

# Published Clinical Data

May 2020 Update

## Papers

Year ↓	1 <sup>st</sup> Author	Title	Published In	Summary
2020	Cornud	MRI-directed high-frequency (29Mhz) TRUS-guided biopsies: initial results of a single-center study	European Radiology	Micro-Ultrasound as second-look for guiding biopsy after bi-parametric MRI. When micro-ultrasound was normal, no significant cancer was found, however micro-ultrasound did find cancers missed by MRI in 24% of men with additional microUS lesions.
2020	Socarras	Prostate Mapping for cancer diagnosis: The Madrid protocol. Transperineal prostate biopsies combining using mpMRI fusion and micro-ultrasound guided biopsies	Journal of Urology	The Madrid Protocol for transperineal biopsy using both Micro-ultrasound and MRI. Micro-US found 12/111 108 (11%) PCa that were missed by all other techniques and 11 (92%) were csPCa
2020	Claros	Comparison of initial experience with transrectal MRI cognitive guided micro-ultrasound biopsies versus established transperineal robotic ultrasound-magnetic resonance imaging fusion biopsies for prostate cancer	Journal of Urology	Micro-US outperformed the Artemis fusion biopsy platform for sampling MRI targets, due to real-time cognitive visualization of lesions.
2020	Shao	Improving PCa Classification Performance by Using Three-Player Minimax Game	IEEE Trans. Med. Imag.	A new deep learning structure is proposed to eliminate the heterogeneity in the micro-ultrasound data caused by user and system variation. A sensitivity of 95% and AUC of 94% are achieved to detect csPCa
2019	Zhang	Micro-Ultrasound Imaging for Accuracy of Diagnosis in Clinically Significant Prostate Cancer: A Meta-Analysis	Frontiers in Oncology	7 studies with 769 patients showed high sensitivity and diagnostic utility. "Based on these findings, micro-ultrasound has superior ability to diagnose clinically significant prostate cancer."
2019	Luger	Does 29Mhz Micro-Ultrasound Provide Uniform Diagnostic Accuracy Within and Beyond the Peripheral Zone?	Annals of Urology & Nephrology	Prospective analysis of PRI-MUS accuracy over 399 biopsy procedures (5833 biopsy samples) Relatively uniform accuracy throughout peripheral zone with AUC up to 0.83. Surprisingly high accuracy in Anterior/Transition zone samples of 0.8.

