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#laser #Stones #HBP #PCa #newtech

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📍 Madrid, Comunidad de Madrid

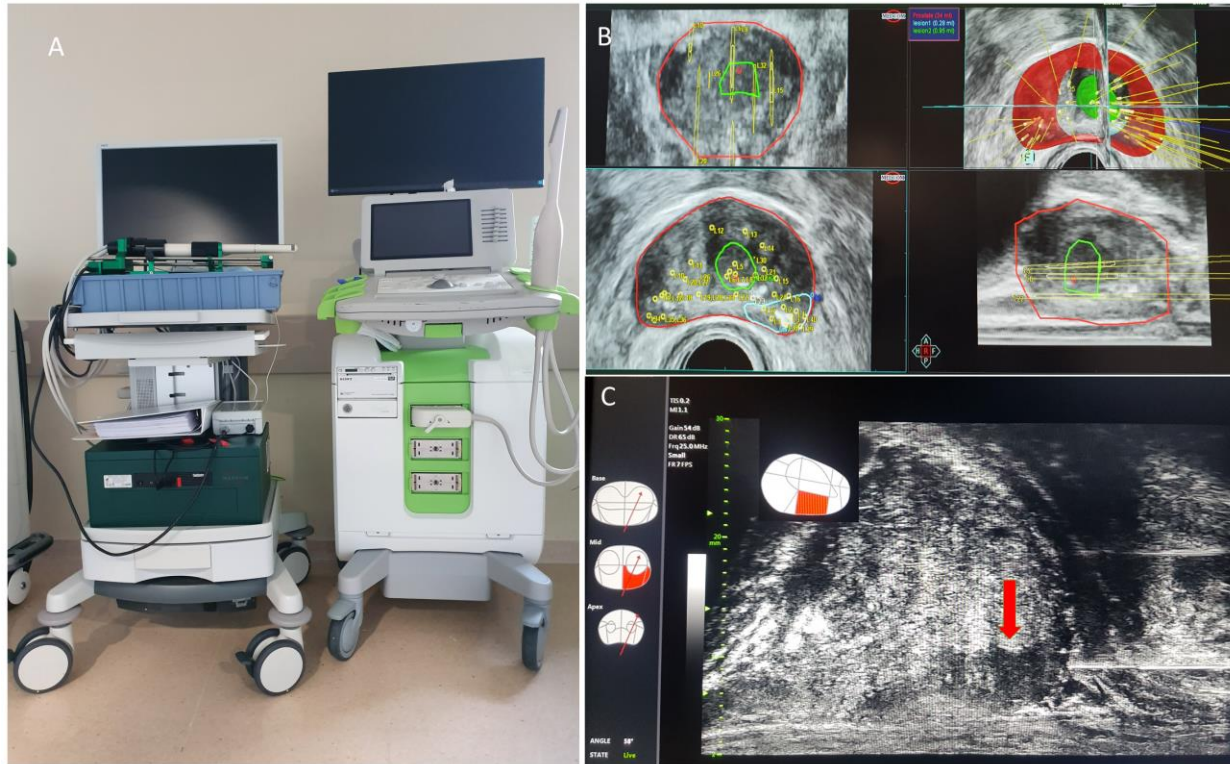
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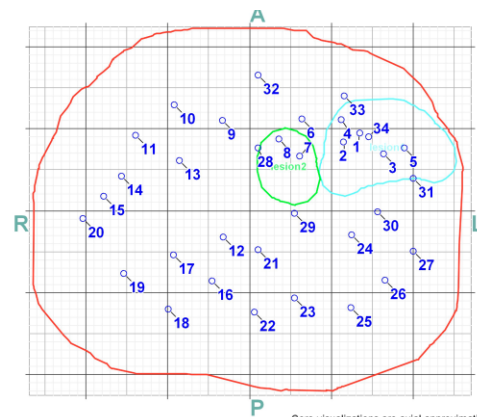
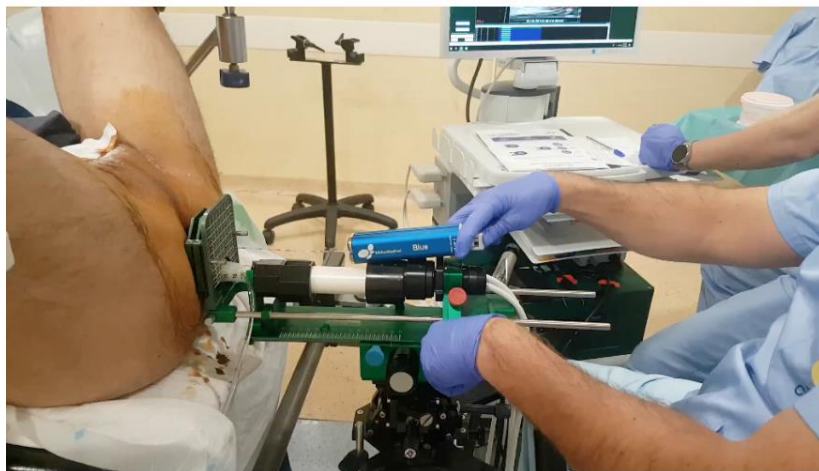


Microultrasonidos ¿qué nos aporta, qué lugar ocupa, reemplaza la RMN?

Moisés Rodríguez Socarrás, ICUA - Madrid, Spain
Septiembre 2023

Prostate mapping for cancer diagnosis: The Madrid Protocol. **Transperineal** prostate biopsies combining **micro-Ultrasound** and mpMRI fusion biopsy.





Core visualizations are axial approximations

Nuestra experiencia

> 600 pacientes biopsiados

Nuestro Protocolo

Dirigidas por Micro-US + Fusión mpMRI + sistemáticas

- ✓ 1 Artículo Journal of Urology
- ✓ 2 Suplementos Journal of Urology
- ✓ 6 trabajos en congresos AUA y EAU 2021,2022
- ✓ 1 Podium AUA 2021
- ✓ 4 trabajos congreso AEU
- ✓ Participacion en el estudio Optimum

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Prostate "Mapeo" for cancer diagnosis: The Madrid protocol. Transperineal prostate biopsies combining Micro-ultrasound and mpMRI fusion biopsy.

M.E. Rodríguez Socarrás, J. Gomez Rivas, J. Reinoso Elibers, L. Llanes Gonzalez, J. Fernandez Del Alamo, P. Juarez Del Diago, I.E. Michel Mercado, B. Wodlinger, F. Gomez Sanchez

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PD41-06 **TRANSPERINEAL PROSTATE BIOPSIES USING MICRO-ULTRASOUND, MRI-GUIDED AND SYSTEMATIC BIOPSIES (MADRID PROTOCOL), AN UPDATE WITH 482 PATIENTS**

Volume 207 Issue Supplement 5 May 2022 Page e68

Miguel Elias Socarrás, Javier Reinoso Elibers, Fabio Sandoval, Isabella Corso, Julio Fernandez del Alamo, Vanessa Cuadros Rivera, Diego Caetano Monrabal, Juan Gomez Rivas, Luis Llanes Gonzalez, and Fernando Gomez Sanchez

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https://doi.org/10.1097/JU.0000000000002022

EAU20
Prostate mapping for cancer diagnosis: The Madrid protocol. Transperineal prostate biopsies combining micro-ultrasound and mpMRI fusion biopsy

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Introduction & Objectives:
mpMRI-targeted biopsy is increasing as a useful tool to improve accuracy of PCA detection. Micro-ultrasound (Micro-US) is a novel high-resolution imaging system allowing real-time targeted biopsies. The aim of this study is to assess transperineal prostate biopsy accuracy for PCA detection combining both Micro-US and mpMRI fusion biopsy during the same procedure.

Materials & Methods:
230 consecutive patients underwent transperineal prostate biopsies combining real-time targeted Micro-US (SheepTV) biopsies and mpMRI fusion biopsy (Bioscope system) in the same procedure. From February 2013 - September 2020, biopsies were performed by Urologists using the "Madrid" 7-step and 17-step protocol for 2306 high-resolution Micro-US (transperineal) procedures. Biopsies included: Age, PSA, prostate volume, MRI lesion, cRPC (cRPC >PSA > 10, Gleason score >= 6) and confirmation according to Gleason Grade, International Prostatic Symptom Score (IPSS) and confirmation according to Gleason Grade, International Prostatic Symptom Score (IPSS) were combined, p < 0.05 were considered statistically significant.

Results:
Median patient age was 63 (IQR 58-67). The overall prostate rate was 17.2% (125) for PCA and 23.5% (27) for cRPC. Micro-US and MRI together detected significantly more PCA and cRPC than mpMRI alone (p < 0.001). mpMRI biopsies in targeted prostate did not reach statistical difference for PCA or cRPC diagnosis and PSA. Regression model (AUC) for Prostate with less than one unit (p < 0.75). Specifically, for PSA < 10 (p < 0.001) there is an improvement in detection rate between MRI-PCA and MRI-PCA + Micro-US (p < 0.001).

Conclusions:
This is the first study using transperineal approach for prostate biopsies combining Micro-ultrasound and mpMRI fusion biopsy. Results show high accuracy for PCA and cRPC diagnosis, without increased complications due to biopsy. The proposed method should be validated in large randomized clinical trials.

