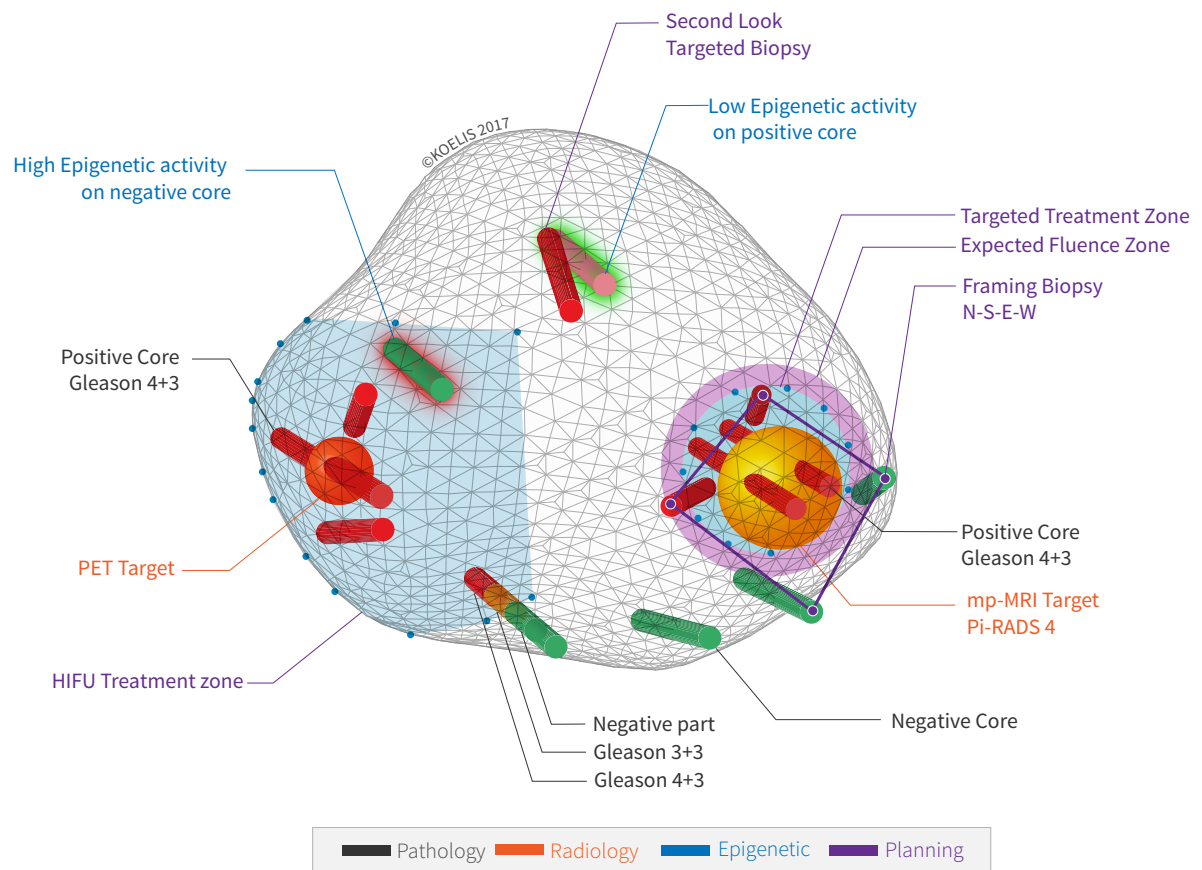


KOELIS BEST PAPERS

2nd Volume - 2015-2016

KOELIS MOlecular MApping



EDITORIAL



10 years now KOELIS has been striving to demonstrate the value of 3D imaging and the mapping technology in improving prostate cancer management. From the beginning research in automatic image fusion in Grenoble to patenting “Molecular Mapping”, it’s been a great journey. In this second edition of KOELIS’ best clinical papers we are proud to display the abstracts of the peer-reviewed publications that were built upon KOELIS products and technology since 2015. In particular (RCTs by Delongchamps, Arsov, Baco) showing a high impact factor and high level of proof deserves a special applause, as it received the Best Scientific Paper Award of European Urology! That success, that volume of high level clinical studies, the international clinical teams involved, and the patients who benefit from our technology drive us forward in innovating further. THANK YOU!

Since the first edition of KOELIS’ best clinical papers, the research topics have shifted from evaluating the precision of KOELIS fusion technology to proposing new concepts and guidelines. The basis evolving towards a more patient-driven, imaging-driven, precision-driven, and economy-driven practice in PCa. What have we proven so far? The possibility to bring quality control to biopsy sampling and diagnosis, by seeing and recording prostate geography. Tripling the cancer detection rate and finding the high-risk index lesion, requires a layer of quality control that we call “MOlecular MApping” – MOMA. The KOELIS MOMA is a multiparametric 3D information map where many complementary inputs gather. Imaging input (mp-MRI, PET, PI-RADS scores), pathology and epigenetic inputs (either on “green” cores or on “red” cores), second look re-visiting inputs and framing biopsy schemes. KOELIS gathers everything for you in a simple process and device, using the MOMA to select, plan and perform a targeted partial treatment or active surveillance. As trials like ProtecT have proven the value of alternatives to radical treatment, it’s now time to find consensus on new universal guidelines promoting 3D imaging and mapping against random, nonpersonalized approaches. The economic benefit of promoting imaging and disruptive innovation to reduce unnecessary interventions looks self-evident as studied by expert associations like AdMeTech. Again in 2017, KOELIS commits to and with you in supporting the paradigm shift in Prostate Cancer.

Yours truly,

Antoine LEROY, PhD, KOELIS Founder and CEO

A handwritten signature of Antoine LEROY in blue ink. The signature is written in a cursive, flowing style. The first part of the signature, 'Antoine', is written in a larger, more prominent script, while the last name 'LEROY' is written in a smaller, more compact script.

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Accuracy of Elastic Fusion of Prostate Magnetic Resonance and Transrectal Ultrasound Images under Routine Conditions: A Prospective Multi-Operator Study.

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PLOS One. Dec 2016

PURPOSE: To evaluate in unselected patients imaged under routine conditions the co-registration accuracy of elastic fusion between magnetic resonance (MR) and ultrasound (US) images obtained by the Koelis Urostation™.