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2019	Abouassaly	Impact of Using 29MHz High Resolution Micro-Ultrasound in Real-Time Targeting of Trans-Rectal Prostate Biopsies: Initial Experience	World Journal of Urology	Retrospective analysis on first 67 biopsy cases at Cleveland Clinic Relative 26.7% improvement in prostate cancer detection rate due to targeted micro-ultrasound samples.
2019	Stanton	Evaluation of the 29 MHz Micro-Ultrasound Imaging for Prostate Cancer Diagnosis and Treatment	Annals of Urology & Nephrology	Case series showing utility of micro-ultrasound during cryotherapy with strong correlation to MRI and prior biopsy results
2019	Saita	Assessing the Feasibility and Accuracy of High-resolution Micro-ultrasound Imaging for Bladder Cancer Detection and Staging	European Urology	Accurate staging of Bladder Cancer in 21/23 cases, potential to avoid MRI and CT staging for discrimination of MIBC and NMIBC
2018	Ghai	Suspicious Findings on Micro-Ultrasound Imaging and Early Detection of Prostate Cancer	Urology Case Reports	Report on case of healthy 50-year-old subject with no known risk factors where prostate cancer was found through volunteer imaging procedure rather than standard clinical workflow
2018	Eure	Comparison of Conventional TRUS, MRI and Micro-Ultrasound for Visualizing Prostate Cancer in an Active Surveillance Population: A Feasibility Study	Canadian Urology Assoc. Journal	9 men on Active Surveillance biopsied with systematic, MRI, conventional-US, and micro-US samples Micro-ultrasound was more sensitive to clinically significant cancer than conventional-US or MRI.
2018	Lughezzani	Comparison of the Diagnostic Accuracy of Micro-Ultrasound and Magnetic Resonance Imaging / Ultrasound Fusion Targeted Biopsies for the Diagnosis of Clinically Significant Prostate Cancer	European Urology Oncology	104 subjects biopsied using micro-ultrasound with mpMRI targets. Only subjects with mpMRI targets were included. 94% relative sensitivity to mpMRI for Gleason >6 cancer A negative micro-ultrasound provided a 72% reduction in the risk of csPCa
2018	Rohrbach	High-Frequency Quantitative Ultrasound for Imaging Prostate Cancer Using a Novel Micro-Ultrasound Scanner	Ultrasound in Medicine and Biology	Application of Quantitative Ultrasound (QUS) AI-based techniques to micro-ultrasound AI system achieved an AUC of 0.81 for detecting high grade cancer, similar to human experts
2016	Ghai	Assessing cancer risk in novel 29 MHz micro-ultrasound images of the prostate: Creation of the micro-ultrasound protocol for prostate risk identification	J. Urology	Retrospective validation of PRI-MUS by 5 readers PRI-MUS was: <ul style="list-style-type: none"> <li>• Easy to learn (1 hour of training)</li> <li>• Effective (all readers achieved significant detection)</li> <li>• Higher scores correlated to higher grade disease</li> </ul>
2014	Pavlovich	High-resolution transrectal ultrasound: Pilot study of a novel technique for imaging clinically localized prostate cancer	Urologic Oncology	25 men scanned with micro-ultrasound and conventional ultrasound prior to Radical Prostatectomy Higher sensitivity and specificity and found higher grade disease than conventional ultrasound

## Conference Abstracts

Year ↓	Lead Author	Title	Published In	Summary
2019	Chessa	Diagnostic Accuracy of the Novel 29MHz Micro-Ultrasound ExactVu for the detection of Clinically Significant Prostate Cancer	American Urology Association	57 subjects biopsied using ExactVu from independent group in Bologna. All Grade Group > 2 cancers were found through targeted samples using PRI-MUS, none were found systematically
2019	Claros	Comparison of Cancer Detection Rates in Micro-Ultrasound Biopsies Versus Robotic Ultrasound-Magnetic Resonance Imaging Fusion Biopsies for Prostate Cancer	American Urology Association	Comparison of initial 48 cases of micro-ultrasound biopsy with previous 223 fusion biopsy cases using Artemis robotic fusion platform. No significant differences overall in risk factors or overall detection rate, but detection rate of targeted biopsies was significantly higher with micro-ultrasound (37.5% vs 22.9%)
2019	Pavlovich	A Multi-Institutional Randomized Controlled Trial Comparing Novel First-Generation High-Resolution Micro-Ultrasound with Conventional Ultrasound	American Urology Association	Report on results of Exact Imaging multi-site randomized clinical trial. Per-patient detection rate in Intent-To-Treat analysis did not differ between micro-US and conv-US arms, however a significant improvement in detection rate was noted in the Per Protocol analysis with micro-US detecting 20% more clinically significant cancer
2019	Klotz	High Resolution 29 MHz Micro-Ultrasound in the Diagnosis of Primary and Recurrent Prostate Cancer	American Urology Association	Initial 50 micro-ultrasound biopsy cases showing high NPV of 96%. This cohort includes a significant number of Active Surveillance and post-Therapy patients where MRI is known to struggle, suggesting that micro-ultrasound may provide additional benefit to this group
2019	Lughezzani	Assessment of the Diagnostic Accuracy of Micro-ultrasound for the Detection of Clinically Significant Prostate Cancer: Results from a Single-institutional Preliminary Experience	American Urology Association	Multi-variate regression to determine man's risk of cancer before biopsy including micro-ultrasound imaging with PRI-MUS. PRI-MUS 4 and 5 findings were significant predictors increasing risk of finding cancer by 3-5x
2019	Maffei	Diagnostic Accuracy of Targeted Prostate Biopsies: Results from a Prospective Trial Comparing Micro-Ultrasound with Multi-Parametric MRI	American Urology Association	Initial 179 biopsy cases with micro-ultrasound at Humanitas University, Milan, Italy Sensitivity very high at 91%, with Negative Predictive Value of 82%
2019	Lughezzani	Assessment of the Diagnostic Accuracy of Micro-ultrasound for the Detection of Clinically Significant Prostate Cancer: Results from a Single-institutional Preliminary Experience	European Association of Urology	Multi-variate regression to determine man's risk of cancer before biopsy including micro-ultrasound imaging with PRI-MUS. PRI-MUS 4 and 5 findings were significant predictors increasing risk of finding cancer by 3-5x

