

Sterile biopsy guides (dark green)

The sterile single-use biopsy guide UA1322-S and UA1322-S14 come assembled in peel packs. Contents are only sterile if the package is intact.



WARNING

Disposable components are packaged sterile and are intended for single-use only.

Do not use if:

- Integrity of packaging is violated
- Expiration date has passed
- Package label is missing

The sterile-packed biopsy guides must be stored at a temperature range from +15 °C (+57 °F) to +25 °C (+77 °F) and at a storage humidity of 30% to 80%.



WARNING

Sterile-packed components must be stored in a safe environment and kept out of direct sunlight. Large temperature changes during storage may cause condensation and violate the integrity of the packaging.

Please refer to *Care, Cleaning and Safety* for an example of how to open a sterile-packed product.

Simultaneous Biplane

The sterile biopsy guide UA1322-S, UA1322-S14 and reusable biopsy guide UA1326 are used for simultaneous biplane imaging.



Figure 4. Reusable biopsy guide UA1326.

The puncture line for UA1322-S, UA1322-S14 and UA1326 on 8808e is shown in Figure 5. UA1322-S and UA1326 have a bore diameter of 1.6 mm, suitable for 17-gauge needles. UA1322-S14 has a bore diameter of 2.1 mm, suitable for 14-gauge needles. The puncture line is angled at 19° to the transducer's axis.

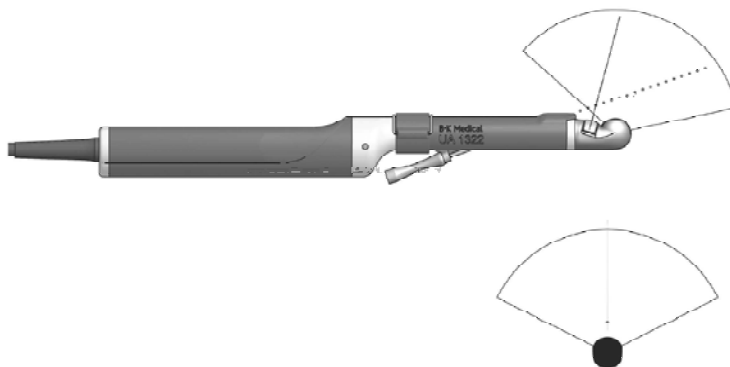


Figure 5. Illustration of the puncture line for biopsy guide UA1322-S, UA1322-S14 and UA1326.

Mounting a Transrectal Biopsy Guide

To mount a biopsy guide on 8808e:

- 1 If a dummy channel bracket is mounted on the transducer, remove it.
- 2 Pull a transducer cover or a standard condom containing a suitable amount of imaging gel over the transducer.
- 3 Slide the needle guide into the biopsy channel bracket.



WARNING

Do not use excessive force when inserting the needle guide.

- 4 Insert the assembled needle guide and biopsy channel bracket into the open channel on the transducer. A small nodule on the end of the channel bracket fits into an indentation in the channel on the transducer to help you place the bracket correctly. Click the channel bracket into position on the transducer and lock it into place (see Figure 6).



Figure 6. Biopsy channel bracket and needle guide mounted on 8808e.



WARNING

Ensure that the channel bracket and needle guide are correctly positioned. Never insert the needle guide while the transducer is inside the patient.

To remove the bracket, remove the outer condom, open the lock and lift the bracket off the transducer.

For Transperineal Puncture

The metal puncture attachment UA1324, shown in Figure 7, is designed for transperineal puncture and biopsy. When UA1324 is being used, the dummy channel bracket UA1325 (shown in Figure 3) must be in place.

Puncture attachment UA1324 must be autoclaved or disinfected by immersion in a suitable solution.

UA1324 consists of a needle guide and a mounting ring with clamp. The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.

Note: The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.



Figure 7. Puncture attachment UA1324.

Mounting the Transperineal Puncture Attachment

To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place. Pull a sterile transducer cover over the transducer. Loosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer. The puncture attachment should be correctly positioned so that the groove slides easily over stud. No force should be used when attaching the puncture attachment to the transducer.



Figure 8. Puncture attachment UA1324 mounted on 8808e.

The puncture lines for UA1324 on 8808e are shown in Figure 9.

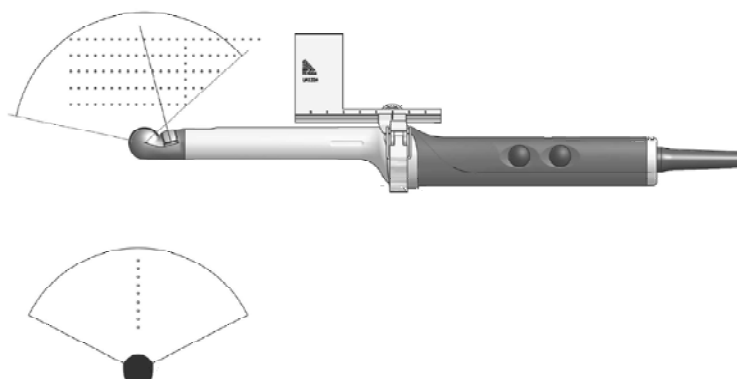


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

Performing Puncture and Biopsy



WARNING

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the system monitor.



WARNING

The puncture line on the image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

If not sterilized, cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

See the Product Data sheet for a list of available transducer covers.

Superimpose
puncture line

Press the system **Puncture** or **Biopsy** control button to superimpose a puncture line on the image.

If more than one puncture line is available, refer to the applicable system user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

The puncture line will differ depending on the imaging plane orientation. In the sagittal plane, the puncture path is indicated by a line of dots. The distance between each puncture dot is 5 mm.

In the transverse plane, a single dot indicates the point at which the needle will transect the imaging plane.



WARNING

If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

If the cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.

To remove the puncture line from the scan image, refer to the applicable system user guide for instructions.



WARNING

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer, disinfection and sterilization processes may not be effective. Therefore, you must clean transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves. See *Care, Cleaning & Safety* for cleaning instructions.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable system user guide for further details.



WARNING

For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.

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Analogic Corporation creates innovative technology to improve the health and ensure the safety of people around the world. We are committed to providing ultrasound solutions under the BK Medical brand name that advance medicine and save lives.



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APPENDIX 1007A

Prostate Biplane Transducer



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The serial number of a BK Medical product contains information about the year of manufacture. To obtain the date of manufacture of a product, please contact your BK Medical representative or write to us at the email address above, including the product's serial number (SN number).

BK Medical Customer Satisfaction

Input from our customers helps us improve our products and services. As part of our customer satisfaction program, we contact a sample of our customers a few months after they receive their orders. If you receive an email message from us asking for your feedback, we hope you will be willing to answer some questions about your experience buying and using our products. Your opinions are important to us. You are of course always welcome to contact us via your BK Medical representative or by contacting us directly.

If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

Contents

Introduction	5
Indications for Use	5
General Information	5
Service and Repair	6
Caring for the Transducer.	6
Cleaning and Disinfection	6
Starting Imaging	7
Connecting the Transducer.	7
Changing Frequency.	7
Using a Transducer Cover	7
Using the Transducer Control Button.	8
Changing Orientation	8
Imaging with Type 8808e	8
Imaging Without Puncture or Biopsy	9
Puncture and Biopsy Facilities	9
For Transrectal Puncture	9
For Transperineal Puncture	12
Performing Puncture and Biopsy	13
Cleaning after Puncture and Biopsy	14
Disposal	14

Introduction

This is the user guide for Prostate Biplane Transducer Type 8808e and must be used together with *Care, Cleaning & Safety* which contains important safety information.

