Comparison of prostate cancer detection at 3-T MRI with and without an endorectal coil: A prospective, paired-patient study

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Abstract

Objectives: To compare the sensitivity of 2 different non–endorectal coil strategies vs. endorectal coil (ERC) magnetic resonance imaging (MRI) for detection of prostate cancer (PCa).

Methods: In this prospective, single-center, paired-patient, paired-reader study, 49 men with a clinical indication for MRI underwent non-ERC (phased-array coil only) T2-weighted imaging and diffusion-weighted imaging followed by the same sequences using both ERC and phased-array coils (ERC Protocol). Patients were randomized into 1 of 2 arms: standard non-ERC protocol and augmented non-ERC protocol. Lesions with Likert score \( \geq 3 \) were defined as suspicious for cancer. Radical prostatectomy specimen or combined systematic plus targeted biopsies served as the standard of reference. Cancers were stratified into risk groups according to the National Comprehensive Cancer Network guidelines. Generalized estimating equations with Bonferroni correction were used for comparisons. The level of reader confidence was inferred by the Likert scores assigned to index lesions.

Results: The ERC protocol provided sensitivity (78%) superior to MRI without ERC for PCa detection, both with a standard (43%) \((P < 0.0001)\) or augmented (60%) \((P < 0.01)\) protocol. The ERC MRI missed less-intermediate or high-risk index lesions (4%) than standard non-ERC (42%) \((P = 0.02)\) and augmented non-ERC MRI (25%), although the latter did not reach significance \((P = 0.09)\). The ERC improved radiologist confidence for the detection of PCa (average Likert score \(= 4.2 \pm 1.4\)) compared to standard \((2.3 \pm 2.3)\) and augmented \((2.9 \pm 2.1)\) non-ERC \((P = 0.001)\).

Conclusions: The use of combined ERC and pelvic phased-array coil for T2-weighted imaging and diffusion-weighted imaging provides superior sensitivity for the detection of PCa compared to an examination performed without the ERC. © 2016 Elsevier Inc. All rights reserved.

Keywords: Prostate cancer; Imaging; MRI; Detection; Endorectal coil

1. Introduction

The role of magnetic resonance imaging (MRI) of the prostate is rapidly evolving [1]. Initially, an imaging technique only used sparingly and predominantly for staging in academic centers, multiparametric MRI (mpMRI) is now utilized more broadly for a range of indications, including detection of areas suspicious for prostate cancer (PCa) before targeted biopsy [2], and in a wide variety of practice settings. When imaging the prostate gland, as in most MRI applications, it is desirable to obtain images with an optimized signal-to-noise ratio (SNR) within a reasonable acquisition time. Initially, the only way to practically achieve this in prostate examinations was by employing an endorectal coil (ERC), prompting its use as a standard of care [3,4].
The SNR boost associated with whole-body 3-T MRI compared with 1.5-T scanners offers an opportunity to avoid the ERC, in light of concerns regarding increased cost, workflow challenges, and patient discomfort. Most of the reported studies comparing non-ERC vs. ERC MRI protocols, however, are retrospective [5–10], did not compare each imaging technique in the same patient (i.e., paired-patient design) [5,7–10], did not include diffusion-weighted imaging (DWI) [5,7,9–12], assessed the diagnostic performance for local staging but not cancer detection [7–9,11,12], were limited to the subjective assessment of image quality [10], used ERC imaging at 1.5 T as the benchmark [5,8–10], or did not use comparable imaging parameters or hardware across ERC and non-ERC protocols [6,10,12].

The paucity of data comparing diagnostic performance risks a default position of convenience and practicality, favoring the use of non-ERC protocols without understanding its effect on PCA detection. This uncertainty is reflected in a position offered in the recent revision of the Prostate Imaging-Reporting and Data System (PI-RADS, version 2) [13], which suggested that the “supervising radiologist strive to optimize imaging protocols to obtain the best and most consistent image quality possible with the MRI scanner used.” Although the committee may “strongly prefer, use, and recommend 3 T for prostate MRI,” the use of both 1.5 T and 3 T with or without an ERC were considered acceptable strategies for the detection of PCs [13]. This leaves clinicians and radiologists with a broad and uncertain set of options.