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PD418 **Prostate Mapping for Cancer Diagnosis: The Madrid Protocol. Transperineal Prostate Biopsies Using mpMRI Fusion and Micro-ultrasound Guided Biopsies**

Miguel Elias Rodríguez Socarrás, Juan Gomez Rivas, Vanessa Cuadros Rivera, Javier Reinoso Elibers, Luis Llanes Gonzalez, Ivan Michel Mercado, Julio Fernandez del Alamo, Pablo Juarez del Diago, and Fernando Gomez Sanchez

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PD48-12 Prostate mapping for cancer diagnosis: The Madrid Protocol. Transperineal prostate biopsies combining micro-Ultrasound and mpMRI fusion biopsy.

Miguel Elias Rodríguez Socarrás*, Juan Gomez Rivas, Vanessa Cuadros, Javier Reinoso Elibers, Luis Llanes, Ivan Michel Mercado, Julio Fernandez del Alamo, Pablo Juarez del Diago, Fernando Gomez Sanchez
ICUA - Madrid, Spain



|

Microultrasonidos: Qué es y
para que sirve?



Ecografía con microultrasonidos de alta resolución (MicroUs).

- 29Mhz , 300% de mayor resolución que la ecografía estándar

What is High Resolution Micro-Ultrasound?

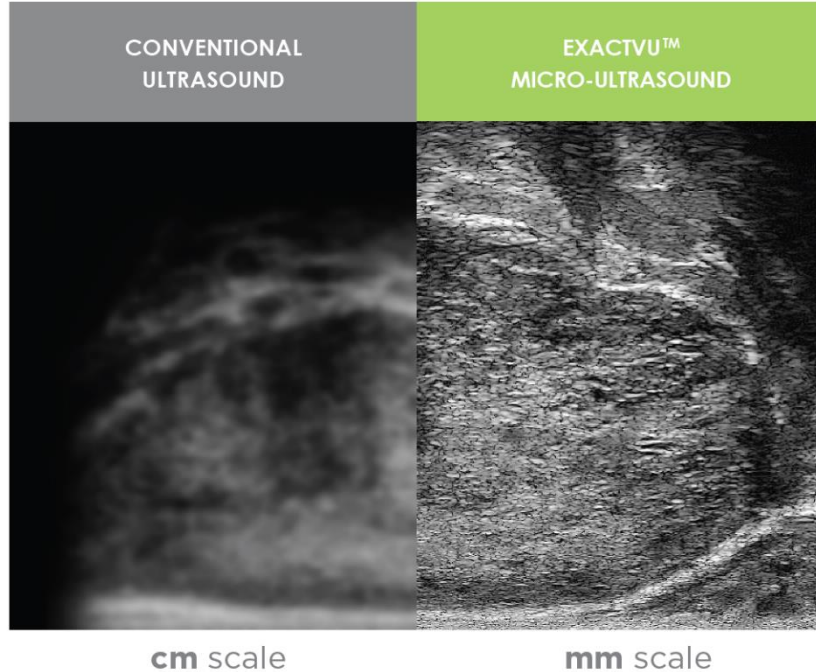
70 μm Resolution – what does that mean?

Our resolution means being able to distinguish structures that are separated by only 70 μm



Micro ultrasonidos de alta resolución

Una nueva escala de detalle.

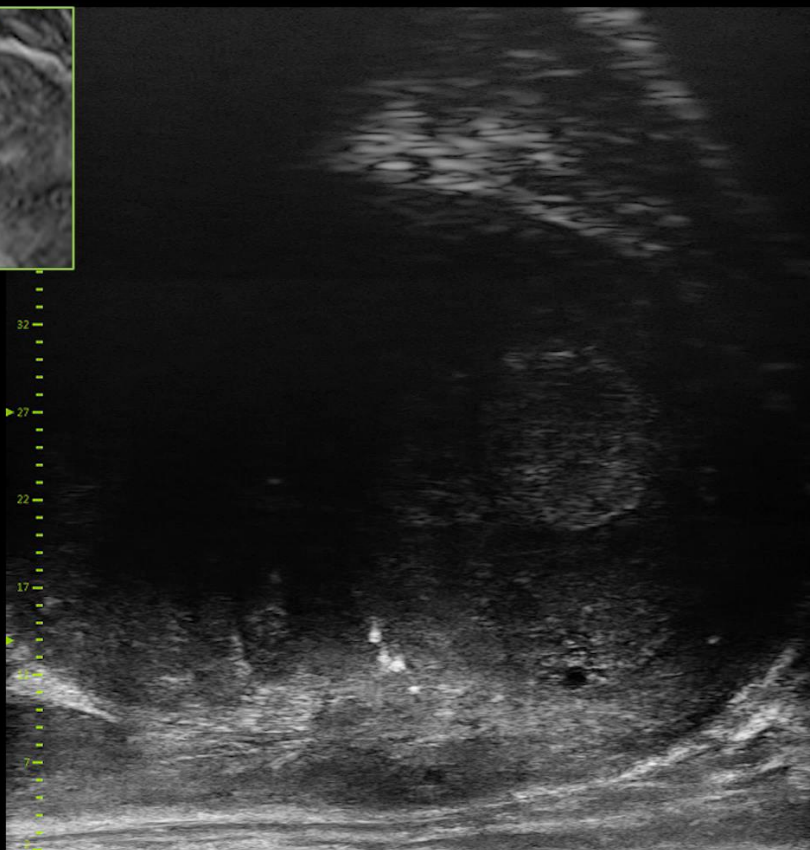
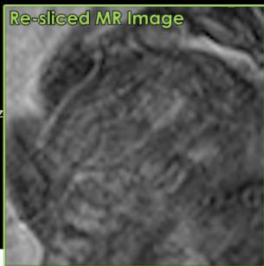


Vastly increased detail providing more information for the urologist.

- Permite ver los ductos y las glándulas prostáticas.
- Visualización detallada de la zona periférica.
- Biopsia en tiempo real de zonas sospechosas.

