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Prostate MRI–TRUS fusion biopsy: a review of the state of the art procedure

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Abstract
Prostate cancer is the fourth most common cancer and population-based screening programmes are being increasingly adopted worldwide. Screening-positive patients undergo routine transrectal ultrasound (TRUS)-guided systematic biopsy, which is the current diagnostic standard for prostate cancer. However, systematic biopsies suffer from poor sensitivity, especially for the tumors of the anterior prostate and apex as well as in large volume glands. In the past decade, MRI-guided targeted biopsies have come up, which utilize the multiparametric capability of MRI to target lesions for sampling. MRI/TRUS fusion biopsies combine the advantages of MRI-targeting with that of real-time guidance made possible by TRUS. MRI–TRUS fusion biopsies are being increasingly used in men with high clinical suspicion of prostate cancer who have had prior negative systematic biopsies. A large number of fusion biopsy platforms are currently available commercially. Although the basic workflow is similar, there are differences in the operational software, biopsy routes offered, TRUS acquisition technique, type of correction applied at the time of fusion and in the probe tracking hardware. The article describes the current role and indications of MRI–TRUS fusion biopsy followed by a discussion on the workflow, patient preparation, biopsy procedure and complications.

Keywords Prostate cancer · Systematic biopsy · Multiparametric MRI · Fusion biopsy

Introduction

Prostate cancer is the fourth most common cancer worldwide and over 1.3 million new cases were diagnosed in 2018 alone. It accounted for 7.1% of all the newly diagnosed cancers and 3.8% of all cancer-related deaths [1]. However, prostate cancer has a high 5-year survival rate of 98%, which can be largely attributed to a high proportion of screening-detected clinically insignificant cancers. Prostate cancer screening is generally performed using serum prostate-specific antigen (PSA) levels. Patients found to have elevated PSA levels (above 4 ng/mL) undergo systematic transrectal ultrasound (TRUS)-guided biopsy, which is the current standard for the diagnosis, grading and prognostication of prostate cancer. Systematic biopsies have a low detection rate, especially for clinically significant cancers and in large volume glands.

In the past decade, significant interest has been generated in MRI-guided targeted prostate biopsy due to improved detection of clinically significant cancers in comparison to systematic TRUS-guided biopsies. MRI–TRUS fusion is one such technique which combines the advantages of high intrinsic contrast of MRI with real-time guidance of ultrasound. Since inception, MRI–TRUS fusion biopsies have been increasingly used in men with high clinical suspicion of prostate cancer who have had prior negative systematic TRUS-guided biopsies. The article describes the current role and indications for MRI–TRUS fusion biopsy followed by a discussion on the workflow, patient preparation, biopsy procedure and complications.

MRI–TRUS fusion biopsy: indications and current role

Prostate cancer screening is indicated in asymptomatic men over 50 years of age having moderate risk for prostate cancer and in men over 40 years with high risk for

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cancer (African-Americans and persons with positive family history of prostate cancer) [2]. Screening is performed using digital rectal examination (DRE) and serum prostate specific antigen (PSA) levels. Patients who have abnormal DRE findings of nodularity or induration and those with elevated PSA levels (usually above 4 ng/mL) undergo systematic transrectal ultrasound (TRUS)-guided biopsy, which is the current standard for the diagnosis, pathologic grading, risk stratification and prognostication of prostate cancer. However, systematic biopsies have low detection rate, with the sextant biopsies missing up to 30% of the clinically significant cancers [3]. The sensitivity further drops in large volume glands. In addition, tumors in difficult-to-access areas like the anterior transition zone, anterolateral peripheral zone and apex are often undersampled. Although increasing the number of biopsy cores increases the detection rate, this advantage is offset by the increased detection of clinically insignificant cancers and higher rate of adverse effects like bleeding and transient urinary retention.

