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MR/US Fusion Technology: What Makes It Tick?

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Abstract MR/US fusion biopsy has emerged as a significant refinement of traditional prostate cancer diagnostic techniques. Utilizing not only quantitative imaging suspicion information from mpMRI but also the spatial accuracy and three-dimensional localization allows such strategies to specifically sample areas of concern with the gland. As such, diagnostic certainty is markedly improved. In this manuscript, we aim to highlight the multidisciplinary approach (amongst urologists, radiologists, pathologists, imaging technologists, nursing staff, and patients) which is required to launch and maintain a successful prostate imaging program.

Keywords Imaging · MR/US fusion biopsy · MRI · Prostate cancer

Introduction

In recent years, the shortcomings of traditional diagnostic paradigms of prostate cancer have been increasingly highlighted. Public health bodies such as the USPTF have even discouraged widespread PSA assay based prostate cancer screening due mainly to concerns of overtreatment and poor balance between harms and benefits of such screening methods [1]. As such, prostate cancer oncologists have increasingly embraced new strategies and technologies aimed to improve the value of diagnosis to their patients. In this light, multiparametric MRI of the prostate has been utilized to not only identify but also localize the presence of prostate cancer within the gland [2•]. Traditional tissue-based sampling with transrectal-guided ultrasound (TRUS) alone could not distinguish cancer from normal tissue on imaging assessment and therefore can result in an underestimation of extent and even missed cancers as much as half of the time [3]. The addition of MRI-based three-dimensional localization of suspicious areas within the gland has been paired with technological and engineering advancements in biopsy equipment which allows navigational biopsy specifically directed towards image-based targets. Such combinations of MRI and US imaging (known as MR/US fusion) have begun to overcome such limitations and have resulted in improved diagnostic power over traditional methods [4, 5, 6••].

In the relatively short intervening period, such breakthrough strategies have transitioned from prototype research applications in select centers to being widely commercially available. As such, it has gone from an "Apollo style moon mission" to a more utilitarian and contemporary satellite launch. Most academic centers and large community-based practices have now embraced image-based prostate cancer diagnosis using MR/US fusion biopsy (FB). In this article, we will discuss best practices and strategies to optimize the implementation of these new technologies aiming to minimize the "learning curves."

MR/US Fusion: a Fundamentally Multidisciplinary Process

In building a successful prostate cancer imaging program, the importance of a multidisciplinary approach cannot be overstated. In more traditional clinical diagnostic applications,

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the urologist will typically be accustomed to being the primary decision maker. However, for MR/US FB to be successful, the ideal situation is a cooperative endeavor between not only the urologist and radiologist but also the pathologist, imaging technologist, and nursing staff. Best practice will require obtaining champions from all of these disciplines. Regular communication and feedback will allow for maximal outcomes. Furthermore, MR/US FB is best considered standard medical care, rather than experimental or overly complex. Once established, the process quickly becomes routine, allowing patients to benefit from these breakthrough technological improvements in diagnosis.

Indications for MR/US Fusion Biopsy

As mentioned, enthusiasm for mpMRI has drastically expanded its use. The most established indication for MR/US FB is persistent clinical suspicion of prostate cancer despite prior negative systematic TRUS-guided biopsy. In this setting, MR/US FB has been noted to identify clinically significant cancers otherwise missed by systematic biopsy alone [5]. Specifically, settings in which cancers can be more likely missed by systematic sampling (anatomically occult) include men with large glands [7, 8], apically located tumors [9], and anteriorly located [10, 11] lesions. In addition, to simply detecting occult cancers, targeted biopsy is also much more likely to accurately stage and characterize it in comparison to systematic biopsy alone. This has resulted in improved detection of adverse pathologic features such as perineural invasion [12], extraprostatic extension [13], and seminal vesical invasion [14]. Owing to the established improved diagnostic utility in such setting, this indication of MR/US FB in the setting of prior negative biopsy has been supported by guideline bodies including the NCCN Guidelines Committee and more recently in a combined consensus document between the American Urologic Association and the Society of Abdominal Radiology [15, 16].