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2019	Pavlovich	A Multi-Institutional Randomized Controlled Trial Comparing Novel First-Generation High-Resolution Micro-Ultrasound with Conventional Ultrasound	European Association of Urology	Report on results of Exact Imaging multi-site randomized clinical trial. Per-patient detection rate in Intent-To-Treat analysis did not differ between micro-US and conv-US arms, however a significant improvement in detection rate was noted in the Per Protocol analysis with micro-US detecting 20% more clinically significant cancer
2019	Maffei	Diagnostic Accuracy of Targeted Prostate Biopsies: Results from a Prospective Trial Comparing Micro-Ultrasound with Multi-Parametric MRI	European Association of Urology	Initial 179 biopsy cases with micro-ultrasound at Humanitas University, Milan, Italy Sensitivity very high at 91%, with Negative Predictive Value of 82%
2019	Saita	Assessing the Feasibility and Accuracy of High-Resolution Micro-Ultrasound Imaging for Bladder Cancer Detection and Staging	European Association of Urology	Accurate staging of Bladder Cancer in 21/23 cases, potential to avoid MRI and CT staging for discrimination of MIBC and NMIBC
2019	Staerman	Can High Resolution Micro-Ultrasound Detect Extra-Prostatic Extension? A New Sonographic Feature	Focal Therapy Symposium	11 subjects with final pathology available after radical prostatectomy analyzed 14/22 prostate lobes were positive for extra-prostatic extension. 8 of these had a new "halo" feature visible on their micro-ultrasound scans indicating that micro-ultrasound may be useful in pre-surgical planning
2019	Abouassaly	Initial Results Evaluating the Performance of Targeted Prostate Biopsy using MRI Fusion and 29 MHz High Resolution Micro-Ultrasound	Focal Therapy Symposium	Retrospective analysis of 19 micro-ultrasound biopsies at Cleveland Clinic with mpMRI targets Micro-ultrasound demonstrated higher sensitivity to significant prostate cancer than mpMRI. 2/10 (20%) subjects would have been underdiagnosed without micro-ultrasound targets
2019	Lughezzani	Comparison of Micro-Ultrasound and Multiparametric MRI Imaging for Prostate Cancer: An International Meta-Analysis	Focal Therapy Symposium	280 subjects at 5 institutions with mpMRI imaging and micro-ultrasound biopsy Micro-ultrasound was significantly more sensitive than mpMRI to detect Gleason >6 cancer
2019	Salomon	Risk Stratification for Equivocal PI-RADS 3 Results: Can Micro-Ultrasound Help Determine Which Men to Biopsy?	Focal Therapy Symposium	Investigation of 41 MRI PI-RADS 3 cases at 7 institutions where micro-ultrasound imaging was available PRI-MUS risk stratification added value even in cases where MRI results were equivocal
2019	Abouassaly	Improving Standard Trans-Rectal Prostate Biopsy Results Using High Resolution Micro-Ultrasound for Real-Time Targeting of Suspicious Areas	Focal Therapy Symposium	Retrospective analysis on first 67 biopsy cases at Cleveland Clinic 8/38 (21%) cases of cancer diagnosed only using targeted micro-ultrasound samples

