



Review Article

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

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ABSTRACT

Only a decade ago, there were insufficient imaging options for the detection and local staging of prostate cancer. However, the introduction of multiparametric magnetic resonance imaging (mpMRI) has advanced a much-needed tool for this scope of application. The possibilities and limitations of mpMRI have been well studied. Imaging must be acquired and evaluated using a standardized protocol (the latest version of Prostate Imaging–Reporting and Data System). Sensitivity has been shown to increase with higher grades and larger tumors, and while the detection rate on a per patient basis is relatively high, the per-lesion detection rate is far inferior. Various specialists have attempted to elevate the use of transrectal ultrasound, a tool frequently used by all urologists. Encouragement for this idea comes from a recently introduced system of high frequency transrectal ultrasound. The level of evidence supporting its use in the detection and staging of prostate cancer is not comparable with mpMRI yet, but initial prospective studies indicate good potential. The sensitivity of micro-ultrasound and mpMRI for clinically significant prostate cancer ranges from 94% to 100% and from 88% to 90%, respectively. Further areas of application, such as local staging for prostate and bladder cancer, are currently being evaluated. In summary, microultrasound presents a promising technology for further improving urological imaging and allows for the possibility of returning prostate cancer imaging to urologists. This review will summarize the current scientific basis for the use of micro-ultrasound in the detection of prostate cancer.

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1. Introduction

For a long time, the best means for the detection of prostate cancer (PC) have been debated. The capabilities and limitations of prostate-specific antigen (PSA) have become increasingly evident with increased follow-up in the European Randomized Study of Screening for Prostate Cancer [1] and thorough assessment in the Prostate, Lung, Colorectal and Ovarian trial [2, 3]. While the use of PSA as a screening tool is still under investigation, its role in the early detection of PC is unquestionable.

The field of imaging PC has evolved over the last decade. Greyscale transrectal ultrasound (TRUS) has long been used for volumetry of the prostate and guidance for systematic biopsy, but its use as a means of early detection has been limited.

The first modality of imaging to provide consistent, reliable results for the diagnosis of PC has been magnet resonance imaging

(MRI). Prostate Imaging–Reporting and Data System (PI-RADS) for multiparametric MRI (mpMRI) has been created through multiple consensus meetings by the European Society of Urogenital Radiology [4]. It has since been validated and improved, resulting in versions 2 and 2.1 [5, 6]. Here, regions of the prostate are scored from 1 (clinically significant PC [csPC] is highly unlikely to be present) to 5 (csPC is highly likely to be present). Multiple prospective studies have evaluated its role as a diagnostic tool for PC [7–10]. In summary, on a patient basis, the primary mpMRI has a negative predictive value (NPV) of 88% for PC and Gleason score of $\geq 3 + 4$ [7]. This can be improved in cases with previous negative systematic biopsy to an NPV of 91–100% [11–13]. The capabilities come with some important limitations. All studies evaluated an MRI that included dynamic contrast enhancement, but this limits its use in patients with impaired renal function. In addition, hip replacements can result in significant artifacts especially in diffusion-weighted imaging while pacemakers often represent a contraindication to perform an MRI altogether. In older men, the most important cohort for the diagnosis of PC, a high number of patients

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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, L	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.

suffer from at least one of these issues. Undoubtedly, mpMRI for PC is here to stay, but supplementary tools are also needed.

Owing to its availability in daily practice, ultrasound has been extensively evaluated for the detection of PC, but due to low sensitivity of 18–55% [14, 15] greyscale ultrasound is considered insufficient for PC detection. Some authors have presented evidence that the addition of TRUS-guided biopsies can significantly improve the positive predictive value of systematic biopsy (30 vs. 40%; $p < 0.001$) [16]. However, inconsistencies in the results, in part attributed to a high interobserver variability, have prevented greyscale ultrasound from playing an important role in the diagnosis of PC. As an alternative, many variations of ultrasound techniques have been evaluated with insufficient results concerning specificity and sensitivity [14, 17, 18]. Real-time elastography had a superior sensitivity compared with grayscale ultrasound (60.8% vs. 15%) for any PC, but the resulting NPV of 59–87.8% was not enough to justify omitting the biopsy [14, 19].