Indications for Use

Prostate Biplane Transducer Type 8808e is designed for transrectal prostate imaging.



Figure 1. Prostate Biplane Transducer Type 8808e.

Imaging Plane

The transducer contains two convex arrays — one for transverse (T) imaging, and one for sagittal (S) imaging (see Figure 2). The advantage of being able to view two planes simultaneously with one transducer is that the true position of the needle can be seen during puncture and biopsy and a suspicious lesion can be viewed in both planes.

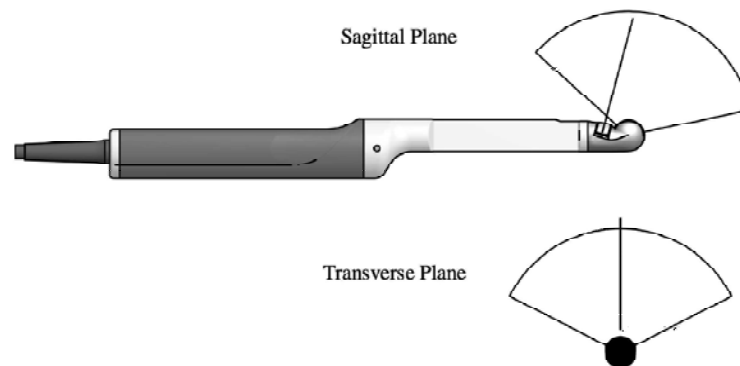


Figure 2. Imaging planes for Prostate Biplane Transducer Type 8808e.

General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are in Technical Data (BZ2100) that accompanies this user guide. A full explanation of acoustic output data is given in your system user guide.

**WARNING**

If at any time the system malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the system is not functioning correctly:

- Remove all transducers from contact with the patient.
- Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked.
- Do not try to repair the system yourself.
- Contact your BK Medical representative or hospital technician.

**WARNING**

Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Service and Repair

**WARNING**

Service and repair of BK Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrical engineer or hospital technician should verify the safety of all equipment.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety*.

Cleaning and Disinfection

To ensure the best results when using BK Medical equipment, it is important to maintain a strict cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Care, Cleaning & Safety* that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more information.

**WARNING**

Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department, or hospital.

Starting Imaging

All equipment must be cleaned and disinfected before use.

Connecting the Transducer



WARNING

Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the system using the array Transducer Socket on the system. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the system socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected, the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the imaging frequency. See the applicable system user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.



WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2 ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

Gel also creates a good acoustic contact between the skin and the transducer; therefore, apply a small amount to the outside of the cover prior to imaging. Re-apply the gel frequently to ensure good screen images.



WARNING

Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover materials.



WARNING

Do not use excessive force during insertion. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

Using the Transducer Control Button

To change the imaging plane, press the button corresponding to that plane (see Figure 1). Pressing the button activates (starts) or freezes (stops) imaging in that plane. One button enables the sagittal or longitudinal array. A second button enables the transverse array. Each time a button is pressed, a beep is emitted.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable system user guide for instructions.

Imaging with Type 8808e

Simultaneous Biplane Imaging

8808e can transmit transverse (T) and sagittal (S) images simultaneously. When you press the system's **Split** key, simultaneous imaging is automatically activated.

Transverse or Sagittal Imaging

Click **Simultan** to toggle simultaneous imaging on or off. When simultaneous imaging is off, you can change which plane is active and which is frozen by pressing the **Split** key or by placing the cursor on the image you want to be active and pressing the **Select** key.

Imaging Without Puncture or Biopsy

- When 8808e is used for transrectal imaging without the puncture facilities, the dummy bracket UA1325 must be in place. This clicks into position on the transducer to cover the open channel (see Figure 3).

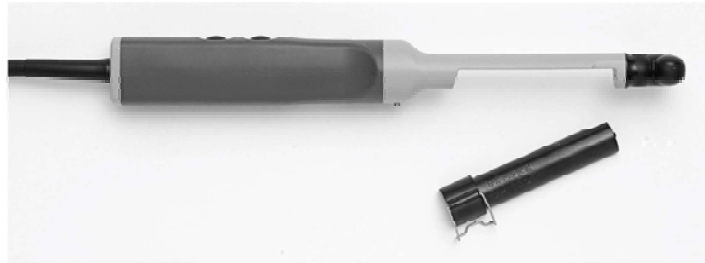


Figure 3. Type 8808e and the dummy channel bracket UA1325.

- Note:** The dummy bracket must be removed before 8808e is prepared for disinfection. The bracket can be disinfected using the same methods as explained later under UA1326.

Puncture and Biopsy Facilities

- Transrectal and transperineal puncture and biopsy are possible with 8808e. The following pages illustrate the various transrectal and transperineal puncture accessories available and briefly describe usage and operating instructions. The transducer has an open channel into which the appropriate puncture accessories fit when the dummy channel bracket (UA1325) has been removed (see Figure 3).



WARNING

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

For Transrectal Puncture

- With 8808e, you can perform transrectal puncture and biopsy by imaging in simultaneous biplane (imaging in both the transverse and sagittal planes).
- The biopsy guide is available in both a non-sterile reusable version (light green) and a sterile-packed single-use version (dark green).

Non-sterile biopsy guides (light green)

- The dummy channel bracket UA1325 and the reusable biopsy guide (UA1326) are non-sterile when supplied and must be disinfected by immersion in a suitable solution and autoclaved. The dummy channel bracket and reusable biopsy guide may be damaged during use or processing, so they must be checked before use for cracks or irregularities in the surface. They should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety*.

Sterile biopsy guides (dark green)

The sterile single-use biopsy guide UA1322-S and UA1322-S14 come assembled in peel packs. Contents are only sterile if the package is intact.



WARNING

Disposable components are packaged sterile and are intended for single-use only.

Do not use if:

- Integrity of packaging is violated
- Expiration date has passed
- Package label is missing

The sterile-packed biopsy guides must be stored at a temperature range from +15 °C (+57 °F) to +25 °C (+77 °F) and at a storage humidity of 30% to 80%.



WARNING

Sterile-packed components must be stored in a safe environment and kept out of direct sunlight. Large temperature changes during storage may cause condensation and violate the integrity of the packaging.

Please refer to *Care, Cleaning and Safety* for an example of how to open a sterile-packed product.

Simultaneous Biplane

The sterile biopsy guide UA1322-S, UA1322-S14 and reusable biopsy guide UA1326 are used for simultaneous biplane imaging.



Figure 4. Reusable biopsy guide UA1326.

The puncture line for UA1322-S, UA1322-S14 and UA1326 on 8808e is shown in Figure 5. UA1322-S and UA1326 have a bore diameter of 1.6 mm, suitable for 17-gauge needles. UA1322-S14 has a bore diameter of 2.1 mm, suitable for 14-gauge needles. The puncture line is angled at 19° to the transducer's axis.