In the past decade, significant interest has been generated in MRI-targeted sampling of the prostate. High inherent tissue contrast and multiparametric assessment capability has made MRI the diagnostic modality of choice for the localization and locoregional staging of prostate cancer. Risk categorization with MRI enables targeting the most aggressive lesion, which has resulted in improved detection of clinically significant cancers in comparison to systematic TRUS-guided biopsies [4–6]. Siddiqui et al. observed that addition of targeted biopsy to routine 12-core systematic biopsy detected 67% additional cases of clinically significant cancer, whereas only 8% of the cases were detected on systematic biopsy alone [7]. An increase in the percentage of positive cores with MRI-targeted biopsy has also resulted in a reduction in the number of cores required. In addition, MRI-targeted biopsy cores were observed to have more comparable Gleason scores with the radical prostectomy specimens than systematic TRUS-guided biopsies [8]. MRI targeting can be performed using MRI–TRUS fusion or using the in-gantry (direct) technique.

MRI–TRUS fusion combines the advantages of both MRI (intrinsic high contrast and lesion detectability) and TRUS (real-time guidance). Apart from the advantages of MRI-targeting, most MRI–TRUS fusion biopsy platforms provide the facility for biopsy tract documentation which could be helpful in patients on active surveillance and in those requiring repetition of sampling. In comparison to fusion biopsy, in-gantry biopsies require the patient to be positioned in an uncomfortable prone position for the duration of the procedure and also takes away valuable gantry time from the diagnostic services [9].

MRI–TRUS fusion biopsies, since inception, have been extensively used in men who continue to remain at high suspicion for prostate cancer despite prior negative systematic TRUS-guided biopsies. At present, MRI-guided biopsies have a role in the following scenarios: (a) patients with persistently elevated PSA in whom TRUS-guided systematic biopsies are repeatedly negative (b) patients with large volume prostate glands (c) active surveillance in patients with biopsy-proven low-risk prostate cancer [10].

New evidence questions the role of routine TRUS-guided systematic biopsies in screening-positive patients. One study observed that the usage of multiparametric MRI as a risk assessment tool could reduce the number of men requiring sampling [11]. The Prostate MR Imaging Study (PROMIS) observed that PI-RADS score less than 3 had high negative predictive value for clinically significant prostate cancer and hence most urologists at present avoid sampling in such cases [12]. This has prompted some guidelines like the UK National Institute for Health and Care Excellence (NICE) to recommend upfront multiparametric MRI in men with clinical suspicion of localized prostate cancer [13].

MRI–TRUS fusion biopsies, like all prostate biopsies, are relatively contraindicated in coagulopathies, acute prostatitis and painful conditions of the anorectum. Disadvantages of MRI–TRUS fusion biopsy include the need for an expensive robotic fusion device, which makes the procedure costlier than systematic TRUS-guided biopsy. In addition, even simple errors in the identification of the target lesion on MRI or misregistration during fusion can result in false-negative biopsies.

MRI–TRUS fusion biopsy: workflow

Fusion biopsies can be cognitive or software-guided. Many low-cost set ups use cognitive fusion, where the radiologist deduces the target lesion on real-time TRUS images by judging the spatial relation of the lesion on the MR images using internal fiducials like normal anatomic landmarks, calcifications etc. [14]. Although simple and inexpensive, misregistration resulting from incorrect judgement of the location of the lesion makes this technique operator-dependent and error prone. The consensus statement by the American Urological Association (AUA) and the Society of Abdominal Radiology (SAR) justifies the use of cognitive biopsies in resource-poor settings [15]. However, software fusion is preferred in most high volume, tertiary care centres.

MRI–TRUS fusion biopsy requires meticulous evaluation of the multiparametric MRI images on a dedicated software to identify and localize suspicious lesions, and categorize the risk for malignancy. Regions of interest (ROI) are then placed over the suspicious area to be targeted for biopsy and the data are transferred onto the fusion biopsy system. The