Another common use of MR/US FB is in active surveillance of men with low-risk cancer. In the setting of confirmatory biopsy for those with documented low-risk prostate cancer, MR/US FB has been noted on numerous studies to identify foci of higher risk disease which were missed with systematic biopsy (with upgrade rates ranging from 20 to 47%) [17–20]. In addition, findings on MRI including number of suspicious lesions, degree of lesion suspicion, and lesion volume have been demonstrated to have predictive value which can used to estimate the likelihood of upgrading [19]. Early reports on the use of MR/US FB in serial biopsy for men on active surveillance demonstrate that the addition of targets result in a doubling of detection of disease progression (with approximately half of progressions missed with systematic biopsy alone) [21•, 22]. While emerging evidence may suggest diagnostic benefit of MR/US FB in the initial setting [6••], consensus bodies currently do not recommend the routine use of MR/US FB in all men prior to initial biopsy. Finally, MR/US FB may be used in the assessment of recurrence following primary treatment [23].

Contraindications and Alternatives to MR/US Fusion Biopsy

When evaluating a man for MR/US FB, routine evaluation for MR compatibility should occur. This should include determination of presence of any exogenous metallic implants (i.e., cardiac stents, aneurysm clips, or ferromagnetic shrapnel). Most radiology departments have well-established protocols regarding such implants in regard to determining MR safety. Of note, stents and other medical implants are not necessarily contraindications (nor is shrapnel per se), and each case merits individual evaluation. The manufacturer of medical devices will have defined MR compatibility based on prior testing. In addition, depending on size, location, and duration of ferrous implant (i.e., non-vital areas, and chronic implantation) may potentially allow for compatibility based on safety alone despite ferromagnetic composition [24]. However, pelvic location of metallic implants (even those which are not ferromagnetic) can also potentially produce attenuation artifacts which precludes the acquisition of meaningful and diagnostic information. Examples of MR compatible implants which interfere with data acquisition are hip prostheses, prostatic fiducials, brachytherapy implants, and Urolift BPH implants. Finally, while patient claustrophobia is often amenable to reassurance, counseling, and an oral dose of short acting benzodiazepine anxiolytic, some men cannot tolerate the confinement of the MRI gantry even briefly. On such occasions that MRI is not feasible for safety or other patient factors, alternatives to MR/US FB such as transperineal template mapping biopsy may be utilized with excellent results [25, 26]. The downside of mapping biopsy over MR/US FB is need for general anesthesia, a relatively high risk of urinary retention (~10%), higher procedure time, and cost.

Imaging Considerations for Optimized Prostate mpMRI Acquisition

First, adequate counseling (beginning in the urologist office) regarding the nature of MR imaging can avoid many issues of confusion regarding the multistep process. Review of the overall rationale and safety of the diagnostic modality, and brief overview of the specifics regarding MRI including length of image acquisition, notification of gantry confinement with loud environment, need for IV and contrast medication, and nature of endorectal coil is helpful to patients who

almost universally have some degree of situational anxiety about the process.

A common scenario for a man seeking MR imaging is after recent prostate cancer diagnosis from a referring physician. However, it should be noted that biopsy related hemorrhage can produce significant artifact which can hinder meaningful image acquisition. For this reason, a waiting period of 8–12 weeks post-biopsy is recommended prior to obtaining MRI (which may need to be extended in the setting of anticoagulation). A similar wait should be instituted after periods of acute inflammation such as UTI to allow for ideal imaging performance. Also, ejaculation has been noted to lower peripheral zone attenuation on T2-weighted sequences as well as to lower ADC values on diffusion-weighted imaging in the peripheral zone [27]. As such, we recommend a period of abstinence for 24 h preceding image acquisition to avoid issues.

Another commonly encountered concern is in optimization of imaging acquisition. Continued feedback regarding imaging quality between the urologist and the entire radiology team (radiologist, MRI physicist, and MRI technicians) can yield marked improvement in image quality. It should be noted that most centers utilize closed MRI with at least 1.5 T field strength and include at least a body surface coil. An endorectal coil may be utilized which can further improve signal to noise ratio. In addition, by fixing the prostate physically, it can minimize motion artifact which can hinder long duration sequences, especially those of the diffusion-weighted sequences. However, many radiology departments do omit endorectal coil placement. A commonly held misconception is that an endorectal coil has no interval improvement at field strengths of 3.0 T and should thus be precluded. However, Turkbey et al. did address this issue by performing 3.0 T prostate mpMRI with and without ER coil prior to radical prostatectomy in 20 men [28•]. All underwent blinded reads which were compared to final histopathologic data from the whole mount prostatectomy specimens. At gross histopathology, they found 51 cancer foci present ranging in size from 2 to 60 mm. Utilizing endorectal coil, sensitivity for detection was 0.76 with PPV 0.80. Omitting the coil resulted in reduced sensitivity of 0.45 and PPV 0.64. Lesions detected without endorectal coil were significantly larger (22 versus 17.4 mm). It should be noted that, almost universally, the endorectal coil (while tolerable) is described as uncomfortable by the patient. However, once trained, MRI imaging technologists and personnel can quickly become adept at placement and adjustment of the coil. More generally, the optimization of imaging sequences should be continually audited and should be adjusted in conjunction with an experienced prostate specialist team. Many academic institutions have excellent MRI physicist support, and they should be brought on board to optimize the sequence programming. However, for those settings who lack such specialized personnel, MRI manufacturers have prostate specific imaging teams who can visit and will similarly optimize images based on standardized protocols. This can often occur at no additional cost as part of existing service contract arrangements. Ultimately, the team should work together to identify areas of improvement in the imaging sequences with iterative change often resulting in long-term benefit to diagnostic performance.

