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Robotic-assisted transrectal MRI-guided biopsy. Technical feasibility and role in the current diagnosis of prostate cancer: an initial single-center experience

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Abstract

Objectives To evaluate the potential clinical and technical utility to manage in practice the use of a robotic MRI in-bore-targeted prostate biopsies in the current work-up of prostate cancer diagnosis.

Methods Thirty patients with a single cancer suspicious lesion interpreted on MRI using PI-RADSv2.1 category ≥ 3 underwent in-bore robotic transrectal MRI remote-controlled-guided biopsy. It was analyzed the technical success, clinical details, biopsy findings in correlation with the MRI examination, complications and cancer detection rate (CDR).

Results The overall CDR for any cancer was 73% (22/30). It was 86% (19/22) for significant tumors (Gleason score of more than 6 or maximum cancer core length greater than 3 mm for Gleason 6) and 77% (17/22) for tumors with Gleason > 6. CDR for biopsy-naïve patients was 89% (16/18) and 50% (6/12) for patients with prior negative transrectal ultrasound-guided biopsies. The CDR for PI-RADS > 3 was 92% (22/24). All the lesions ($n = 30$) were reachable with the robotic MRI device. A self-limited rectal hemorrhagic complication was reported.

Conclusion This initial data show that a robotic MRI-guided biopsy could be useful, efficient and feasible procedure in the new paradigm to diagnose significant prostate cancer in selected patients.

Keywords Prostate cancer · Magnetic resonance imaging · Biopsy · Robotics

Introduction

Prostate multiparametric magnetic resonance imaging (mpMRI) has come to the forefront of prostate cancer (PCa) diagnosis over the last decade. mpMRI addresses the shortcomings of the prostate biopsy while providing several other advantages. mpMRI allows some men to avoid an immediate biopsy and permits visualization of areas likely to harbor clinically significant cancer prior to biopsy to facilitate use of MR-targeted prostate biopsies. This allows for reduction in diagnosis of clinically insignificant disease as well as improved detection and better characterization of higher risk cancers [1].

Some guidelines have recently supported to include mpMRI for biopsy-naïve patients, such as the European Association of Urology [2], while others include mpMRI as optional before biopsy, such as the North America NCCN guidelines [3]. The main role of mpMRI is to detect clinically significant prostate cancer (csPCa) and avoid to detect insignificant cancer [4]. It is well established the accuracy to detect csPCa on mpMRI from the multiple studies published [5, 6]. Nevertheless it should be recognized the results of studies have been undertaken in high-volume expert centers, with the advantages of state-of-the-art equipment, optimized protocols, and highly experienced subspecialized

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radiologists, may not be applicable to clinical practice everywhere. For multiparametric MRI and MRI-directed biopsy to deliver the intended pathway benefits, the quality of the entire diagnostic process must be ensured by having robustly trained technologists, experienced radiologists, and practitioners who conduct MRI-directed biopsy while working within multidisciplinary teams.

Current guidelines still recommend systematic biopsies as a supplement to target biopsies on biopsy-naïve patients. Target biopsies (TB) only are recommended on patients with previous negative biopsies [2]. Nevertheless changing continuous paradigm on PCa diagnosis are evolving and individual MRI-directed biopsies could be deployed in a first-line diagnostic strategy [7]. It is recognized that finally an individualized approach needs to be adopted and different MRI-directed biopsy strategies can be deployed. The key point is that prostate MRI and MRI-directed biopsy is a worthy first-line diagnostic strategy, backed up by systematic biopsy, used alone or as a supplement to target biopsy, depending on individual patient risk and patient preferences [7].

Different target biopsy techniques can be used: in-bore MRI-TB, performed in the MRI scanner, MRI-TRUS (Transrectal Ultrasound) fusion TB (FUS-TB) and cognitive TRUS TB (COGTB) [8]. The initial in-bore MRI-TB technique was challenging due to impracticalities (such as availability, required expertise, time-consuming and costly nature) [9]. To overcome these limitations, technical advances have developed MR-compatible manipulators for in-bore-guided biopsy to be performed using a robotic assistance device; which has been shown higher accurate success [10–12] than previous ones and with a short MRI room occupation time. The purpose of this study was to evaluate the potential clinical and technical utility to manage in practice robotic-assisted MRI in-bore-targeted prostate biopsies in the current work-up of prostate cancer diagnosis.

Materials and methods

The prospective study was approved by the institutional review board, and informed consent was waived. Men with a single focal prostate abnormality detected on bi or multiparametric MRI were included from July 2019 to March 2020 (Fig. 1). The decision to refer patients for direct MRI-guided prostate biopsy was made by the referring physician, on patients with a mpMRI Prostate Imaging Reporting and Data System (PI-RADS 2.1) category ≥ 3 target lesions. All patients underwent biopsy after an initial diagnostic endorectal bi or multiparametric MRI examination, performed in less than 4 weeks, revealed one target lesion. Our standard endorectal 1.5-T (Signa Horizon HDx; GE Medical Systems, Milwaukee, Wis, USA) bi-multiparametric MRI protocol

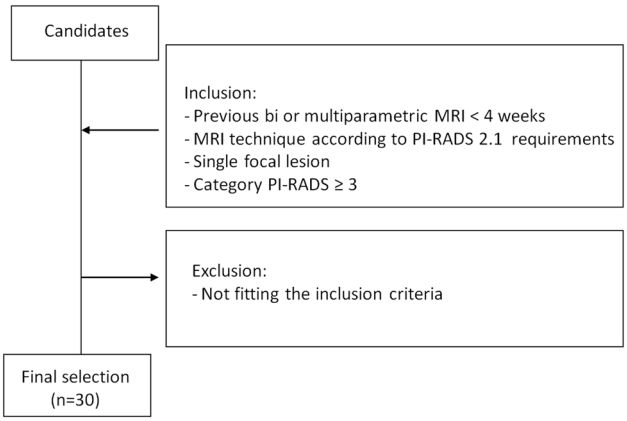

Fig. 1 Flow diagram of patient selection

was performed for 23 patients according the recommendations from PI-RADS 2.1 guidelines [13]. The other seven patients underwent bi-multiparametric MRI performed at outside institutions, and these studies were imported into our institutional PACS (Impax, Agfa). Outside studies were reviewed by two attending radiologists, with 24 and 11 years experience in prostate MRI and biopsy procedures, and were only used for target identification if the studies included T2-weighted, diffusion-weighted and/or DCE (dynamic contrast enhanced) images and if both radiologists considered the studies of diagnostic quality according to the PI-RADS 2.1 requirements [13]. The same two attending radiologists reviewed all images (internal and external) on a PACS workstation and identified the biopsy target by consensus. The consensus identification of target by both readers was performed prospectively, to ensure that both readers (who were also the radiologists performing the biopsies) were in agreement regarding patient selection before scheduling of the biopsy procedure.