target lesion is then identified on TRUS images after fusion of the 3D prostate volumes on MRI and TRUS. Biopsy is then performed under TRUS guidance using real-time probe navigation. The first ever commercial MRI–TRUS fusion biopsy platform, UroNav (FDA approved in 2006), was developed by the US National Institutes of Health (NIH) in collaboration with Philips/Invivo healthcare. As of now, the other available platforms include Artemis (Eigen, USA), BioJet (D&K Technologies, Germany), BiopSee (Pi Medical, Greece), iSR'obot Mona Lisa (Biobot Surgical, Singapore), Logiq 9 (GE Healthcare, UK), MIM Symphony Bx (MIM Software Inc, USA), Navigo (UC-Care, Israel), Real-time Virtual Sonography/RVS (Hitachi, Japan), Virtual Navigator (Esaote, Italy) and Urostation (Koelis, France) [16]. Apart from the software interface, these platforms also differ in the volumetric TRUS acquisition method, image fusion algorithm, biopsy routes offered and needle tracking method. A stepwise description of the workflow is summarized in Fig. 1 and detailed in the sections below. The Artemis system is demonstrated in Fig. 2. The basic differences in the modulus operandi of the various commercially available fusion biopsy platforms are demonstrated in Table 1.

Patient preparation

MRI-guided biopsies are performed as outpatient procedures and patient preparation is no different from TRUS-guided biopsies. Antibiotic prophylaxis is usually provided with a single oral dose of quinolone few hours prior to the procedure [17]. Quinolones are preferred since they cover the risk of gram-negative bacterial infections inherent with the transrectal route and demonstrate excellent tissue penetration of the prostate gland. It is also preferable to administer a cleansing enema on the morning of the procedure.

In view of the increased risk of minor bleeding, patients on dual antiplatelets (low-dose aspirin and clopidogrel) should be advised to skip clopidogrel 1 week prior to the procedure. Patients on single antiplatelets should continue the drug periprocedurally. However, in the critical period following coronary intervention (2 weeks after coronary angioplasty, 6 weeks after bare-metal stent and 12 months after drug-eluting stent insertion), dual antiplatelets should be continued. Although oral anticoagulants are usually discontinued 5 days prior to procedure, bridging therapy with intravenous heparin should be considered in patients with high risk of adverse thromboembolic events [18].

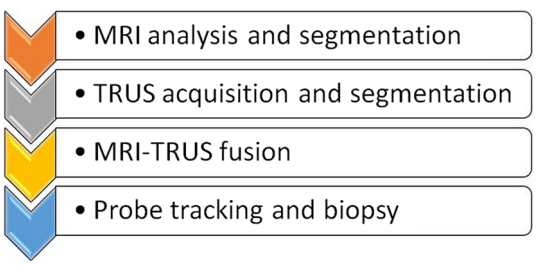

Fig. 1 Diagram representing the four key steps in the MRI–TRUS fusion biopsy of the prostate

Fig. 2 **a** The Artemis MRI–TRUS fusion biopsy platform (Eigen, Grass Valley, CA, USA). **b** The system has a transducer holder into which the probe can placed and locked. The holder is attached to an articulated arm which enables mechanically stabilized freehand sweep. The arm is connected to the tracking assembly, which enables real-time probe tracking and navigation. A monitor and workstation are provided as the operator interface

Steps in MRI–TRUS fusion biopsy

Step 1: MRI analysis and segmentation

The first step in the fusion biopsy is MRI image analysis on a dedicated image processing software, usually provided by the vendor. Some such platforms include DynaCAD (Invivo), ProFuse (Eigen), McDraw (Koelis) and UroFusion (Biobot Surgical). The images are first carefully analyzed to

Table 1 Basic operational differences in the workflow of the various commonly available MRI/TRUS fusion biopsy platforms

Fusion biopsy system	TRUS acquisition	Tracking mechanism	Biopsy route	Fusion method
Artemis	Mechanically stabilized sweep	Mechanical arm with encoders	Transrectal and transperineal	Elastic registration
BiopSee	Motorized sweep	Stepper with built-in encoders	Transrectal and transperineal	Rigid registration
RVS	Freehand sweep	Electromagnetic	Transrectal and transperineal	Rigid registration
UroNav	Freehand sweep	Electromagnetic	Transrectal and transperineal	Elastic registration
Urostation	3D TRUS probe	TRUS–TRUS registration	Transrectal and transperineal	Elastic registration
Virtual navigator	Freehand sweep	Electromagnetic	Transrectal	Rigid registration

identify the lesions and assess the risk using the PI-RADS v2 guidelines. The prostate gland and the lesions to be biopsied are then segmented to generate 3-dimensional (3D) images, which are then transferred onto the fusion biopsy system (Fig. 3).