TIS 0.4
MI 0.9

Gain 65 dB
DR 70 dB
Frq 25.0 MHz
Large
FR 4 FPS



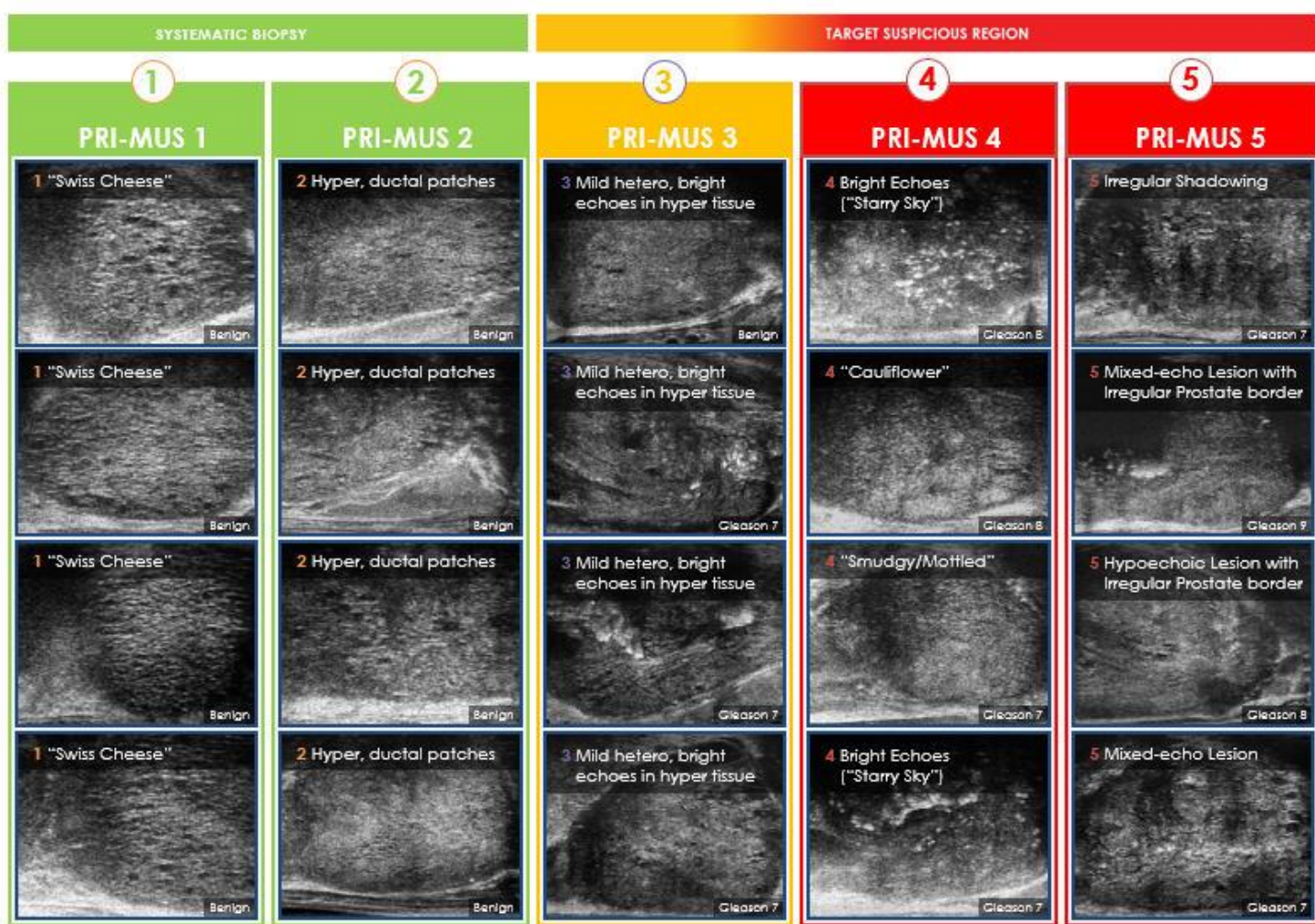
STATE Live
SERVICE Active



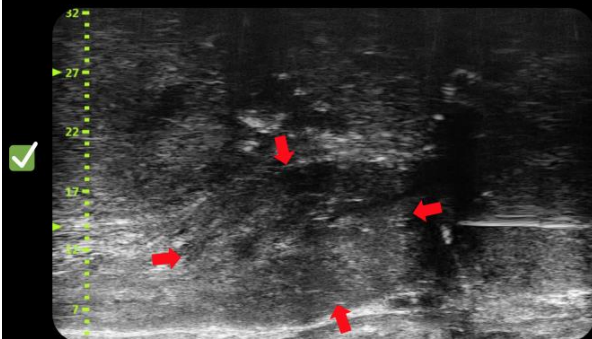
Protocolo PRI-MUS™

Prostate
Risk
Identification using
Micro-
Ultra-
Sound

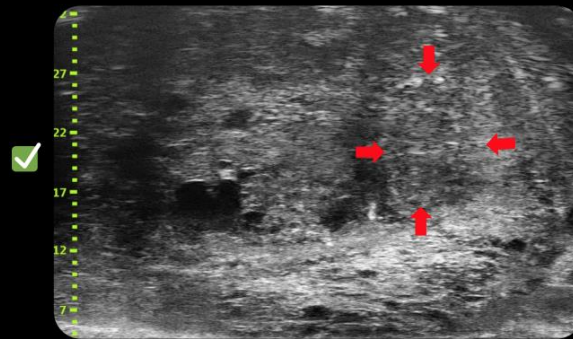
Protocolo desarrollado
para el usuario de
ExactVu™, basado en
evidencia científica



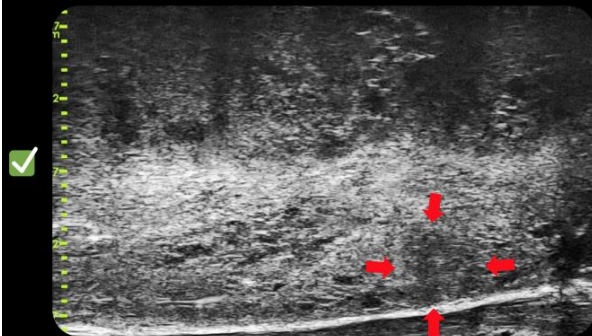
PRI-MUS 4 on the Right: Grade Group 4



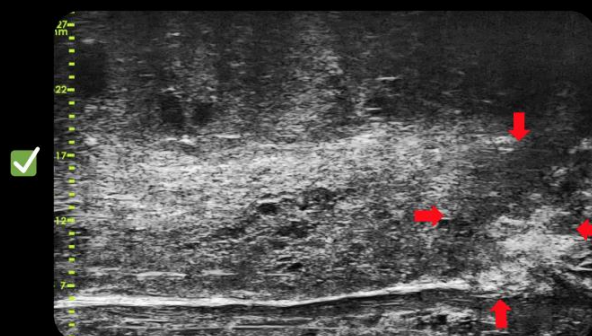
PRI-MUS 4 on the Right: Grade Group 2



PRI-MUS 3 on the Left: Grade Group 1



PRI-MUS 4 on the Left: Grade Group 2



EXACTVU™ + FUSIONVU™

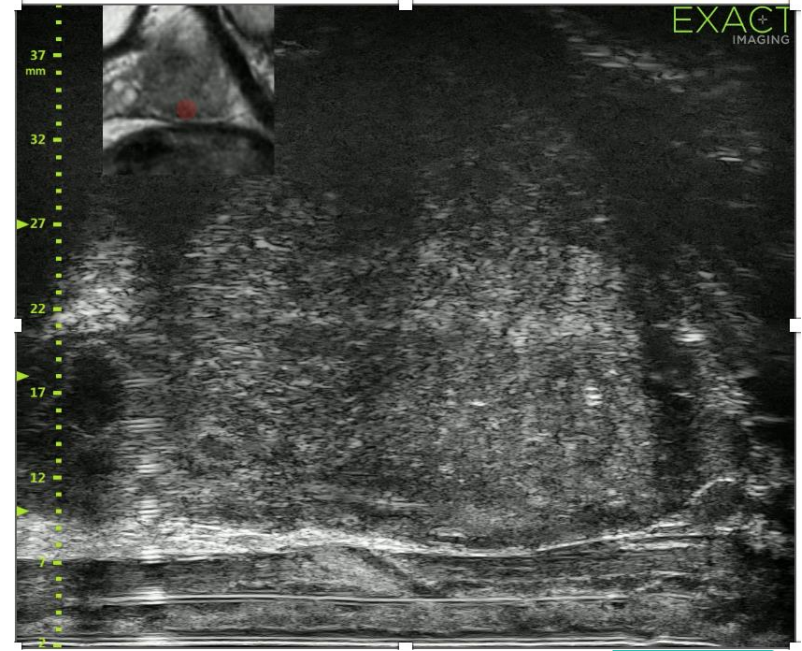
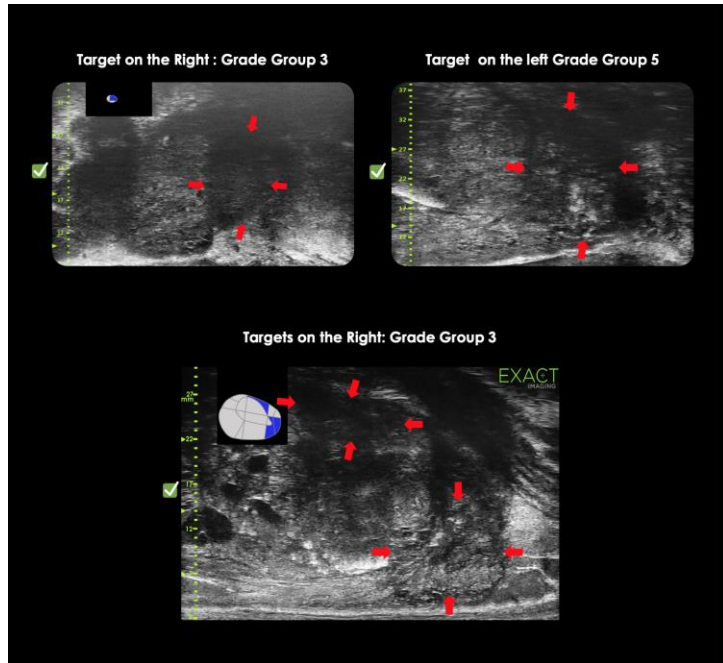
29MHz Micro-Ultrasound
for targeted prostate biopsies

Micro-Ultrasound / MRI Fusion

EXACT⁺VU + FUSION⁺VU

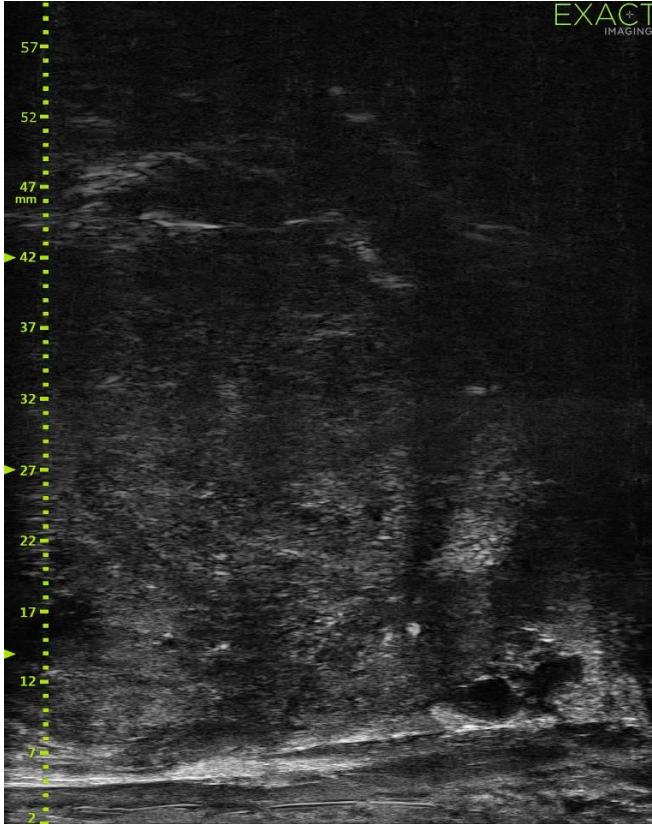
29MHz Micro-Ultrasound
for targeted prostate biopsies

Micro-Ultrasound / MRI Fusion



Instituto de Cirugía Urológica Avanzada (ICUA), Dept. of Urology, Madrid, Spain

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UROLÓGICA AVANZADA



63 años, prostata 75 ml, psa 3.59 ng/ml,

RNM sin lesiones PIRADS 2

Trublood positivo.

