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ORIGINAL ARTICLE

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Feasibility and preliminary clinical tolerability of low-field MRI-guided prostate biopsy

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Abstract

Objective: We evaluate the clinical feasibility of a portable, low-field magnetic resonance imaging (MRI) system for prostate cancer (PCa) biopsy.

Methods: A retrospective analysis of men who underwent a 12-core systematic transrectal ultrasound-guided prostate biopsy (SB) and a low-field MRI guided transperineal targeted biopsy (MRI-TB). Comparison of the detection of clinically significant PCa (csPCa) (Gleason Grade [GG] ≥ 2) by SB and low field MRI-TB, stratified by Prostate Imaging Reporting & Data System (PI-RADS) score, prostate volume, and prostate serum antigen (PSA) was performed.

Results: A total of 39 men underwent both the MRI-TB and SB biopsy. Median (interquartile range [IQR]) age was 69.0 (61.5–73) years, body mass index (BMI) was 28.9 kg/m^2 (25.3–34.3), prostate volume was 46.5 cc (32–72.7), and PSA was 9.5 ng/ml (5.5–13.2). The majority (64.4%) of patients had PI-RADS ≥ 4 lesions and 25% of lesions were anterior on pre-biopsy MRII. Cancer detection rate (CDR) was greatest when combining SB and MRI-TB (64.1%). MRI-TB detected 74.3% (29/39) cancers. Of which, 53.8% (21/39) were csPCa while SB detected 42.5% (17/39) csPCa ($p = 0.21$). In 32.5% (13/39) of cases, MRI-TB upstaged the final diagnosis, compared to 15% (6/39) of cases in which SB upstaged the final diagnosis ($p = 0.11$).

Conclusion: Low-field MRI-TB is clinically feasible. Although future studies on the accuracy of MRI-TB system are needed, the initial CDR is comparable to those seen with fusion-based prostate biopsies. A transperineal and targeted approach may be beneficial in patients with higher BMI and anterior lesions.

KEYWORDS

low-field MRI, magnetic resonance, office-based MRI, prostate cancer, targeted prostate biopsy

1 | INTRODUCTION

Prostate cancer (PCa) remains a leading cause of death for males with a reported 1.4 million new cases and 375,304 deaths worldwide in 2020 alone.[1] The development of multiparametric magnetic resonance imaging (mpMRI) has revolutionized the diagnostic workup of PCa and paved the way for the development of MRI-based biopsy techniques such as in-bore and targeted MRI-guided biopsies.[2] These techniques are promoted for their higher detection rate of clinically significant PCa (csPCa) and lower detection rate of insignificant PCa compared to systematic biopsy (SB) such as transrectal ultrasound-guided prostate biopsy (TRUSBx).[3] In the last decade, fusing real-time ultrasound with pre-acquired mpMRI has gained traction in PCa biopsy procedures; the protocol combines the benefits of MRI and ultrasound, while imposing some tradeoff.[4]

Although MRI-ultrasound fusion biopsy (FB) has a higher accuracy with reported overall detection rates and csPCa detection rates (CDR) of 43%–51% and 24%–33%, respectively, and samples a fewer number of cores, there is a steep learning curve in registering between disparate imaging modalities in real-time, and gland deformation from the rectal probe which may result in significant target registration errors.[5,6] Halstuch et al. characterized the FB learning curve and found that proficiency is attained after more than a 100 transrectal FB prostate biopsies.[6] The low-field MRI system (Promaxo©) coregisters the diagnostic preprocedural mpMRI with day-of-procedure MRI and identifies the lesion targets based on brachytherapy grid template coordinates therefore avoiding cross modality registration and anatomic deformation from patient positioning. In the initial assessment of navigation accuracy of the low-field MRI system on prostate phantom model, the low-field MRI system had lower average registration errors (1.84–2.57 mm) compared to those reported for FB (3.25–3.94 mm).[7–9] In fact Hu et al. found registration errors to over 6 mm in some systems.[10] Utilizing a low field MRI system can potentially avoid cross-modality registration therefore minimizing the experience of the operator as a factor in biopsy error.