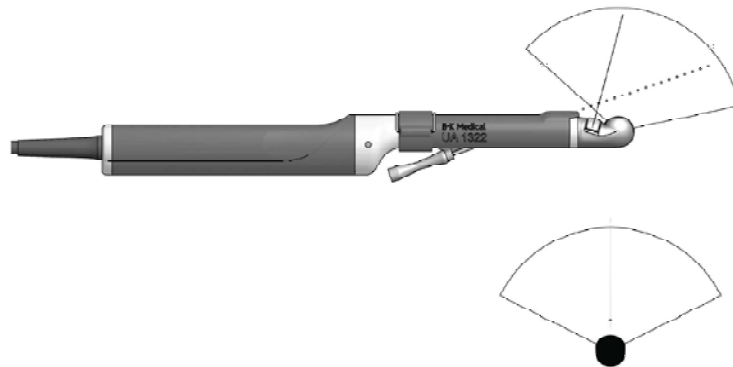


Figure 5. Illustration of the puncture line for biopsy guide UA1322-S, UA1322-S14 and UA1326.

Mounting a Transrectal Biopsy Guide

To mount a biopsy guide on 8808e:

- 1 If a dummy channel bracket is mounted on the transducer, remove it.
- 2 Pull a transducer cover or a standard condom containing a suitable amount of imaging gel over the transducer.
- 3 Slide the needle guide into the biopsy channel bracket.



WARNING

Do not use excessive force when inserting the needle guide.

- 4 Insert the assembled needle guide and biopsy channel bracket into the open channel on the transducer. A small nodule on the end of the channel bracket fits into an indentation in the channel on the transducer to help you place the bracket correctly. Click the channel bracket into position on the transducer and lock it into place (see Figure 6).



Figure 6. Biopsy channel bracket and needle guide mounted on 8808e.



WARNING

Ensure that the channel bracket and needle guide are correctly positioned. Never insert the needle guide while the transducer is inside the patient.

To remove the bracket, remove the outer condom, open the lock and lift the bracket off the transducer.

For Transperineal Puncture

The metal puncture attachment UA1324, shown in Figure 7, is designed for transperineal puncture and biopsy. When UA1324 is being used, the dummy channel bracket UA1325 (shown in Figure 3) must be in place.

Puncture attachment UA1324 must be autoclaved or disinfected by immersion in a suitable solution.

UA1324 consists of a needle guide and a mounting ring with clamp. The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.

Note: The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.



Figure 7. Puncture attachment UA1324.

Mounting the Transperineal Puncture Attachment

To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325 is in place. Pull a sterile transducer cover over the transducer. Loosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer. The puncture attachment should be correctly positioned so that the groove slides easily over stud. No force should be used when attaching the puncture attachment to the transducer.

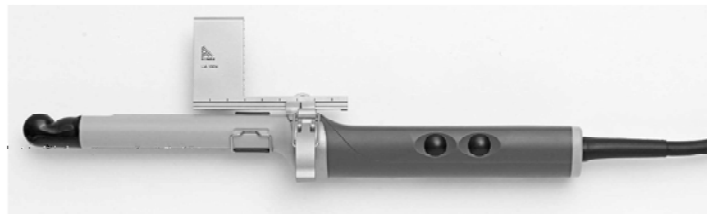


Figure 8. Puncture attachment UA1324 mounted on 8808e.

The puncture lines for UA1324 on 8808e are shown in Figure 9.

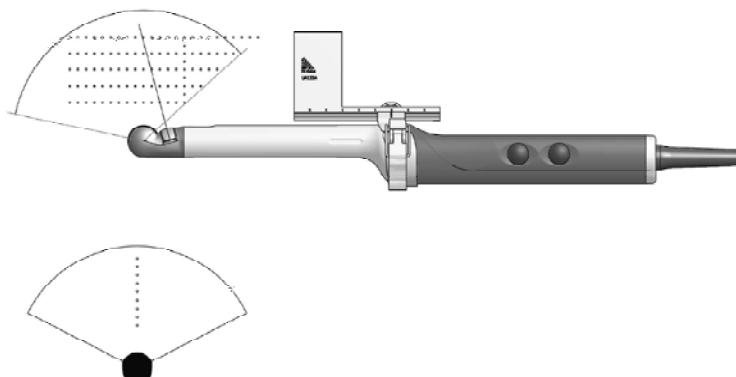


Figure 9. Illustration of the puncture line for puncture attachment UA1324.

Performing Puncture and Biopsy



WARNING

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the system monitor.



WARNING

The puncture line on the image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

If not sterilized, cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

See the Product Data sheet for a list of available transducer covers.

Superimpose
puncture line

Press the system **Puncture or Biopsy** control button to superimpose a puncture line on the image.

If more than one puncture line is available, refer to the applicable system user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

The puncture line will differ depending on the imaging plane orientation. In the sagittal plane, the puncture path is indicated by a line of dots. The distance between each puncture dot is 5 mm.

In the transverse plane, a single dot indicates the point at which the needle will transect the imaging plane.



WARNING

If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

If the cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.

To remove the puncture line from the scan image, refer to the applicable system user guide for instructions.



WARNING

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer, disinfection and sterilization processes may not be effective. Therefore, you must clean transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves. See *Care, Cleaning & Safety* for cleaning instructions.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable system user guide for further details.



WARNING

For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department or hospital.

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Transducer	Applications	
00448 A resolution revolution in image guided prostate therapy. Resolute, clear and detailed images of the prostate, for accurate volume studies and source dose planning.	Prostate brachytherapy Transrectal scanning Transperineal puncture Transvaginal scanning Prostate cryotherapy Spectral and CFM Doppler Contrast imaging*	
00666 The most advanced laparoscopic ultrasound transducer on the market. Rigid and 4-way laparoscopic scanning in one. A versatile built in biopsy guide for staging.	Laparoscopic ultrasound Intraoperative ultrasound Ultrasound guided: Radiofrequency tumor ablation (RFA) Biopsy Drainage	
00667 Endfire prostate imaging. A wide endfire image plane enables you to locate a lesion and then rotate the plane around a central	Endorectal scanning Interventional procedures Spectral, CFM and Power Doppler Tissue harmonic imaging	



BK Medical Ultrasound Transducers

Click on the number for an indepth look at that specific transducer and to download a brochure