Todas las biopsias con los micros positivas

ESTUDIO MICROSCÓPICO Y DIAGNÓSTICO

Próstata: Adenocarcinoma prostático, Adenocarcinoma prostático, Gleason 7 (4+3). 80% de grado 4. No se identifica patrón cribiforme, glomeruloide ni carcinoma intraductal.

Grupo pronóstico OMS 2.016: III de 5. ISUP 3.

El tumor está presente en los siguientes cilindros con los siguientes porcentajes de afectación y muestran las dimensiones de tumor referidas:

Cilindro	%	mm
A	5	0'60
B	7	0'50
C	82	9
D	64	7
E	40	4
8	100	10
9	50	6'5
13	92	5'5
14	50	3'5
15	35	3'5
17	5	0'75
22	100	11

MicroUS

Se ve invasión perineural.

- Foco de PIN de alto grado identificado en el cilindro 25.
- Los restantes cilindros se encuentran dentro de límites de la normalidad.



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Prostate Mapping for Cancer Diagnosis: The Madrid Protocol. Transperineal Prostate Biopsies Using mpMRI Fusion and Micro-ultrasound Guided Biopsies

Moises Elias Rodríguez Socarrás , Juan Gomez Rivas, Vanesa Cuadros Rivera, Javier Reinoso Elbers, Luis Llanes González, Ivan Michel Mercado, Julio Fernandez del Alamo, Pablo Juarez del Dago, and Fernando Gomez Sancha

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FIGURES REFERENCES RELATED **DETAILS**



Supplementary
Materials

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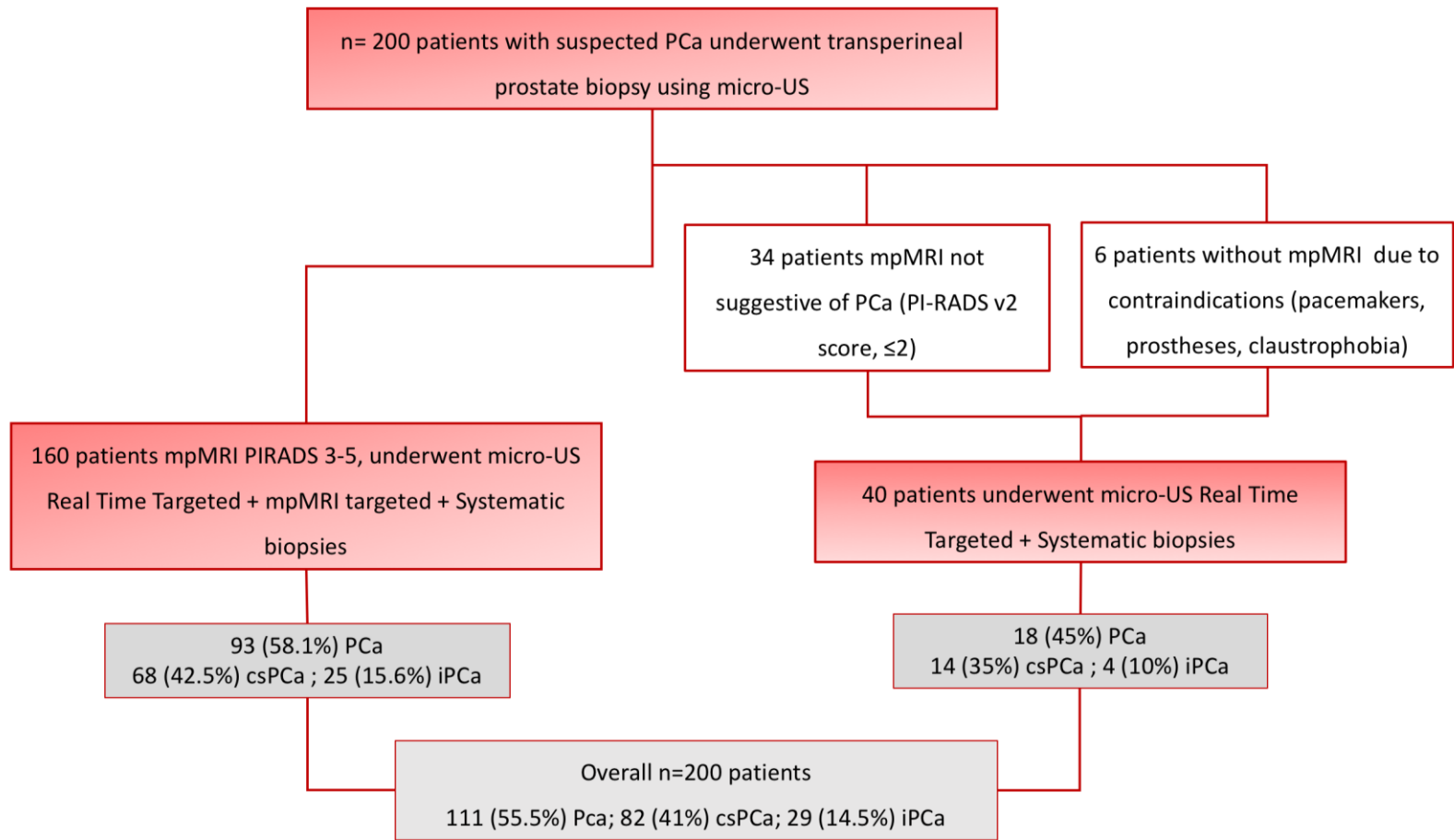


Figure 1. Diagnostic of Prostate Cancer (Pca), insignificant Prostate Cancer (iPCa) and clinical significant Prostate Cancer (csPCa) using micro-ultrasounds (micro-US) Real Time targeted biopsies and multiparametric MRI (mpMRI) targeted Biopsies combined with systematic biopsies; by transperineal approach, n=200 patients

✓ **Non-significant statistical difference when comparing mpMRI biopsies vs targeted micro-US biopsies for PCa or csPCa diagnosis.**

Table 2. findings n=200 underwent Transperineal prostate biopsies using micro-US Real Time Targeted, mpMRI targeted and systematic biopsies (Mapping).

	micro-US	mpMRI Targeted†	Systematic	Mapping (micro-US + mpMRI-T + Systematic)	p value
Benign, n (%)	125 (62.5%)	90 (45%)	82 (41%)	67 (33.5%)	
PIN, n (%)	8 (4%)	5 (2.5%)	7 (3.5%)	10 (5%)	
ASAP, n (%)	7 (3.5%)	2 (1%)	12 (6%)	12 (6%)	
PCa, n (%)	61 (30.5%)^a	70 (35%)^a	99 (49.5%)^{**}	111 (55.5%)^{**}	*p= 0.24, ** p<0.001
csPCa, n (%)	47 (23.5%)^b	54 (27%)^b	64 (32%)^{**}	82 (41%)^{**}	*p= 0.20, ** p<0.001
Number of lesions n; mode [IQR]	407; 2 [1-5]¶	258; 1 [1 - 3] §	-	-	
Biopsy cores, n; mean [IQR]	911; 5 [3 - 6]	1269; 6 [5 - 9]	6340; 32 [30 - 37]	8520; 44 [38 - 48]	
Cores involved, mean [IQR]	2 [1 - 3]	2 [1 - 4]	3 [1 - 5]	5 [1 - 8]	

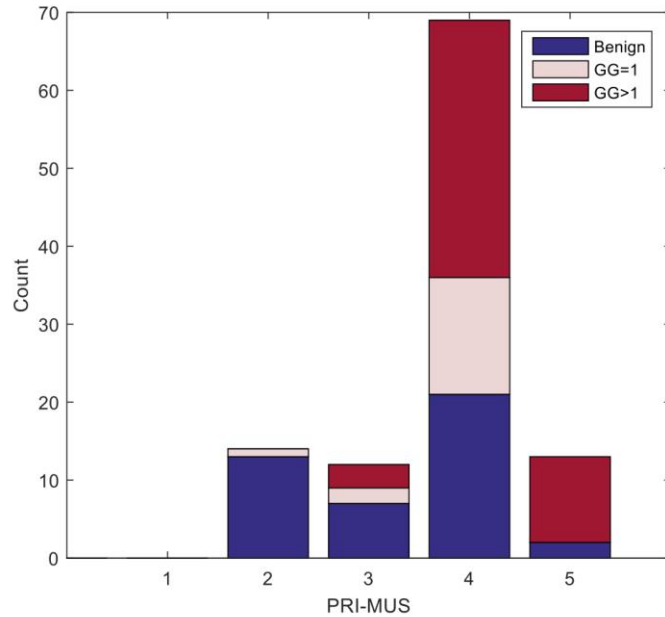
¶ PRIMUS ≥ 3; § PIRADS ≥ 3. †40 patients Negative mpMRI PIRADS 2 (no lesions)= 34 (17%), † No mpMRI performed (contraindication) = 6 (3%)

micro-US = micro-ultrasounds (micro-US); mpMRI-T= multiparametric MRI Targeted biopsies; PIN = Prostatic intraepithelial neoplasia; ASAP= atypical small acinar proliferation; Pca = Prostate Cancer; csPCa= clinical significant Prostate Cancer.