Therefore, we evaluate the clinical feasibility of the portable, low-field MRI for transperineal MRI-guided targeted PCa biopsy (MRI-TB). We defined feasibility as a study design that can be handled in clinical settings and allow us to gain early insight on the oncological outcome during the development process of the low-field system. This study represents the final cohort of a previous published study consisting of 16 men who underwent both SB and MRI-TB however the previous data did not comprehensively discuss the oncological outcome. This study will focus on the oncological outcomes of an expanded cohort utilizing MRI-TB system.[11]

2 | METHODS

2.1 | Study objective

To assess the feasibility of MRI-TB in a small cohort by evaluating the cancer detection rate (CDR) of MRI-TB and SB. Second, we will compare the rate of csPCa upgrading from MRI-TB to standard SB by TRUSBx.

2.2 | Patient cohort

Men with an elevated prostate serum antigen (PSA) ≥ 4 ng/ml or abnormal digital rectal exam who were referred to a single community site for a prostate biopsy between December 2020 and February 2022 were screened for candidacy. This study is an extension and inclusion of a previously reported cohort.[11]

2.3 | Study design

All men underwent a pre-biopsy 3 Tesla (T) mpMRI without an endorectal coil which complied with Prostate Imaging-Reporting and Data System (PI-RADS) v2. Other inclusion criteria for participation in the study included: (a) appropriateness for transperineal prostate biopsy as recommended by the urologist, and (b) no prior previous biopsies at least 3 months before the scheduled procedure. The study was institutional review board (IRB) approved (Western IRB #20203968) and HIPAA-compliant. Written consent from the patient was required to participate.

2.4 | Low-field MRI system and biopsy procedure

Patients were administered general anesthesia, as per the Mississippi Urology clinic standard protocol for patients undergoing transperineal procedures, including prostate biopsies. Patients were given ceftriaxone and gentamicin day of the procedure, then a week of cipro or Bactrim post op. Patients underwent the low-field MRI-TB procedure followed by the standard of care TRUSBx. The entire procedure was conducted under the supervision of a board-certified urologist (J. A.) trained on the use of the low field MRI System.

The Promaxo MRI System is a United States Food and Drug Agency (USFDA) cleared, single-sided MRI operating between 58 and 74 mT designed for MRI-TB without an endorectal coil as previously described.[9,11,12] Once 3 T mpMRI is obtained, a board-certified radiologist with more than 10 years of experience in prostate MRI identified and annotated regions of interest (ROIs) for each patient. All annotations were performed using the standalone Promaxo DICOM Viewer. Annotated DICOM images were uploaded to the low-field MRI System before the MRI-TB procedure.

For the MRI-TB procedure, patients were placed in a high-lithotomy position with the perineum centered in the axial MRI field of view (120 mm) (Supporting Information: Figure 1). A transperineal template grid was placed on the perineum and a 5-channel surface receive coil was positioned over the pelvic region. MRI-visible fiducials with an additional single channel, dedicated receive coil were rigidly placed around the template grid for localization on the low-field image.

The MRI protocol starts with a localizer scan (three dimensional [3D] cartesian sampled RARE spin echo sequence; TR/TE = 1200/46 ms; echo train length [ETL] = 8; number of excitations [NEX] = 2; 50% undersampling with a fully sampled calibration region) to locate the prostate and ensure proper patient positioning. Once positioning was confirmed, a T2-weighted image (T2WI) was acquired (3D radially sampled RARE spin echo sequence; TR/TE = 1500/15.3 ms; ETL = 7; NEX = 1). 40 slices of T2W images with a 2.8 mm slice thickness and reconstructed FOV of 180 mm, resulting in an approximate voxel size of 1.5 × 2.0 × 2.8 mm (approximately 9 cc).