MATERIALS AND METHODS: We prospectively included 15 consecutive patients referred for placement of intraprostatic fiducials before radiotherapy and who gave written informed consent by signing the Institutional Review Board-approved forms. Three fiducials were placed in the prostate under US guidance in standardized positions (right apex, left mid-gland, right base) using the Koelis Urostation™. Patients then underwent prostate MR imaging. Four operators outlined the prostate on MR and US images and an elastic fusion was retrospectively performed. Fiducials were used to measure the overall target registration error (TRE3D), the error along the antero-posterior (TREAP), right-left (TRERL) and head-feet (TREHF) directions, and within the plane orthogonal to the virtual biopsy track (TRE2D).

RESULTS: Median TRE3D and TRE2D were 3.8-5.6 mm, and 2.5-3.6 mm, respectively. TRE3D was significantly influenced by the operator ($p = 0.013$), fiducial location ($p = 0.001$) and 3D axis orientation ($p < 0.0001$). The worst results were obtained by the least experienced operator. TRE3D was smaller in mid-gland and base than in apex (average difference: -1.21 mm (95% confidence interval (95%CI): -2.03; -0.4) and -1.56 mm (95%CI: -2.44; -0.69) respectively). TREAP and TREHF were larger than TRERL (average difference: +1.29 mm (95%CI: +0.87; +1.71) and +0.59 mm (95%CI: +0.1; +0.95) respectively).

CONCLUSIONS: Registration error values were reasonable for clinical practice. The co-registration accuracy was significantly influenced by the operator's experience, and significantly poorer in the antero-posterior direction and at the apex.

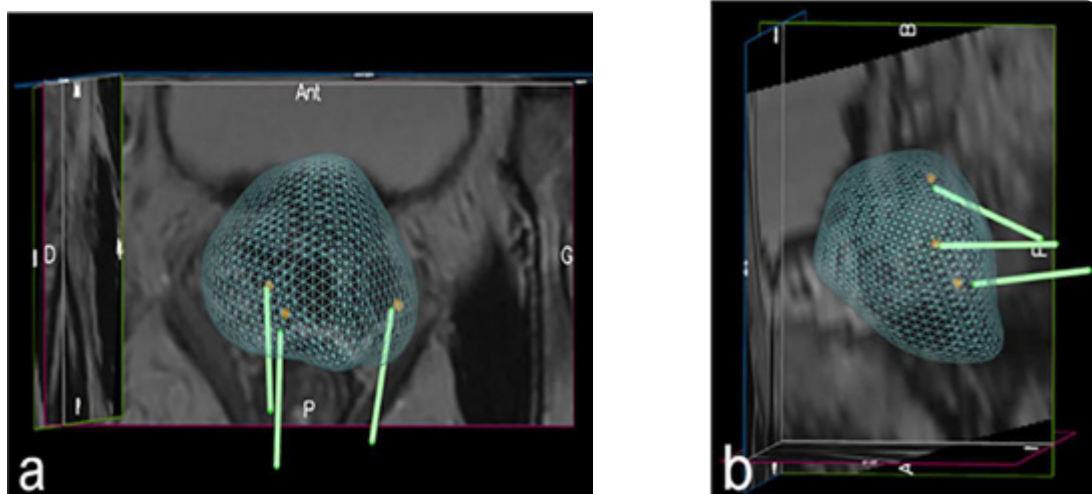


Figure 1. Three dimensional co-registration images showing the relative position of the virtual biopsies and the MR targets from an inferior (A) and lateral (B) perspective. The gap between the tip of the virtual biopsies and the center of the MR targets shows the error in the co-registration process.



Prostate biopsies assisted by comanipulated probe-holder: first in man.

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¹Sorbonne Universités UPMC Univ. Paris

Int J Comput Assist Radiol Surg. 2016

OBJECTIVE: Acomanipulator for assisting endorectal prostate biopsies is evaluated through a first-in-man clinical trial. This lightweight system, based on conventional robotic components, possesses six degrees of freedom. It uses three electric motors and three brakes. It features a free mode, where its low friction and inertia allow for natural manipulation of the probe and a locked mode, exhibiting both a very low stiffness and a high steady-state precision.

METHODS: Clinical trials focusing on the free mode and the locked mode of the robot are presented. The objective was to evaluate the practical usability and performance of the robot during clinical procedures. A research protocol for a prospective randomized clinical trial has been designed. Its specific goal was to compare the accuracy of biopsies performed with and without the assistance of the comanipulator.

RESULTS: The accuracy is compared between biopsies performed with and without the assistance of the comanipulator, across the 10 first patients included in the trial. Results show a statistically significant increase in the precision.

Patient	Group	Min	Q1	Median	Mean	Q3	Max	STD	N
2	manual	0.88	1.55	2.08	2.39	3.03	5.03	1.2	15
3	manual	0.73	1.51	1.78	1.97	2.52	4.3	0.91	15
4	robot	0.27	0.45	0.74	0.93	1.17	2.34	0.63	14
5	manual	1.07	1.33	1.56	1.82	2.01	3.16	0.65	15
6	robot	0.33	0.52	1.01	1.28	1.74	3.14	0.94	15
7	robot	0.24	0.44	1.07	1.08	1.52	2.8	0.75	15
9	manual	0.65	0.91	1.27	1.34	1.65	2.28	0.51	15
10	robot	0.16	0.54	0.8	0.9	1.2	1.66	0.45	14

Table 1. Distance between virtual and real biopsies (in mm).

Group	Min	Q1	Median	Mean	Q3	Max	STD	N
robot	0.74	0.78	0.9	0.9	1.02	1.07	0.16	4
manual	1.27	1.49	1.67	1.67	1.86	2.08	0.34	4

Table 2. Median distance between virtual and real biopsies (in mm) per group.



The Efficacy of Multiparametric Magnetic Resonance Imaging and Magnetic Resonance Imaging Targeted Biopsy in Risk Classification for Patients with Prostate Cancer on Active Surveillance.

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J Urol. Aug 2016

PURPOSE: We determined whether multiparametric magnetic resonance imaging targeted biopsies may replace systematic biopsies to detect higher grade prostate cancer (Gleason score 7 or greater) and whether biopsy may be avoided based on multiparametric magnetic resonance imaging among men with Gleason 3+3 prostate cancer on active surveillance.

MATERIALS AND METHODS: We identified men with previously diagnosed Gleason score 3+3 prostate cancer on active surveillance who underwent multiparametric magnetic resonance imaging and a followup prostate biopsy. Suspicion for higher grade cancer was scored on a standardized 5-point scale. All patients underwent a systematic biopsy. Patients with multiparametric magnetic resonance imaging regions of interest also underwent magnetic resonance imaging targeted biopsy. The detection rate of higher grade cancer was estimated for different multiparametric magnetic resonance imaging scores with the 3 biopsy strategies of systematic, magnetic resonance imaging targeted and combined.