Table 2. findings n=200 underwent Transperineal prostate biopsies using micro-US Real Time Targeted, mpMRI targeted and systematic biopsies (Mapping).

- ✓ Interestingly **Micro-US** found 12/108 (11%) PCa that were missed by all other techniques and 11 (92%) were csPCa.
- ✓ No fever or clinical infection was observed, 17 (8.7%) patients presented minor complications (Clavien Dindo I).

✓ Ambos PI- RADSy PRI-MUS son altamente predictivos de CPCS



Factor	OR	p-value	VIF
Log10(PSA)	2.49 [10.26 - 0.61]	0.21	1.05
Age/10	1.42 [2.20 - 0.92]	0.11	1.13
DRE	1.42 [3.65 - 0.55]	0.47	1.03
Previous biopsy	0.67 [1.40 - 0.32]	0.28	1.06
PI-RADS 2	3.17 [9.59 - 1.05]	0.04	1.42
PI-RADS 3	Reference	-	-
PI-RADS 4	2.04 [5.00 - 0.84]	0.12	1.63
PI-RADS 5	6.37 [23.26 - 1.75]	0.01	1.65
PRI-MUS 2	0.00 [Inf - 0.00]	1	1.58
PRI-MUS 3	Reference	-	-
PRI-MUS 4	3.10 [8.40 - 1.14]	0.03	1.93
PRI-MUS 5	8.60 [41.39 - 1.79]	0.01	1.7

Figure 3. Logistic Regression Model (AUC for model with leave-one-out validation = 0.76) n=194 patients .

Logistic Regression Model (AUC for model with leave-one-out validation = 0.7). Specifically, for PSA >4, PIRADS>3 there is an improvement in detection rate between PRI-MUS 4 and PRI-MUS 5 (36% GG>1 to 60% GG>1).

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PD41-06 TRANSPERINEAL PROSTATE BIOPSIES USING MICRO-ULTRASOUND, MRI-GUIDED AND SYSTEMATIC BIOPSIES (MADRID PROTOCOL), AN UPDATE WITH 482 PATIENTS

Moises Elias Socarras, Javier Reinoso Elbers, Fabio Esposito, Isabella Graco, Julio Fernandez del Alamo, Yanina Cuadros Rivera, Diego Carrion Monsalve, Juan Gomez Rivas, Luis Llanes Gonzalez, and Fernando Gomez Sanchez

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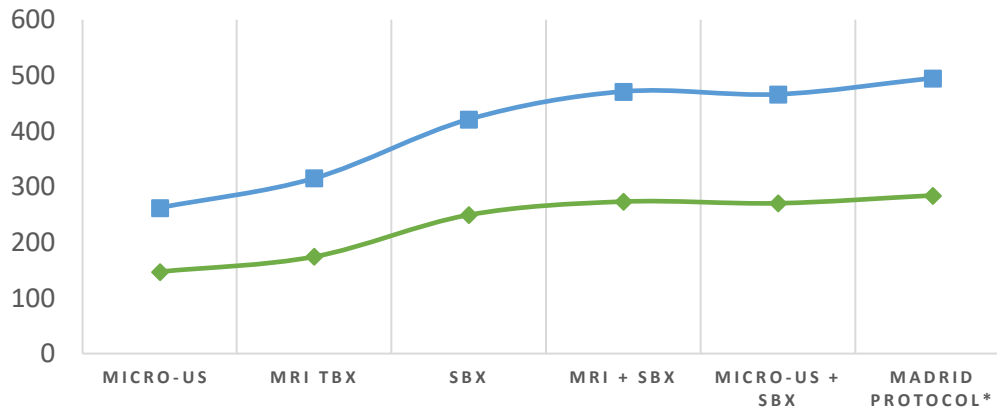
Table 2. TP using micro-US + MRI TBx + SBX (Madrid Protocol) n=482

	Micro-US	MRI TBx	SBX	MRI + SBX	Micro-US + SBX	Madrid Protocol*	p
PCa n,(%)	147 (30.49%)	174 (36%)	249 (51.6%)	273 (56.63%)	270 (56.01%)	284 (58.92%)	<0.001
csPCa n, (%)	115 (23.85%)	141 (29.2%)	172 (35.6%)	198 (41.07%)	196 (40.66%)	211 (43.77%)	<0.001

Table 1. Demographics of n=482 patients TP prostate Biopsies using micro-US + MRI TBx + SBX (Madrid Protocol)

		95% CI
Age mean, SD, (IQR)	63.46 ± 7.91 (58.15- 63.75)	62.64 – 64.17)
Prostate Volume SD, (IQR)	54.87 ± (34.75 – 69)	(51.92-57.72)
PSA, SD (IQR)	7.76 ± 6.35 (58.15 - 69.23)	(7.08 – 8.35)
DRE suspicious n, %	82 (17%)	

◆ Pca ■ csPCa



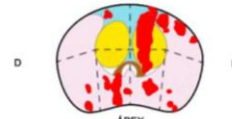
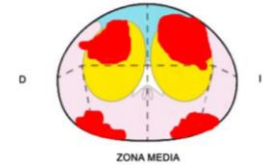
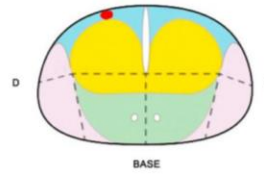
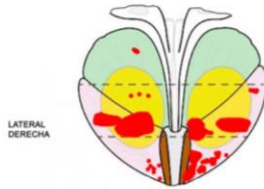
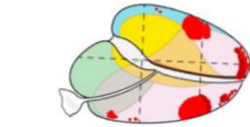
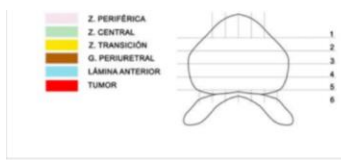


Micro-Ultrasound–Guided vs Multiparametric Magnetic Resonance Imaging–Targeted Biopsy in the Detection of Prostate Cancer: A Systematic Review and Meta-Analysis

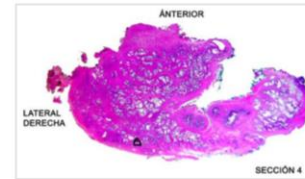
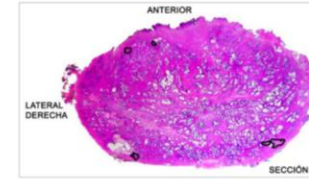
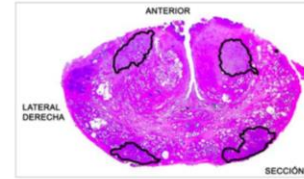
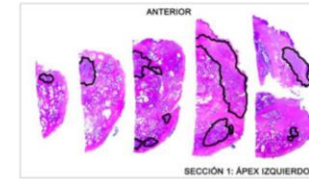
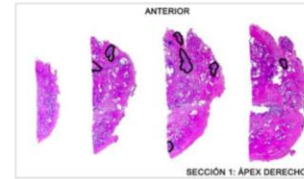
Petros Sountoulides,* Nikolaos Pyrgidis, Stergios A. Polyzos, Ioannis Mykoniatis, Eirini Asouhidou, Athanasios Papatsoris, Athanasios Dellis, Anastasios Anastasiadis, Lukas Lusuardi and Dimitrios Hatzichristou

From the Urology Department (PS, NP, IM, AA, DH), School of Medicine, Faculty of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece, First