In 12 patients (12/30, 40%), a previous biopsy showing no cancer had been performed 1–2 years before robotic-assisted MRI-guided biopsy. The remaining 18 patients were biopsy-naïve and were scheduled for robotic-assisted MRI-guided biopsy.

Biopsy technique

All biopsies were performed using a remote-controlled manipulator robot MRI-compatible device (Soteria Medical BV, Arnhem, the Netherlands) [10]. The robot is placed between the patient's legs on the MRI table (Fig. 2). In combination with a stand-alone computer and dedicated interventional software for planning purposes (Fig. 3) and remote control, the manipulator positions the needle guide (Fig. 2) relative to the suspicious area by using the acquired images. This combination allows for a quick interaction to fine-tune the needle guide relative to the gland to adjust for

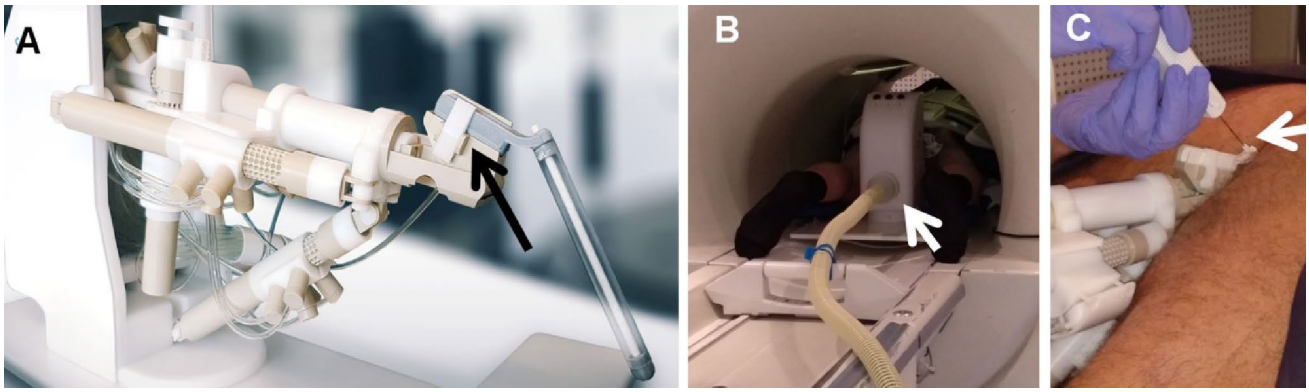

Fig. 2 Robotic remote-controlled manipulator for in-bore prostate biopsy. **a** After the needle guide is inserted rectally is attached at front of the device (arrow). The device includes the motors to move the position of the needle guide remotely. **b** Set-up of the remote-controlled manipulator device (arrow) positioned between the patient's leg on prone position on the MRI table inside the magnet. **c** After the desired target for biopsy is selected, the table is moved out of the bore and a biopsy sample is taken with a standard compatible biopsy gun. The precise position to place the biopsy gun needle (arrow) according to the distance from the distal tip of the guide and lesion is provided by the planning software (Fig. 3)