RESULTS: Of 206 consecutive men on active surveillance 135 (66%) had a multiparametric magnetic resonance imaging region of interest. Overall, higher grade cancer was detected in 72 (35%) men. A higher multiparametric magnetic resonance imaging score was associated with an increased probability of detecting higher grade cancer (Wilcoxon-type trend test $p < 0.0001$). Magnetic resonance imaging targeted biopsy detected higher grade cancer in 23% of men. Magnetic resonance imaging targeted biopsy alone missed higher grade cancers in 17%, 12% and 10% of patients with multiparametric magnetic resonance imaging scores of 3, 4 and 5, respectively.

CONCLUSIONS: Magnetic resonance imaging targeted biopsies increased the detection of higher grade cancer among men on active surveillance compared to systematic biopsy alone. However, a clinically relevant proportion of higher grade cancer was detected using only systematic biopsy. Despite the improved detection of disease progression using magnetic resonance imaging targeted biopsy, systematic biopsy cannot be excluded as part of surveillance for men with low risk prostate cancer.



Is multiparametric MRI able to characterize margin for focal brachytherapy in low-grade prostate cancer?

Ken S¹, Graff-Cailleaud P, Bachaud J-M, Aziza R, Arnault S, Lusque A, Arnaud F-X, Brun T, Portalez D, Malavaud B.

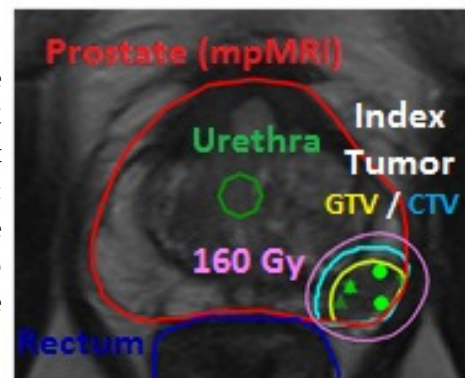
¹ Institut Universitaire du Cancer de Toulouse - Oncopole, Toulouse, France

J Clin Oncol. 2017

BACKGROUND: Focal brachytherapy is proposed in our institute as an alternative treatment to active surveillance for low-grade prostate cancer (PCa). This study aims at characterizing the tumor focus and its margin with multiparametric Magnetic Resonance Imaging (mpMRI).

METHODS: Patients pre-qualified for this study were positive for PCa (Gleason 3+3) on a previous standard biopsy series. New series of mp-MRI-guided and ultrasound-targeted biopsies were performed and in total, 17 patients with confirmed tumor and diameter < 20mm were included in this phase II clinical trial (NCT01902680). mpMRI were acquired on a 1.5T Magnetom Aera Siemens scan. Anatomic imaging consists in Fast Spin Echo T2-weighted MRI (T2-MRI) and functional Diffusion Weighted MRI (DWI-MRI) and Dynamic Contrast Enhanced MRI (DCE-MRI) were also performed. After mpMRI registration, tumor volumes of interest (VOI) were drawn on anatomic T2-MRI. VOI and VOI+2mm were reported on functional DWI-MRI and DCE-MRI. Extracted parameters were Apparent Diffusion Coefficient (ADC) and KTrans. All parameters distributions were analyzed with Olea Sphere v3.0 and compared to contralateral normal appearing tissue. Focal brachytherapy was then delivered to all patients with linked 125I seeds with a dose prescription of 152 Gy on the Planning Target Volume (PTV = VOI+2mm).

RESULTS: ADC parameters (mean, median, 25th and 75th percentiles) are found to be significantly lower in tumor volume (VOI) compared to contralateral normal tissue ($p < 0.012$ for all ADC parameters), confirming diffusion tumor mass restriction. Different distributions of ADC and KTrans were observed among patients: majority (66.66%) of low ADC and abnormal KTrans values were included in the VOI but interestingly, the 2mm margin allows us to treat additional abnormal ADC and KTrans volumes on 1/3 of the patients.



CONCLUSIONS: This study confirms that mpMRI is a non-invasive technique able to characterize tumor margin for focal brachytherapy in low-grade PCa. Target volume margin definition is a hot topic when focal treatments (e.g. cryotherapy or HIFU) are considered and mpMRI can bring quantitative answers.

MRI/TRUS fusion-guided prostate biopsy : Value in the context of focal therapy

Franz T¹, von Hardenberg J, Blana A, Cash H, Baumunk D, Salomon G, Hadaschik B, Henkel T, Herrmann J, Kahmann F, Köhrmann KU, Köllermann J, Kruck S, Liehr UB, Machtens S, Peters I, Radtke JP, Roosen A, Schlemmer HP, Sentker L, Wendler JJ, Witzsch U, Stolzenburg JU, Schostak M, Ganzer R.

¹Klinik und Poliklinik für Urologie, Universitätsklinikum Leipzig

Urologe A. 2016

BACKGROUND: Several systems for MRI/TRUS fusion-guided biopsy of the prostate are commercially available. Many studies have shown superiority of fusion systems for tumor detection and diagnostic quality compared to random biopsy. The benefit of fusion systems in focal therapy of prostate cancer (PC) is less clear.

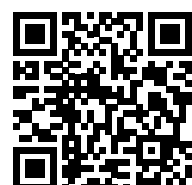
OBJECTIVES: Critical considerations of fusion systems for planning and monitoring of focal therapy of PC were investigated.

MATERIALS AND METHODS: A systematic literature review of available fusion systems for the period 2013-5/2016 was performed. A checklist of technical details, suitability for special anatomic situations and suitability for focal therapy was established by the German working group for focal therapy (Arbeitskreis fokale und Mikrotherapie).

RESULTS: Eight fusion systems were considered (Artemis™, BioJet, BiopSee®, iSR´obot™ Mona Lisa, Hitachi HI-RVS, UroNav and Urostation®). Differences were found for biopsy mode (transrectal, perineal, both), fusion mode (elastic or rigid), navigation (image-based, electromagnetic sensor-based or mechanical sensor-based) and space requirements.

DISCUSSIONS: Several consensus groups recommend fusion systems for focal therapy. Useful features are «needle tracking» and compatibility between fusion system and treatment device (available for Artemis™, BiopSee® and Urostation® with Focal One®; BiopSee®, Hitachi HI-RVS with NanoKnife®; BioJet, BiopSee® with cryoablation, brachytherapy).