Following image acquisition, template calibration was performed, with MR-visible markers on the physical template biopsy grid manually identified on the T2WI. Previously acquired 3 T images were then manually coregistered with the newly acquired T2WI using the graphical user interface on the low field system. The system overlays a virtual version of the physical template, which allows the urologist to view the needle location if inserted through each template location along a straight line. After completing registration of 3 T and low-field MRI, the urologist identified biopsy target(s) within each ROI. Corresponding planning guidance (template coordinates and needle insertion depth) was provided for each target location on the Promaxo user interface. After planning all targets, needle(s) were inserted transperineally (without real-time monitoring), and tissue samples were extracted. Using the low field MRI, cores were extracted from a maximum of three biopsy targets for each patient. A 20 cm biopsy gun with an 18 G biopsy needle and either a 13 or 17 G cannula (Becton; Dickinson and Company) was used for the MRI-TB procedure. Images of patient positioning and the transperineal template grid can be found in our previous publication.[8]

2.5 | SB procedure and pathology

The 12-core TRUSBx procedure was performed immediately after the MRI-TB with the samples collected and sent along with the MRI-TB biopsy cores to a third-party reference laboratory for pathologic analysis. Standard light microscopic examinations of hematoxylin and eosin (H&E)-stained tissue sections were performed as part of pathologic analysis.

2.6 | Statistical methods

A retrospective analysis of the prospectively collected data was performed. Results are reported in accordance with the Standards of Reporting for MRI-targeted Biopsy Studies recommendations. In evaluating the 2 biopsy methods, we compared the detection of csPCa (defined as Gleason Grade [GG] ≥ 2) by SB (TRUSBx) or by low field MRI-TB, stratified by PI-RADS version 2 score, prostate volume, and PSA, using the McNemar paired test. All tests were 2-sided with an α of 0.05 for statistical significance.

3 | RESULTS

Patient characteristics are shown in Table 1. A total of 39 men underwent both the MRI-TB and SB procedures. Median (interquartile range [IQR]) age was 69.0 (61.5–73) years, body mass index (BMI) was 28.9 kg/m^2 (25.3–34.3), prostate volume was 46.5 cc (32–72.7), and PSA was 9.5 ng/ml (5.5–13.2). The majority (64.4%) of patients had PIRADS ≥ 4 lesions on prebiopsy MRI and 25% of lesions were anterior on MRI. Median (IQR) region of interest (ROI) was one (1–1) lesion per patient. Of note, no complications were reported.

The CDR by both methods was significantly higher in men with PI-RADS scores of 4 (17 of 22 men [74%]) or 5 (5 of 6 men [83%]) than men with a score of 3 (3 of 11 men [18%]; $p = 0.01$). MRI-TB detected significantly more csPCa in men with PI-RADS score of 4 or 5 ($p = 0.02$), and there was no difference in the CDR in men with PI-RADS 3 ($p = 0.09$) (Figure 1). Overall, MRI-TB detected 74.3% (29/39) cancers including GG < 2.

TABLE 1 Patient demographics.

N	39	100%
Age, years[a]	69	(61.5–73)
BMI	28.9	(25.3–34.3)
Race, *n* (%)		
White	24	61.5%
Black	15	38.5%
Hypertension	25/39	64.1%
DM	5/39	12.8%
Biopsy naïve	25/39	64.1%
PSA, ng/ml[a]	9.5	(5.5–13.2)
Prostate volume by mangetic resonance imaging, cm^3[a]	46.5	(32–72.7)
PIRADS		
3	16	36.4%
4	22	50.0%
5	6	13.6%
ROI per patient[a]	1	(1–1)
No. of region of interest		
1	29	74.4%
2	8	20.5%
3	2	5.1%
Maximal diameter of index lesion	8.3	(6.6–10.8)
Location of index lesion		
Anterior	10	25.6%

Abbreviations: DM, Diabetes Mellitus; PI-RADS, Prostate Imaging–Reporting and Data System; ROI, region of interest.
[a]Value reported as median (interquartile).