Several approaches to objectify the results, for example, by analysis through a neuronal network, showed promising results in some retrospective (and one prospective) studies but never reached a satisfactory level where it could be included in clinical guidelines [20–22]. Similarly, the automated approach by Prostate HistoScanning™ could not fulfill initial hopes with NPV in a large prospective trial of 41.3% [23].

Multiparametric approaches, as is standard in MRI, have shown good potential but need to be further validated [15].

Recently, microultrasound [24] has been introduced and shows promising potential. The first results of a system using 21 MHz micro-ultrasound (MUS) (from Exact Imaging, formerly Imagistx, Inc., Toronto, Canada) compared with standard TRUS were presented by Pavlovich *et al* [25]. in 2014. This system has been further improved, and a standardized protocol based on the 29 MHz ExactVue System, called prostate risk identification using micro-ultrasound (PRI-MUS™), was established [26]. With a combination of high-frequency ultrasound waves of 29 MHz and a very high crystal density, a spatial resolution of 70 microns compared with around 300 microns on conventional TRUS is achieved [27]. Physiological glandular ducts and acini of the prostate have a diameter of 150 to 300 microns; therefore, the histological architecture of the prostate can be visualized by this modality [28].

2. Materials and methods

To identify current relevant literature on the role of MUS in PC diagnostics, a systematic literature search was conducted in October 2020 using pubmed.gov. Search terms used included “microultrasound”, “prostate cancer”, “high resolution ultrasound”, “PRI-MUS”, “detection rate”, “extracapsular extension”, “seminal vesical invasion”, “ultrasonography”, “pathologic stage”, and “PI-RADS”. In addition, references of included articles were screened

for further relevant publications. To be included, manuscripts had to be original articles written in English, and to ensure topicality, manuscripts older than 10 years were excluded.

2.1. Micro-Ultrasound and PRI-MUS

Ultrasound is an established tool for diagnosis of multiple malignancies [29, 30]. Although the use for PC appears obvious through the ability to place the probe in proximity of the organ, the images provided thus far have insufficient quality and precision for reliable diagnostics. In 2014, Pavlovich *et al.* [25] first introduced a system with higher frequency which produced superior spatial resolution. As a result, alterations as tracks of prior biopsies that have not been visible before can be detected (Fig. 1) To address the second point of contention of conventional TRUS, that is, inter-reader variability, Ghai *et al.* [26] created a scoring system for prostatic tissue named PRI-MUS. The 5-point scoring from very likely benign to highly likely malignant (Fig. 2) has since been validated in the studies described in the following paragraphs.

2.2. Comparison of MUS vs. mpMRI

Currently, mpMRI has evolved to be the gold standard in imaging of the prostate for the diagnosis of PC [7–10]. While studies providing a comparison of MUS and MRI are still sparse and mostly retrospective, recently published data are promising (Table 1). Claros *et al.* [31] compared two cohorts with 222 and 47 patients undergoing MRI-targeted and MUS-targeted biopsy, respectively. The detection rate of PC overall was not significantly different between both groups, suggesting that the approaches are comparable.

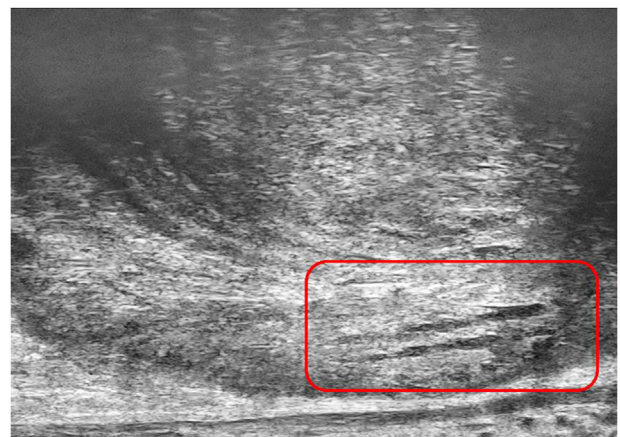


Fig. 1. Micro-Ultrasound of tracks of a preceding transperineal biopsy of the prostate (two years prior).