References	Study Period	Compared Techniques	Population	No. Pts	Mean±SD Age (yrs)	Mean±SD PSA (ng/dl)	No. Abnormal DRE	Mean±SD Prostate Vol (ml)	No. Pts Undergoing Micro-US +mpMRI Biopsy	Cores/Micro-US Target	Cores/mpMRI Target
Abouassaly et al ²²	01/18–08/18	Micro-US vs mpMRI vs SB	Suspicion of PCA	67	65±7.4	5.9±3.4	7	37.5±19.3	19	Mean±SD	Mean±SD
Cornud et al ³³	02/19–07/19	Micro-US vs mpMRI	Suspicion of PCA+at least 1 mpMRI lesion (PI-RADS ≥3)	118	66±13	11±19	16	53±26	118	2.3±0.7	2.9±0.4
Eure et al ²³	12/16–12/16	Micro-US vs mpMRI vs SB vs conventional transrectal US	Men with PCA in active surveillance protocol	9	65.6±4.4	6±1.1	9	38.8±8.2	9	5±2	5±2
Klotz et al ²⁴	Not available	Micro-US vs mpMRI vs SB	Suspicion of PCA	77	Not available	Not available	Not available	Not available	77	Not available	Not available
Lopez et al ²⁵	Not available	Micro-US vs mpMRI vs SB	Elevated PSA or abnormal DRE	51	Not available	Not available	Not available	Not available	51	Not available	Not available
Luger, as reported by Klotz et al ²⁴	Not available	Micro-US vs mpMRI vs SB	Suspicion of PCA	62	Not available	Not available	Not available	Not available	62	Not available	Not available
Lughezzani et al ²⁶	10/17–09/19	Micro-US vs mpMRI vs SB	Suspicion of PCA+at least 1 mpMRI lesion (PI-RADS ≥3)	320	64.7±8.2	7.5±3.5	72	48.3±29.6	320	4.3±2.2	4.3±2.2
Martel et al ³⁴	05/18–03/19	Micro-US vs mpMRI vs SB	Biopsy-naïve pts, pts with previous neg biopsy or on active surveillance, or pts undergoing PCA stratification	148	66.3±8.2	7.3±4.3	Not available	Not available	148	Not available	Not available
Pereira-Arias et al ²⁷	02/17–01/18	Micro-US vs mpMRI vs SB	Elevated PSA or abnormal DRE	96	67±5.5	7.5±5.6	Not available	56±16.3	79	2	2
Perez ²⁸	Not available	Micro-US vs mpMRI vs SB	Suspicion of PCA+available mpMRI	55	Not available	15.3±9	Not available	Not available	55	Not available	Not available
Claros et al ²⁹	02/17–09/18	Micro-US vs mpMRI vs SB	Suspicion of PCA+at least 1 mpMRI lesion (PI-RADS ≥3)	269	67.5±7.4	7.8±3.5	Not available	49.5±21.5	47	Mean±SD	Mean±SD
Shore, as reported by Klotz et al ²⁴	Not available	Micro-US vs mpMRI vs SB	Suspicion of PCA	14	Not available	Not available	Not available	Not available	14	3±1.5	3±1.5
Rodríguez-Socarrás et al ³⁰	02/18–09/19	Micro-US vs mpMRI vs SB	Elevated PSA or suspicious DRE or PI-RADS ≥3 in mpMRI	194	62±7.4	6.5±3.3	31	58.1±33.3	194	Not available	Not available
Staerman ³¹	11/17–04/19	Micro-US vs mpMRI vs SB	Men with PCA in active surveillance protocol	44	Not available	Not available	Not available	Not available	39	2±1.5	2.3±2.2
Wiemer et al ³²	02/18–12/18	Micro-US vs mpMRI vs SB	Suspicion of PCA	159	69.5±7.4	8.2±4.2	42	54.5±17	159	2-3	2-3



HOJA 3 / 3



Concordancia ISUP Mapeo con MU vs Pieza de Prostatectomía Radical Robótica

(96,4%).

Corelacion ISUP Mapeo vs ISUP 0,97 IC 95%

Correlación intraclase 0,98 (0,867 - 0,993)

Correlacion intraclase de 0,90 (0,789 - 0,954) IC 95%

Table 1. n=307 patients, concordance prostate Biopsy and Robotic Radical Prostatectomy specimen

Type of Biopsy	Count	Upgrade	95%CI	Downgrade	95%CI
Mapping = TP micro-US + MRI Targeted + Sys	76	7 (9.41%)	(4.21-17.2)	5 (6.77%)	(2.54-13.8)
TRUS	138	69 (50.00%)	(41.8-58.3)	6 (4.46%)	(1.84-8.76)
MRI-TBSB	90	27 (30.01%)	(21.3-40.0)	11 (12.40%)	(6.68-20.1)
MRI-TB	3	1 (35.30%)	(3.9-82.2)	1 (6.72%)	(0.01-53.3)

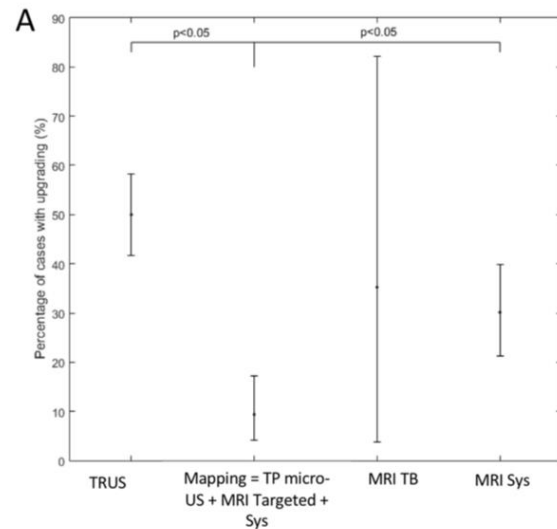
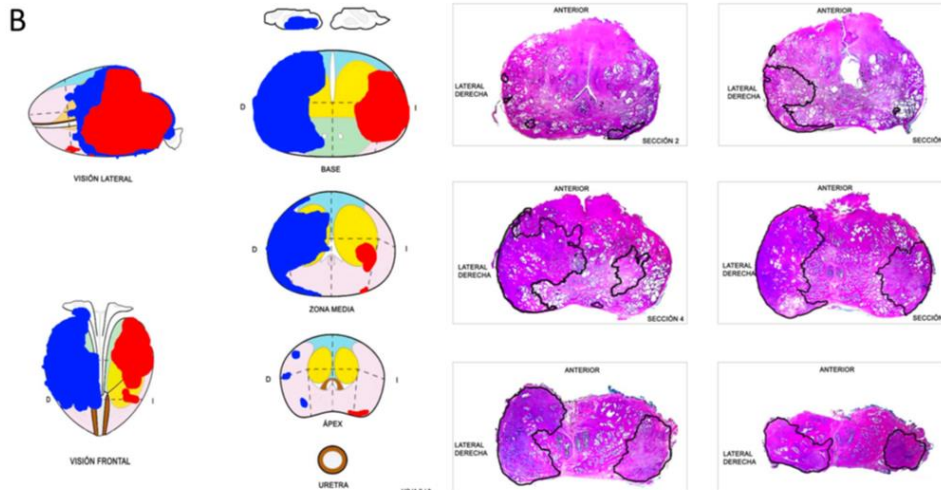


Table 1 = n=307 patients, concordance prostate Biopsy and Robotic Radical Prostatectomy specimen. Fig A= Graphic, Mapping = TP micro-US + MRI Targeted + Sys better than MRI TB + Sys and TRUS ($p<0.05$) B= Radical Prostatectomy specimen CS PCa C – D = Microultrasound (Exact Vu) console and High resolution 29 MHz transducer and TP guide attached with rotational movement for TP Biopsies.

Prostate Cancer

Side-specific, Microultrasound-based Nomogram for the Prediction of Extracapsular Extension in Prostate Cancer

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Abstract

Background: Prediction of extracapsular extension (ECE) is essential to achieve a balance between oncologic resection and neural tissue preservation. Microultrasound (MUS) is an attractive alternative to multiparametric magnetic resonance imaging (mpMRI) in the staging scenario.

Objective: To create a side-specific nomogram integrating clinicopathologic parameters and MUS findings to predict ipsilateral ECE and guide nerve sparing.

Design, setting, and participants: Prospective data were collected from consecutive patients who underwent robotic-assisted radical prostatectomy from June 2021 to May 2022 and had preoperative MUS and mpMRI. A total of 391 patients and 612 lobes were included in the analysis.

Outcome measurements and statistical analysis: ECE on surgical pathology was the primary outcome. Multivariate regression analyses were carried out to identify predictors for ECE. The resultant multivariable model's performance was visualized

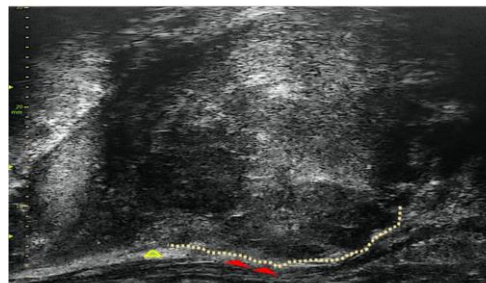
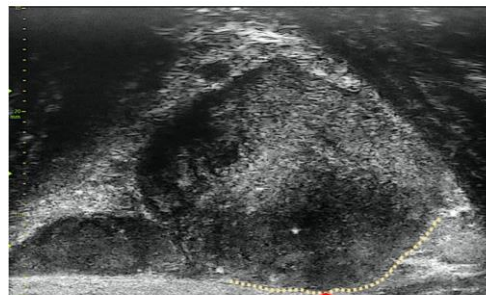


Fig. 1 – Examples of MRI-derived parameters to detect ECE with MUS: capsular contact length ≥ 15 mm, capsular bulging and irregularity (yellow dotted line), visible breach of the prostate (red arrow), and obliteration of the prostatic-seminal vesicle angle (green arrow). ECE = extracapsular extension; MRI = magnetic resonance imaging; MUS = microultrasound.

5. Conclusions

We have developed a side-specific model to predict ipsilateral ECE based on clinical variables combined with MUS findings. Its performance was comparable with that of a mpMRI-based model using the same clinicopathologic variables (AUC 80.9%). The implementation of this nomogram can be helpful in tailoring nerve-sparing approaches. Nevertheless, external validation of our findings and prospective trials are required to corroborate the results.