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2019	Staerman	Initial Clinical Experience with 29 MHz Micro-Ultrasound for Real-Time Targeted Prostate Biopsies	Focal Therapy Symposium	Retrospective analysis of 87 micro-ultrasound biopsy cases including 52 with mpMRI reports available Micro-ultrasound was more sensitive (82% vs 76%) and less specific than mpMRI, for Gleason > 6 cancer. Only 1 case of 15% Gleason 7 cancer was found systematically
2019	Wodlinger	Accuracy of Micro-Ultrasound for Identification of Prostate Cancer: A Comparative Study with Whole Mount Pathology	Focal Therapy Symposium	Comparison of 25 whole-mount radical prostatectomy cases with micro-ultrasound imaging The highest grade cancer was found in 24/25 subjects, and 85% of all grade group >1 cancers were seen prospectively
2019	Lopez	Added Value of MRI and High Resolution Micro-Ultrasound Image-Based Targeting During Prostate Biopsy on Suspicion of Prostate Cancer	Focal Therapy Symposium	Retrospective analysis of 24 initial cases presenting for biopsy using micro-ultrasound. 22/24 cases had mpMRI imaging results available. MRI alone detected 2/15 Grade Group 1 cancers, while Micro-ultrasound alone also detected 2/15 cancers these were higher grade with Group 2 and 4. Micro-ultrasound targeting added more clinical value in this cohort than MRI.
2019	Perez	Initial Results Comparing High Resolution Micro-Ultrasound with Multiparametric Magnetic Resonance Imaging for Prostate Cancer Detection	Focal Therapy Symposium	Retrospective analysis of 37 initial micro-ultrasound biopsy cases, all subjects also having MRI imaging performed. For Grade Group >1 cancer, micro-ultrasound and MRI provided equal sensitivity (6/7, 86%) and similar negative/positive predictive values.
2019	Pavlovich	A multi-institutional randomized controlled trial comparing novel first generation high-resolution micro-ultrasound with conventional frequency ultrasound for transrectal prostate biopsy	Focal Therapy Symposium	Report on results of Exact Imaging multi-site randomized clinical trial. Per-patient detection rate in Intent-To-Treat analysis did not differ between micro-US and conv-US arms, however a significant improvement in detection rate was noted in the Per Protocol analysis with micro-US detecting 20% more clinically significant cancer
2019	Luger	A Prospective Validation of the Diagnostic Accuracy of PRI-MUS for Prostate Cancer Risk Identification	Focal Therapy Symposium	Initial 142 micro-ultrasound biopsy cases at Ordens Klinikum, Linz, Austria. AUC of 0.79 for PRI-MUS higher than predicted during retrospective analysis (Ghai 2016).
2018	Lughezzani	Assessment of the Diagnostic Accuracy of Micro-ultrasound for the Detection of Clinically Significant Prostate Cancer: Results from a Single-institutional Preliminary Experience	American Urology Association	Initial 78 biopsy cases with micro-ultrasound at Humanitas University, Milan, Italy Sensitivity and negative predictive value both 89%, rising to 100% with 1 retrospectively identified lesion

