White Paper

Virtual Navigator Transperineal Urology





"Biparametric and multiparametric magnetic resonance fused in real-time with Ultrasound improves the accuracy by reducing time and number of biopsies"

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Introduction

Prostate cancer is the most common tumor in male patients and the second/third cause of death by cancer in the United States and Europe.^{1,2,3,4}

The early and accurate diagnosis and localization of suspect cancer areas is of fundamental importance to providing more appropriate therapy management. The current diagnostic algorithm, based on rectal examinations, PSA testing, and ultrasound-guided prostate biopsies, provides limited information in this regard.⁴

Magnetic resonance imaging of the prostate

Magnetic resonance imaging of the prostate with T2-weighted sequences was first documented in the mid-1980s.⁵

T2-weighted sequences demonstrated relatively low sensitivity and specificity in the diagnosis of prostate cancer and moderate accuracy in locoregional staging.

Multiparametric nuclear magnetic resonance imaging (mpMRI) of the prostate, which includes morphological (T2-weighted) and functional (water diffusion and contrastographic) sequences, is currently the reference standard for the diagnosis, localization, and staging of suspicious prostate cancer.^{6,7,8,9}

The limitations of mpMRI include costs, the time required to carry out the examination, and the need to use a paramagnetic contrast medium (gadolinium). In addition, the potential risk of compromising the renal function and the accumulation of paramagnetic contrast within the central nervous system represent further limitations that are significant to the use of the paramagnetic contrast medium.¹⁰

Various studies recently demonstrated that the data provided by the contrastographic sequences is limited and that the added diagnostic value of the contrast medium is low.¹⁷

Biparametric magnetic resonance imaging (bpMRI), which includes T2– and diffusion-weighted sequences, was introduced in a bid to overcome these limitations.^{11,12,13,14,15,16,18}

The advantages of bpMRI include cost reductions, a decrease in the time required to carry out the examination, and the absence of gadolinium. In addition, bpMRI has generated results that correlate with mpMRI.^{14,15,19}

Fusion biopsy

Biparametric and multiparametric magnetic resonance makes it possible to identify high suspicious for prostate areas on which to focus "targeted" sampling (fusion biopsy) with the aim of improving the accuracy and rate of diagnosing high-risk prostate cancer by reducing the amount of time and number of biopsies required to obtain a diagnosis.^{20,21}

The aim of fusion biopsies is to maximize and accelerate the diagnosis of prostate cancer by reducing the need to resort to multiple sets of biopsies carried out "blind," increasing the diagnosis of aggressive tumors while reducing that of slow-growing tumors, and guiding urologists in selecting the type of management most suitable for the patients involved.

There are currently various image fusion systems. They are all based on the principle of overlaying MRI images with real-time ultrasounds, with the aim of guiding sampling to prostatic areas of concern using ultrasound guiding.

The first relevant difference is the type of access to the gland. Some systems use transrectal access, while others use transperineal access. In recent years, the latter has been widely reevaluated, both as regards its superiority in sampling the apex and front section of the gland and its significantly lower risk of lesions to the prostatic venous plexus.

In addition, the inevitable movement of the convex probe used for transrectal access alters the capsular profile, particularly in apical sampling, thereby decreasing the accuracy of the fusion.²²

Lastly, the recent significant increase of infectious complications following prostatic biopsies carried out transrectally (from 1% in 1996 to 4.1% in 2005, with associated episodes of sepsis at 72%) is increasingly bringing into question the use of this type of access. With the transperineal approach, the rate of hospitalization for post-procedure infectious complications is negligible.^{23,24,25}

Another difference involves the use of a transperineal template. The potential advantage of using a transperineal template is the provision of spatial coordinates with which every biopsy can potentially be repeated, and applications in the event of active surveillance or indication to focal therapy. The main disadvantage, however, is the need to have multiple access to the perineum. The examination must therefore be carried out in an surgery room and under spinal/general anesthetic. Conversely, the absence of a template makes access to the gland possible via a



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single entry point in the perineum through which a potentially unlimited number of biopsies can be carried out with a significant reduction in pain and lesions in the surrounding organs (venous plexus, nerve fascicles).²⁴

These advantages mean that the examination can be carried out as a outpatient procedure under simple local anesthetic.

Despite these differences, studies have yet to conclusively prove the superiority of one system over the other.

Fusion-guided prostate biopsy with transperineal access and without the aid of a template: the technique

With the aid of an Esaote TRT33 Bi-Plane endocavity probe, local anesthetic is applied (4 cc Mepivacaine 2% via 21 G needle) with access on the median raphe approximately 1.5 cm from the anal orifice.

The anesthetic is injected behind the apex of the prostate and extended in a "horseshoe" shape around the side of the apex itself.

The virtual navigator system then proceeds with the fusion of US-MRI images with continuous real-time control of the correct overlap of images.

Real-time fusion is achieved through continuous communication between the ultrasound probe equipped with a tracking device and a magnet, which is placed on the patient's abdomen and verifies in real time the spatial coordinates of the biopsy needle and the virtual targets (suspect areas) to be biopsied.

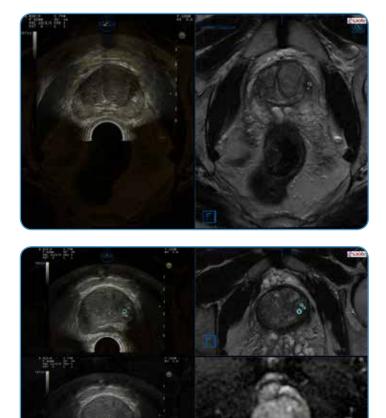
An 18 G 200 mm biopsy needle is introduced into the access point in the anaesthetized area and, with the aid of navigation, reaches the virtual targets planned for MRI using axial ultrasound scanning. In prostates of a volume >60 g, it is possible to make two access points, at approximately 1 cm to the side of the median raphe, to prevent the path of the needle from being too centrifugal in comparison to the access point. By convention, the virtual target is positioned in the most apical portion of the suspect lesion to ensure that the needle carriage can advance into the area to be biopsied. This is possible only with the transperineal approach, in which the needle always advances with the same orientation in the apical-basal direction.

This method of sampling the gland helps the anatomical pathologist in the spatial reconstruction of the biopsied lesion. In ad-

dition, the inevitable movement of the convex probe used for transrectal access alters the capsular profile, particularly in apical sampling, thereby decreasing the accuracy of the fusion.

Results

The results gathered thus far reflect the literature data, with a diagnostic rate for neoplasms generally higher than 50%. This rate is significantly higher if we consider diagnoses involving highly suspect lesions, for which the detection rate ranges from 70% to over 90% for lesions with PI-RADS scores of 4 and 5 respectively. Furthermore, in our experience, MRI of the prostate has avoid some 30% of patients subjected to the examination from undergoing "unnecessary biopsies.



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