Thus, there remains a critical need for prospective data about the effect of the MRI protocol and use of ERC in the sensitivity of contemporary mpMRI, particularly for cancer detection. The objective of our study was to compare the sensitivity of 2 different non-ERC strategies vs. ERC MRI for the detection of tumors in men with suspected PCa.

2. Materials and methods

2.1. Eligibility criteria

Consecutive patients with a clinical indication for mpMRI of the prostate were invited to participate in this institutional review board–approved, Health Insurance Portability and Accountability Act–compliant, prospective, single-center study. Patients were invited during regular working hours when the study coordinator was available for consenting. Exclusion criteria included incomplete imaging datasets, contraindications to MRI or ERC or to both, and lack of direct radiological-histopathological correlation.

2.2. Imaging protocols

All patients underwent non-ERC T2-weighted imaging (T2WI) and DWI with a surface phased-array coil only followed immediately by insertion of the ERC and acquisition of our clinical mpMRI examination. Our clinical protocol consists of T2WI, DWI, and dynamic contrast-enhanced (DCE) imaging with both the ERC and the pelvic phased-array coil (ERC protocol). The non-ERC and ERC images for each patient were obtained in the same setting without removing the subject from the scanner. The second set of T2WI images and DWI represent the ERC clinical protocol routinely used at the authors’ institution. As DCE data were exclusively available for the ERC clinical protocol, these were not considered in this investigation.

All MRI studies were performed in 3-T scanners. To assess the effect of SNR on the performance of 2 different non-ERC protocols, patients were randomized using a 1:1 sequential strategy into 1 of 2 arms: (1) standard non-ERC protocol using the same imaging parameters as those of the ERC clinical protocol and meeting the minimum requirements recommended by the PI-RADS Committee [14]; and (2) augmented non-ERC protocol with twice as many signal averages. All other acquisition parameters were similar across non-ERC and ERC protocols (Supplemental Table S1).

Patients in both the arms underwent ERC imaging. The ERC imaging dataset was independently and prospectively reviewed by the attending radiologist covering the clinical schedule (1 of 6 radiologists with advanced body MRI training), who was blinded to the clinical information. Each radiologist interprets on average 3 ERC prostate MRI examinations per day when covering the clinical MRI service. Following a washout period of at least 3 months, the same radiologist reviewed the non-ERC imaging dataset. Each lesion was assigned a Likert scale score [15] by the interpreting radiologist and lesions with score ≥ 3 were defined as suspicious for cancer [16,17].

2.3. Standard of reference

Radical prostatectomy specimens served as the standard of reference. Gleason score, percentage of the prostate involved by tumor, and presence or absence of extraprostatic extension were tabulated. All specimens were prospectively analyzed by 1 of 3 experienced uropathologists using the report template recommended by the College of American Pathologists [18]. Imaging-pathology agreement was defined as the presence of cancer on radical prostatectomy specimen in the location (e.g., posterolateral right base) where an MRI lesion suspicious for cancer was identified.

In patients who did not undergo radical prostatectomy, combined systematic and targeted biopsy results were used as the standard of reference. Targeted biopsies were performed using a software-based MRI-transrectal ultrasound fusion system (UroStation, Koelis). Each biopsy was performed by 1 of 4 urologists with 3 years of experience with targeted biopsies. The targeted biopsy generally consisted of 2 or 3 cores from each target and was performed immediately after the systematic, 12-core systematic biopsies. For each target, the presence or absence of cancer, Gleason score, number of positive cores, and maximum percentage of core involvement by tumor were...
Imaging-pathology agreement was defined as the presence of cancer in the targeted cores, and absence of cancer in the systematic cores in the sextants other than the one where the target was located. Cancers were stratified into very low-risk, low-risk, intermediate-risk, and high-risk groups according to the version 2.2014 of the National Comprehensive Cancer Network guidelines [19]. Index lesion [20] was defined as the cancer focus with highest Gleason score in each patient; if the highest Gleason score was assigned to more than 1 lesion in the same patient, the index lesion was the largest lesion or the one associated with extraprostatic extension if present.