Step 2: TRUS acquisition and segmentation

A routine ultrasound machine attached to the fusion biopsy system is used to acquire 2D TRUS images, which are then converted to volumetric 3D images for MRI–TRUS fusion.

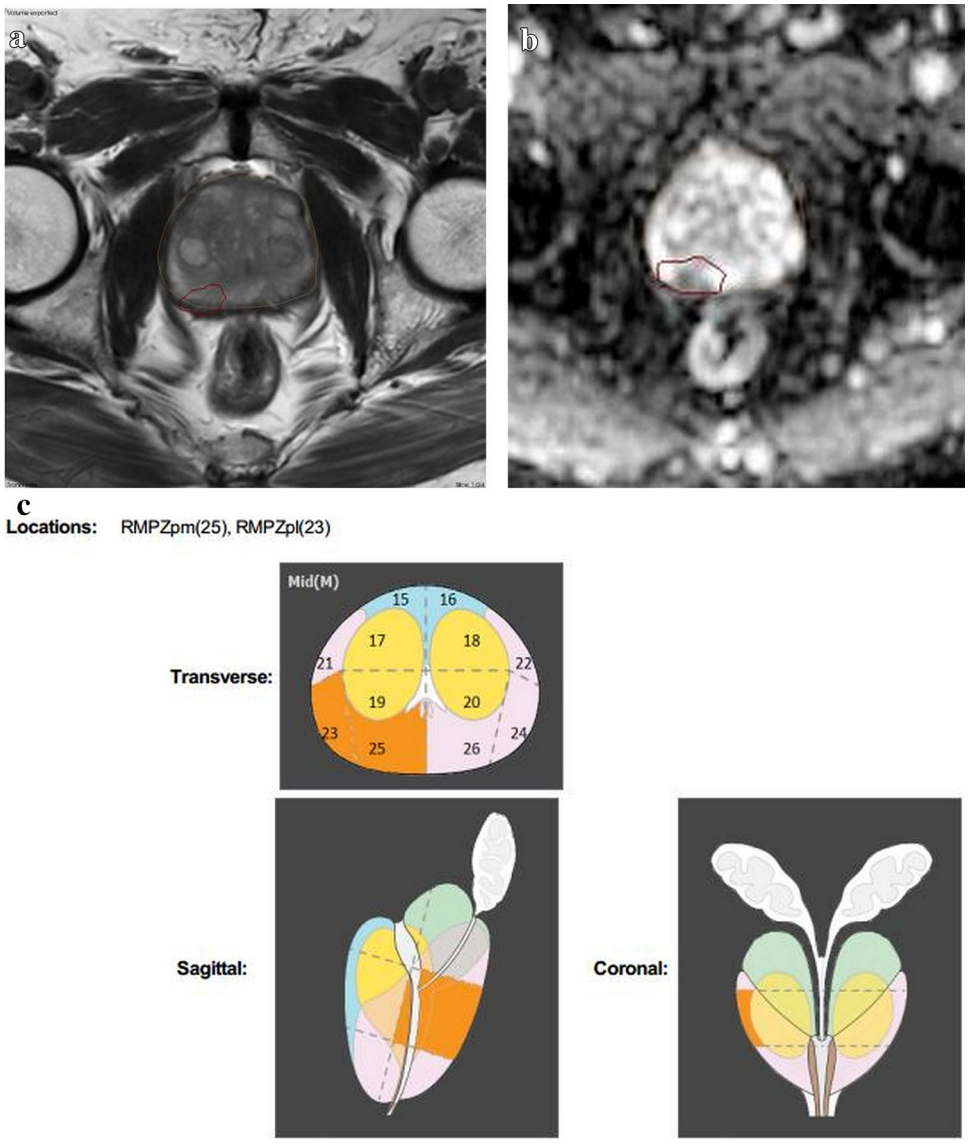

Fig. 3 MR image analysis and segmentation of the suspicious lesion in a 72-year-old patient who had elevated serum PSA (12 ng/mL). **a** T2-weighted image and **b** ADC maps show a lesion of size 1 cm showing diffusion restriction in the right posterior peripheral zone (RMPzpm and RMPzpl), consistent with a PI-RADS score of 5. The lesion and the prostate gland are segmented on the ProFuse software (Eigen, USA) to generate the respective 3D volumes, which are then transferred onto the fusion biopsy system. **c** The lesion is labelled (orange sector) on the PI-RADS v2 prostate sector map