CONCLUSIONS: There are a few studies for treatment planning. However, studies on treatment monitoring after focal therapy are missing.



Prostate Cancer Volume Estimation by Combining Magnetic Resonance Imaging and Targeted Biopsy Proven Cancer Core Length: Correlation with Cancer Volume.

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¹USC Institute of Urology, Keck School of Medicine, University of Southern California, Los Angeles, California; Department of Urology, Kyoto Prefectural University of Medicine, Kyoto, Japan.

J Urol. 2015

PURPOSE: Multiparametric magnetic resonance imaging often underestimates or overestimates pathological cancer volume. We developed what is to our knowledge a novel method to estimate prostate cancer volume using magnetic resonance/ultrasound fusion, biopsy proven cancer core length.

MATERIALS AND METHODS: We retrospectively analyzed the records of 81 consecutive patients with magnetic resonance/ultrasound fusion, targeted biopsy proven, clinically localized prostate cancer who underwent subsequent radical prostatectomy. As 7 patients each had 2 visible lesions on magnetic resonance imaging, 88 lesions were analyzed. The dimensions and estimated volume of visible lesions were calculated using apparent diffusion coefficient maps. The modified formula to estimate cancer volume was defined as the formula of vertical stretching in the anteroposterior dimension of the magnetic resonance based 3-dimensional model, in which the imaging estimated lesion anteroposterior dimension was replaced by magnetic resonance/ultrasound targeted, biopsy proven cancer core length. Agreement of pathological cancer volume with magnetic resonance estimated volume or the novel modified volume was assessed using a Bland-Altman plot.

RESULTS: Magnetic resonance/ultrasound fusion, biopsy proven cancer core length was a stronger predictor of the actual pathological cancer anteroposterior dimension than magnetic resonance estimated lesion anteroposterior dimension ($r = 0.824$ vs 0.607 , each $p < 0.001$). Magnetic resonance/ultrasound targeted, biopsy proven cancer core length correlated with pathological cancer volume ($r = 0.773$, $p < 0.001$). The modified formula to estimate cancer volume demonstrated a stronger correlation with pathological cancer volume than with magnetic resonance estimated volume ($r = 0.824$ vs 0.724 , each $p < 0.001$). Agreement of modified volume with pathological cancer volume was improved over that of magnetic resonance estimated volume on Bland-Altman plot analysis. Predictability was more enhanced in the subset of lesions with a volume of 2 ml or less (ie if spherical, the lesion was approximately 16 mm in diameter).

CONCLUSIONS: Combining magnetic resonance estimated cancer volume with magnetic resonance/ultrasound fusion, biopsy proven cancer core length improved cancer volume predictability.

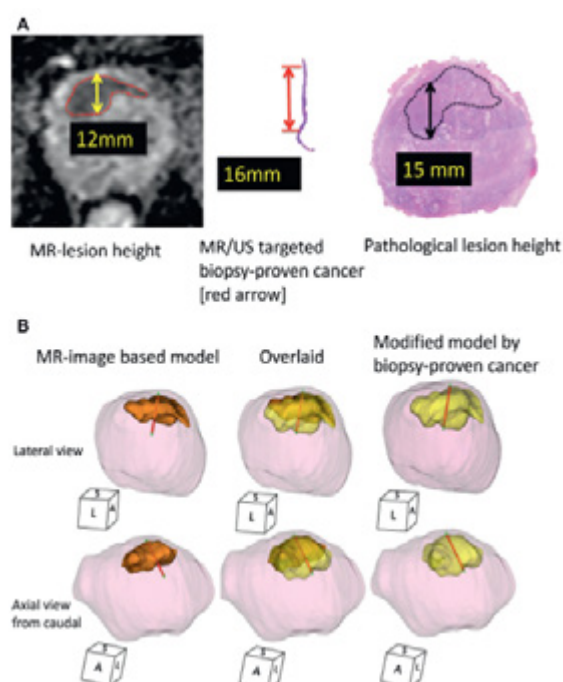


Figure 1. Case presentation of MR visible lesion modification using MR/US fusion biopsy proven cancer core length. A, MR, targeted biopsy and prostatectomy data on 69-year-old man with PSA 7.4 ng/ml in whom prebiopsy MRI demonstrated PI-RAD level 5 suspicious lesion in anterior prostate. Height was 12 mm on DWI-ADC and MR/US image fusion targeted biopsy showed Gleason 3 + 4 with 16 mm core length. Subsequent robot-assisted RP revealed pathological T2c prostate cancer with dominant anterior cancer with maximum 15 mm anteroposterior lesion height. B, 3D tumor model, MRI based model and modified model created by replacing MR estimated lesion height with MR/US targeted biopsy proven cancer core length and vertically stretching height of original MRI based 3D model according to cancer core length. Final PCV of this index lesion was 4.5 ml. Model of 3D MCV (orange area) was 2.5 ml (56%). Newly developed, modified MCV (yellow area) was 3.6 ml (80%). Overlaid, MR/US targeted biopsy trajectory overlay of both 3D models using documented digitalized coordinates obtained from real-time 3D TRUS tracking technology with Urostation. Red areas indicate pathologically proven cancer tissue. Green areas indicate benign tissue. S, sagittal. L, lateral. A, anterior.



Comparative Effectiveness of Targeted Prostate Biopsy Using Magnetic Resonance Imaging Ultrasound Fusion Software and Visual Targeting: a Prospective Study

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J Urol. 2016

PURPOSE: We compared the diagnostic outcomes of magnetic resonance-ultrasound fusion and visually targeted biopsy for targeting regions of interest on prostate multiparametric magnetic resonance imaging.

MATERIALS AND METHODS: Patients presenting for prostate biopsy with regions of interest on multiparametric magnetic resonance imaging underwent magnetic resonance imaging targeted biopsy. For each region of interest 2 visually targeted cores were obtained, followed by 2 cores using a magnetic resonance-ultrasound fusion device. Our primary end point was the difference in the detection of high grade (Gleason 7 or greater) and any grade cancer between visually targeted and magnetic resonance-ultrasound fusion, investigated using McNemar's method. Secondary end points were the difference in detection rate by biopsy location using a logistic regression model and the difference in median cancer length using the Wilcoxon signed rank test.