2.4. Statistical analysis

According to an a priori power analysis with a projected PCa prevalence of 80%, correlation between ERC and standard non-ERC of 0.3 and between ERC and enhanced non-ERC of 0.4, and a sensitivity of 80% for ERC, 40% for standard non-ERC and 50% for enhanced non-ERC, a sample size of 45 men (20 in the standard and 25 in the enhanced arm) would have a statistical power greater than 0.80 when testing the null hypothesis that there is no difference between the sensitivity of ERC, standard and enhanced non-ERC imaging for PCa detection. The diagnostic performance of each imaging approach was compared using generalized estimating equations with Bonferroni correction. Random effects were added to the per-sextant analysis to adjust for within patient correlation [21]. The per-sextant data were used to generate the receiver operating characteristic curves for each imaging strategy and compare the areas under these curves (AUC). Finally, we used linear mixed models with Bonferroni correction to compare the Likert scale scores assigned with each imaging approach in patients with confirmed cancer as a surrogate for level of reader confidence. These analyses were performed using SAS software version 9.4 (SAS Institute). A P < 0.05 was considered statistically significant.

3. Results

3.1. Patient cohort

Of the 173 men referred for mpMRI of the prostate between December 2014 and March 2015 at our institution, 78 men performed their examinations during business hours when the study coordinator was available for consenting and were invited to participate. A total of 13 patients chose not to participate and 16 of the remaining 65 patients were excluded because of the lack of direct radiological-histopathological correlation (i.e., no targeted biopsy or prostatectomy at the time of this report). Therefore, 49 patients met eligibility criteria and comprised our patient cohort (Fig. 1). The patient characteristics are listed in Table 1. The indications for MRI included biopsy planning (n = 35) and local staging of known cancer (n = 14). Overall, 47% (23/49) and 53% (26/49) were prospectively randomized to the standard non-ERC and augmented non-ERC arms, respectively. Cancer was detected in 74% (36/49) of the patients (74% [17/23] in the standard arm and 73% [19/26] in the augmented arm). Overall, 14% (5/36), 8% (3/36), 36% (13/36), and 42% (15/36) had very low-risk, low-risk, intermediate-risk, and high-risk tumors, respectively. Overall, 51% (25/49) of the men

![Fig. 1. Patient cohort. Flowchart of the criteria for eligibility and number (n) of men enrolled and randomized to each arm. mpMRI, multiparametric MR imaging; ERC, endorectal coil.](http://example.com/fig1.png)
underwent radical prostatectomy and 49% (24/49) men had combined targeted and systematic biopsies. Of the 25 men who underwent surgery, organ-confined (T2) disease, extraprostatic extension (T3a), and seminal vesicle invasion (T3b) were present, respectively, in 60% (15/25), 24% (6/25), and 16% (4/25) of the patients.

### 3.2. Diagnostic performance (per sextant)

On a per-sextant basis (Table 2), the sensitivity of the ERC protocol was higher than that of the standard non-ERC and augmented non-ERC protocols. No significant difference in sensitivity was noted between the standard and augmented non-ERC protocols.

No significant difference in specificity or accuracy was noted between the ERC and the standard non-ERC protocol; ERC and augmented non-ERC protocol; or standard and augmented non-ERC protocols.

The AUC (Fig. 2) of the ERC protocol was higher than that of the standard non-ERC and not significantly different of that of the augmented non-ERC (Table 2). No significant difference was noted between AUC of the standard vs. augmented non-ERC protocols.