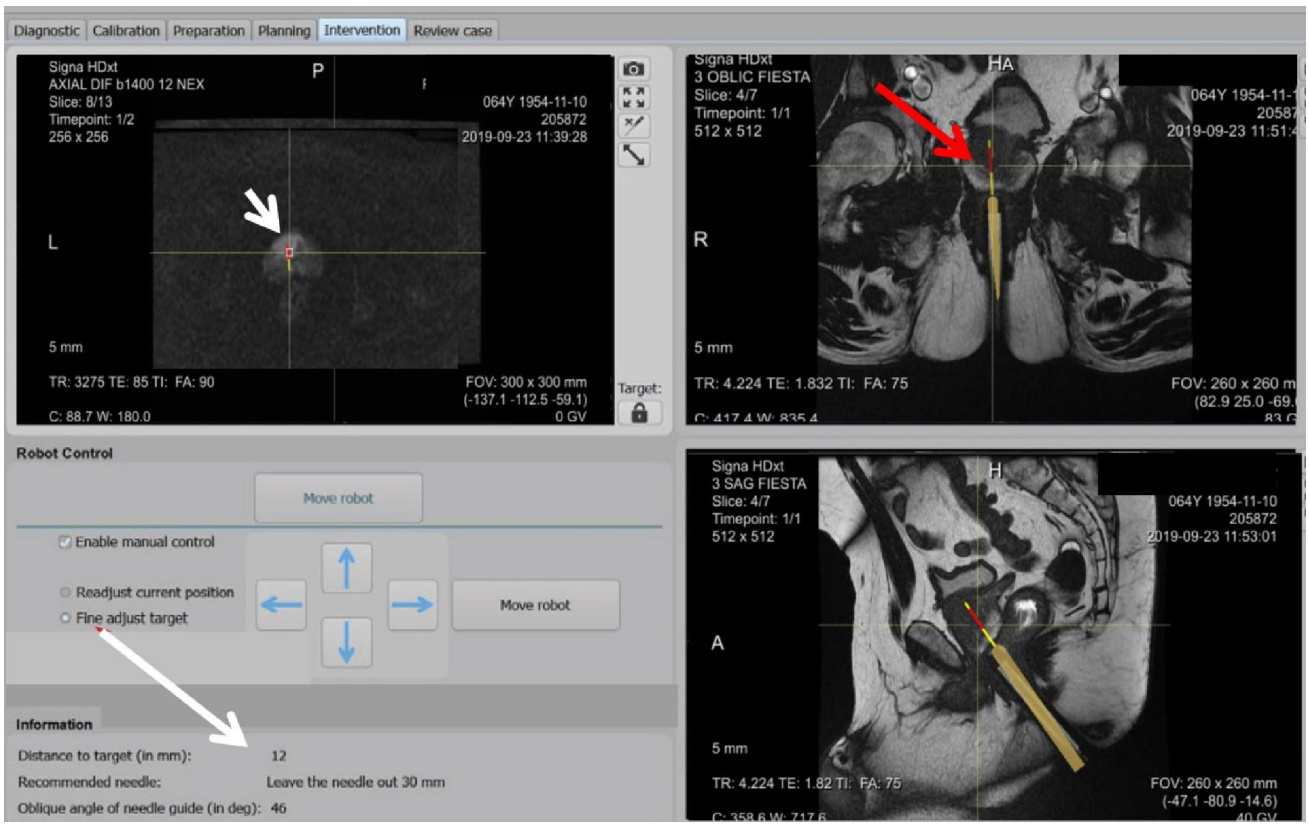

Fig. 3 Screenshot oft the planning software accompanying the remote-controlled manipulator. The desired and planned target for the ill defined nodule of 2 cm is shown on the right transition zone with restricted diffusion on DWI image (short arrow). The current position of the needle guide is represented by the orange line overlay from the needle guide with the optimal path after the remote movement of the guide. The needle track and sample core are represented by yellow and red line, respectively (red arrow). The measurements of the distance from the distal tip of the guide and the lesion are provided automatically by the software (long arrow). The biopsy was from a 64-year-old man with prostate-specific antigen value of 13.2 ng/mL with two previous negative biopsies. Histopathologic examination revealed a Gleason 7 (4 + 3) carcinoma

either patient motion or tissue obstruction. The stand-alone computer and controller are located in the control room next to the MR console. The second part is a controller unit (comprising a computer, motion control elements, and electropneumatic and electronic interfaces) located outside the MRI room. The robot and the controller are connected by plastic tubes. Compressed air, generated by a compressor outside the MRI room, is delivered to the robot through these plastic tubes, to activate the motors, which permits the alignment of the needle guide and the lesion.

Antibiotic prophylaxis was started the day before the biopsy and was given for 48 h. Biopsies were performed with the pelvic phased array coil. Patients were placed in the prone position for the biopsy, which was performed without local anesthesia, a lubricated MRI-compatible needle guide was inserted intrarectally, and the needle guide was attached to the robot (Fig. 2). Short (20 s) fast imaging employing steady-state acquisition (FIESTA) sequence (Steady-State Free Precession: TR 4.2 ms, TE 1.8 ms, thickness - gap 4–1 mm, 7–10 sections, FOV 260 mm^2, acquisition time 20–25 s) was used for fast control imaging. Slices were aligned with the MR-visible needle guide (tilted axial and oblique sagittal). FIESTA images were sent to the dedicated interventional software, which automatically detected the needle guide and displayed its position with a color overlay on the MR images. T2-weighted and DWI with ADC images were also acquired to better localize the lesion.

After the desired target for biopsy was selected on T2, DWI and ADC images, a graphic overlay of the new position was displayed, and motion of the robot was activated remotely. Motion of the robot was repeated until the needle guide was correctly aligned with the lesion. Confirmation of the accuracy of tumor relocalization was performed with FIESTA acquisition (Fig. 4). The table was then moved out of the bore and a biopsy sample was taken with a standard compatible biopsy gun (200 mm - 18 G) (Fig. 2). Two cores were obtained from each target lesion. Patients were discharged 2 h after the biopsy procedure was performed, if their vital signs were stable and if they had successfully urinated. Adverse events were reported and complications were classified according to the modified Clavien system for reporting surgical complications [14]. All biopsies were fixed in 10% buffered formalin and evaluated by a urogenital pathologist with 29 years experience on prostate cancer. All biopsy samples that were positive for PCa were assigned a Gleason score (GS). The final histology result following this assessment was used for outcome purposes. A tumor was considered significant according to two definitions: first, the University College of London (UCL) definition (i.e., any Gleason grade 4 component in the biopsy core or a maximum cancer core length (MCCL) > 3 mm); and second, the presence (any percentage) of a Gleason grade 4 component in a biopsy core [15].

Statistical analysis

Statistical analysis was performed using SPSS software (version 23.0, IBM). Continuous values are expressed as means with SDs and categoric variables as counts and percentages.

Results

Thirty men (mean age, 66 ± 7 [SD] years, range 51–81) were included in the study. Mean PSA level were 13,1 ± 21 [SD] ng/mL (range 4–120). All patients clinical, and MRI characteristics are shown in Table 1. All the lesions ($n = 30$) were reachable with the robotic MRI device and biopsy was performed in all patients after the software-based adjustments of the robot of the needle guide.

Twenty-four lesions (24/30, 80%) originated in the peripheral zone (PZ) and 6 (6/30 20%) in the transition (TZ)/central zone (CZ) (2 lesions in the CZ and 2 lesions anterior in the TZ). Two lesions of the PZ were in the anterior horn of the PZ. The 22 posterior PZ lesions were located 11 posterolateral, according to the sector map of PI-RADSv2.1 [13].

The overall cancer detection rate (CDR) for any cancer was 73% (22/30). It was 86% (19/22) for significant tumors (Gleason score of more than 6 or maximum cancer core length greater than 3 mm for Gleason 6) and 77% (17/22) for tumors with Gleason > 6. CDR for biopsy-naïve patients was 89% (16/18) and 50% (6/12) for patients with prior negative transrectal ultrasound-guided biopsies (Table 2). CDR for significant tumors and non-significant tumors was higher for biopsy-naïve patients, 74% (14/19) and 67% (2/3) respectively, than for negative previous biopsy 26% (5/19) and 33% (1/3) respectively (Table 2). All the PI-RADS score 3 ($n = 6$) were negative for prostate cancer (Fig. 5). The CDR for PI-RADS > 3 was 92% (22/24). Histopathologic negative biopsy negative results were: glandular atrophy ($n = 2$), normal gland with fibromuscular stroma ($n = 3$), fibromuscular stroma, prostatitis and high-grade prostatic intraepithelial neoplasia (HGPIN).