RESULTS: We identified 396 regions of interest in 286 men. The difference in the detection of high grade cancer between magnetic resonance-ultrasound fusion biopsy and visually targeted biopsy was -1.4% (95% CI -6.4 to 3.6, $p=0.6$) and for any grade cancer the difference was 3.5% (95% CI -1.9 to 8.9, $p=0.2$). Median cancer length detected by magnetic resonance-ultrasound fusion and visually targeted biopsy was 5.5 vs 5.8 mm, respectively ($p=0.8$). Magnetic resonance-ultrasound fusion biopsy detected 15% more cancers in the transition zone ($p=0.046$) and visually targeted biopsy detected 11% more high grade cancer at the prostate base ($p=0.005$). Only 52% of all high grade cancers were detected by both techniques.

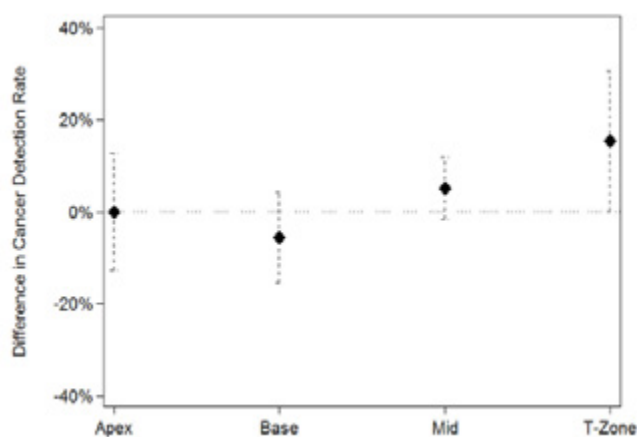


Figure 1. Difference in Rate of Cancer Detection by Biopsy Location with 95% confidence interval. Positive differences indicate a higher rate of cancer detection using the MR-F biopsy.

CONCLUSIONS: We found no evidence of a significant difference in the detection of high grade or any grade cancer between visually targeted and magnetic resonance-ultrasound fusion biopsy. However, the performance of each technique varied in specific biopsy locations and the outcomes of both techniques were complementary. Combining visually targeted biopsy and magnetic resonance-ultrasound fusion biopsy may optimize the detection of prostate cancer.



Gleason Score Determination with Transrectal Ultrasound-Magnetic Resonance Imaging Fusion Guided Prostate Biopsies--Are We Gaining in Accuracy?

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J Urol. 2016

PURPOSE: We evaluated the accuracy of prostate magnetic resonance imaging- transrectal ultrasound targeted biopsy for Gleason score determination.

MATERIALS AND METHODS: We selected 125 consecutive patients treated with radical prostatectomy for a clinically localized prostate cancer diagnosed on magnetic resonance imaging-transrectal ultrasound targeted biopsy and/or systematic biopsy. On multiparametric magnetic resonance imaging each suspicious area was graded according to PI-RADS™ score. A correlation analysis between multiparametric magnetic resonance imaging and pathological findings was performed. Factors associated with determining the accuracy of Gleason score on targeted biopsy were statistically assessed.

RESULTS: Pathological analysis of radical prostatectomy specimens detected 230 tumor foci. Multiparametric magnetic resonance imaging detected 151 suspicious areas. Of these areas targeted biopsy showed 126 cancer foci in 115 patients, and detected the index lesion in all of them. The primary Gleason grade, secondary Gleason grade and Gleason score of the 126 individual tumors were determined accurately in 114 (90%), 75 (59%) and 85 (67%) cases, respectively. Maximal Gleason score was determined accurately in 80 (70%) patients. Gleason score determination accuracy on targeted biopsy was significantly higher for low Gleason and high PI-RADS score tumors.

CONCLUSIONS: Magnetic resonance imaging-transrectal ultrasound targeted biopsy allowed for an accurate estimation of Gleason score in more than two-thirds of patients. Gleason score misclassification was mostly due to a lack of accuracy in the determination of the secondary Gleason grade.

TB %G4	RP %G4											Totals	Accuracy
	0	10	20	30	40	50	60	70	80	90	100		
0	27	1	0	0	1	0	0	0	0	0	0	29	93
10	7	4	3	1	0	0	0	0	0	0	0	15	56
20	19	2	5	4	0	0	0	0	0	0	0	30	56
30	4	2	1	8	0	0	0	0	0	0	0	15	56
40	2	2	2	3	2	1	0	0	0	0	0	12	56
50	0	0	0	0	1	0	0	0	0	0	0	1	56
60	1	1	0	2	3	0	3	1	0	0	1	12	33
70	0	0	2	0	1	0	0	2	1	0	0	6	33
80	0	0	0	0	1	0	0	0	0	0	2	3	33
90	0	0	0	0	0	0	0	0	0	0	0	0	33
100	0	0	1	0	0	0	0	0	1	0	1	3	33

Figure 1. Percentage of grade 4 and Gleason score correlation analysis between TB and RP specimen for the 126 tumor foci correctly identified with TB.

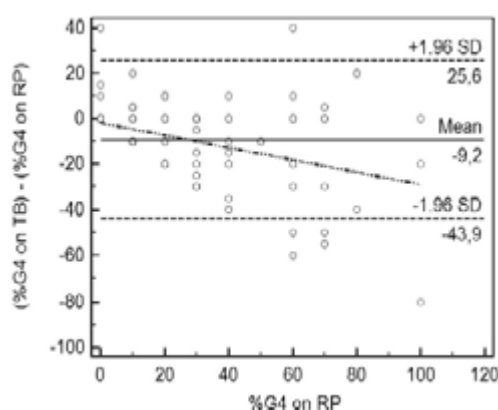


Figure 2. Bland-Altman plot showing agreement between percentages of grade 4 (%G4) obtained from pathological examination of TB and that observed from RP specimen for 126 tumor foci identified by TB. Horizontal (solid) line drawn at mean difference corresponds to difference between percentage of grade 4 measured at biopsy and that measured on pathological RP specimen slices. Horizontal broken lines correspond to mean difference of 95% confidence limits (2 standard deviations). Observations within 95% limits of agreement likely result from measurement error. Observations outside 95% limits of agreement likely result from true differences between percentage of grade 4 present on pathological slices. Regression line equation is $y = 1.9 - 0.27x$.



Magnetic resonance/transrectal ultrasound fusion biopsy of the prostate compared to systematic 12-core biopsy for the diagnosis and characterization of prostate cancer: multi-institutional retrospective analysis of 389 patients.

