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MRI Detection of Prostate Cancer with the UroNav MRI Fusion Platform

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Abstract

The UroNav three dimensional MRI fusion platforms fuse the patient's MRI images with real-time ultrasound in the office setting. Electromagnetic field tracking of the biopsy probe allows targeting of MRI detected prostate lesions. In the present study 86 men underwent UroNav MRI fusion prostate biopsy. Of the men biopsied using this platform, 53 (61%) had prostate cancer detected. There were 44 true positive predictions, 16 false positive predictions, 17 true negative predictions and 9 false negative predictions (chi-square, $p<0.05$). Of the 53 prostate cancers detected, 31 were classified as high grade (ie, Gleason Score 7 or greater; Prostate Grade Group 2 or greater). UroNav MRI Fusion prostate biopsy correctly identified 28 (90%) of 31 men with high grade prostate cancers.

Introduction

Magnetic Resonance Imaging (MRI) was initially utilized for prostate cancer staging [1-4]. We and others then applied this advanced technology to identify prostate cancer in men not previously diagnosed [5,6]. Registration of the prostate MRI and real time ultrasound for prostate biopsy was at first done visually using a number of models and this is known as cognitive (visual) fusion. Investigators have shown significant variation in visual fusion. In a study of 45 patients [7], the overall spatial difference in targeting lesions was 10.6 ± 6.0 mm. This variation in accuracy exceeds the size of many lesions now being detected in clinical practice. The investigators concluded that visual registration could improperly and inaccurately target lesions detected on MRI.

Sophisticated software now allows device mediated targeting of MRI lesions [8,9]. The UroNav three dimensional MRI fusion platforms fuse the patient's MRI images with real-time ultrasound in the office setting. Electromagnetic field tracking of the biopsy probe allows targeting of MRI detected prostate lesions. We herein report our experience with the UroNav MRI fusion platform in 86 consecutive patients.

Materials and Methods

Patients

All patients undergoing UroNav MRI fusion prostate biopsy during the inclusion period comprise the study cohort. Patient's presented with either elevated serum PSA level or had a digital rectal examination of the prostate suspicious for cancer. Patients may have had prior prostate biopsy.

Prostate MRI

Multiparametric MRI with 3T magnet was performed in all cases. Imaging incorporated high resolution T2 weighted images with diffusion weighted imaging and dynamic contrast enhancement to identify areas in the prostate suspicious for cancer to be targeted (Figure 1). Interpretation and reporting of lesions detected on MRI was in accordance with the Prostate Imaging-Reporting and Data System (PI-RADS). This system was developed to promote standardization in reporting multiparametirc MRI examinations and is reproducible [10].

Patient preparation and biopsy of MRI target

Patients received mechanical bowel preparation, flouroquinolone and oral benzodiazepam prior to procedure. Periprostatic nerve block was performed with 20 cc of 1% lidocaine. TRUS images and measurements were made in the transverse and axial plane. The static MRI and dynamic TRUS were co-registered and underwent both translational and rotational adjustments to most accurately align the two modalities (Figure 2). One or more targets when present were targeted in both the axial and sagital planes. Template mapping biopsy was performed in all patients in the event of an MRI-

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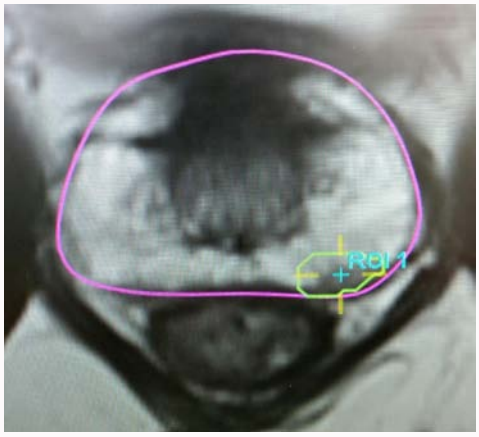

Figure 1: Target lesion identified on MRI.

Table 1: Performance of UroNav MRI fusion prostate biopsy in detection of prostate cancer.

Measure	Outcome
Sensitivity	83%
Specificity	51%
Accuracy	71%
Positive Predictive Value	73%
Negative Predictive Value	65%

invisible cancer [11,12].

Assessment of UroNav MRI fusion detection of prostate cancer

The 3T mpMRI was correlated with the targeted and template mapping biopsy pathologic result. True Positive (TP) represents the number of cases where a PI-RADS ± 3 lesions on mpMRI correlated with the presence of prostate cancer. False Positive (FP) represents the number of cases where a PI-RADS ± 3 lesion did not correlate with the presence of prostate cancer. True Negative (TN) represents the number of cases where a negative MRI correlated with the absence of prostate cancer. False Negative (FN) represents the number of cases where prostate cancer was detected in a patient with a negative 3T mp MRI.