A Brief Overview of Alternative MRI Targeting Platforms Utilized in Prostate Cancer

Prior to the development of MR/US FB, direct lesional targeting was performed on patients while in the MRI gantry (typically by radiologists). The success of this method has been extensively published in the international literature, however is less commonly utilized in the USA. One specific indication where in gantry targeting continues to be particularly helpful is in the setting of men who lack a rectum (i.e., post-extirpation for rectal cancer), which precludes easy use of ultrasound probe for targeting.

Beyond in MRI gantry lesional targeting, MR/US FB has developed as a practical method to allow for lesion-specific tissue sampling. The advantage to this technique is that it opens this diagnostic pathway to the outpatient in-office setting which has proven very practical in the setting of healthcare delivery. There are several methods to accomplish MRI FB which we will briefly cover here [29•]. The first method involves surgeon review of films and visual coregistration of MR data without the aid of software tools or technological adjuncts. This method has been described as "cognitive" MR/US FB [30]. In expert hands, this method has been shown on prospective blinded trial to be not significantly inferior to more technological-based methods of image fusion [31•]. In this trial of 125 men, software-based FB detected 55 (32.0%) cancers, and "cognitive" visual registration detected 46 (26.7%) cancers which was not significantly lower. In fact, the AUA/SAR guideline committee has deemed this method as a reasonable strategy in skilled hands, though included caveats that smaller lesions and more anterior distant lesions can be more easily missed [16]. We include a caveat that the commonly utilized TRUS image with endfire array will offer images which are more axial at the prostate apex, but are more coronally oriented as the base of the prostate is imaged. As such, direct targeting utilizing pure axial images on MRI can be complex and should be approached with care.

Software-based image coregistration and biopsy trajectory tracking for MR/US FB has been increasingly embraced as a useful adjunct to assisting in lesion targeting. Three major methods have been utilized in various commercially available systems in order to precisely track needle trajectory and motion [29•]. The first utilizes a mechanically encoded arm (used in the Artemis/Eigen and Biojet/D&K systems). In this

method, the needle guide is attached to a floating arm which has sensors in the joints which allow for careful calculation of the needle trajectory. The second method involves electromagnetic tracking (used in the Uronav/Philips and HI-RVS/Hitachi systems). Here, an electromagnetic field generator emits a signal which can be detected by a tracking sensor applied to the TRUS probe. This method has been likened to GPS satellite (field generator) and terrestrial GPS unit (probe tracker). The last method utilizes three dimensional image-based coregistration captured before, during, and after needle deployment (utilized in the Urostation/Koelis system). Many systems utilizing these methods have been developed and more are being introduced as time marches. All systems have been demonstrated to have superiority over systematic biopsy sampling alone in numerous retrospective reviews.

Preparations Prior to MR/US Fusion Biopsy Procedure

In the spirit of the multidisciplinary nature of the procedure, the urologist should ideally prospectively review imaging and interpretation in preparation for the procedure. The formality of such review widely varies, from stringent in person multidisciplinary conferences held in many academic centers, to more informal ad hoc discussion between radiology and urology in others. However, without feedback of this information, diagnostic success will certainly suffer. Focus should be made on any missed lesions, standardization of lesion suspicion scores, and finally accuracy of prostatic segmentation (prostatic border delineation). Auditing of reads is especially important when multiple radiologists are reading, as those early in experience tend to "overcall" lesions for fear of missing cancer. Segmentation should be scrutinized as many systems will utilize a computer algorithm to identify such borders. However, it is vital that this is manually audited and adjusted by the radiologist and urologist in all three planes (axial, sagittal, and coronal). If left to the automated tools alone, discrepancies can occasionally occur and the urologist may be misled during the coregistration leading to inevitable spatial inaccuracy. The rationale of stringent focus on accurate and consistent prostatic segmentation is that all software-based systems utilize these prostatic boundaries as the foundational frame of reference to match MRI with ultrasound data.