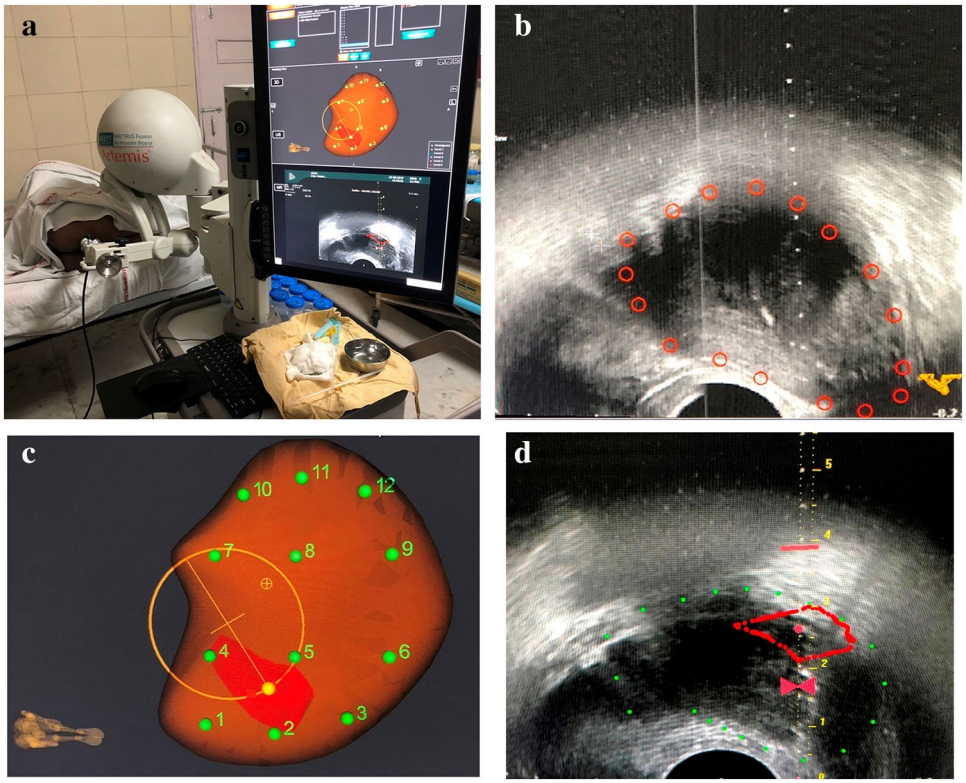

Fig. 4 Biopsy procedure of a 66-year-old patient with elevated serum PSA (17 ng/mL) who had a prior negative systematic TRUS-guided biopsy. Multiparametric MRI showed a PI-RADS 5 lesion involving the anterior fibromuscular stroma and transitional zone at the base of the gland on the left side (LBAFS, LBTZa). **a** TRUS probe attached to the articulated arm of the Artemis system is inserted into the rectum and a mechanically stabilized freehand swipe is performed. **b** The prostate gland is segmented on the TRUS images to generate a 3D volume. **c** The MRI and TRUS volumes are then fused to extrapolate and identify the lesion (labelled in red colour) on the TRUS volume. Using real-time tracking, the needle is then navigated towards the lesion. **d** The system marks the target lesion (outlined in red) on the real-time 2D TRUS image to guide sampling. A red bow-tie serves as the marker to correctly position the needle tip so that the lesion is adequately covered

Some platforms like Urostation directly use a 3D probe for volumetric acquisition. There are also differences in the 2D-image acquisition techniques between vendors. UroNav uses manual freehand sweep and care must be taken to perform a smooth and steady sweep to ensure an artifact-free 3D image. On the other hand, iSR'obot Mona Lisa and MIM Symphony Bx use motorized translation, whereas the Artemis system uses an articulated arm to mechanically stabilize the sweep. Subsequently, prior to the MRI–TRUS fusion, the prostate gland is segmented on the TRUS images (Fig. 4a, b).