Urology	Transducer	Applications
	<u>8848</u> A resolution revolution in image guided prostate therapy. Resolute, clear and detailed images of the prostate, for accurate volume studies and source dose planning.	Prostate brachytherapy Transrectal scanning Transperineal puncture Transvaginal scanning Prostate cryotherapy Spectral and CFM Doppler Contrast imaging*
	<u>8666</u> The most advanced laparoscopic ultrasound transducer on the market. Rigid and 4-way laparoscopic scanning in one. A versatile built in biopsy guide for staging.	Laparoscopic ultrasound Intraoperative ultrasound Ultrasound guided: Radiofrequency tumor ablation (RFA) Biopsy Drainage
	<u>8667</u> Endfire prostate imaging. A wide endfire image plane enables you to locate a lesion and then rotate the plane around a central axis.	Endorectal scanning Interventional procedures Spectral, CFM and Power Doppler Tissue harmonic imaging
	<u>8670</u> Small part, musculoskeletal and vascular scanning. Its excellent Doppler makes it a great choice for penile Doppler and testis scanning.	Small part Breast scanning Testis scanning Penile Doppler Musculoskeletal Peripheral vascular Interventional procedures Contrast Imaging*
	<u>8808</u> Simultaneous biplane imaging of the prostate. The 8808 uses two convex arrays, one for transverse scanning and one for sagittal scanning.	Transrectal scanning Transrectal puncture Transperineal puncture Spectral and CFM Doppler Tissue harmonic imaging
	<u>8808e</u> Orient yourself for biopsy with simultaneous biplane. The 8808e gives you real-time images of the sagittal and transverse planes which are invaluable for orientation.	Transrectal scanning Transrectal puncture Transperineal puncture Spectral and CFM Doppler Tissue harmonic imaging
	<u>8811</u> A broadband linear array transducer with high frequencies unprecedented for scanning equipment of its class. Your benefit: excellent high-resolution imaging with good penetration during near-field small part scanning at a reasonable price.	Small part scanning Musculoskeletal scanning Peripheral vascular scanning Pediatric scanning Tissue harmonic imaging
	<u>8818</u> Triplane imaging - all prostate zones with one transducer. The 8818 gives you unsurpassed image quality in three visionary planes that open up the entire prostate.	Transrectal prostate scanning Transrectal puncture and biopsy Transperineal puncture and biopsy Transvaginal scanning Spectral and CFM Doppler Tissue harmonic imaging Contrast imaging*
	<u>8820e</u> Comfort and quality in abdominal ultrasound. Broadband scanning and excellent image quality with a new,	Liver Pancreas Bladder General abdominal

Urology	Transducers	Applications
	design. The 8820e delivers the depth and sharpness you need from ultrasound images.	Interventional procedures
	 8823 Easy access to kidney diagnostics. The convenient 8823 renal transducer provides superior image quality for anatomical details while minimizing patient discomfort during intercostal scanning.	Kidney Bladder Pediatric Difficult to access areas
Surgery		
	 8862 Craniotomy Transducer Premium performance neuroimaging, unmatched transducer function and design, convenient, sterile needle guides, STERRAD NX & 100NX compatible	Neurosurgical scanning Intraoperative scanning Pediatric scanning Interventional procedures Spectral and CFM Doppler examinations
	 8863 Burr Hole Transducer Premium performance neuroimaging, unmatched transducer function and design, convenient, sterile needle guides, STERRAD NX & 100NX compatible	Neurosurgical scanning Intraoperative scanning Interventional procedures Spectral and CFM Doppler
	 8809 Uniquely optimized for intraoperative vascular scanning, general intraoperative scanning and musculoskeletal applications. Its small flexible tip easily reaches difficult to access areas, and its very high frequency provides unsurpassed resolution in the extreme near field.	Intraoperative vascular General intraoperative Musculoskeletal scanning Small part scanning Interventional procedures
	 8814 The ultimate tool for ultrasound-guided needle placement. A breakthrough in surgical imaging for precise needle guidance: simultaneous live biplane imaging.	Intraoperative Ultrasound guided: Tumor Ablation (RF, Microwave) Biopsy RF Ablation Drainage
	 8815 Designed especially for interventional ultrasound during surgery. I-shaped intraoperative transducer guided intraoperative biopsy with a variety of angles and positions.	Intraoperative Ultrasound guided biopsy and RF ablation Pediatric scanning Spectral and CFM Doppler
	 8816 A small, T-shaped transducer designed primarily for hepatic surgery. Excellent image quality and a wide near field view.	Intraoperative Abdominal scanning Spectral and CFM Doppler Coded excitation Contrast imaging* Harmonic Imaging
	 8824 A small T-shaped intraoperative transducer. Choose between the I, T or simultaneous imaging. Combined I and T array for improved orientation Flexibility to take free hand biopsies from the front, back, left, or right.	Intraoperative scanning Vascular scanning Contrast imaging Tissue harmonic imaging Optimized for liver scanning 3D freehand
	 8666 The most advanced laparoscopic ultrasound transducer on the market. Rigid and 4-way laparoscopic scanning in one. A versatile built in biopsy guide for staging.	Laparoscopic Intraoperative Ultrasound guided: RFA Biopsy Drainage
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	<u>8809</u> Uniquely optimized for intraoperative vascular scanning, general intraoperative scanning and musculoskeletal applications. Its small flexible tip easily reaches difficult to access areas, and its very high frequency provides unsurpassed resolution in the extreme near field.	Intraoperative vascular General intraoperative Musculoskeletal Small part Interventional
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Prostate Biopsy: The Transperineal Approach

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Abstract

Objective: Review the literature concerning transperineal transrectal ultrasound (TRUS)-guided prostate biopsy (PBx), providing an update on the topic.

Methods: The literature review was performed using PubMed through a free text search strategy. The authors reviewed the abstracts of the retrieved records to select the relevant papers.

Results: The search retrieved 196 records; 68 were relevant to the issue. No high-level evidence recommends a particular kind of preparation/prophylaxis for transperineal PBx. It can be performed with a brachytherapy template under general or spinal anesthesia, or with a local periprostatic nerve block through a single-access fan technique. In the former case, up to 50 cores are obtained; in the latter, 12–26 cores. Prostate cancer detection rates range from 24% to 51%, with figures of 27–49% in patients undergoing their first PBx for a prostate-specific antigen level of 4–10 ng/ml. Such percentages are directly related to the number of cores obtained. In repeat biopsy and in prostates > 50 cc, the number of cores should be increased, paying particular attention in sampling the anterior zone. Among the studies comparing transrectal and transperineal PBx, only two demonstrated differences in detection rates in favor of the transperineal approach. Major complications are rare, with fever occurring in 0–5.2% and hospitalization in 0–1.4% of cases.

Conclusion: Transperineal TRUS-guided PBx is a safe procedure, with high detection rates and wide applications both in first and in repeat sampling. Although having a strong rationale, the transperineal approach has so far not resulted in higher detection rates than transrectal biopsies.

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1. Introduction

From an historical viewpoint, the transperineal route has been the first one to be used to reach the prostate, both for diagnostic and therapeutic purposes [1]. For histologic diagnosis of prostate cancer, surgical perineal prostate biopsy (PBx) first and finger-guided perineal punch biopsy later on were the only possible approaches in the early 20th century [2].

The transrectal route has been used for finger-guided PBx since the mid-1950s [3], becoming the gold standard after Hodge et al demonstrated higher detection rates for sextant transrectal ultrasound (TRUS)-guided PBx than for sextant finger-guided analog sampling [4].

To date, because it seems to be more invasive and difficult, the TRUS-guided transperineal route is less used worldwide than the transrectal one, with figures ranging from 1.9% to 25% of the biopsies [5,6]. Nevertheless, supporters of such an approach report a lower risk for infective complications, a more selective sampling of the peripheral gland [7,8], an easier approach to the anterior zone of the prostate [9], and a higher detection rate [10] than transrectal PBx.

With this perspective, the aim of our study was to review the literature concerning transperineal TRUS-guided PBx and to provide up-to-date recommendations on the topic.

2. Methods

The review of the literature was performed using PubMed through a free text search strategy including the following entry terms: “transperineal” or “trans-perineal” or “perineal” and “prostate biopsy.” The following limits were used to restrict the search: publication date after 1987, English, Title/Abstract. The authors reviewed the abstracts of the retrieved records to select the papers relevant to the topic of the study.