Our median procedure time was 35 min with a range of 24–59 min. The total procedure time was defined from the acquisition of the first localizer to the last confirmation image with the biopsy needle in situ.

A minor adverse event was refereed, classified as Clavien Grade 1, rectal bleeding 24 h after the procedure which was self-limited. This patient had the lesion lateral at the base, in the central zone nearby the vascular bundle, which might had puncture of the vessel during the procedure.

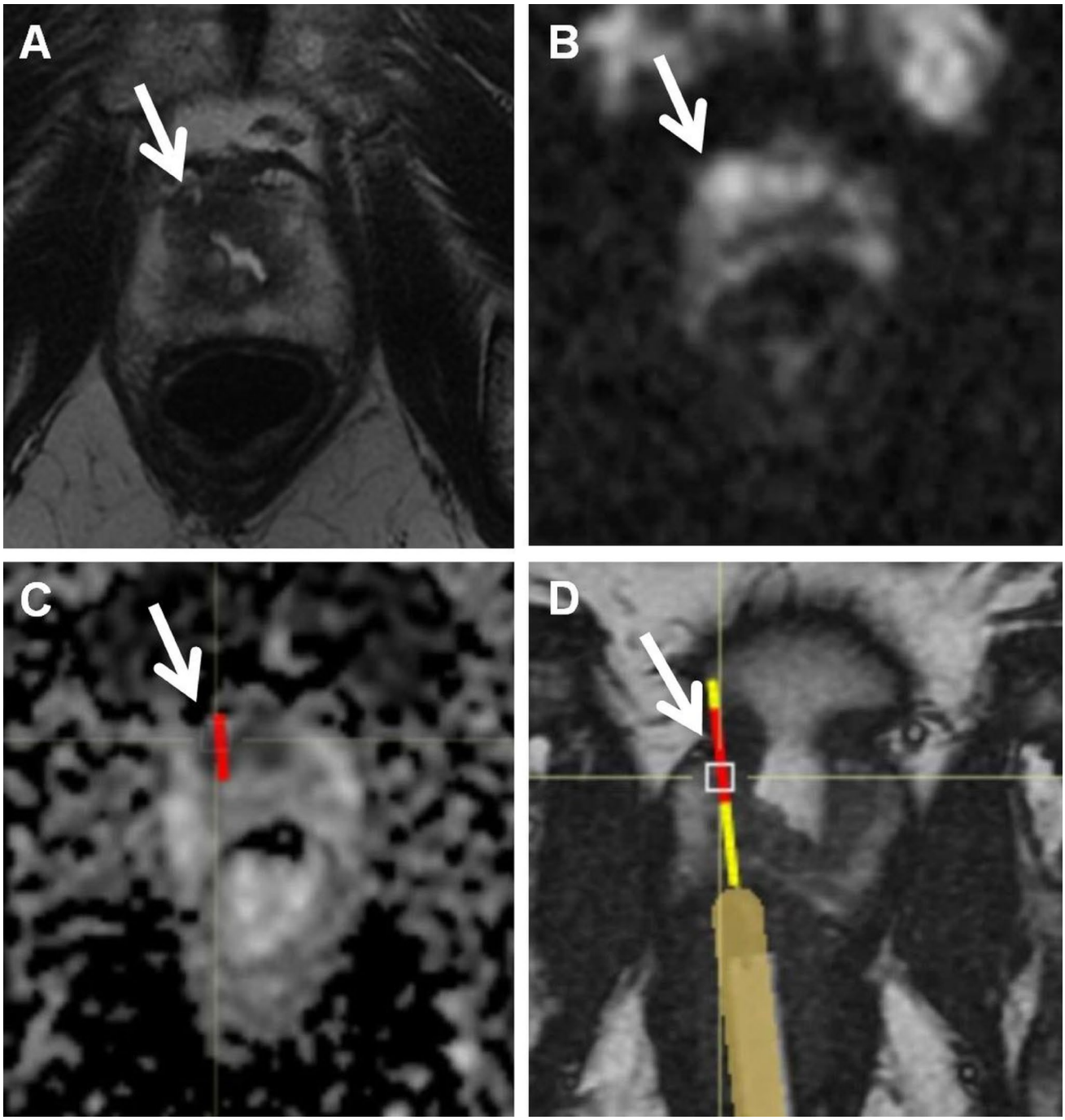

Fig. 4 67-year-old man with prostate-specific antigen value of 17.5 ng/mL with previous adenomectomy. MpMRI showed a PI-RADS 4 lesion in the right anterior transition zone not well defined on T2 WI (**a**), with two previous negatives biopsy on TRUS. **b** DWI depicts the lesion with restricted diffusion in the apex of the prostate (arrow). **c** ADC image showing the planned biopsy position using the software in the low signal lesion (arrow). **d** Oblique axial control image after remote robotic movement to the desired position of the biopsy, the needle track is overlay with the optimal path and represented the sample core (red line). Histopathologic examination revealed a Gleason 7 (4 + 3) carcinoma

Discussion

This initial evaluation of a robotic assistance system MR-targeted biopsies to detect prostate cancer might provide and confirm evidence for the clinical benefit to perform in-bore MR-targeted biopsies, in the new paradigm of prostate cancer diagnosis. The robotic system provides an accurate and feasible tool to localize and diagnose significant prostate

Table 1 Clinical, and MRI findings

Variable	Value
Age (y), mean ± SD (range)	66 ± 7 (51–81)
PSA level (ng/mL), mean ± SD (range)	13.1 ± 20 (4–120)
PSA density (ng/ml^2), mean ± SD (range)	0.28 ± 0.24 (0.06–1.25)
Prostate volume (cm^3), mean ± SD (range)	47.2 ± 27.4 (18–129)
Without biopsies, no. of patients (no./total no., %)	18 (18/30, 60)
Previous biopsy, no. of patients (no./total no., %)	12 (12/30, 40)
Lesion size (mm), mean ± SD (range)	
All lesions	13.5 ± 7.7 (5–36)
PZ	13.8 ± 8.4 (5–36)
TZ	12.3 ± 4.2 (8–20)
Lesion location, no. of lesions (no./total no., %)	
PZ	24 (24/30.,80)
Sector	
Anterior	2 (2/24, 8)
Posterolateral	11 (11/24, 46)
Posteromedial	11 (11/24, 46)
Level	
Base	4 (4/24, 17)
Mid	14 (14/24, 58)
Apex	6 (6/24, 25)
TZ	6 (6/30, 20)
Sector	
Anterior	2 (2/6, 33)
Posterolateral	3 (3/6, 50)
Posteromedial	1 (1/6, 17)
Level	
Base	3 (3/6, 50)
Mid	1 (3/6, 17)
Apex	2 (2/6, 33)
PI-RADS, no. of lesions (no./total no., %)	
PI-RADS 3	6 (6/30, 20)
PI-RADS 4–5	24 (24/30, 80)