The Day of the MR/US Procedure

Preparations TRUS-guided systematic biopsy is almost a nearly ubiquitous practice in urologist's offices. Thus, preparations for MR/US FB should be not be burdensome on an office staff, as they can be reminded that the procedure will closely mirror that of systematic biopsy with which they are much more familiar. In this light, periprocedural preparations should be handled no differently in MR/US FB cases than in standard systematic biopsy cases, including in scheduling of block time, holding of anticoagulation, antibiotic preparations, and enema if utilized. In addition, the patient is counselled that periprocedural harms and risks (including bleeding, infection, and urinary complications such as retention) will closely mirror those of systematic prostate biopsy if performed correctly. One common misconception is that MR/US FB may require more sedation than in those men undergoing systematic TRUS-guided biopsy. This has not been our experience. Indeed, we caution that a well counselled and anesthetized patient under local technique may more effectively avoid motion (and consequent targeting challenges) than a patient on intravenous conscious sedation. Not surprisingly, oral short acting benzodiazepine can be helpful as an anxiolytic, but is rarely needed.

A distinction in MR/US FB is that a "dry run" including loading of the patient imaging data should be performed prior to the biopsy session. On occasion, technologic errors can prevent transfer of imaging information from DICOM/radiology systems to the urologist-based fusion platform. It is important that this is done ahead of time in order to avoid unnecessary patient anxiety and discomfort. In addition, as target labelling is variable between patients, this should be performed in advance of the procedure to avoid errors. Avoid solely using numeric labels of pathology specimens (i.e., targets 1, 2, 3, etc.). Standardized labelling of specimen containers and pathology requisition labels should ideally include detailed and specific location information (left/right; base/mid prostate/apex; anterior/posterior; lateral/medial; peripheral zone/central gland/anterior fibromuscular stroma; etc.). This will avoid confusion in assigning pathology specimen findings to specific imaging lesions once evaluated, especially in the setting of multiple lesions.

Room setup and layout will be quite variable based on the room size, number of participating personnel, specific targeting platform being utilized, physician preference, etc. We have found that the procedure can easily and routinely be performed with a surgeon with the assistance of a single nurse with experience with the procedure (a complement identical in number and experience to that used in traditional systematic biopsy). MR/US FB has been described as being performed alone, but this would likely result in suboptimal duration of procedure. The key to formulating an ideal room layout will be acceptance of feedback and iterative change from all members of the team. We have found that in so doing, workflow has improved and case time has reached approximately 10–15 min consistently (comparable to systematic TRUS biopsy timing).

It should be commented that a strict timeout procedure should be adhered to, and should confirm that imaging data

loaded onto the software platform is truly for the corresponding patient. Given that the data loading can be complex, and the workflow may include multiple patients, the loading of an erroneous biopsy plan has been described. As this will result in missed lesions by definition, special vigilance should be exercised in this matter throughout the procedure.

Anesthesia The first step, prior to prostatic measurements and coregistration, should be the application of local anesthesia. Most providers use between 10 and 20 cm^3 of lidocaine 1% (many include bicarbonate buffering for comfort). An adjunct to this can include intrarectal 2% lidocaine jelly. Standard technique of infiltration of the neurovascular bundle adjacent to bilateral seminal vesicle is utilized. In addition, many include additional adjuncts of hydrodissection of analgesic into the peri-prostatic space adjacent to rectal wall, as well as a focus on the apical prostate in the area of the urogenital diaphragm. The latter techniques can be helpful in maintaining patient comfort especially with the need for application of greater than usual torque for anteriorly and apically positioned lesions. In the awake patient, many providers will provide music and other non-pharmacologic stress relief, which have been demonstrated to significantly alleviate anxiety and pain [32]. In addition to pain control, headphones with music or earplugs have been utilized to mask the biopsy gun noise (which can exceed 100 dB) in order to minimize the startle reflex and consequent patient movement which can complicate accurate coregistration and targeting.