Step 3: MRI–TRUS fusion

Fusion is the most important step in the entire process, wherein the volumetric ultrasound image of the prostate is co-registered and fused with the MR image. This enables the suspicious area outlined on the MR image to be overlayed on the 3D TRUS images, so that real-time TRUS-guided navigation and targeting are possible. However, accurate fusion is a challenge since the geometry and orientation of the gland differs between the two modalities due to differences in the position and time at which they were acquired. TRUS is performed in lateral decubitus position, whereas MRI is acquired in the supine position. This results in translational and rotational differences in the orientation of the gland as well as distorted geometry from variable distension of the bladder and application of transrectal probe and coil.

Depending on the type of correction applied, software fusion can be rigid or non-rigid (elastic). Rigid fusion used with RVS and Virtual Navigator is a shape-preserving transformation model and compensates for only the differences in the rotational and translational orientation of the gland between the TRUS and MRI volumes. On the other hand, Artemis and Urostation use non-rigid fusion which can compensate for geometrical differences as well. The accuracy of fusion has been studied and a registration error of approximately 3 mm has been observed [19, 20].

Step 4: biopsy procedure—probe tracking, biopsy technique

Probe tracking refers to identifying the position and orientation of the probe in relation to the prostate gland and the target lesion, so that real-time navigation is possible. For this purpose, UroNav, Virtual Navigator and RVS use electromagnetic tracking technology where a small electromagnetic generator producing 0.1 Tesla is placed at a fixed position relative to the patient's body and synced with a sensor attached to the probe. Artemis, BiopSee and BioJet use angle sensing position encoders, whereas Urostation uses entirely software-based elastic registration between the initial TRUS volume and the subsequently acquired TRUS images. Real-time tracking enables the needle to be accurately guided to the target site for sampling (Fig. 4c, d).

Prior to the actual biopsy, local anaesthesia is provided to reduce pain and discomfort. A total volume of 10 mL of 1% lignocaine is administered into the Denonvillier's fascia at the base and apex of the gland bilaterally in equal aliquots using a long, 22-Gauge Chiba needle [21]. It is important to target the periprostatic plexus by administering the anaesthetic into the echogenic triangle of fat at the junction of the seminal vesicle and the posterior margin of prostate on the axial TRUS image (Fig. 5). Accidental introduction of air must be avoided for the fear of obscuring the gland at the time of the biopsy. Once the effect of local anaesthetic has set in, biopsy is performed using an automatic, spring-loaded gun (18-Gauge, 26 cm long, 20 mm throw). The usual route of biopsy is transrectal, although many centres prefer the transperineal route due to lesser risk of infection and better access to the lesions in the apex and anterior portions of the gland. Majority of the fusion biopsy systems hence provide options for both routes. The AUA–SAR recommendations require two spatially distributed samples to be obtained from the target lesion in addition to routine systematic 12-core biopsy [15]. The sampled biopsy cores must be labelled separately for histopathological analysis before being dispatched. The devices also provide the facility to record the location of the biopsy cores which is useful for patients who are on active surveillance and in whom repeat biopsy is planned (Fig. 6).