All the papers were ranked according to the grade of evidence as stated by Phillips and Sackett [11]. Meta-analyses of randomized clinical trials (RCTs) constitute the highest evidence (level 1a), followed by an adequately sampled, single RCT (level 1b); low-quality RCTs, prospective cohort studies, and high-quality case-control studies give level 2 evidence. A lower grade of evidence was provided by retrospective case-control studies or good-quality case series (level 3), whereas poor-quality case series, case reports, or expert opinion provide level 4 evidence [11].

3. Results

The search retrieved 196 records. Abstracts concerned with the issue of transperineal PBx numbered 68. The full texts of the 68 interesting articles

were reviewed. No level 1a evidence was retrieved and only two randomized trials (level 1b) were found [8,12]. Among those with level 2 evidence, most of the studies comparing different biopsy approaches or different core numbers used the same patients as internal controls [10,13–16]. Two further studies evaluated computer- or autopsy-based simulations of different approaches for PBx [7,17]. The remaining articles described non-controlled case series or case reports (level 3–4).

3.1. Preparation

No study specifically dealing with antibiotic prophylaxis, bowel preparation, or anticoagulant therapy suspension in transperineal PBx was retrieved.

Because the biopsy needle does not pass through the rectum, the transperineal approach should be considered a sterile procedure. For this reason, antibiotic prophylaxis should be recommended only for patients with a high risk of infection, such as diabetic or immunosuppressed patients, those with a poor general health status, cardiac prostheses, or cardiac valve pathologies, and those with an indwelling catheter or high postvoiding residual. In those patients, fluoroquinolones are indicated as first-choice antimicrobials. Alternatively, ampicillin, β -lactamase inhibitors, cephalosporins, or cotrimoxazole can be used as second-choice antibiotics. For patients with cardiac valve pathologies or prostheses, double antibiotic prophylaxis with ampicillin/vancomycin associated with aminoglycosides is indicated [18,19]. No univocal indication exists concerning the length of antibiotic prophylaxis in these patients. Similarly to what happens with the transrectal route, antibiotic usage should be prolonged for 3 d [20]. According to descriptive literature data, most of the centers performing transperineal PBx usually prescribe an antibiotic prophylaxis the day before the procedure; only some of them continue antibiotic usage for 2–3 d after the procedure [6,12,21]. In our clinical practice [13], we prefer to use antimicrobial prophylaxis in all patients scheduled for PBx. Our scheme includes a single-dose fluoroquinolone before the procedure. In our series, clinically significant urinary tract infections occurred in < 1% of cases. Only 3 patients (0.6%) of the 480 prospectively evaluated needed hospitalization for fever and urinary tract infections [13].

Roughly 80% of urologists will prescribe an enema as a preparation for transrectal PBx [22]. The reduction of the bacterial load on rectal mucosa may decrease procedure-related infections [23]. More recent data, from a Japanese PBx survey

including both transrectal and transperineal procedures (76% and 24%, respectively) report the use of a cleansing enema in only 44% of cases [6]. In transperineal biopsies, because the needle is not contaminated by fecal material, a preparation enema may be pointless. Nevertheless, currently it is preferable to perform an enema some hours before the procedure. In this way it is possible to reduce the discomfort due to the concomitant presence of the transrectal probe and fecal material in the rectum and to improve the quality of the ultrasound image [19].

As far as anticoagulant therapy is concerned, no specific study dealt with transperineal PBx. The few studies concerning transrectal PBx and suspension of anticoagulant therapy concluded there were no advantages in patients suspending aspirin ingestion before biopsy [24,25]. A recent meta-analysis confirmed such conclusions [26] and more recent data from a survey report 59% of United Kingdom urologists do not stop aspirin before PBx because the cerebrovascular risks of stopping aspirin outweigh the benefits on bleeding expected by aspirin discontinuation [27]. Similar conclusions have been drawn concerning with warfarin and other anti-coagulants [28].

3.2. Transperineal biopsy technique

We retrieved 28 articles from 16 groups describing a transperineal PBx (Table 1). Five groups performed the biopsy through the guide of a brachytherapy template device, with one skin puncture for each single core, whereas 11 used a fan technique, using a common access for all the cores. All authors

performed this kind of biopsy in the dorsal lithotomy position (only 1 used the extended lithotomy [33]), exposing the perineum and executing TRUS as a preliminary procedure.

3.2.1. Anesthesia

Even though no specific study compared different kinds of anesthesia for transperineal PBx, all authors agree with the need to perform some kind of anesthesia.

Among the authors performing PBx with the fan technique, some groups preferred spinal anesthesia, whereas others performed the biopsy under local anesthesia with a periprostatic nerve block. Regional differences exist: for example, Japanese authors prefer the locoregional approach, whereas Italian ones routinely use local anesthesia (Table 1). Among the groups performing a transperineal PBx with the guide of a brachytherapy template, most of them use a general or spinal anesthesia. More specifically, the execution of multiple punctures on perineal skin and multiple perineal paths for the brachytherapy template makes it almost impossible to perform adequate local anesthesia; on the contrary, as the fan technique implies the execution of only one or two skin punctures following the same perineal path, local anesthesia is feasible with good results. For the execution of the periprostatic nerve block and for the following biopsies, some authors use a double access situated on the two sides of the midline above the anus at a 45° angle from midline at about 1.5 cm from the anus [21], whereas other authors prefer a single transperineal access on the midline 1.5 cm above the anus [12]. Though presenting a theoretically higher risk of

Table 1 – Groups proposing an original transperineal prostate biopsy technique

Author	Region	Anesthesia	Template	Cores (range)	Set
Saitoh 1997 [29]	Japan	Spinal	No	12	First
Emiliozzi 2001 [21]	Italy	Local	No	12	First
Kojima 2001 [30]	Japan	Spinal	No	12	First
Igel 2001 [31]	USA	General/spinal	Yes	17	Repeat
Novella 2003 [12]	Italy	Local	No	14	First
Kawakami 2004 [32]	Japan	Spinal	No	14	First
Bott 2005 [33]	UK	General	Yes	24 (12–36)	Repeat
Pepe 2005 [34]	Italy	Local	No	12–18	First
Satoh 2005 [9]	Japan	Spinal	Yes	22	Repeat
Watanabe 2005 [16]	Japan	Spinal	No	6 TP + 6 TR	First
Yamamoto 2005 [35]	Japan	General	No	12	First
Demura 2005 [36]	Japan	Spinal	Yes	20 (9–38)	Mixed
Luciani 2006 [37]	Italy	Local	No	12	First
Kawakami 2006 [38]	Japan	Spinal	No	14 TP + 12 TR	First
Takenaka 2006 [15]	Japan	Spinal	No	12	First
Moran 2006 [39]	USA	General	Yes	41	Repeat
Merrick 2007 [40]	USA	General	Yes	50	Repeat

TP = transperineal; TR = transrectal.

bulbar urethra and corpus spongiosus lesions, the median access reduces the risk of lesions to the bulbourethral arteries and perineal hematomas, thus improving the tolerability of the examination [12].

3.2.2. Fan technique

According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path [21]. To minimize the invasiveness of the technique, a coaxial needle can be used with the aim of performing the several needle passages through the same path [12]. The coaxial needle makes the procedure easier and quicker, allowing the repeated introduction of the needle with low perineal trauma. The results of a prospective, randomized study comparing 51 patients undergoing conventional transperineal PBx and 51 patients undergoing transperineal PBx using the coaxial needle showed a reduction of pain during the biopsy and a better compliance for patients using the coaxial needle [12].