Sensitivity: The sensitivity of UroNav MRI fusion prostate biopsy is its ability to determine the patient with prostate cancer correctly. To estimate it, we calculate the proportion of true positive in patient cases. Mathematically, this can be stated as: Sensitivity=TP/TP+FN

Specificity: The specificity of UroNav MRI fusion prostate biopsy is its ability to determine the patients without prostate cancer correctly. To estimate it, we calculate the proportion of true negative in healthy cases. Mathematically, this can be stated as:Specificity=TN/TN+FP

Accuracy: The accuracy of UroNav MRI fusion prostate biopsy represents the ability to differentiate the patients with prostate cancer from those without prostate cancer. Accuracy is calculated using the proportion of true positive and true negative in all evaluated cases. Mathematically, this is calculated as: accuracy=TP+TN/TP+TN+FP+FN

Positive predictive value: The Positive Predictive Value (PPV) represents how likely a patient with PI-RADS > 3 lesion on mpMRI will be found to have prostate cancer on UroNav MRI fusion prostate biopsy. PPV=TP/TP+FP.

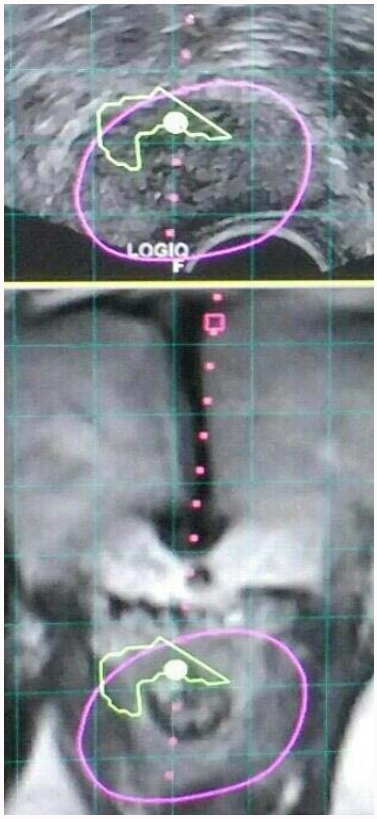

Figure 2: UroNav fusion of ultrasound (top image) and MRI (bottom image).

Negative predictive value: The Negative Predictive Value (NPV) represents how likely a patient with a negative mpMRI will have no cancer detected on UroNav MRI fusion prostate biopsy. NPV=TN/TN + FN.

Chi square analysis: Chi square analysis tests for association between two categorical variables. The Chi-Square statistic aids in the assessment of the null hypothesis that the frequencies of each category deviate from one another in the way observed purely by chance. Depending on the Chi-Square statistic calculated, we can reject or not reject the null hypothesis.

Results

A total of 86 men underwent UroNav MRI fusion biopsy between February 15th, 2018 and January 18th, 2019 and comprise the cohort studied. Serum PSA ranged from 0.8 ng/ml to 36 ng/ml (median, 6.8 ng/ml). Eight men had digital rectal examination of the prostate recorded as suspicious for prostate cancer. Thirty men had 1 (n=20), 2 (n=8) or 3 (n=2) prior negative prostate biopsies. Of 86 patients, 53 (61%) had prostate cancer detected. There were 44 true positive predictions, 16 false positive predictions, 17 true negative predictions and 9 false negative predictions (Table 1).

Of the 53 prostate cancers detected, 31 were classified as high grade (ie, Gleason Score 7 or greater; Prostate Grade Group 2 or greater). UroNav MRI Fusion prostate biopsy correctly identified 28 (90%) of 31 high grade prostate cancers.

In the 30 men with prior negative prostate biopsy, prostate cancer

was detected in 11 (55%) of 20 men with 1 prior negative prostate biopsy, 5 (62%) of 8 men with 2 prior negative prostate biopsies and 1 (50%) of 2 men with 3 prior negative prostate biopsies.

The performance of UroNav MRI fusion prostate biopsy was assessed statistically. The chi-square =11.4989. The *p*-value=0.000696 ($p<0.05$). The chi-square statistic with Yates correction =9.92. The p-value =0.001635 ($p<0.05$).

Conclusion

In the present manuscript, we report on our experience using the UroNav MRI fusion prostate biopsy platform to detect prostate cancer. Our findings indicate that UroNav MRI targeted biopsy has the potential to detect high grade prostate cancer in biopsy naive men as well as those having 1 or more prior negative prostate biopsies.

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