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Original article

Magnetic resonance/transrectal ultrasound fusion biopsy of the prostate compared to systematic 12-core biopsy for the diagnosis and characterization of prostate cancer: multi-institutional retrospective analysis of 389 patients

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Abstract

Objective: To determine the incremental diagnostic value of targeted biopsies added to an extended sextant biopsy scheme on a per-patient, risk-stratified basis in 2 academic centers using different multiparametric magnetic resonance imaging (MRI) protocols, a large group of radiologists, multiple biopsy systems, and different biopsy operators.

Materials and Methods: All patients with suspected prostate cancer (PCa) who underwent multiparametric MRI of the prostate in 2 academic centers between February 2013 and January 2015 followed by systematic and targeted MRI-transrectal ultrasound fusion biopsy were reviewed. Risk-stratified detection rate using systematic biopsies was compared with targeted biopsies on a per-patient basis. The McNemar test was used to compare diagnostic performance of the 2 approaches.

Results: A total of 389 men met eligibility criteria. PCa was diagnosed in 47% (182/389), 52%(202/389), and 60%(235/389) of patients using the targeted, systematic, and combined (targeted plus systematic) approach, respectively. Compared with systematic biopsy, targeted biopsy diagnosed 11% (37 vs. 26) more intermediate-to-high risk ($P < 0.0001$) and 16% (10 vs. 16) fewer low-risk tumors ($P < 0.0001$). These results were replicated when data from each center, biopsy-naïve patients, and men with previous negative biopsies were analyzed separately.

Conclusion: Targeted MRI-transrectal ultrasound fusion biopsy consistently improved the detection of clinically significant PCa in a large patient cohort with diverse equipment, protocols, radiologists, and biopsy operators as can be encountered in clinical practice.

Keywords: Early detection of cancer; Risk assessment; Prostatic Neoplasms; Biopsy; Magnetic Resonance Imaging

1. Introduction

When addressing men with known or suspected prostate cancer (PCa), it is desirable to prevent over-detection of low-risk disease and to improve identification of high-risk

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tumors. Several studies have shown that targeted multiparametric magnetic resonance imaging (mpMRI)-transrectal ultrasound (TRUS) fusion prostate biopsy improves the detection of PCa [1–12] and compensates for recognized shortcomings of the sextant-based, systematic TRUS biopsies [10,13].

However, most of the reported results comparing the diagnostic yield and performance of targeted vs. systematic biopsies of the prostate were single-center studies [10], had only 1 [7] or 2 radiologists [10,14,15] interpreting the mpMRI studies, only 1 [7,15], or 2 [14] providers performed the biopsies, used a single image fusion system [2,10], established arbitrary lesion size thresholds for inclusion [2], performed a per-lesion rather than a per-patient analysis [16] or did not address the effect in risk stratification [2], therefore limiting the applicability of such results to other institutions. By assessing the performance of targeted vs. systematic biopsies performed with a heterogeneous group of radiologists and urologists using different mpMRI protocols and image fusion systems across different patient populations, it is possible to achieve a better representation of general clinical practice.

The goal of this study, hence, was to determine the incremental diagnostic value of targeted biopsies added to an extended sextant biopsy scheme on a per-patient, risk-stratified basis in 2 academic centers using different mpMRI protocols, a large group of radiologists, multiple biopsy systems, and different biopsy operators.

2. Materials and methods

2.1. Study design and patient eligibility

This institutional review board-approved and health insurance portability and accountability act-compliant study is a retrospective analysis of prospectively generated clinical, imaging, and pathological data according to the standards of reporting for MRI-targeted biopsy studies consortium [17] recommendations.

Patients with suspected PCa who underwent mpMRI of the prostate in 2 academic centers between February 2013 and January 2015 with abnormal results (i.e., at least 1 Likert scale score ≥ 3 lesion) followed by a targeted MRI-TRUS fusion biopsy within 1 year from the date of the MR examination were included in this study. Indications for mpMRI included elevated prostate-specific antigen (PSA) or abnormal rise in PSA (PSA velocity) based on the interpretation of the provider or abnormal digital rectal examination (defined as nodule or induration). Patients with previous diagnosis of PCa were excluded. A total of 389 men met eligibility criteria (Fig. 1).

2.2. MR imaging protocol and interpretation

All MRI studies included T2-weighted imaging, diffusion-weighted imaging and dynamic contrast-enhanced imaging

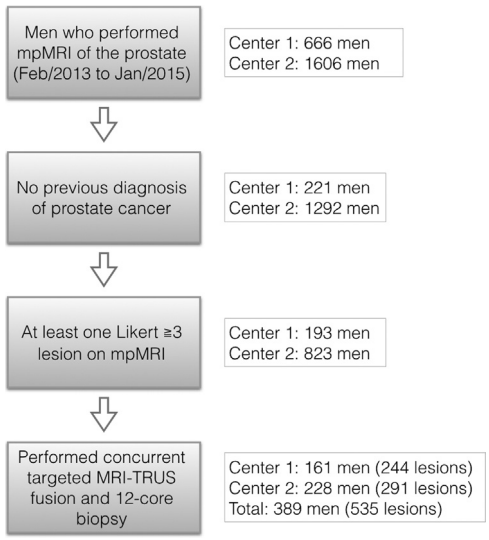

Fig. 1. Patient cohort. Flowchart of the criteria for eligibility and number of men enrolled. Center 1 University of Texas Southwestern; center 2, Hospital Israelita Albert Einstein.

and were performed on 3T scanners—center 1, Ingenia or Achieva (Philips Healthcare, Best, The Netherlands); center 2, Magnetom Trio (Siemens Healthcare, Erlangen, Germany) with a phased-array coil and with (center 1) or without (center 2) an endorectal coil. Each MRI examination was prospectively and independently interpreted by 1 of 6 radiologists at center 1 (median of 8 years of experience; range: 1–20 years) and by 1 of 3 radiologists at center 2 (median of 7 years of experience; range: 5–15 years) with advanced training in body MRI and not blinded to the clinical context. Each lesion was prospectively assigned a Likert scale score by the interpreting radiologist. This Likert score is a subjective assessment on the likelihood of the presence of cancer [18] on a 5-point scale and has been proven to be a strong and consistent predictor of targeted biopsy positivity [19,20]. Lesions with score ≥ 3 were defined as targets for MRI-TRUS fusion biopsy.

2.3. MR imaging—transrectal US fusion biopsy

Targeted biopsies were performed using different MRI-TRUS real-time fusion systems—center 1: elastic registration UroStation system (Koelis, La Tronche, France); Center 2: 3 different rigid registration systems MyLab 60 (Esaote, Florence, Italy); Aplio 500 Smartfusion (Toshiba, Nasu, Japan); and Logiq E9 VNav (GE Healthcare, Milwaukee). Each biopsy was performed by 1 of 4 urologists at center 1 (median of 13 years of experience with TRUS biopsies and 3 years with targeted MRI-TRUS fusion biopsies; range: 10–23 years and 1–3 years) and by 1 of 9 radiologists at center 2 (median of 9 years of experience with TRUS biopsies and 2 years with targeted MRI-TRUS fusion biopsies; range: 5–15 years and 2–2