3.2.3. Template-guided stereotactic technique

With the aim of improving detection rates in patients with a previous negative biopsy or at high risk for prostate cancer, some authors proposed use

of the transperineal brachytherapy template device as a guide for the needle. This type of biopsy has been designed to perform saturation biopsy, being able to sample extensively the prostate with a higher tridimensional space control [31], but it has been used also for first-set biopsies [36,41]. The main disadvantage of this technique is the need for spinal or general anesthesia [42].

3.2.4. Number and location of cores

The optimal number and site of cores to be sampled in transperineal PBx is currently under debate [13]. Because the procedure is always preformed under anesthesia, the number of cores is usually higher than in the transrectal route, starting from 12 in the first set up to 50 in template saturation biopsies (Table 1).

Prostate cancer detection rates widely vary according to the population sampled (first or repeated biopsy), number of cores taken, prostate-specific antigen (PSA) value, and prostate volume (Table 2).

In patients undergoing their first PBx for a PSA between 4 and 10 ng/ml (Table 3), fan PBx yields a positive result in 27–45%; template PBx is rarely used in the first set, providing detection rates approximating 50%, whereas it is frequently used as a saturation sampling method in patients repeating PBx, providing a 22–43% rate of prostate cancer

Table 2 – Features of the transperineal prostate biopsy published series

Author	Patients	Cores (range)	PSA range	Median PSA	Median postate volume	Negative DRE	First set	Template	Detection rate
Igel 2001 [31]	88	17	NR	13.1	NR	NR	0%	Yes	43%
Emiliezzi 2001 [21]	141	12	4.1–5000	8	NR	NR	100%	No	51%
Kojima 2001 [30]	541	12	NA	NR	NR	68.8%	100%	No	24%
Emiliezzi 2003 [10]	107	6TR + 6TP	4–240	8.2	NR	NR	100%	No	40%
Furuno 2004 [41]	113	18.2 (9–33)	4–10	NR	NR	88.5%	23.9%	Yes	42%
Emiliezzi 2004 [8]	72	12	4–10	NR	NR	71%	100%	No	49%
Kawakami 2004 [32]	289	14	2.5–40	10.7	47	81.4%	100%	No	36%
Bott 2005 [33]	60	24 (18–36)	4.5–35.7	12.9	54	93%	0%	Yes	38%
Demura 2005 [36]	371	20.1 (9–38)	NR	NR	42.5	63.6%	84.1%	Yes	49%
Pinkstaff 2005 [43]	210	21.212–41)	NR	13.6	NR	NR	0%	Yes	37%
Ficarra 2005 [13]	480	14	2.5–20	7.6	41.6	67.3%	100%	No	44%
Pepe 2005 [34]	372	12–18	NR	NR	NR	76.1%	NR	No	42.7%
Satoh 2005 [9]	128	12	2.4–170	10.3	43.9	98.5%	0%	Yes	22.7%
Watanabe 2005 [16]	402	6TR + 6TP	0.6–460	NR	NR	67.8%	100%	No	48.5%
Yamamoto 2005 [35]	300	12	2.5–20	7.25	28.3	35.1%	100%	No	36%
Moran 2006 [39]	180	41	0.8–40.1	8.1	46.5	NR	0%	Yes	38%
Kawakami 2006 [38]	321	14TP + 12TR	0.9–38	6	36	82%	100%	No	34%
Luciani 2006 [37]	122	12	> 0	16.3	38	100%	100%	No	75%
Rocco 2006 [44]	63	12	0.2–9.1	1.2	NR	NR	100%	No	17.2%
Takenaka 2006 [15]	247	12	3.2–99	9.4	39.2	75.3%	76.6%	No	39.7%
Merrick 2007 [40]	102	50	NR	8.3	78.6	NR	1%	Yes	42%
Kawakami 2007 [14]	235	14TP + 12TR	5.8–2.2 (i.r.)	8.3	41	82%	0%	No	37%

PSA = prostate-specific antigen; DRE = digital rectal examination; TP = transperineal; TR = transrectal; NR = not reported; NA = not available i.r. = interquartile range.

Table 3 – Cancer detection rates in patients undergoing the first transperineal prostate biopsy for 4–10 ng/ml PSA

Author	Patients	Cores (range)	Template	Detection rate
Emiliozzi 2001 [21]	97	12	No	45%
Kojima 2001 [30]	541	12	No	40.8%
Emiliozzi 2003 [10]	70	6TP + 6TR	No	30%
Emiliozzi 2004 [8]	72	12	No	49%
Kawakami 2004 [32]	148	14	No	27%
Furuno 2004 [41]	86	18 (9–33)	Yes	49%
Ficarra 2005 [13]	389	14	No	42.4%
Watanabe 2005 [16]	180	14TP + 12TR	No	33.9%
Yamamoto 2005 [35]	184	12	No	31%

PSA = prostate-specific antigen; TP = transperineal; TR = transrectal.

diagnoses. Such detection rates are usually higher than in transrectal saturation biopsies, reportedly between 13% and 41% [45]. Probably, this might be justified by the higher precision in sampling all prostatic zones and in particular the anterior part of the gland [41].

To date, six studies have compared schemes sampling a different core number, two using different patient samples [8,34] and four using internal controls [13–15,40]. Emiliozzi et al demonstrated an increasing detection rate with higher core numbers, particularly in patients with a PSA of 4–10 ng/ml (30% in 6-core transperineal biopsy vs. 49% in 12-core transperineal biopsy). Pepe et al confirmed these data comparing 12 versus 18 transperineal cores, with detection rates reaching 35% and 51%, respectively [34].

In the studies comparing different schemes through a recursive partitioning within the same patient population, Takenaka et al compared their complete scheme (12 cores) with the standard sextant, obtaining a 20% increase in diagnoses with the additional cores [15]. More detailed studies have been conducted by Ficarra et al in 2005 and by Merrick et al in 2007; both of them confirmed an increase in diagnoses proportional to the increase in core number, reaching 43.8% detection rates in a 14-core first biopsy series [13] and 42.1% in a 24-core repeat biopsy series [40]. These two studies report prostate volume as the strongest predictor for prostate cancer detection [13,40], highlighting the need to increase the number of cores in prostates > 50 cc [13].

Another variable to be taken into account for prostate cancer detection is the location of the cores. In studies coming from transrectal biopsy series, prostate cancer has been reported to be located in the peripheral zone in 85% of nonpalpable [46] and in 74% of palpable tumors [47].

On the other hand, transperineal PBx series demonstrate that up to 70% of prostate cancers are located in the anterior part of the prostate [32],

with a more frequent involvement of this area in nonpalpable cancers than in palpable ones [32,36] and in repeat biopsy than in the first set [9,41]. Moreover, the transitional zone is involved by cancer in up to 76% of patients with a positive result after a repeat biopsy with a transperineal template approach [31].

With this perspective, prostate sampling should include at least a minimum number of anterior cores in the first set, preferably in the far lateral peripheral zone (anterior horn). According to Ficarra et al, sampling this region with a single core per lobe provides an additional cancer diagnosis in 11% of cases [13].