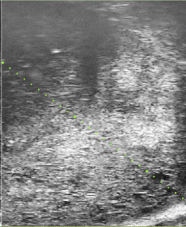
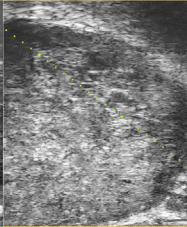
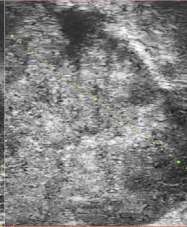
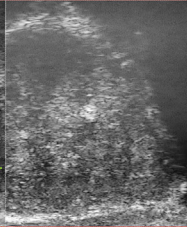
PRI-MUS™	1	2	3	4	5
Example					
Definition	Intact ductal architecture "Swiss Cheese"	Hyperechoic with or without ductal patches	Mild heterogeneity or bright echoes in hyperechoic tissue	Heterogeneous echo "cauliflower", blurry or bright echoes ("Starry Sky")	Irregular shadowing or mixed-echo lesions or irregular prostate border

Fig. 2. PRI-MUS™ classification with exemplary micro-ultrasound images.

In contrast, the detection rates for csPC were significantly different with 23% and 38% for MRI-guided biopsy (MRIGB) and MUS-guided biopsy (MUSGB) ($p = 0.02$), respectively [31].

Some groups have evaluated MRIGB and MUSGB via in-patient comparison. Cornud *et al.* [32] compared in-patient targeted biopsies and reported sensitivities of MUS and MRI of 100% and 88%, respectively. Only patients with PI-RADS ≥ 3 were included in the analysis, resulting in a potential risk for selection bias. In addition, both procedures were performed by the same surgeon, without blinding to the results of either one [32].

Lughezzani *et al.* [33] performed biopsies on 104 patients with suspicion of PC and an MRI confirmed target of PI-RADS ≥ 3 according to PI-RADS, version 2. The MUSGB was performed by a urologist blinded to the MRI results, and an independent urologist performed MRIGB and systematic biopsy. The results were comparable with the previously described publication with a detection rate for csPC of 23% and 40% for MRIGB and MUSGB, respectively. As for most studies, the inclusion criterion of PI-RADS ≥ 3 renders a comparison of the sensitivity of both modalities impossible. The sensitivity of MUSGB of 94% in this selected cohort is nevertheless promising [33].

Wiemer *et al.* [34] reported on a cohort of 159 patients with mostly PI-RADS ≥ 3 . The urologists were blinded to the MRI until the conclusion of the MUSGB. The group did not report separate

detection rates, but MUS sensitivity for csPC was comparable with the other groups on a patient level (95%). The positive predictive value on a lesion level of MRI and MUS was 30% and 41% ($p = 0.02$), respectively [34].

Lastly, Rodríguez Socarrás *et al.* [35] similarly included all patients with suspicion of PC, based on PSA, digital rectal exam, or MRI findings. This cohort included 35 (17.8%) patients with PI-RADS ≤ 2 . Sensitivity for csPC was 99.7% and 84.3% ($p < 0.001$) for MUS and MRI, respectively. The difference in specificity was not significantly different with 23.1% and 18.8% for MUS and MRI, respectively [35]. The authors explain the reduced sensitivity of MRI in this cohort, compared with other studies as caused by addition of MUSGB, although this does not sufficiently account for a reduction in comparison with mapping biopsy [7].

The first multicenter prospective analysis of 1040 patients found a sensitivity and NPV for PC of Gleason grade group ≥ 2 of mpMRI vs. MUS of 90% vs. 94% ($p = 0.03$) and 77% vs. 85%, respectively [36]. The NPV of mpMRI and MUS for Gleason group ≥ 3 of 93% is comparable with the 88% found in the PROMIS trial for Gleason grade group ≥ 3 or cancer core length ≥ 6 mm. The biopsy protocol differed somewhat between the participating sites reducing the quality of the data. In summary, these studies form a sufficient basis for further prospective evaluation of MUSGB as an alternative or addition to MRIGB. The fact that some lesions are undetectable by