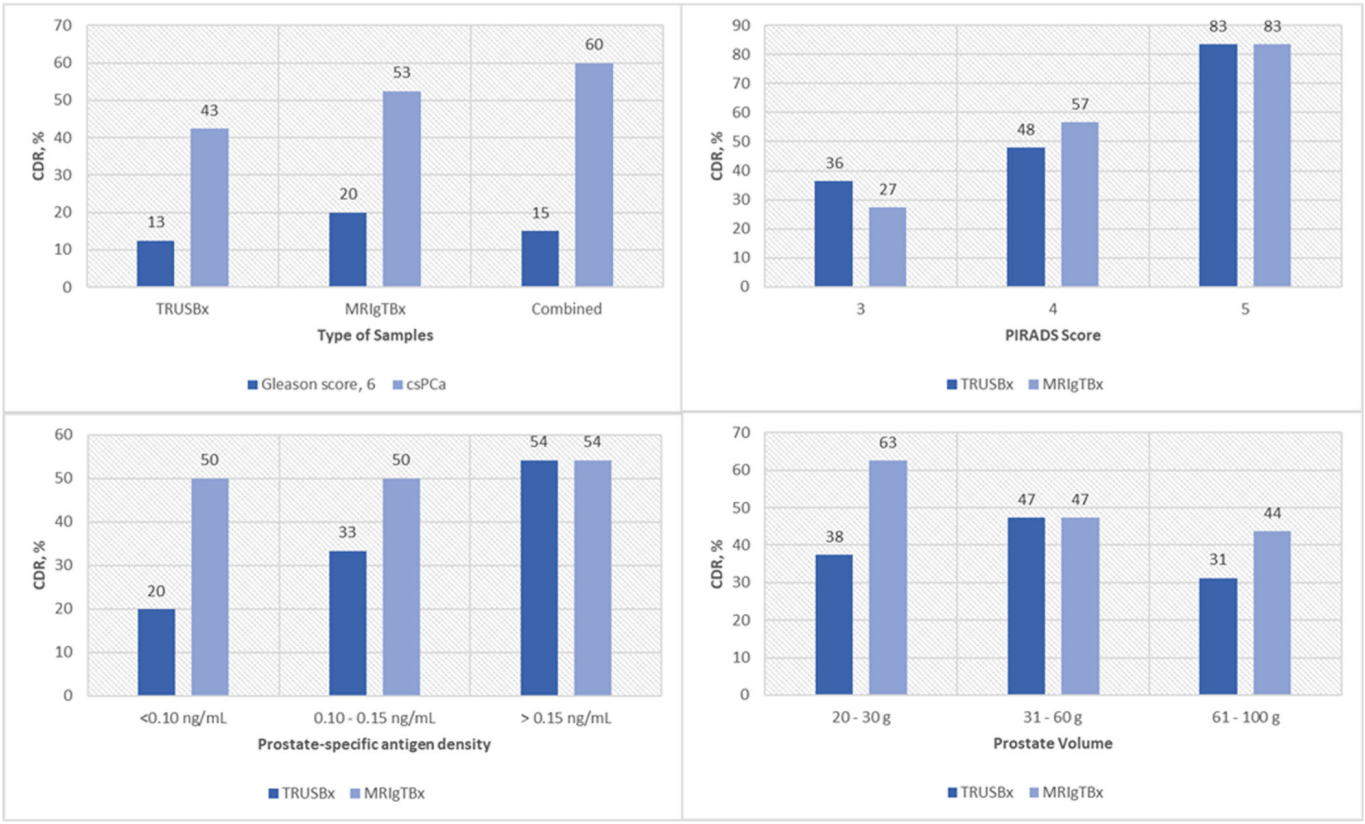

FIGURE 1 (A) Cancer detection rate (CDR) stratified by TRUSBx, MRI-TB and combined. There was no significant difference in CDR between TRUSBx and MRI-TB biopsy method ($p = 0.21$) (B) CDR stratified by Prostate Imaging Reporting & Data System (PI-RADS) version 2 grade. There was no significant difference when comparing CDR by PI-RADS 3, 4, or 5 categories ($p = 0.16$, $p = 0.50$, $p = 1.0$, respectively). (C) CDR stratified by PSAD. There was no difference when comparing CDR by PSAD by <0.10, 0.10–0.15, and >0.15 ($p = 0.08$, $p = 0.32$, $p = 1.00$, respectively). (D) CDR stratified by prostate volume size. There was no significant difference when comparing CDR by prostate volume 20–30 g, 30–60 g and 61–100 g ($p = 0.16$, $p = 1.00$, $p = 0.16$). MRI-TB, magnetic resonance imaging-guided targeted PCa biopsy; TRUSBx, transrectal ultrasound-guided prostate biopsy. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Compares CDR from MRI-TB and the final biopsy pathology.