Mariotti GC¹, Costa DN, Pedrosa I, Falsarella PM, Martins T, Roehrborn CG, Rofsky NM, Xi Y, M Andrade TC, Queiroz MR, Lotan Y, Garcia RG, Lemos GC, Baroni RH.

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Urol Oncol. 2016

OBJECTIVE: To determine the incremental diagnostic value of targeted biopsies added to an extended sextant biopsy scheme on a per-patient, risk-stratified basis in 2 academic centers using different multiparametric magnetic resonance imaging (MRI) protocols, a large group of radiologists, multiple biopsy systems, and different biopsy operators.

MATERIALS AND METHODS: All patients with suspected prostate cancer (PCa) who underwent multiparametric MRI of the prostate in 2 academic centers between February 2013 and January 2015 followed by systematic and targeted MRI-transrectal ultrasound fusion biopsy were reviewed. Risk-stratified detection rate using systematic biopsies was compared with targeted biopsies on a per-patient basis. The McNemar test was used to compare diagnostic performance of the 2 approaches.

RESULTS: A total of 389 men met eligibility criteria. PCa was diagnosed in 47% (182/389), 52%(202/389), and 60%(235/389) of patients using the targeted, systematic, and combined (targeted plus systematic) approach, respectively. Compared with systematic biopsy, targeted biopsy diagnosed 11% (37 vs. 26) more intermediate-to-high risk ($P<0.0001$) and 16% (10 vs. 16) fewer low-risk tumors ($P<0.0001$). These results were replicated when data from each center, biopsy-naïve patients, and men with previous negative biopsies were analyzed separately.

CONCLUSION: Targeted MRI-transrectal ultrasound fusion biopsy consistently improved the detection of clinically significant PCa in a large patient cohort with diverse equipment, protocols, radiologists, and biopsy operators as can be encountered in clinical practice.

		Standard Biopsy Results			Total
		Negative	Positive (risk)		
			Low	Intermediate-High	
Targeted Biopsy Results	Negative	34% (66)	10% (24)	2% (5)	46% (113)
	Positive (risk)	Low	4% (9)	4% (10)	8% (20)
		Intermediate-High	4% (10)	10% (25)	32% (78)
	Total		42% (103)	24% (59)	34% (84)

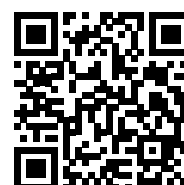
Values within parentheses represent number of patients

Figure 1. Systematic versus targeted biopsy results with risk stratification on a per-patient basis for biopsy-naïve men

			Standard Biopsy Results			Total
			Negative	Positive (risk)		
				Low	Intermediate-High	
Targeted Biopsy Results	Negative		49% (70)	15% (21)	2% (3)	66% (94)
	Positive (risk)	Low	4% (5)	6% (9)	2% (3)	12% (17)
		Intermediate-High	6% (9)	8% (11)	8% (12)	22% (32)
		Total	59% (84)	20% (41)	12% (18)	100% (143)

Values within parentheses represent number of patients

Figure 2. Systematic versus targeted biopsy results with risk stratification on a per-patient basis for men with previous negative biopsies



Prostate Cancer Detection Rate with Koelis Fusion Biopsies versus Cognitive Biopsies: A Comparative Study

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¹Department of Surgical Sciences, Urology, University of Turin, Turin, Italy.

Urol Int. 2016

OBJECTIVE: Targeted fusion biopsies have led to an improved prostate cancer (PCa) detection rate (CDR). Our aim was to assess if device-assisted fusion biopsies are superior to cognitive ones in terms of CDR. The association between multiparametric MRI parameters and PCa was also evaluated.

METHODS: mpMRI targeted prostate biopsy results in a higher detection rate of significant prostate cancer, and a lower probability of detecting insignificant tumors, compared to systematic biopsy. mpMRI-targeted biopsies have improved diagnosis of significant anterior tumors. A small proportion of high-grade tumors is missed by mpMRI and targeted biopsy. However, the majority of these tumors are small-volume, Gleason grade 3 + 4 cancers, and their clinical significance is unknown.

RESULTS: The groups did not significantly differ in terms of age, prostate-specific antigen, prostate volume and previous biopsies. Mean number of random cores was significantly inferior in KB group (8.4 vs. 12.1) and mean number of targeted biopsies was significantly higher (3.6 vs. 2.6). CDR was higher in fusion biopsies (64 vs. 40%), with the gap becoming significant when considering CDR of MRI targets only (59 vs. 27%). The difference was marked for lesions ≤10 mm, where CDR was 52% in KB against 21% in CB group.

CONCLUSIONS: According to our study, elastic fusion biopsies performed with Koelis achieve an increased per-patient and per-lesion CDR as compared to cognitive biopsies, especially in the case of lesions ≤10 mm.

Variables	Cognitive fusion, n/N (%)	Elastic fusion, n/N (%)	p value
PCa detection rate per patients	10/25 (40)	16/25 (64)	0.16
Negative biopsy but ASAP	1/25 (4)	0/25 (0)	≥0.99
PCa found in random cores	4/25 (16)	2/25 (8)	0.66
PCa Gleason score			
PCa, GS 6	2/10 (20)	12/16 (75)	0.01
PCa, GS 6 with >2 positive cores	0/10 (0)	8/16 (50)	0.009
PCa, GS 7	7/10 (70)	4/16 (25)	0.04
PCa, GS 8	1/10 (10)	0/16 (0)	0.38
PCa detection per MRI location			
Cancers found on target	7/26 (27)	16/27 (59)	0.03
Negative biopsy but ASAP	0/26 (0)	1/27 (3.7)	≥0.99
PCa, GS 6	0/26 (0)	13/27 (48.1)	0.0001
PCa, GS 6 with >2 positive cores	0/26 (0)	10/27 (37)	0.0007
PCa, GS 7	6/26 (23)	3/27 (11.1)	0.29
PCa, GS 8	1/26 (3.8)	0/27 (0)	≥0.99
PCa found in targets PIRADS 3	1/8 (12.5)	2/2 (100)	0.13
PCa found in targets PIRADS 4	2/12 (16.7)	11/19 (57.9)	0.05
PCa found in targets PIRADS 5	3/6 (50)	3/6 (50)	≥0.99
PCa found in targets ADC ≥0.9	2/9 (22.2)	4/10 (40)	0.74
PCa found in targets ADC <0.9	5/17 (29.4)	10/17 (58.8)	0.16
PCa found in targets size <7 mm	1/7 (14.3)	5/9 (55.5)	0.24
PCa found in targets size 7–10 mm	2/7 (28.5)	6/12 (50)	0.67
PCa found in targets size >10 mm	5/12 (41.6)	5/6 (83.3)	0.24

Figure 1. Association of MRI with CDR



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

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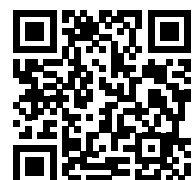
Urol Int. 2016

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.