Table 2 Biopsy results by clinical scenario

Clinical scenario	All	Prostate cancer	Significant tumors[a]	Non-significant tumors
Biopsy-naïve	18 (60)	16/18 (89)	14/19 (74)	2/3 (67)
Negative previous biopsy	12 (40)	6/12 (50)	5/19 (26)	1/3 (33)
All	30 (100)	22/30 (73)	19/22 (86)	3/22 (14)

Data are number (percentage) of patients

[a]University College of London (UCL) definition: any Gleason grade four component in the biopsy core or a maximum cancer core length of more than 3 mm

cancer on MRI. Our results confirm other in-bore MRI-guided biopsy reports showing the accurate outcome and mainly the latest published results using a robotic system using a remote-controlled manipulator [11, 12, 16], with a short MRI room occupation time and high detection rate of prostate cancer. This study also corroborates the high detection rate of prostate cancer using this in-bore MRI procedure; and more important the high clinically significant cancer detection. It is relevant the short MRI room occupation time of the procedure [11], which is not higher than other MRI diagnostic multiparametric studies, thus it does not interfere on the routine workflow of the MRI room

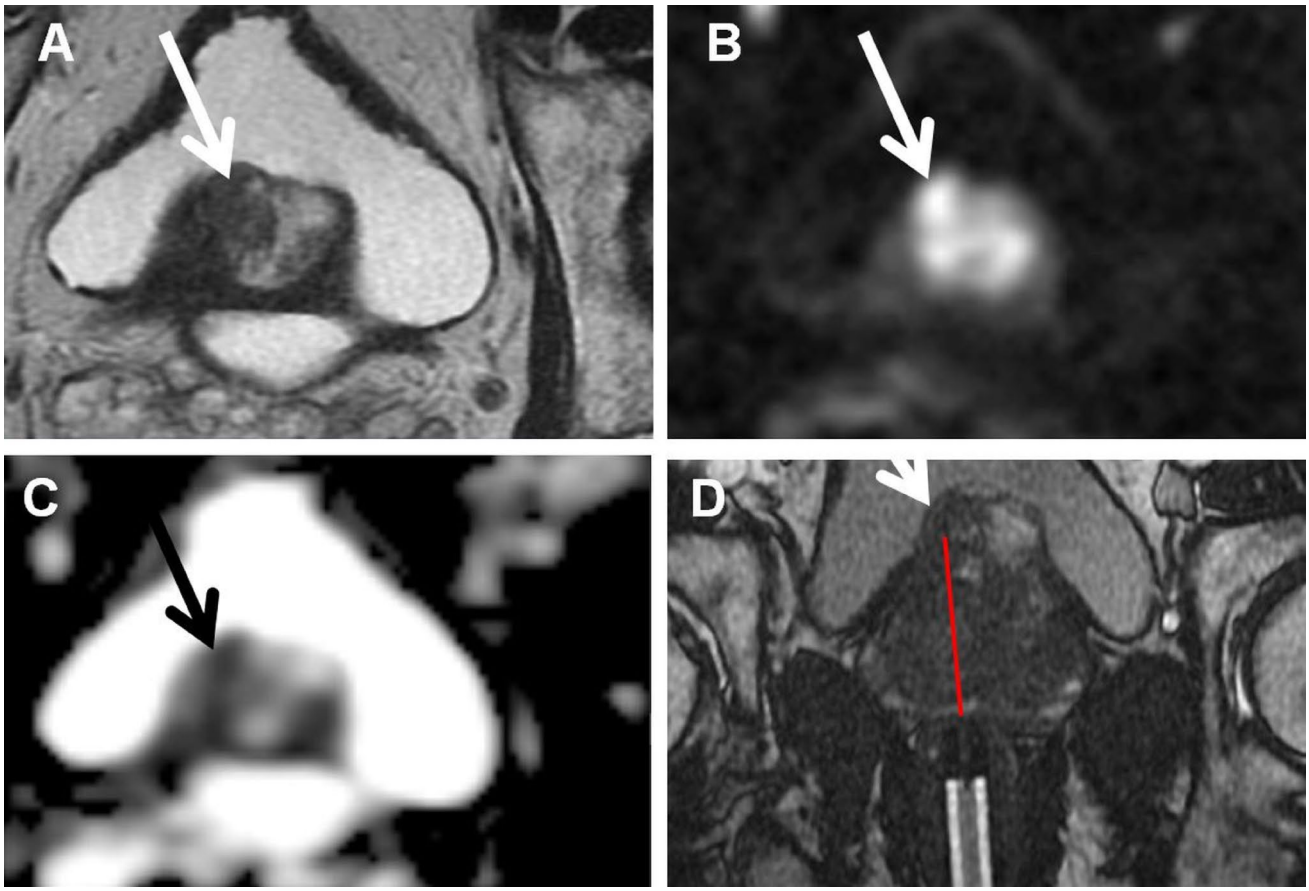

Fig. 5 77-year-old man with prostate-specific antigen value of 6.7 ng/mL. MpMRI showed a PI-RADS 3 lesion in the base of the transition zone. **a** T2 WI shows a non-completely encapsulated nodule ("atypical nodule") (arrow) related to a PI-RADS score of 2 but with restricted diffusion shown on DWI (**b**) and ADC (**c**) (arrows) which upgrades the category to PI-RADS 3. **d** Oblique axial control image after remote robotic movement to the desired position of the biopsy, shows the expected needle traject (red line) from the biopsy guide. The distance from the tip of the guide to the lesion is calculated automatically by the software planning. Histopathologic examination revealed fibromuscular stroma without malignant cells

schedule. Our initial scheduled occupational time at the beginning of the procedure was 60 min and currently after the learning curve of the procedure is scheduled at 45 min.

