrence (ISUP GG >/= 2) were found in 7 patients (11.1%). Subsequent salvage treatment included robotic radical prostatectomy 2, radiotherapy 4, second focal cryotherapy 1. No deterioration in EPIC score was observed across all domains before and after treatment. Improvement in Urinary Irritative/Obstructive domain was observed in focal cryotherapy (78.3 vs 91.5, p=0.011) and TMA (75.7 vs 84.9, p=0.019) at 12 months.

CONCLUSIONS: Multi-modality FT with à la carte approach provides versatility in ablative strategies and offers a reasonable functional and oncological outcome for low- to intermediate-risk prostate cancer.

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