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2018	Rohrbach	Machine learning-based lesion detection via quantitative high frequency ultrasound for prostate-cancer imaging using a novel high resolution micro-ultrasound platform	American Urology Association	Application of Quantitative Ultrasound (QUS) AI-based techniques to micro-ultrasound AI system achieved an AUC of 0.75 for detecting high grade cancer, similar to human experts
2018	Lughezzani	Comparison of Micro-Ultrasound and mpMRI for Prostate Cancer: An International Meta-Analysis	EAU Section of Urological Imaging	280 subjects at 5 institutions with mpMRI imaging and micro-ultrasound biopsy Micro-ultrasound was significantly more sensitive than mpMRI to detect Gleason >6 cancer
2018	Wodlinger	Accuracy of Micro-Ultrasound for Identification of Prostate Cancer: A Comparative Study with Whole Mount Pathology	EAU Section of Urological Imaging	Comparison of 25 whole-mount radical prostatectomy cases with micro-ultrasound imaging The highest grade cancer was found in 24/25 subjects, and 85% of all grade group >1 cancers were seen prospectively
2018	Abouassaly	Improving Standard Transrectal Prostate Biopsy Results Using High-Resolution Micro-Ultrasound for Real-Time Targeting of Suspicious Areas	EAU Section of Urological Imaging	Retrospective analysis on first 67 biopsy cases at Cleveland Clinic 8/38 (21%) cases of cancer diagnosed only using targeted micro-ultrasound samples
2018	Luger	A Prospective Validation of the Diagnostic Accuracy of PRI-MUST™ for Prostate Cancer Risk Identification	EAU Section of Urological Imaging	Initial 142 micro-ultrasound biopsy cases at Ordens Klinikum, Linz, Austria. AUC of 0.79 for PRI-MUS higher than predicted during retrospective analysis (Ghai 2016).
2018	Abouassaly	Initial Results Comparing High Resolution Micro-Ultrasound with mpMRI for Prostate Cancer Detection	EAU Section of Urological Imaging	Retrospective analysis of 19 micro-ultrasound biopsies at Cleveland Clinic with mpMRI targets Micro-ultrasound demonstrated higher sensitivity to significant prostate cancer than mpMRI. 2/10 (20%) subjects would have been underdiagnosed without micro-ultrasound targets
2018	Staerman	Can High-Resolution Micro-Ultrasound Detect Extra-Prostatic Extension? A New Sonographic Feature	EAU Section of Urological Imaging	11 subjects with final pathology available after radical prostatectomy analyzed 14/22 prostate lobes were positive for extra-prostatic extension. 8 of these had a new “halo” feature visible on their micro-ultrasound scans indicating that micro-ultrasound may be useful in pre-surgical planning
2018	Salomon	How to manage PI-RADS 3 lesions: Can enhanced TRUS solve the problem?	EAU Section of Urological Imaging	Investigation of 41 MRI PI-RADS 3 cases at 7 institutions where micro-ultrasound imaging was available PRI-MUS risk stratification added value even in cases where MRI results were equivocal

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2018	Staerman	Initial Results Comparing High Resolution Micro-Ultrasound with mpMRI for Prostate Cancer Detection	European Multidisciplinary Congress on Urological Cancers	Retrospective analysis of 87 micro-ultrasound biopsy cases including 52 with mpMRI reports available Micro-ultrasound was more sensitive (82% vs 76%) and less specific than mpMRI, for Gleason > 6 cancer. Only 1 case of 15% Gleason 7 cancer was found systematically
2018	Lughezzani	Where Do Micro-Ultrasound and MRI Find Prostate Cancer? A Target Localization Study	European Multidisciplinary Congress on Urological Cancers	Comparison of targeting accuracy and sensitivity for micro-ultrasound and MRI in 104 subjects Both modalities had similar overall sensitivities, but areas where cancer was found differed, particularly laterally and at apex. Micro-ultrasound performed surprisingly well in Anterior/Transition zones, finding 2/3 cancers in those areas with fewer false positives than MRI
2018	Lughezzani	Diagnostic Accuracy of Targeted Prostate Biopsies: A Prospective Trial Comparing Micro-Ultrasound with mpMRI	European Multidisciplinary Congress on Urological Cancers	Prospective ongoing database study of micro-ultrasound biopsy reporting on first 104 subjects. All subjects MRI-positive. Micro-ultrasound detected 94% of those with Gleason >6 prostate cancer. Only 1 subject in cohort had cancer found with systematic samples alone, while micro-ultrasound alone found 3 and mpMRI targets alone found 4. Both targeting modalities together found 27.
2018	Astobieta	Initial Results Comparing 29 MHz Micro-Ultrasound with Multi-Parametric MRI for Targeted Prostate Biopsy: Relative Sensitivity to Clinically Significant PCa	European Association of Urology	Updated results from 2017 ESUI meeting, with 79 retrospective biopsy cases Micro-ultrasound was more sensitive and less specific than MRI (98% vs 68%)
2018	Lughezzani	Comparison Between The Diagnostic Accuracy Of Micro-ultrasound Vs. mpMRI In The Detection Of Prostate Cancer: Preliminary Results From A Single-institutional Ongoing Prospective Trial	European Association of Urology	60 subjects biopsied at Humanitas University with micro-ultrasound, MRI, and systematically directed samples Micro-ultrasound had a 92% negative predictive value for excluding csPCa at the patient level. 63% agreement with MRI was noted, suggesting independence between the imaging techniques, however 15/22 MRI lesions "missed" by micro-ultrasound were not significant cancer
2018	Hyndman	Prospective validation of PRI-MUS™, the Prostate Risk Identification using Micro-Ultrasound protocol for real-time detection of prostate cancer using high-resolution micro-ultrasound imaging	American Urology Association	Report on 2 <sup>nd</sup> half of randomized clinical trial PRI-MUS accuracy better than predicted by retrospective analysis, worked in real-time with 18 investigators Initial learning curve found to be 15 cases