According to these data, it seems reasonable to deduce that in the first transperineal biopsy setting a minimum of 12 cores should be taken, including the far lateral peripheral zone (anterior horn). Sampling of the transition zone might be omitted in these patients. On the other hand, repeat PBx should include a thorough sampling of the posterior and anterior zones, including transitional cores (Fig. 1). The brachytherapy template in repeat biopsy theoretically provides a more rational prostatic sampling, even though higher anesthetic support is necessary.

3.2.5. Comparing transperineal and transrectal PBx

Five studies have been identified comparing transrectal and transperineal PBx, all of them performing transperineal and transrectal PBx on the same patients (Table 4). The first one [7] was a simulation of transperineal (longitudinal) and transrectal (transverse) PBx conducted on radical prostatectomy surgical specimens. In this study, cancer had been initially diagnosed through transrectal biopsy. Nevertheless, 82.5% of the 40 analyzed cancers was redetected by sextant transperineal biopsy, whereas only 72.5% of cases was redetected by transrectal sextant biopsy. These experimental data were confirmed in clinical practice in 2003, when Emiliozzi et al studied 107 patients under-

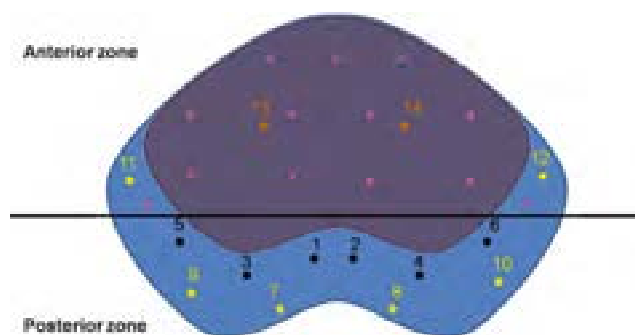


Fig. 1 – Number and location of cores in transperineal prostate biopsy. 1–6 (black) sextant cores; 7–12 (yellow) lateral sextant cores; 13–14 (orange) transition zone cores. Not numbered (pink) cores: possible additional cores in the anterior zone of the prostate.

going 12 biopsies using a combination of the transrectal (6 cores in the peripheral zone) and transperineal (6 cores in the peripheral zone) approach. The authors reported higher detection

rates for the transperineal technique. In particular, the study showed an overall cancer detection rate of 40%, with 38% imputable to transperineal 6-core biopsy and 32% due to 6-core transrectal approach. In the subset of patients with a PSA of 4–10 ng/ml, the detection rates of the transperineal and transrectal biopsy were 27% and 20%, respectively [10]. A nearly identical study was performed by Watanabe et al, with different results. In their study, the authors reported an overall detection rate of 48%, significantly lower than the one produced by the six transrectal cores (40%) or by the one produced by the transperineal ones (41.2%). This difference could be due to the different prostatic sampling (6 peripheral transrectal cores versus 4 peripheral and 2 transitional transperineal cores) [16].

A different scenario was proposed by Kawakami et al, one using a systematic transrectal (12 cores) and transperineal (14 cores) prostatic sampling in patients undergoing their first [38,48] or repeated biopsy [14]. In both cases, the route of sampling

Table 4 – Studies comparing transrectal versus transperineal prostate biopsy

Author	Patients	Cores	PSA range	Set	Detection rate (all)	Detection rate (TR)	Detection rate (TP)	p (TR vs. TP)	p (TP vs. all)
Vis 2000 [7]	40	6TR + 6 TP	NA	NA	NA	72.5%	82.5%	NR	NR
Emiliozzi 2003 [10]	107	6TR + 6TP	4–240	First	40%	32%	38%	0.012	>0.05
Watanabe 2005 [16]	180	6TR + 6TP	4–10	First	48.5%	40%	41.3%	>0.05	0.019
Kawakami 2006 [38]	321	14TP + 12TR	0.9–38	First	34%	21.1%	NR	NR	NR
Kawakami 2007 [14]	235	14TP + 12TR	5.8–12.2 (i.r.)	Repeat	37%	29.3%	30.2%	>0.05	>0.05

PSA = prostate-specific antigen; TP = transperineal; TR = transrectal; NA = not applicable; NR = not reported; i.r.: interquartile range.

Table 5 – Major complications of transperineal prostate biopsy series

Author	Patients	Cores	Set	Severe hematuria	AUR	Fever	Hospitalization
Emiliozzi 2001 [21]	141	12	First	NR	0.7%	0%	0%
Kojima 2001 [30]	679	12	First	2.6%	7.2%	5.2%	NR
Igel 2001 [31]	88	17 T	Repeat	3.4%	2.2%	1.1%	0%
Emiliozzi 2003 [10]	107	6TP + 6TR	First	NR	0%	0%	0%
Novella 2003 [12]	102	14	First	NR	3%	1%	0%
Emiliozzi 2004 [8]	107	12	First	NR	0%	0%	0%
Kawakami 2004 [32]	289	14	First	1%	0%	0%	1.4%
Buskirk 2004 [49]	157	12	First	NR	11%	NR	NR
Furuno 2004 [41]	113	18 T	Mix	NR	1%	0%	0%
Ficarra 2005 [13]	480	14	First	0.4%	0.6%	0.6%	0.6%
Pepe 2005 [34]	372	18	NR	NR	4.3%	0.8%	NR
Watanabe 2005 [16]	402	6TR + 6TP	First	0.5%	0.5%	0.5%	NR
Bott 2005 [33]	60	24 T	Repeat	2%	NR	NR	NR
Demura 2005 [36]	371	20 T	Repeat	1.6%	1.6%	0%	0
Pinkstaff 2005 [43]	210	21 T	Repeat	NR	11%	NR	NR
Sato 2005 [9]	128	18 T	Repeat	NR	3.2%	0.8%	0.8%
Kawakami 2006 [38]	321	12TR + 14TP	First	NR	0%	0.6%	0.6%
Moran 2006 [39]	180	41 T	Repeat	NR	10%	NR	NR
Merrick 2007 [40]	102	50 T	Repeat	1%	38%	NR	NR
Kawakami 2007 [14]	235	12TR + 14 TP	Repeat	0.4%	0.4%	0.8%	1.3%

AUR = acute urinary retention; TP = transperineal; TR = transrectal; T = template; NR = not reported; i.r. = interquartile range.

seems not to affect the ability to detect prostate cancer (88% vs. 88% of the cancers in the first biopsy set and 79% vs. 82% in repeat biopsy), whereas the combination of the two techniques allowed detection of a significantly higher number of cancers, with an overall cancer diagnosis of 34% in case of first biopsy and of 37% in case of repeat biopsy [14,48].

Unfortunately, no study specifically assessed the differences in time consumption and in costs for these two techniques. Nevertheless, because the only differences are in patient preparation and position and the materials to be used are similar, it can be supposed that no substantial differences exist between transrectal and transperineal PBx.

In conclusion, though having a strong rationale, the transperineal approach has not convincingly been demonstrated to provide detection rates higher than transrectal biopsy. High-quality, comparative studies must be performed to assess which kind of biopsy provides better results.