PATIENTS 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.



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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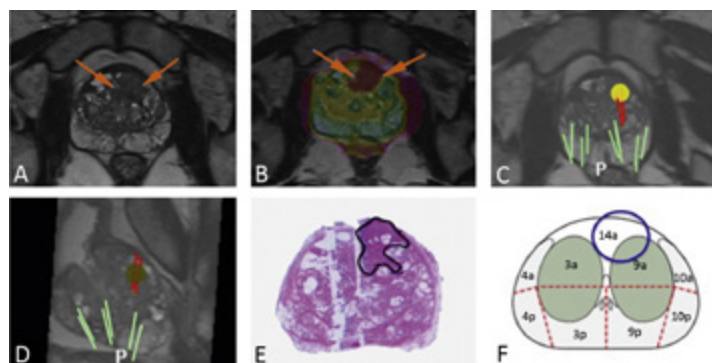
Eur Urol. 2015

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.

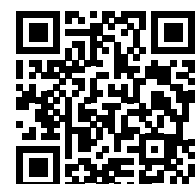


OUTCOMES MEASUREMENTS AND STATISTICAL ANALYSIS: The detection rates for any cancer and csPCa were compared between the two groups and between TB and RB.

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.

CONCLUSION: 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.



Detection of Prostate Cancer Using Magnetic Resonance Imaging/Ultrasonography Fusion Targeted Biopsy in African-American Men.

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BJU Int. 2017

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

PATIENTS ND METHODS: We retrospectively analyzed 661 patients (117 A-A and 544 Caucasian) who underwent pre-biopsy mp-MRI and the following MRI/US fusion biopsy (UroStation, Koelis) (10/2012 - 8/2015). The mp-MRIs were reported on a 5-point Likert scale of suspicion. Clinically significant prostate cancer (CSPCa) was defined as biopsy Gleason score ≥ 7 .

RESULTS: After controlling for age, prostate-specific antigen (PSA) level and prostate volume, there were no significant differences between A-A and Caucasian men in detection rate of overall cancer (35.0% vs 34.2%, $p=0.9$) and CSPCa (18.8% vs 21.7%, $p=0.3$) with targeted biopsy. There were no significant differences between 2 races in the location of dominant lesions on MRI, and in the proportion of 5-point Likert scoring. In A-A

Likert score	African-American	Caucasian	
1-2	14.0% (8/57)	18.5% (42/227)	$p=0.429$
3	47.6% (20/42)	28.9% (55/190)	$p=0.019$
4-5	70.6% (12/17)	69.6% (87/125)	$p=0.934$
Total	35.0% (41/117)	34.2% (186/544)	$p=0.915$

Figure 1. Overall cancer detection rate with targeted biopsy

men, targeted biopsy from the grade 4-5 lesions outperformed random biopsy in detection rate of overall cancer (70.6% vs 37.2%, $p=0.003$) and CSPCa (52.9% vs 12.4%, $p<0.001$). Targeted biopsy outperformed random biopsy in cancer core length (5.0mm vs 2.4mm, $p=0.001$), in cancer rate per core (24.9% vs 6.8%, $p<0.001$), and in efficiency for detecting one patient with CSPCa (13.3 vs 81.9, $p<0.001$), respectively.

CONCLUSIONS: Our key finding confirms lack of racial differences in detection rate of overall prostate cancers and CSPCa with MRI/US fusion targeted biopsy between A-A and Caucasian men. MRI/US fusion targeted biopsy detected more CSPCa using fewer cores compared with random biopsy.



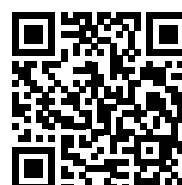
The economic effect of using magnetic resonance imaging and magnetic resonance ultrasound fusion biopsy for prostate cancer diagnosis

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Urol Oncol. 2016

ABSTRACT: Prostate magnetic resonance imaging (MRI) is a maturing imaging modality that has been used to improve detection and staging of prostate cancer. The goal of this review is to evaluate the economic effect of the use of MRI and MRI fusion in the diagnosis of prostate cancer. A literature review was used to identify articles regarding efficacy and cost of MRI and MRI-guided biopsies. There are currently a limited number of studies evaluating cost of incorporating MRI into clinical practice. These studies are primarily models projecting cost estimates based on meta-analyses of the literature. There is considerable variance in the effectiveness of MRI-guided biopsies, both cognitive and fusion, based on user experience, type of MRI (3T vs. 1.5T), use of endorectal coil and type of scoring system for abnormalities such that there is still potential for improvement in accuracy. There is also variability in assumed costs of incorporating MRI into clinical practice. The addition of MRI to the diagnostic algorithm for prostate cancer has caused a shift in how we understand the disease and in what tumors are found on initial and repeat biopsies. Further risk stratification may allow more men to pursue noncurative therapy, which in and of itself is cost-effective in properly selected men. As prostate cancer care comes under increasing scrutiny on a national level, there is pressure on providers to be more accurate in their diagnoses. This in turn can lead to additional testing including Multiparametric MRI, which adds upfront cost. Whether the additional cost of prostate MRI is warranted in detection of prostate cancer is an area of intense research.



The role of MRI in active surveillance for men with localized prostate cancer

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Curr Opin Urol. 2015

PURPOSE OF REVIEW: Active surveillance is the preferred management strategy for men with low-risk prostate cancer. Challenges in this field include improving patient selection, optimizing follow-up strategies, and identifying appropriate triggers for intervention. Advances in multiparametric MRI (mpMRI) have lead to improved detection of prostate tumors, and MRI has emerged as a tool to monitor men on active surveillance. We aim to review the latest developments in mpMRI to monitor active surveillance patients and describe areas of future research.

RECENT FINDINGS: mpMRI targeted prostate biopsy results in a higher detection rate of significant prostate cancer, and a lower probability of detecting insignificant tumors, compared to systematic biopsy. mpMRI-targeted biopsies have improved diagnosis of significant anterior tumors. A small proportion of high-grade tumors is missed by mpMRI and targeted biopsy. However, the majority of these tumors are small-volume, Gleason grade 3 + 4 cancers, and their clinical significance is unknown.