This robotic system has technically improved from previous versions devices [17, 18] which allows to perform the procedure in shorter time and feasible approach [10–12]. This work provides some more preliminary evidence for the clinical benefit to perform in-bore MRI prostate biopsies using a robotic device as it can be reached and target any lesion regardless of the location, from the base (Fig. 4) including the central zone to the apex and from anterior (Fig. 6) to posterolateral sector (Fig. 4) which are the most challenging locations to reach with the needle [19]. The improved precision of the latest version of the robot software enable to adjust and align the needle guide remotely to reach the target and achieve the success on the procedure. This aspect is crucial in order to provide a feasible method to achieve a high detection rate of prostate cancer, but more data should be evaluated to confirm these preliminary results. Reports have shown comparable detection rates of prostate cancer among men with prior negative biopsies using the three different techniques of targeted biopsy based on MRI; MRI-transrectal ultrasound (TRUS) fusion target biopsy (FUS-TB), cognitive registration TRUS target biopsy, or in-bore MRI target biopsy [8]. In this sense, the latest results using in-bore MRI target biopsy show high detection rate of prostate cancer with the robotic device (67–70%) [10–12], as it also has shown in this study (73%). Data result from manual in-bore MRI target biopsy has shown a cancer detection rate from 37 to 59% [17], lower than the ones from the robotic device. The comparison of our results from fusion-guided target biopsies shows a high detection rate from our study, as it has been reported to be between 50 and 60% [20] on FUS-TB. This difference is probably related to the high number of lesions with a PI-RADS score of 4 and 5 in our series (24/30–80%). It is remarkable that 86% (19/22) of prostate cancer is clinically significant. Our data show

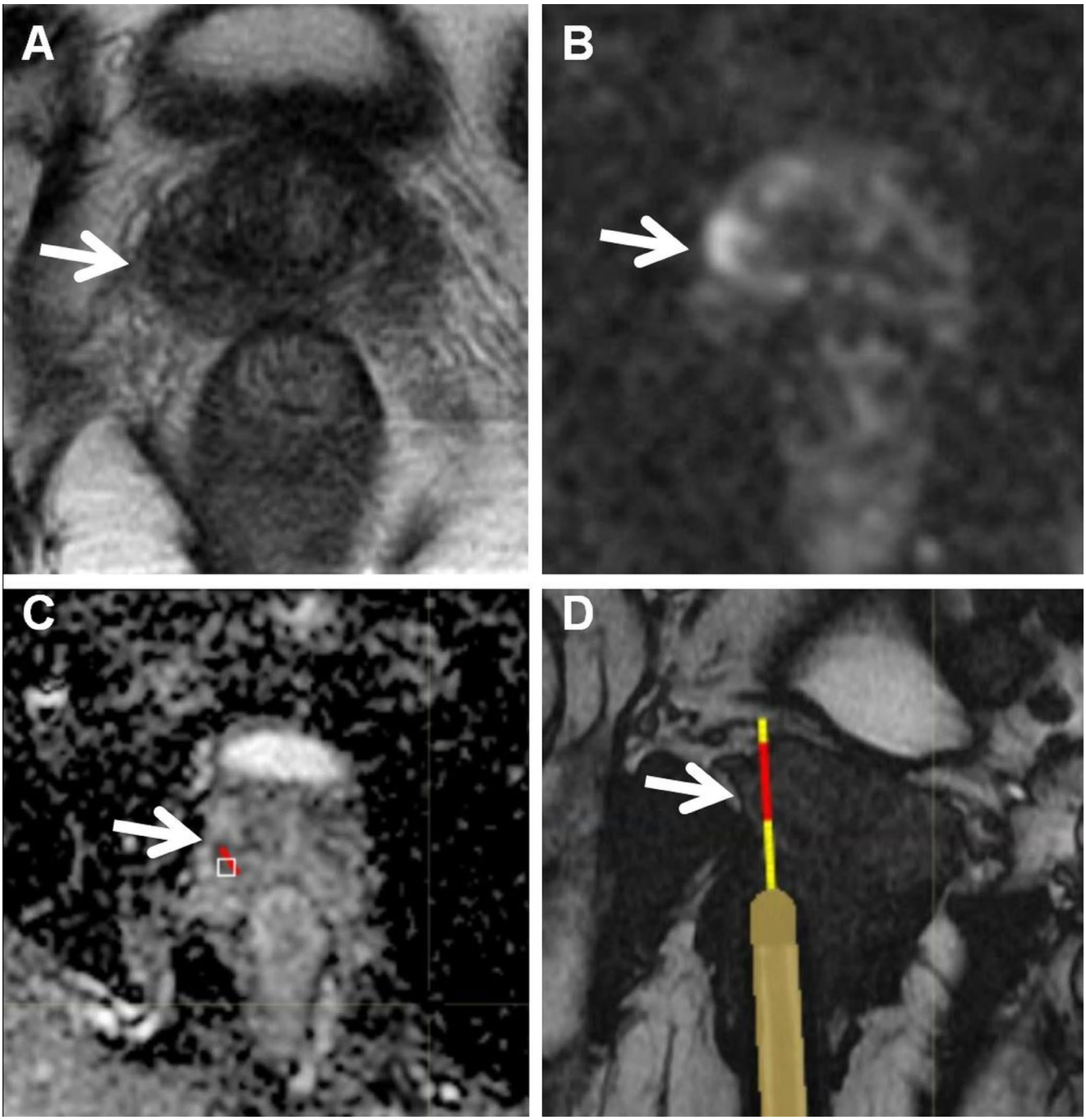

Fig. 6 69-year-old man with prostate-specific antigen value of 5,6 ng/mL with a previous negative systematic biopsy. MpMRI showed a PI-RADS 4, seven mm lesion in the right base posterolateral peripheral zone not defined on T2 WI (arrow) (**a**). **b** DWI depicts the lesion with restricted diffusion (arrow). **c** ADC image with the planned biopsy position of the lesion showing the low signal restricted diffusion to confirm the target (arrow). **d** Oblique axial control image after remote robotic movement to the desired position of the biopsy, the needle track is overlay with the optimal path and represented the sample core (red line). Histopathologic examination revealed a Gleason 7 (3 + 4) carcinoma

higher detection rate of significant and also for non-significant tumors for biopsy-naïve patients, although this small sample cannot provide specific conclusions, furthermore the procedure has been performed on higher number of biopsy-naïve patients than for negative previous biopsy ones.