### 3.3. Sensitivity and level of confidence for the detection of the index lesion

For the detection of index lesions (Table 3), the sensitivity of the ERC protocol was higher than that of the standard non-ERC and of the augmented non-ERC protocol (Fig. 3). When the 2 non-ERC protocols were combined and compared to the ERC protocol, the latter again demonstrated superior sensitivity (Table 3). No significant difference in index lesion sensitivity was noted between the standard and augmented non-ERC protocols.

Among the 28 patients with intermediate-risk or high-risk index lesions, ERC missed fewer (4%, 1/28) cancers than the standard non-ERC protocol (42%, 5/12) ($P = 0.02$), whereas no significant difference was noted between the number of lesions missed with ERC vs. augmented non-ERC protocol (25%, 4/16) ($P = 0.09$), or standard vs. augmented non-ERC protocol ($P = 1.0$).

An increased level of reader confidence for the detection of index lesions (i.e., higher Likert score) was found for the ERC protocol compared with either non-ERC protocol (Table 3).

### 4. Discussion

The use of a combined ERC and pelvic phased-array coil for T2WI and DWI provided superior sensitivity for the detection of PCa compared to 2 non-ERC MRI protocols. In addition to detecting fewer cancers, non-ERC imaging missed more intermediate-risk and high-risk tumors, although this difference was not shown to be significant for the augmented non-ERC arm likely secondary to an underpowered study for this particular secondary analysis.

Our results are in agreement with those from other investigators. Although retrospectively and with differences in hardware between ERC and non-ERC protocols, Turkbey et al. [6] reported sensitivity and positive predictive value of 76% and 80% for ERC vs. 45% and 64% for non-ERC imaging, respectively, using T2WI and DWI in 20 men who underwent radical prostatectomy in the only other paired-patient study available in the literature. Heijmink et al. [12] found a significant increase in the AUC for localization of PCa when MRI using the ERC only (0.68) was compared with a non-ERC MRI (phased-array coil alone) (0.62) in the same patient in a cohort of 46 men who underwent radical prostatectomy. Our study differs from most of the above

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**Table 1**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Number of subjects</th>
<th>Age, y (52–73)</th>
<th>PSA, ng/ml (2.5–35.6)</th>
<th>Prostate volume, ml (58–150)</th>
<th>Interval between MRI and biopsy or surgery, d (5–118)</th>
<th>Body mass index, kg/m² (29.3–30.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard non-ERC + ERC</td>
<td>23</td>
<td>63</td>
<td>7.9</td>
<td>58</td>
<td>55</td>
<td>29.3</td>
</tr>
<tr>
<td>Enhanced non-ERC + ERC</td>
<td>26</td>
<td>63</td>
<td>14.1</td>
<td>52</td>
<td>37</td>
<td>30.0</td>
</tr>
<tr>
<td>Overall</td>
<td>49</td>
<td>63</td>
<td>11.2</td>
<td>55</td>
<td>37</td>
<td>29.7</td>
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</table>

Means and range (within parentheses); PSA = prostate-specific antigen.

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**Table 2**

<table>
<thead>
<tr>
<th>Diagnostic performance of each imaging strategy for the detection of cancer on a per-sextant basis</th>
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<tr>
<td><strong>Comparison</strong></td>
</tr>
<tr>
<td>Sensitivity</td>
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<tr>
<td>Specificity</td>
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<td>Accuracy</td>
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<td>AUC</td>
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Although ERC imaging demonstrated superior sensitivity for PCa detection and increased reader confidence in our study, concerns for cost, workflow challenges, potential complications, and contraindications to the ERC remain a sound rationale to pursue non-ERC imaging strategies that can offer diagnostic performance comparable with that provided by 3-T ERC imaging. This could be attempted with further protocol optimization and the use of novel coil designs with improved SNR in the lower pelvis. Although our augmented non-ERC protocol did not match the ERC protocol in sensitivity for PCa detection, the results from such an augmented protocol are encouraging and seem to indicate that a combination of protocol optimization and further hardware developments may improve the diagnostic performance of the non-ERC examination to levels comparable to those of the ERC protocol. Until such refinements have been validated, however, an inferior sensitivity of a non-ERC strategy needs to be recognized when implementing MRI protocols in clinical practice.