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2017	Astobieta	Initial Results Comparing 29 MHz Micro-Ultrasound with Multi-Parametric MRI for Targeted Prostate Biopsy: Relative Sensitivity to Clinically Significant PCa	EAU Section of Urological Imaging	Analysis of 41 retrospective biopsy cases with micro-ultrasound, MRI, and systematically directed biopsies Micro-ultrasound was more sensitive and less specific than MRI (95% vs 57%)
2017	Lin	Correlating Micro-Ultrasound Sonographic Features and PRI-MUS™ Ranking of Prostate Cancer Lesions with Underlying Histopathology	EAU Section of Urological Imaging	20 biopsy samples with clear PRI-MUS features compared to detailed histopathology results Strong correlation noted for all features, particularly Bright Echoes (with Comedonecrosis) and Irregular Shadowing (with Cribriform cancer)
2017	Astobieta	Feasibility Study for Avoiding or Postponing Biopsy using Improved Imaging: Negative Predictive Value of Micro-Ultrasound for Subjects with Low PSAD	EAU Section of Urological Imaging	Initial 41 biopsy cases with micro-ultrasound at IMQ, Bilbao, Spain Overall negative predictive value for targeted-only samples was 91%, increasing to 94% when high-risk subjects excluded. This suggests systematic biopsy could be avoided on more than 50% of subjects while maintaining high negative predictive value
2017	Eure	Comparison of Conventional TRUS, MRI and Micro-Ultrasound for Visualizing Prostate Cancer in an Active Surveillance Population: A Feasibility Study	EAU Section of Urological Imaging	9 men on Active Surveillance biopsied with systematic, MRI, conventional-US, and micro-US samples Micro-ultrasound was more sensitive to clinically significant cancer than conventional-US or MRI.
2016	Wodlinger	Micro-ultrasound of the prostate, PRI-MUS protocol guidance along with clinical variables: Combined approach for reducing unnecessary biopsies	EAU Section of Urological Imaging	Retrospective analysis on low-risk patients with low PRI-MUS scores at biopsy Could have avoided 11% of biopsies without significantly changing diagnosis
2016	Rohrbach	Promising initial results of semi-automated quantitative-ultrasound-based algorithm for assessment of prostate cancer using a novel 29MHz micro-ultrasound	EAU Section of Urological Imaging	Quantitative Ultrasound technique demonstrated AUC of 0.74 for detection of significant prostate cancer, similar to PRI-MUS experts
2016	Wodlinger	Using patient screening data and machine learning algorithms to improve PRI-MUS accuracy with micro-ultrasound based prostate biopsies	EAU Section of Urological Imaging	Incorporating clinical patient data such as PSA, age, and family history improved the PRI-MUS cancer risk score accuracy by 11%
2015	Ghai	Assessing cancer risk in 29 MHz micro-ultrasound images of the prostate	EAU Section of Urological Imaging	First report detailing creation of PRI-MUS Reports on sonographic features used, relative risks with confidence intervals