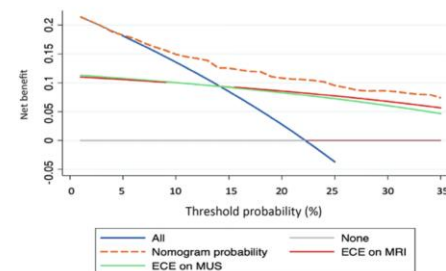


Fig. 3 – Decision curve analysis showing net benefit of using our model based on MUS. ECE = extracapsular extension; MRI = magnetic resonance imaging; MUS = microultrasound.

Table 1 n=42 patients TP postate biopsies for patients with previous prostate surgery using micro-US + MRI TBX + SBX (Madrid Protocol)

		95% CI
Age mean, SD, (IQR)	68.5 ± 6.42 (64.68 – 73.16)	65.9 -71.1
Prostate Volume	45.45 ± 6.45 (21 – 55)	32.25 – 58.65
PSA	5.46 ± 0.79 (2.2 – 6.79)	4.1 – 7.35
DRE suspicious	7 (16%)	-

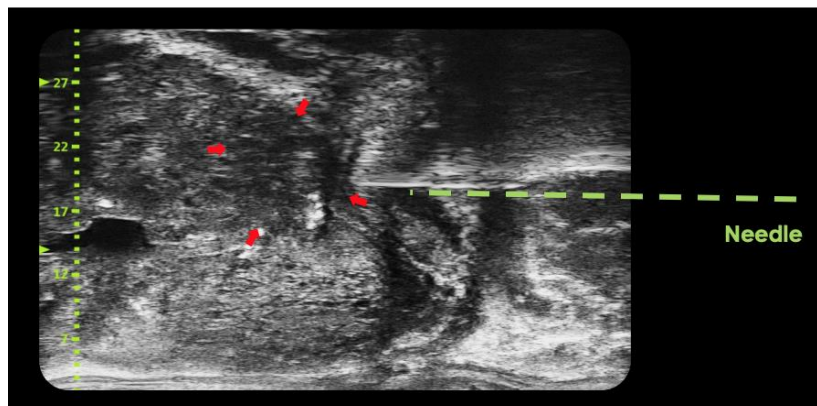
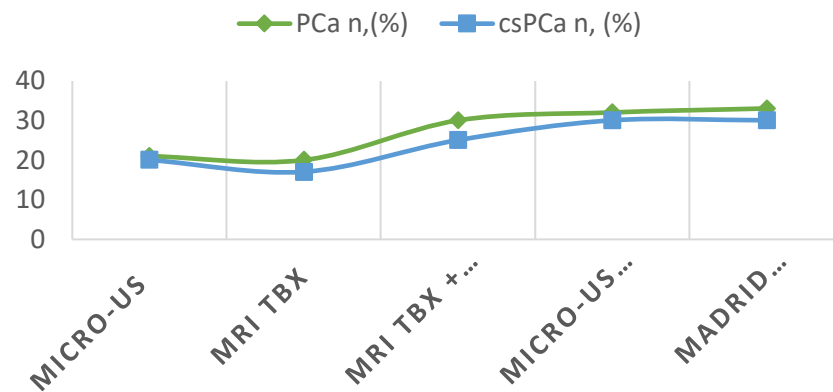


Table 2 n=42 patients TP postate biopsies for patients with previous prostate surgery using micro-US + MRI TBX + SBX (Madrid Protocol)

	Micro-US	MRI TBx	SBX	Madrid Protocol*
PCa n,(%)	21 (50%)	20 (47.6%)	29	33 (78.5%)
csPCa n, (%)	20 (47.6%)	17 (40.47%)	25	30 (71.4%)





70 años, **Recidiva Bioquimica,**
despues de Prostatectomia
radical + RT
PSA .2.12 ng/ml.

RNMmp: lesion en lecho /
Anastomosis 9 mm
PET colina No lesiones

Resultado Biopsia
Microultrasonidos:
PCA Gleason 8 (4+4).



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Review Article

Micro-Ultrasound: a way to bring imaging for prostate cancer back to urology

Niklas Harland*, Arnulf Stenzl

Department of Urology, University Hospital Tübingen, Tübingen, Germany



62

Prostate International 9 (2021) 61–65

Table 1

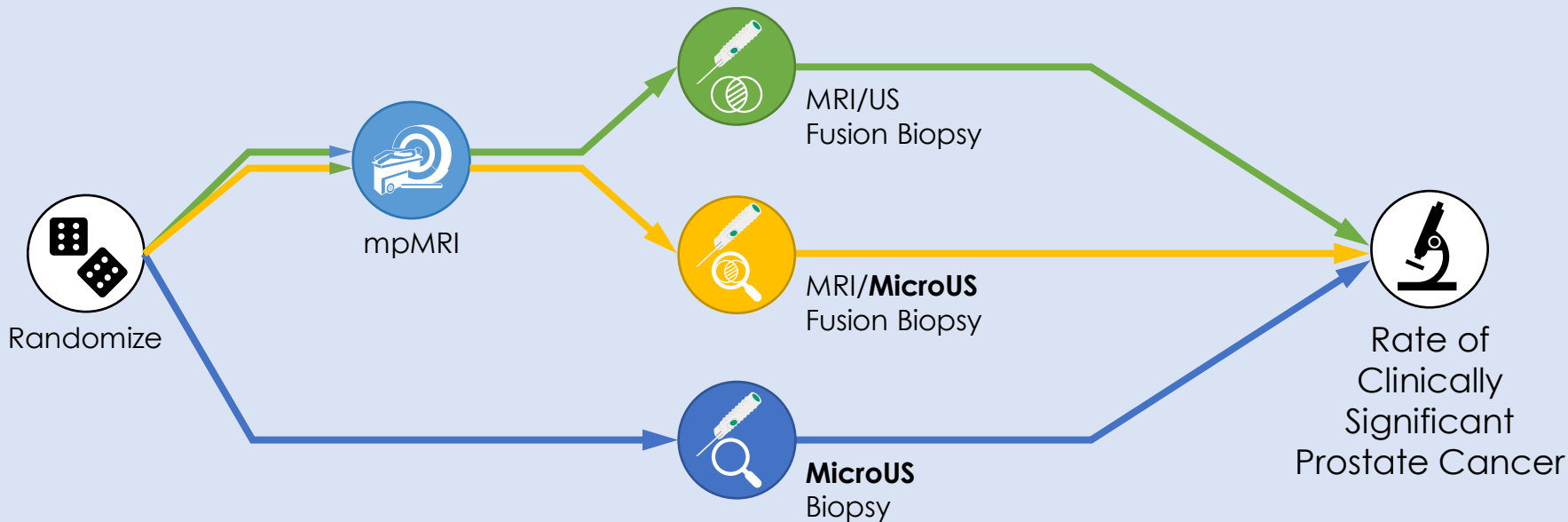
Summary of studies comparing micro-ultrasound and MRI-guided biopsy.

Year	First author	n	Sensitivity csPC		Specificity MUS	PPV csPC		NPV MUS	Detection rate csPC	
			MUS	MRI		MUS	MRI		MUS	MRI
2020	Cornud, F	118	100%	88%	23%				51.40%	
2019	Abouassaly, R	19							21%	11%
2019	Lughezzani, G	104	94%		28%	40%	34%	90%	40%	23%
2020	Roja Claros, O	269							38%	23%
2020	Rodriguez Socarras, ME	194	98.9%	85.5%	29.3%	62.3%	56.3%	95.6%	24%	28%
2020	Wiemer, L.	159	95%		15%	52%		75%		
2020	Klotz, J.	1040	94%	90%	22%	44%	43%	85%		

csPC = clinically significant prostate cancer; MUS = micro-ultrasound; MRI = magnetic resonance imaging; PPV = positive predictive value; NPV = negative predictive value.