Previous results have questioned the accuracy of MRI-guided biopsy performed with a manual device (Dynatrim,

Invivo) [17] as it can miss significant tumors originating very laterally in the PZ [19]. The latest increased precision of the robot [10] improve this limitation, as in this study, all the lesions were reached in spite of the anterior (Fig. 4) or lateral (Fig. 6) location. In our study, 11 lesions were laterally located, and precise alignment of the needle guide and the lesion was achieved.

An important issue to take in mind is that; whether MRI is the optimal imaging technique to diagnosis prostate cancer [4], it could be also much powerful whether we apply the same MRI technique to perform the biopsy. Moreover, we use DWI as the most sensitive technique to detect a lesion, for this reason it is useful to place the needle on the DWI or ADC image to be more efficient on the sample, and mainly weather the lesions might only be visible on DWI/ADC images (Fig. 6). This is possible and helpful using this in-bore MRI procedure as we have shown in this analysis, and with a reasonable room occupational time.

The current accuracy of the in-bore MRI system is a reality, but is it reasonable to avoid systematic biopsies on biopsy-naïve patients? The most recent data show that the omission of systematic biopsy would lead to missing 6% of clinically significant cancer but also systematic biopsy overdiagnose 8% of non-significant cancer [21]; in addition MRI target biopsy is an attractive alternative diagnostic strategy to systematic biopsy [22]. Previous reports have also questioned to perform target biopsy only strategy [23, 24], while others consider that may become the reference standard [25, 26]. Considering our preliminary results with high accuracy to detect clinically significant prostate cancer, it could be clinically useful to use only target biopsies on in-bore MRI for a score ≥ 3 in PI-RADS with a single defined lesion as a diagnostic strategy, as the ones we have used to include patients for biopsy. Nevertheless to achieve this utility, larger studies comparing current technique with other MR in-bore and MR-US fused techniques should be performed. Using this selection we had a high detection rate of prostate cancer on PI-RADS 4–5 for biopsy-naïve patients of 89% (16/18). One of the negative result was a focal prostatitis and the other was fibrostromal tissue on the central zone. This potential challenge strategy MRI-directed biopsy for biopsy-naïve patients would require probably more individualized selection depending on the patient risk and also to ensure a high quality MRI examination [7]. In this new paradigm to diagnose prostate cancer using MRI, we might reach in some future similar work-up as being performed on whatever organ on our body. That is, to detect on imaging a suspicious lesion and then to provide the accurate biopsy of the target, without the need to take sample of the rest of the organ. That means that we could avoid to perform systematic biopsies whether we can provide an excellence diagnostic tool, mpMRI, and then a feasible and optimal target biopsy procedure as we have performed in this initial analysis.

In evaluating the procedure cost of in-bore MRI-guided biopsy on clinical management, the cost-effectiveness of this technology compared with the standard of care must be considered. MRI-guided biopsy in-bore may be cost-effective compared with systematic biopsies and fusion-guided-targeted biopsy [27, 28]. This may be explained, at least partly, by the high cost of fusion-guided-targeted biopsy systems, which include the TRUS platform and the software used for the fusion. Also, the decrease of the biopsy time achieved with the use of the robot saves occupation time of the MRI room and thus decreases the overall cost of the procedure. Moreover, these procedure does not need anesthesia, without any additional personal cost, such as it could be the cooperation with the urologist. Considering the disposable MRI-compatible material, it has become less expensive from the initial cost as it is has progressively increased the number of procedures on this biopsy new proposed strategy.

This study has several limitations. The data are from a small patient population, as one of the main objectives was to evaluate the preliminary detection rate of significant cancer on a highly suspicion result on MRI of the prostate. The second limitation is that is has not been compared with other target-guided devices such as fusion ultrasound biopsy. Finally it was not compared the results with surgical pathology. Further correlation and follow up is expected to be done once higher number of procedures will be done and the analysis of the possible failed or missed cancer.

Conclusion

This initial data show that a robotic MRI-guided biopsy could be useful, efficient and feasible procedure in the new paradigm to diagnose significant prostate cancer in selected patients.

Author contributions All authors whose names appear on the submission made substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data; or the creation of new software used in the work. Approved the version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Compliance with ethical standards

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Conflict of interest The authors of this manuscript declare relationships with the following companies: Soteria Medical: Martijn Hoogenboom. The authors: Joan C. Vilanova, Anna Pérez de Tudela, Josep

Puig, Joaquim Barceló, Montse Planas, Sònia Sala, Santiago Thio-Henestrosa of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional Review Board approval was obtained.