Coregistration of US and MRI Data The first step of coregistration of MRI and US data involves three-dimensional collection of US in order to get a realtime model. It is important that probe pressure is governed carefully in order to avoid major deformation of the gland. Maximizing consistency between prostatic shape between MR image acquisition and realtime US aids in accurate coregistration. At this time, multiplanar coregistration (axial, sagittal, and coronal) should take place by aligning the prostatic boundaries, taking note of sonographically evident anatomy as further landmarks (prostatic cysts, peripheral zone/central gland interface, urethral course, and intravesical lobe asymmetry). As mentioned beforehand, as the majority of the coregistration is based on alignment of the prostatic boundary, it is vital that both MRI and US are interpreted similarly by radiologist and urologist.

A common challenge to adequate US capture of gland extent includes men with extremely large glands in which the intravesical lobe becomes difficult to capture. It is important to adjust the depth and gain sliders such that the software can adequately interpret the entire extent of the gland. Less commonly, calcifications can impede sonographic transmission and can result in acoustic shadowing. In both of these instances, manual adjustments to the computerized algorithmic US segmentation in all three planes are crucial to successful and accurate coregistration. In the case of more spheroid glands (which are more difficult to coregister than glands which are oblong) a focus on the intraprostatic anatomy such as PZ/CG boundary and urethral location can be helpful for orientation.

Elastic transformations have been widely offered by multiple commercial platforms and can help overcome inconsistency between the two data sets, especially in prostatic shape. However, the use of elastics can represent a "double edged sword," especially if applied prior to meticulous multiplanar coregistration. This is especially true in the case of small target lesions. It is our practice to toggle elastic transformations on and off during the procedure to assess for major discrepancy. When training new users of the platform, we have noted a tendency to utilize elastics in replacement of coregistration (a strategy which will mask and amplify errors). This is should be avoided, and indeed if utilized in this fashion, a pure rigid coregistration strategy would be likely result in improved results.

Targeted Biopsy It is our practice to perform target biopsy prior to systematics to minimize gland edema, hemorrhage, and other issues with coregistration. Dynamic assessment and auditing of coregistration throughout the case, with realtime adjustment, is critical to success. Anterior lesions can sometimes be quite distant from the rectum. These can be reached by "floating" the needle into the prostate and firing only when the lesion extent is reached. This is well tolerated by patients. In large glands, longer biopsy needles may be necessary for appropriate reach of such anterior lesions, especially when located at the bladder base (needle length as long as 25 cm are readily available from manufacturers). When targeting such lesions, beware of needle deflection, which can be detected by the absence of the needle's characteristic hemorrhage flash on US. It should be emphasized that probe should not move when needle is out of sheath, as lacerations can occur once the needle is exposed. Of note, at least two core samples per target are recommended to overcome spatial accuracy/registration errors [16, 33]. This is especially true in smaller lesions and in the setting of intermediate risk disease. This strategy can overcome the issue of approximately an 8% discordance (missed or upgraded on one of the two targeted cores), which even with supplemented systematic biopsy would result in an as high as 5% missed cancer [33]. The importance of supplementing targets with systematic biopsies has been emphasized by guideline bodies [15, 16]. While the merits of a target only approach have been proposed, this should only be embarked upon after acknowledgement with the patient that missed cancers are much more likely including missed or undergraded cancers in over 13% of men, and 6.5% of clinically relevant cancers greater than Gleason 3 + 3 = 6 [6••]. In addition, this is in the hands of expert sites, and local

institutional audits should be performed documenting lack of missed disease on targeting prior to offering such new strategies.

Multidisciplinary Feedback—Auditing and Quality Improvement Ideally, outcomes should be captured in a computerized database at minimum in regard to cancer detection rate as stratified by MRI suspicion level, as well as correlation with findings on paired systematic biopsy. It is typical to experience a learning curve which includes both the urologist and the radiologist. As mentioned, specific review of missed clinically significant targeted lesions as well as negative lesions should be performed. Negative lesions may represent either overcalling of benign areas, or missed cancer due to spatial accuracy issues. Men with negative findings in the setting of highly suspicious lesions should be followed closely with repeat clinical evaluation and potentially repeat imaging and biopsy [16].

Conclusions

The widespread adoption of image-based prostate cancer diagnosis has offered patients greater certainty in their diagnosis. Ideally, this can result in avoidance of treatment (more observational approaches) as well as fewer missed cancers leading to potentially earlier detection and more effective outcomes. Adoption of such new technologies will require a multidisciplinary approach in order to maximize the potential benefits to our patients.

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Compliance with Ethical Standards

Conflict of Interest Srinivas Vourganti, Norman Starkweather, and Andrij Wojtowycz each declare no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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