OPTIMUM

Indication for Prostate Biopsy
↑PSA or Suspicious DRE



Optimization of prostate biopsy – Micro-Ultrasound versus MRI (OPTIMUM): A 3-arm randomized controlled trial evaluating the role of 29 MHz micro-ultrasound in guiding prostate biopsy in men with clinical suspicion of prostate cancer

Laurence Klotz¹, Gerald Andriole², Hannek Gosh³, Matthew Cooperberg⁴, E David Crawford⁵, Mark Emberton⁶, **Fernando Gomez-Sanchez⁷**, Eric Klein⁸, Giovanni Lughezzani⁹, Leonard Marks¹⁰, Francesco Montorsi¹¹, Georg Salomon¹², Rafael Sanchez-Salas¹³, Neal Shore¹⁴, Samir Taneja¹⁵

Affiliations + expand

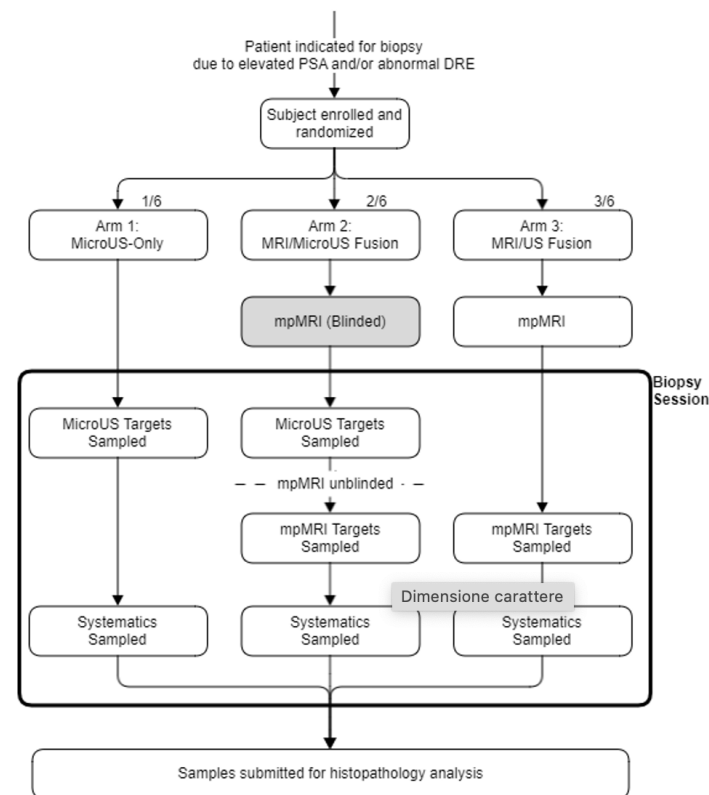
PMID: 34728381 DOI: 10.1016/j.cct.2021.106618

Abstract

Background: Micro-ultrasound (microUS) is a novel ultrasound-based imaging modality which has demonstrated the ability to visualize prostate cancer. Multiparametric MRI/ultrasound (mpMRI/US) fusion has recognized advantages for the performance of prostate biopsy, however, it encompasses additional cost, time and technical expertise to performing prostate biopsy in comparison to conventional trans-rectal ultrasound biopsy. MicroUS may simplify and optimize this pathway.

Methods: OPTIMUM is a 3-arm randomized controlled trial comparing microUS guided biopsy with MRI/US fusion and MRI/MicroUS "contour-less" fusion. This trial will investigate whether microUS alone, or in combination with mpMRI, provides effective guidance during prostate biopsy for the detection of clinically significant prostate cancer (csPCa) for biopsy naïve subjects. 1200 subjects will be randomized. The economic impact will be evaluated.

Results: The rate of csPCa (defined as Grade Group 2 and above) in each arm will be compared. The primary hypothesis is non-inferiority of csPCa rate between the MRI/US fusion arm and the microUS-only arm (including the blinded microUS-only portion of the MRI/MicroUS arm). As a secondary objective, the csPCa rate between MRI/MicroUS fusion and MRI/US fusion arms will also





EXACT+ IMAGING

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Dr. Moisés Rodríguez Socarrás

Instituto de Cirugía Urológica Avanzada

as an

Expert Micro-Ultrasound User

September 9, 2022
 Date

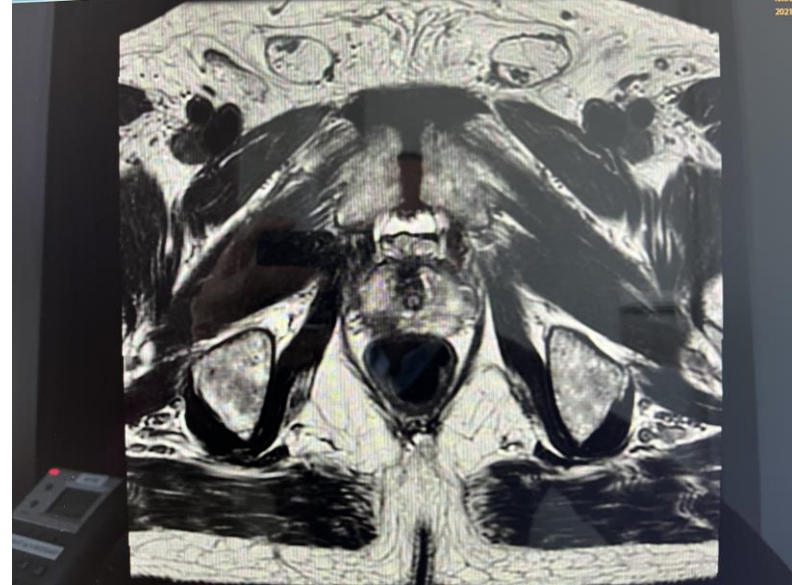
Randy Auguin
 Randy Auguin, President & CEO

1 2 3 4

II

MicroUS: Reemplaza la RNM?

mpMRI



Tiempo, Listas de Espera, Costes *aparato y para los pacientes , Fobia, marcapasos, protesis

mpMRI

Evidencia sólida

Protocolo

Estandarizada

Planificación
quirúrgica

5.2.4.3 Guidelines for MRI imaging in biopsy decision

Introductory statement	LE
Systematic biopsy is an acceptable approach in case MRI is unavailable.	3

Recommendations for all patients	Strength rating
Do not use magnetic resonance imaging (MRI) as an initial screening tool.	Strong
Adhere to PI-RADS guidelines for MRI acquisition and interpretation and evaluate MRI results in multidisciplinary meetings with pathological feedback.	Strong

Recommendations for biopsy-naïve patients	Strength rating
Perform MRI before prostate biopsy.	Strong
When MRI is positive (i.e. PI-RADS ≥ 3), combine targeted and systematic biopsy.	Strong
When MRI is negative (i.e., PI-RADS ≤ 2), and clinical suspicion of PCa is low (e.g. PSA density < 0.15 ng/mL), omit biopsy based on shared decision-making with the patient.	Weak

Recommendations for patients with prior negative biopsy	Strength rating
Perform MRI before prostate biopsy.	Strong
When MRI is positive (i.e. PI-RADS ≥ 3), perform targeted biopsy only.	Weak
When MRI is negative (i.e., PI-RADS ≤ 2), and clinical suspicion of PCa is high, perform systematic biopsy based on shared decision-making with the patient.	Strong

<https://uroweb.org/guideline/prostate-cancer/>

mpMRI

- Curva de aprendizaje.
- Variabilidad interobservador.
- Bajo VPP.
- Costes
- Lesiones indeterminadas
- imprecisiones de calibracion de FBX (software, Eco)



MicroUS reemplaza la RNM?

- **NO**, pero son muy utiles cuando la RNM no esta disponible
- Mejor que Bx TRUS convencional: **Si**
- Agregan valor a la RNM. Enriquece las biopsias de fusión (Permiten biopsiar las lesiones viendolas) **Si**
- Me siento confiado de hacer una Biopsia con MicroUS sino tengo RNM: **SI**

Ventajas microultrasonidos

- Tiempo real, rapido, se ven las lesiones
- Puede ayudar a ver mejor imagenes visibles o No en MRI
- Mejoria sobre Biopsia de Fusión
- Se ve muy bien el apex y las bandeletas
- Bueno para Extension extracapsular
- Muy util cuando no hay RNMP *marcapasos, Fobia.
- No hay listas de espera
- Permite biopsiar casos de recidivas
- Programa de formacion muy bueno (e learn exact imagin, Mastery programme).
- Muy Buen soporte postventa

Microultrasonidos aplicaciones clinicas

- Diagnostico
- Seguimiento, vigilancia activa.
- Terapia focal (crio, HIFU, laser..)
- Biopsia de recidiva local.

** Posibilidades: proteger recto, esfinter, bandeletas.

Desventajas

- Vision solo longitudinal, no biplanar.
- Tecnologia muy buena, vision muy buena..software de fusion e informes mejorable.
- La clasificacion PRIMUS solo usa informacion de patrones de imagenes, no toma en cuenta otros datos usados por MRI o PET (ejmp tamaño del tumor, uso de contraste)

The best is yet to come

- Improvement in software, reports and fusion software.
- More users, more experience, more evidence, Optimum trial.
- Anterior zone
- Focal therapy and follow-up
- AI



THE BEST IS YET TO COME - Frank Sinatra -

MU es una técnica sencilla, dinámica, rápida de reproducir, curva de aprendizaje corta...Pero hay que estudiar y actualizarse.

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1 - E-Learning Modules for Physicians from EU

Learning Plan

Completed




2 - Physicians' Pre on-site training - EU (optional videos)

27m 08s

Learning Plan

Completed



Continuing Education

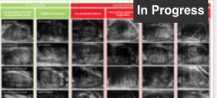
EXACTVU

3 - Your Continuing Education

2h 10m

Learning Plan


In Progress



Anterior Prostate Cancer with Micro-Ultrasound Resources

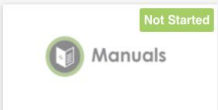
Learning Plan

Not Started




Exact Imaging Published Research Module

Not Started



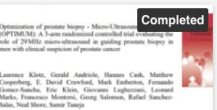
ExactVu User Manuals & Guides

Completed



Information about the ExactVu Mastery Program

Completed



OPTIMUM Trial Manuscript

US



Microultrasound



you with training



**HARD WORK
BEATS TALENT
WHEN TALENT
DOESN'T WORK
HARD**



Gracias!