References

1. O'Connor LP, Lebastchi AH, Horuz R, et al (2020) Role of multiparametric prostate MRI in the management of prostate cancer. World J Urol. https://doi.org/10.1007/s00345-020-03310-z
2. Professionals S-O EAU Guidelines: Prostate Cancer. In: Uroweb. https://uroweb.org/guideline/prostate-cancer/. Accessed 22 Mar 2020
3. NCCN Guidelines for Prostate Cancer. 2019. https://www.nccn.org/about/news/ebulletin/ebulletindetail.aspx?ebulletinid=161. Accessed 2 Jul 2020
4. Padhani AR, Barentsz J, Villeirs G, et al (2019) PI-RADS Steering Committee: The PI-RADS Multiparametric MRI and MRI-directed Biopsy Pathway. Radiology 182946. https://doi.org/10.1148/radiol.2019182946
5. Kasivisvanathan V, Rannikko AS, Borghi M, et al (2018) MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis. N Engl J Med 378:1767–1777. https://doi.org/10.1056/NEJMoa1801993
6. Ahmed HU, El-Shater Bosaily A, Brown LC, et al (2017) Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study. Lancet 389:815–822. https://doi.org/10.1016/S0140-6736(16)32401-1
7. Schoots IG, Padhani AR, Rouvière O, et al (2020) Analysis of Magnetic Resonance Imaging-directed Biopsy Strategies for Changing the Paradigm of Prostate Cancer Diagnosis. Eur Urol Oncol 3:32–41. https://doi.org/10.1016/j.euo.2019.10.001
8. Wegelin O, Exterkate L, van der Leest M, et al (2019) The FUTURE Trial: A Multicenter Randomised Controlled Trial on Target Biopsy Techniques Based on Magnetic Resonance Imaging in the Diagnosis of Prostate Cancer in Patients with Prior Negative Biopsies. Eur Urol 75:582–590. https://doi.org/10.1016/j.eururo.2018.11.040
9. Beyersdorff D, Winkel A, Hamm B, et al (2005) MR Imaging–guided Prostate Biopsy with a Closed MR Unit at 1.5 T: Initial Results. Radiology 234:576–581. https://doi.org/10.1148/radiol.2342031887
10. Bomers JGR, Bosboom DGH, Tigelaar GH, et al (2017) Feasibility of a 2nd generation MR-compatible manipulator for transrectal prostate biopsy guidance. Eur Radiol 27:1776–1782. https://doi.org/10.1007/s00330-016-4504-2
11. Barral M, Lefevre A, Camparo P, et al (2019) In-Bore Transrectal MRI-Guided Biopsy With Robotic Assistance in the Diagnosis of Prostate Cancer: An Analysis of 57 Patients. AJR Am J Roentgenol 1–9. https://doi.org/10.2214/AJR.19.21145
12. Linder N, Schaudinn A, Petersen T-O, et al (2019) In-bore biopsies of the prostate assisted by a remote-controlled manipulator at 1.5 T. MAGMA 32:599–605. https://doi.org/10.1007/s10334-019-00751-5
13. PI-RADS. https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/PI-RADS. Accessed 13 Jun 2019
14. Dindo D, Demartines N, Clavien P-A (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 240:205–213. https://doi.org/10.1097/01.sla.0000133083.54934.ae
15. Ahmed HU, Hu Y, Carter T, et al (2011) Characterizing clinically significant prostate cancer using template prostate mapping biopsy. J Urol 186:458–464. https://doi.org/10.1016/j.juro.2011.03.147
16. Meermeier NP, Foster BR, Liu J-J, et al (2019) Impact of Direct MRI-Guided Biopsy of the Prostate on Clinical Management. AJR Am J Roentgenol 213:371–376. https://doi.org/10.2214/AJR.18.21009
17. Felker ER, Lee-Felker SA, Feller J, et al (2016) In-bore magnetic resonance-guided transrectal biopsy for the detection of clinically significant prostate cancer. Abdom Radiol (NY) 41:954–962. https://doi.org/10.1007/s00261-016-0750-7
18. Schouten MG, Bomers JGR, Yakar D, et al (2012) Evaluation of a robotic technique for transrectal MRI-guided prostate biopsies. Eur Radiol 22:476–483. https://doi.org/10.1007/s00330-011-2259-3
19. Schouten MG, van der Leest M, Pokorny M, et al (2017) Why and Where do We Miss Significant Prostate Cancer with Multiparametric Magnetic Resonance Imaging followed by Magnetic Resonance-guided and Transrectal Ultrasound-guided Biopsy in Biopsy-naïve Men? Eur Urol 71:896–903. https://doi.org/10.1016/j.eururo.2016.12.006
20. Delongchamps NB, Peyromaure M, Schull A, et al (2013) Prebiopsy magnetic resonance imaging and prostate cancer detection: comparison of random and targeted biopsies. J Urol 189:493–499. https://doi.org/10.1016/j.juro.2012.08.195
21. Ahdoot M, Wilbur AR, Reese SE, et al (2020) MRI-Targeted, Systematic, and Combined Biopsy for Prostate Cancer Diagnosis. N Engl J Med 382:917–928. https://doi.org/10.1056/NEJMoa1910038
22. Kasivisvanathan V, Stabile A, Neves JB, et al (2019) Magnetic Resonance Imaging-targeted Biopsy Versus Systematic Biopsy in the Detection of Prostate Cancer: A Systematic Review and Meta-analysis. Eur Urol 76:284–303. https://doi.org/10.1016/j.eururo.2019.04.043
23. Gorin MA, Walsh PC (2018) Magnetic Resonance Imaging Prior to First Prostate Biopsy-Are we there yet? Eur Urol 74:409–410. https://doi.org/10.1016/j.eururo.2018.05.018
24. Ploussard G, Borgmann H, Briganti A, et al (2019) Positive prebiopsy MRI: are systematic biopsies still useful in addition to targeted biopsies? World J Urol 37:243–251. https://doi.org/10.1007/s00345-018-2399-z
25. Garcia Bennett J, Vilanova JC, Gumà Padró J, et al (2017) Evaluation of MR imaging-targeted biopsies of the prostate in biopsy-naïve patients. A single centre study. Diagn Interv Imaging 98:677–684. https://doi.org/10.1016/j.diii.2017.06.010
26. Delongchamps NB, Lefèvre A, Bouazza N, et al (2015) Detection of significant prostate cancer with magnetic resonance targeted biopsies–should transrectal ultrasound-magnetic resonance imaging fusion guided biopsies alone be a standard of care? J Urol 193:1198–1204. https://doi.org/10.1016/j.juro.2014.11.002
27. de Rooij M, Crienen S, Witjes JA, et al (2014) Cost-effectiveness of magnetic resonance (MR) imaging and MR-guided targeted biopsy versus systematic transrectal ultrasound-guided biopsy in diagnosing prostate cancer: a modelling study from a health care perspective. Eur Urol 66:430–436. https://doi.org/10.1016/j.eururo.2013.12.012
28. Pahwa S, Schiltz NK, Ponsky LE, et al (2017) Cost-effectiveness of MR Imaging-guided Strategies for Detection of Prostate Cancer in Biopsy-Naive Men. Radiology 285:157–166. https://doi.org/10.1148/radiol.2017162181