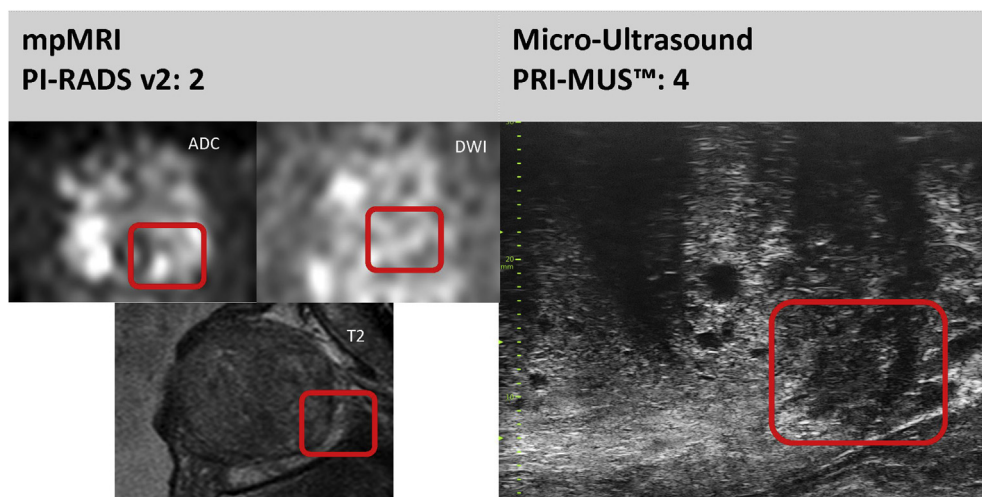


Fig. 3. Case of prostate cancer Gleason 7b, undetected by mpMRI but graded PRI-MUS™ 4 on micro-ultrasound. mpMRI = multiparametric magnetic resonance imaging.

mpMRI but clearly visible on MUS is supported by our own finding (Fig. 3). More studies are urgently needed to find a clear place for MUS in the field of PC detection.

2.3. Prediction of locally advanced stages

To achieve the highest oncological safety and at the same time preserve continence and potency, it is of utmost importance to stage patients correctly that are scheduled for radical prostatectomy. The Partin tables, as most tools that are best evaluated to predict locally advanced stages, defined as extracapsular extension or seminal vesical invasion, are based on PSA values, biopsy results, and digital rectal examination [37]. In validation studies of the Partin tables, the diagnostic accuracy was limited, with an area under the curve (AUC) of 0.62 to 0.71 [38, 39]. In this field, mpMRI could not provide similar improvement as in initial diagnosis [40]. The only study providing evidence for MUS in local staging is a brief correspondence of Regis *et al.* [41] showing a sensitivity and specificity for organ-confined disease of 87.5% and 80%, respectively. This study evaluated only 54 patients and was not a full peer-reviewed publication. Further studies are warranted to support the use of MUS in the field of local staging [41].

2.4. Potential outside of PC

Local staging of bladder cancer has long been limited to computer tomography. Recently, a protocol for mpMRI from the Vesical Imaging–Reporting and Data System has been presented [42]. Multiple studies have evaluated its capabilities in detecting muscle invasive bladder cancer, and a meta-analysis showed a sensitivity and specificity of 83% and 90%, respectively [43]. A feasibility study for MUS in a study limited to 24 patients undergoing transurethral resection of a bladder tumor was able to detect all 4 cases with muscle invasive disease [44]. This provides hope for further fields of application for MUS, but caution is warranted until supportive validation studies are published.

3. Conclusion

MUS is a new imaging modality with multiple possible uses. The mostly retrospective data on the diagnosis of PC are promising, but its future role needs to be determined by further prospective, controlled trials to compete with the level of evidence supporting mpMRI. For patients with contraindication for mpMRI, MUS already presents the best available option. Whether it is possible to rely on MUS in local staging of prostate and bladder cancer depends upon further evaluation. In summary, with a growing body of evidence supporting the use of MUS as an alternative to mpMRI has the potential to bring imaging of PC back into the hands of the urologists.

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Conflicts of interest

All authors have no conflict of interest to declare.

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