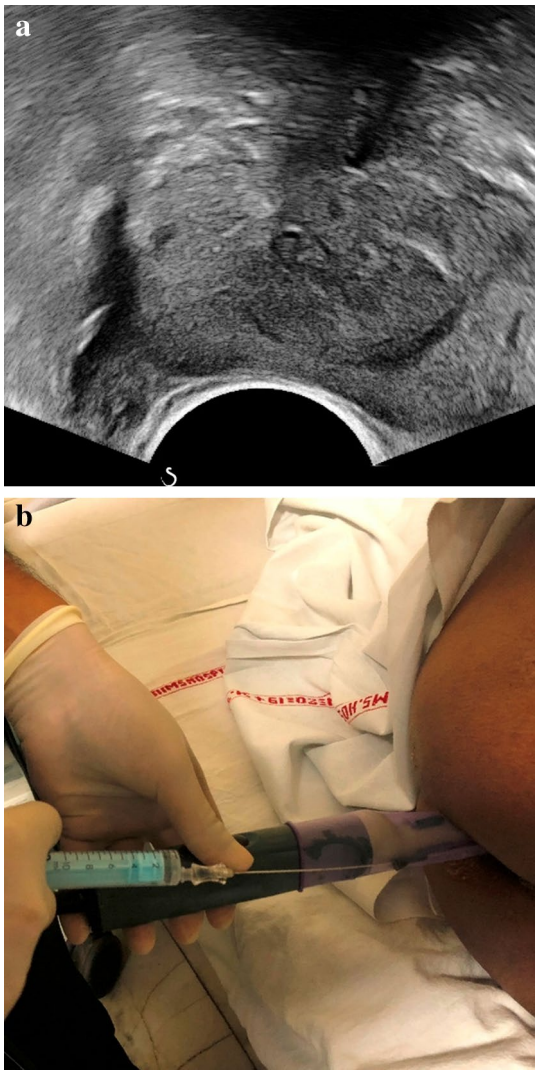

Fig. 5 The local anaesthesia procedure. **a** The anaesthetic is administered into the echogenic fat triangle at the junction of the seminal vesicle and the posterior margin of prostate on the axial TRUS image to create a fluid bleb. Care must be taken to avoid injecting air which could obscure the gland during the subsequent biopsy procedure. **b** A long (20 cm), 22-Gauge Chiba needle is usually used to administer the anaesthetic

Complications

The complications of MRI–TRUS fusion biopsy are similar to those of routine TRUS-guided biopsies. Transient hematuria and hematochezia commonly occur for a few days following the biopsy and require only reassurance. In the ProtecT (Prostate Testing for Cancer and Treatment) trial, 92.6% of the patients had hemoejaculate, whereas 65.8% had hematuria and 36.8% had hematochezia [22]. Most cases of rectal bleed resolve within 48 h and compression with the probe or a balloon immediately after the procedure often helps in arresting the bleed.

There is a risk of infection due to the inherent contaminated nature of the transrectal route. Although this can be mostly prevented with the routine use of prophylactic antibiotics, quinolone-resistant strains may cause local infection and sepsis. In these cases, intravenous third-generation cephalosporins or aminoglycosides should be administered [23]. Acute urinary retention and worsening of the lower urinary tract symptoms may occur due to gland edema and

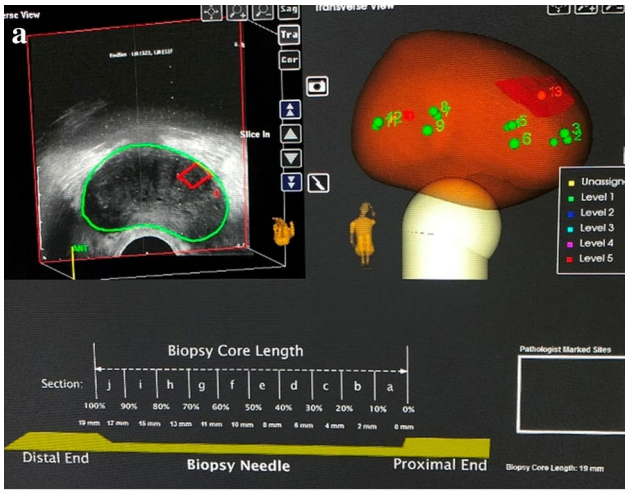

Fig. 6 **a**, **b** After sampling, the software provides the facility for recording the biopsy tracks on the 3D volume for future reference

can be managed with temporary catheter placement. Erectile dysfunction and vasovagal syncope may also rarely occur.

Conclusion

The systematic 12-core TRUS-guided biopsy is still the most widely used technique despite having limited sensitivity for the detection of clinically significant prostate cancer. Targeted biopsy techniques such as MRI–TRUS fusion biopsy are highly effective and have excellent detection rate for clinically significant prostate cancers. Since many urologists increasingly prefer an upfront MRI in screening-positive patients, it is highly likely that MRI-targeted biopsies replace systematic TRUS-guided biopsy schemes in the near future.

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