Our study has some limitations. First, for those patients who did not undergo radical prostatectomy we used concurrent systematic and targeted biopsies as the standard of reference. The diagnostic accuracy of this approach for detection of PCa, however, has been validated [17,23]. Second, readers could not be blinded to the type of protocol because of the obvious presence of the ERC in one of the datasets, which may have influenced the subjective identification of suspicious regions. However, by introducing randomization for the non-ERC component in the study design reviewers were unaware of the particular non-ERC protocol used. Third, although the Likert scale has been previously validated as a predictor of PCa by our group [17] and others [24], its use may limit the reproducibility of our results elsewhere. The original version of PI-RADS, which was available at the time of the design of this study, had limited reported accuracy for PCa [24]. Fourth, we did not include DCE imaging—a component of the mpMRI protocol—because it is impractical to administer intravenous contrast twice to each patient on the same day. Focusing on T2WI and DWI, as we did, would seem acceptable as these sequences are considered the most important among those used for mpMRI of the prostate [13]. Given that the ERC protocol was used prospectively for clinical management, the potential for verification bias against the non-ERC protocol also needs to be recognized. Finally, it should be

Table 3
Sensitivity and level of reader confidence (expressed as the mean Likert scores) for the detection of index lesions

<table>
<thead>
<tr>
<th></th>
<th>Standard non-ERC</th>
<th>Enhanced non-ERC</th>
<th>Non-ERC overall</th>
<th>ERC</th>
<th>Comparison</th>
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</thead>
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<tr>
<td></td>
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<td>ERC vs.</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>standard</td>
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<td>enhanced</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>non-ERC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>non-ERC</td>
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<tr>
<td>Sensitivity</td>
<td>47%: 8/17</td>
<td>63%: 12/19</td>
<td>56%: 20/36</td>
<td>92%: 33/36</td>
<td>P = 0.001</td>
</tr>
<tr>
<td>Likert score (mean ± SD)</td>
<td>2.3 ± 2.3</td>
<td>2.9 ± 2.1</td>
<td>2.6 ± 2.2</td>
<td>4.2 ± 1.4</td>
<td>P &lt; 0.001</td>
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</table>

Fig. 2. Receiver operating characteristic curves for the detection of cancer with the standard non-ERC (green), augmented non-ERC (red), and ERC (blue) imaging protocols. Areas under the curve and comparisons are found in Table 3. ERC, endorectal coil.
noted that MRI protocol optimization is complex and requires adjustment of multiple parameters before satisfactory quality images can be obtained. In our study, we increased the number of signal averages and have not assessed further optimization with different parameters such as matrix, field of view, and slice thickness. It is possible that further protocol optimization would result in better diagnostic performance. As testing all available imaging parameters would result in an unmanageable number of permutations, we chose to compare 2 protocols with differences only in the number of acquisitions, which correlates proportionally with the SNR.

**Conclusion**

The ERC MRI protocol in our study was more sensitive than 2 non-ERC MRI protocols for detection of tumors in men with suspected PCa. Although optimization of non-ERC MRI protocols by increasing SNR seems to reduce the diagnostic performance gap compared to examinations with the ERC, those opting for a non-ERC MRI protocol need to recognize its potential limitations. However, the implementation of an optimized non-ERC MRI protocol as a screening tool or an intermediate step between positive screening and biopsy might help improve the clinical management of patients with clinically suspected PCa with a less invasive approach. Until then, nevertheless, an ERC MRI protocol should be favored in patients being evaluated for possible PCa. Further studies are needed to evaluate the potential role of further non-ERC protocol optimization, technical developments such as redesigned external coils, and the effect of such protocol choices on patient outcomes.

**Appendix A. Supplementary materials**

Supplementary material cited in this article is available online at http://dx.doi.org/10.1016/j.urolonc.2016.02.009.

**References**