SUMMARY: mpMRI and targeted prostate biopsy have emerged as tools to improve the accuracy of systematic biopsy to select patients for active surveillance. The role of mpMRI to monitor and trigger intervention in these patients is understudied, and integration of MRI data with clinical characteristics can help many men avoid routine confirmatory biopsy.



Integrated US-MR fusion images and MR targeted biopsies. What are their role and value in the detection and follow-up of prostate cancer

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Arch Esp Urol. 2015

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. Organ based registration 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. The concept of an MR-US fusion TB strategy only is gaining more and more widespread acceptance. In a TB only strategy, fewer men could be biopsied overall, with a greater proportion of men diagnosed with clinically significant prostate, as well as fewer men «over diagnosed» with clinically insignificant cancer. However, more clinical research is required before this strategy is ready for widespread adoption.



MRI/US fusion prostate biopsy: Our initial experience

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Arch Ital Urol Androl. 2016

AIM: The objective of this study is to present our initial experience with magnetic resonance imaging/ultrasound (MRI/US) fusion biopsy using the Koelis Trinity device after the first consecutive 59 patients.

MATERIALS AND METHODS: 59 consecutive patients with suspected prostate cancer (PCA) underwent prostate biopsy using Trinity Koelis® (Koelis, Grenoble, France). We divided the patients into 2 groups: patients with a previous negative mapping underwent to a MRI/US fusion re-biopsy (Group A); and biopsy-naïve patients who underwent to a first stereotactic 3-D mapping of the prostate (Group B). Group A (22 patients): mean age 64 years (CI 48-73), mean PSA = 7.7 ng/ml (CI 4.2- 9.9); mean prostate volume 55 ml (CI 45-82), Digital Rectal Examination (DRE) positive in 2/22, number of lesions detected by MRI 1.4, mean cores from each MRI target lesion 3 (CI 2-5), mean total cores 15 (CI 12-19). Group B (37 patients): mean age 66 years (CI 49-77), mean PSA= 4.7 (3.2- 7.9); mean prostate volume 45 ml (33- 67), DRE positive in 5/37, mean total cores 14 (CI 10-16) Results: In Group A 10/22 patients were positive for PCA (overall detection rate of 45.5%): 6 PCA were detected by target biopsy and 4 cancer by random biopsy. Significant prostate cancer (defined as the presence of Gleason pattern 4) was detected in 4/10 patients (Significant PCA detection rate of 40%) and all significant PCA were detected by MRI target biopsy. All PCA detected by random biopsy had Gleason score 3 + 3 = 6. In Group B (biopsy naïve patients) 14/37 patients were positive for PCA (overall detection rate of 37.8%), Significant prostate cancer was detected in 5/14 patients (Significant PCA detection rate of 35.7%). No significant side effects were recorded.

Overall PCA detection rate	10/22 (45.5%)	14/37 (37.8%)
Significant PCA detection rate	4/10 (40%)	5/14 (35.7%)
PCA in target lesion	6/10	
PCA in random biopsy core	4/10	
Significant PCA detected in target lesion	4/6	
PIRADS 3	1 /6	
PIRADS 4	2 /6	
PIRADS 5	1/6	
Significant PCA in random biopsy core	0/4	

Table 1. Results

CONCLUSIONS: Our overall detection rate was 45.5% and 37.8% in Group A (patients with previous negative biopsy and persistent suspicion of PCA) and in Group B (biopsy naïve patients) respectively; clinical significant PCA detection rate was respectively 40% and 35.7%. These results are similar to current literature and promising for the future. We believe that using platforms of co-registered MRI/US fusion biopsy can potentially improve risk stratification and reduces understaging, undergrading and the need for repeat biopsies in biopsy naïve patients (using a stereotactic first mapping) and in patients with previous negative biopsy and persistent suspicion of PCA (using a second MRI/US fusion biopsy).

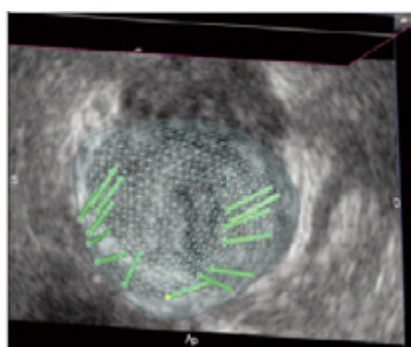


Figure 1. Stereotactic 3D mapping of the prostate in a biopsy-naïve patient.

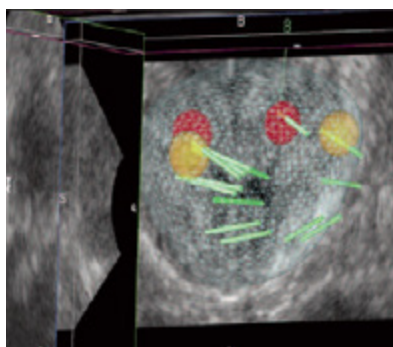
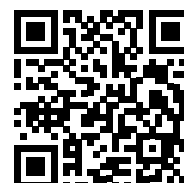


Figure 2. MRI/US fusion target and random re-biopsy: 2 MRI lesions with a PIRADS score of 3 (orange) and 2 MRI lesions with PIRADS 4 (red).



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

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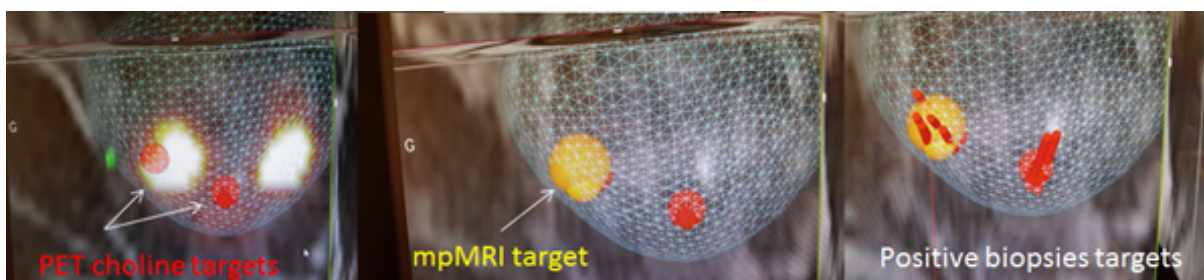
EAU 2017

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, from December 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 patient. 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 biopsies. 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, the 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 positive biopsies respectively in 43% and 62%. Compared to mpMRI, for one patient only TEP gave a positive target but failed 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.



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