		MRI-TB					
		No cancer	GG 1	GG 2	GG 3	GG 4	GG 5
Final pathology	No cancer	100%	0%	0%	0%	0%	0%
	GG 1	17%	83%	0%	0%	0%	0%
	GG 2	9%	27%	64%	0%	0%	0%
	GG 3	0%	0%	20%	80%	0%	0%
	GG 4	0%	0%	0%	0%	100%	0%
	GG 5	0%	0%	17%	0%	0%	83%

Note: In 32.5% (13/39) cases, MRIgTBxMRI-TB upstaged the final diagnosis, compared to 15% (6/4039) of cases in which SB upstaged the final diagnosis.

CDR was greatest when combining SB and MRI-TB (64.1%). MRI-TB detected 53.8% (21/39) csPCa while SB detected 42.5% (17/39) csPCa ($p = 0.21$) (Table 2). In 32.5% (13/39) of cases, MRI-ıB upstaged the final diagnosis, compared to 15% (6/39) of cases in which SB upstaged the final diagnosis ($p = 0.11$).

The procedure time for MRI-TB has three major components: preprocedure, which includes patient preparation; intra-procedure, which includes scan time with MR; and postprocedure. The pre-procedure time is similar to standard biopsy, except for an additional screening of patients for MRI compatibility. The average intraprocedure time with the first scout scan after the patient is positioned to needle placement totaled to 22 min per patient. A major contributor to the intraprocedure time is the T2W scan to guide the biopsy, which takes on average about 18 min.

After the targets are located, the time for final needle placement and biopsy averaged 12 min. The postprocedure activities averaged 24 min (Supporting Information: Table 1). The average procedure time for TRUSBx was 5–10 min which includes positioning, administration of local anesthetic, and patient-care counseling.

4 | DISCUSSION

MRI-TB detected 53.8% (21/39) csPCa with a sensitivity of 0.84 which comparable to that reported of other fusion biopsies techniques (vs. 0.86–0.92).[13] In our study, MRI-TB detected 10% more cases of csPCa compared to TRUSBx, which is comparable to the 10%–12% difference reported in previous trials.[14,15] Additionally, in 32.5% (13/39) cases, MRI-TB upstaged the final diagnosis, exceeding the 15% (6/39) of cases upstaged by TRUSBx. Therefore, we are able to demonstrate the feasibility of low-field MRI-TB in this pilot feasibility study.

MRI-TB had a higher CDR compared to TRUSBx (60% [6/10] vs. 40% [4/10], respectively) in patients with anterior lesions on MRI. Anterior lesions made up 25% (10/39) of the cohort which is higher than that previously reported (10%–15%).[16,17] In all 10 men with exclusively anterior lesions, MRI-TB detected PCa. MRI-TB utilizes a transperineal approach, which is known to offer better sampling of the anterior and apical area of the prostate.[17,18] Additionally, the majority of the cohort was obese obese (BMI > 25) (87.5%, 35/39), implying that a targeted transperineal technique could be more favorable. Gold et al. retrospectively compared prostatectomy specimens with TRUSBx and target biopsy result in 487 patients. They demonstrated that, in obese patients, targeted biopsy was better able to predict final GS than TRUSBx (60% vs. 47%, $p = 0.0474$, odd ratio 1.67 [1.00–2.80]).[19] Because of body habitus and positioning, it is often difficult to visualize the prostate on TRUSBx. Obese patients tend to be underdiagnosed and, at the time of diagnosis, tend to present with higher grade PCa and upstaging.[20–22] Also, adipose tissue makes visualization on ultrasound difficult, which may affect the fusion aspect. Using this low field MRI system avoids the cross-modality registration of the diagnostic MRI images to the volumetric TRUS image and may thus be beneficial in this population.

Our results confirm that SB cannot be omitted, as 15% of csPCa may be missed. To investigators interested in focal therapy, SB is an essential step to exclude csPCa in mpMRI-negative areas and to ensure that the patient truly has a discrete lesion suitable for focal therapy. As systematic biopsies might overlap into MRI suspicious areas, the true utility of these systematic biopsies that only include nontargeted areas remain unclear. Lee et al. showed that nontargeted SB had a csPCa detection rate of 21% and found that omitting SB (excluding overlapping cores into the MRI lesion) would only result in only 3% of patients having csPCa missed.[23] A transperineal approach would be more favorable. A recent meta-analysis concluded that both approaches have similar diagnostic accuracy however systematic transperineal template biopsies have a lower risk of infection and rectal bleeding compared to transrectal approaches.[24] Additionally, transperineal approach can potentially reduce total cost in the active surveillance cohort by reducing the number of future biopsies. In a retrospective study of 671 men with negative biopsies, men who underwent transperineal systematic biopsies had three times lower rate of rebiopsy compared to those who underwent transrectal biopsies.[25]

Although currently the system does not allow real-time assessment of needle positioning during the procedure, the next step for the low-field MRI system is to apply it as a system to monitor real-time treatment with temperature mapping, such as in the use of ablation therapy for PCa. Currently real-time temperature monitoring using thermistors with ultrasound guidance is cumbersome and poorly studied. Using MRI-ultrasound fusion as an imaging modality for real-time monitoring has been proposed previously, but most of the data examining its viability consist of small feasibility cohorts. Although an MRI-ultrasound fusion modality may seem more cost-effective short term, co-registration of images obtained in the same axial orientation of similar modalities may require less training, compared to the training required for traditional FB procedures registering ultrasound with MRI images.

Small sample size is a limitation of our study. Image quality and MRI-TB scan time also represent additional challenges to wider clinical adoption of this approach in its current state. We emphasize that this is a preliminary report on an initial experience with the low-field MRI system, and as such, our study lacks the statistical power to evaluate whether the improvement in CDR with MRI-TB is statistically significant. In the future, it will be important to evaluate a larger cohort and to compare results with FB to gain a better understanding of the advantages of MR–MR over MR-ultrasound registration. With ongoing technological developments in the utilization of artificial intelligence for automatic registration, we anticipate that improvements aiming to enhance imaging quality and shorten MRI-TB scan time will streamline the procedure and eventually allow for progression to fully outpatient settings.

Our experience demonstrates that the low field MRI system is feasible in a community practice where neither FB nor transperineal biopsy is traditionally performed. Two to three days of system training were offered, and a clinical specialist accompanied each procedure. There is no published data on the learning curve of the system but by the end of 1 month, our single surgeon felt comfortable operating the system without a clinical specialist. The low-field and compact configuration of the MRI allows the MRI magnet and electronic cart to be placed in the same room where the TRUSBx is performed, with little to no adaptation (e.g., no shielding for the magnetic field or reconfiguration of electrical outlets). This setup mitigates the costs associated with housing the magnet, and obviates the need for dedicated MRI electronics rooms, special quench vents for cryogens, and dedicated MRI technologists. Currently there is minimal published data on the oncological outcome of the system.[11] Therefore, this is the first comprehensive report of the oncological outcomes of the system.

The Promaxo system's average navigation errors are below the clinically significant threshold of 5 mm, the TRE from registration found to be clinically acceptable, and nonrigid registration is not required.[9,12] Previous study Nasri et al. focused on the clinical workflow and technical aspect of the system. Briefly it reported basic characteristics of 16 men accrued at that time. Of note, these 16 men were included in this final cohort report. Selin et al. also reported further details on the Promaxo MRI system and navigation accuracy in prostate phantom studies in different size prostates. In five 3D models targeted lesions were identified by two urologists results in targeted registration errors that ranged from 2.05 to 2.57 mm depending on target definition. Further assessment of the systems accuracy was performed in a small cohort of 5 men with PCa. The lesions in this cohort was determined by four prostate MRI radiologists and the accuracy was slightly better with an error of 1.84 mm (95% confidence interval 1.27–2.41). These two studies imply that targeting the lesions do not require prior technical expertize but rather identification of lesions on the 3 T mpMRI.

5 | CONCLUSIONS

Low-field MRI-TB system is clinically feasible. Although future studies on the accuracy of MRI-TB are needed, the initial CDR is comparable to those seen with fusion-based prostate biopsies. A transperineal and targeted approach may be beneficial in patients with higher BMI.

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CONFLICT OF INTEREST STATEMENT

Poorvi Sayta, Aleksander Nacev, and Dinesh Kumar are Promaxo employees. Bilal Chughtai is a consultant for Allerga, Boston Scientific and Promaxo. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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