3.3. Complications

Most of the series reporting on transperineal PBx provide data concerning the complications related to the procedure. According to those data, transperineal biopsy is a safe procedure. Major complications, such as severe hematuria, acute urinary retention, fever, and other problems requiring hospitalization are rare (Table 5). Considering that in transperineal PBx the needle does not pass through the rectum, fever occurs in 0–1% of cases. Only one series reports fever occurring in 5.2% of cases [30].

Minor complications are more frequent but, because they rarely need treatments, they are seldom reported. In particular, self-limiting hematuria occurs in percentages ranging from 8.6% [34] to 52% [12], hemospermia happens in up to 79% of patients [8], and perineal discomfort or perineal hematoma has lower percentages (1–6%) [12,21]. Unfortunately, only a few authors reported the methods used to collect data concerning complications.

4. Conclusion

Transperineal TRUS-guided PBx is a safe procedure, with high detection rates and low morbidity.

The specific preparation for transperineal biopsy has not been studied through prospective controlled studies. Because the infectious risk of this procedure seems to be low, a single-dose fluoroquinolone prophylaxis has been advised in patients with a

standard risk for infection. The execution of a cleansing enema is recommended, and anticoagulant therapy should be stopped only if the hemorrhagic risk exceeds the thrombotic risk.

At least local anesthesia with periprostatic nerve block should be performed. Particularly in repeat PBx or when using the brachytherapy template, some groups propose using spinal or (more rarely) general anesthesia.

Because 6-core schemes provide insufficient detection rates, at least 12 cores are usually taken in the first prostatic sampling. Repeat biopsy, with or without a brachytherapy template, should include more cores, with particular attention to the anterior zone of the prostate.

High-quality, randomized, controlled studies must be performed to support the available evidence that the transperineal approach provides better results than the transrectal one both in terms of complications and results.

Conflicts of interest

The authors have nothing to disclose.

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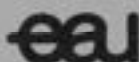
- Transperineal prostate biopsy:
 - Has to be performed without the guide of transrectal ultrasound (TRUS).
 - Cannot be performed without general anesthesia.
 - Has to be performed in selected centers only.
 - Has to be performed with some kind of anesthesia.
- In transperineal prostate biopsy, the template technique:
 - Requires multiple skin accesses and paths to take the cores.
 - Requires one or two skin accesses for all the cores.
 - Is the technique of implanting the seeds for brachytherapy at the same moment of prostate biopsy.
 - Has to be performed with three-dimensional ultrasound equipment.
- A good-quality first-set transperineal prostate biopsy:
 - Should include at least six cores.
 - Should sample the anterior far lateral aspects of the prostate (anterior horn).
 - Should include at least four cores from the transition zone.
 - The transition zone should be sampled only for prostate-specific antigen levels > 10 ng/ml.
- Comparing transperineal versus transrectal prostate biopsy:
 - There is a theoretical minor risk for infection in transperineal biopsy.
 - Detection rates are higher in transrectal procedures than in transperineal ones.
 - Transrectal biopsy requires a more difficult preparation.
 - Complication rates are higher in transperineal biopsy.
- To improve detection rates, it is advisable:
 - To increase the number of cores proportionally to prostate-specific antigen levels.
 - To decrease the number of cores proportionally to the transition zone volume.
 - To increase the number of cores proportionally to prostate volume.
 - To decrease the number of cores in patients undergoing repeat biopsy.
- In transperineal prostate biopsy, the cleansing enema:
 - Has the aim to reduce the bacterial load of the rectal mucosa.
 - Might improve TRUS images and reduce the discomfort during the procedure.
 - Is contraindicated.
 - Is rarely performed.

APPENDIX 1008A

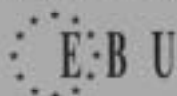
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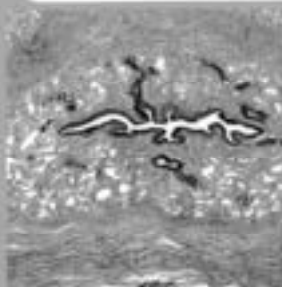
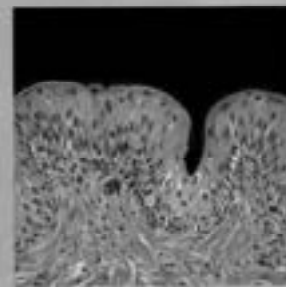


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The Challenge of the Overactive Bladder: From Laboratory to New Drugs M. Lazzeri, M. Porena	250
Answers to the CME Questions Published in EAU-EBU Update Series Volume 5, Issue 5	259

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Prostate Biopsy: The Transperineal Approach

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Abstract

Objective: Review the literature concerning transperineal transrectal ultrasound (TRUS)-guided prostate biopsy (PBx), providing an update on the topic.

Methods: The literature review was performed using PubMed through a free text search strategy. The authors reviewed the abstracts of the retrieved records to select the relevant papers.

Results: The search retrieved 196 records; 68 were relevant to the issue. No high-level evidence recommends a particular kind of preparation/prophylaxis for transperineal PBx. It can be performed with a brachytherapy template under general or spinal anesthesia, or with a local periprostatic nerve block through a single-access fan technique. In the former case, up to 50 cores are obtained; in the latter, 12–26 cores. Prostate cancer detection rates range from 24% to 51%, with figures of 27–49% in patients undergoing their first PBx for a prostate-specific antigen level of 4–10 ng/ml. Such percentages are directly related to the number of cores obtained. In repeat biopsy and in prostates > 50 cc, the number of cores should be increased, paying particular attention in sampling the anterior zone. Among the studies comparing transrectal and transperineal PBx, only two demonstrated differences in detection rates in favor of the transperineal approach. Major complications are rare, with fever occurring in 0–5.2% and hospitalization in 0–1.4% of cases.

Conclusion: Transperineal TRUS-guided PBx is a safe procedure, with high detection rates and wide applications both in first and in repeat sampling. Although having a strong rationale, the transperineal approach has so far not resulted in higher detection rates than transrectal biopsies.

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1. Introduction

From an historical viewpoint, the transperineal route has been the first one to be used to reach the prostate, both for diagnostic and therapeutic purposes [1]. For histologic diagnosis of prostate cancer, surgical perineal prostate biopsy (PBx) first and finger-guided perineal punch biopsy later on were the only possible approaches in the early 20th century [2].

The transrectal route has been used for finger-guided PBx since the mid-1950s [3], becoming the gold standard after Hodge et al demonstrated higher detection rates for sextant transrectal ultrasound (TRUS)-guided PBx than for sextant finger-guided analog sampling [4].

To date, because it seems to be more invasive and difficult, the TRUS-guided transperineal route is less used worldwide than the transrectal one, with figures ranging from 1.9% to 25% of the biopsies [5,6]. Nevertheless, supporters of such an approach report a lower risk for infective complications, a more selective sampling of the peripheral gland [7,8], an easier approach to the anterior zone of the prostate [9], and a higher detection rate [10] than transrectal PBx.

With this perspective, the aim of our study was to review the literature concerning transperineal TRUS-guided PBx and to provide up-to-date recommendations on the topic.

2. Methods

The review of the literature was performed using PubMed through a free text search strategy including the following entry terms: "transperineal" or "trans-perineal" or "perineal" and "prostate biopsy." The following limits were used to restrict the search: publication date after 1987, English, Title/Abstract. The authors reviewed the abstracts of the retrieved records to select the papers relevant to the topic of the study.

All the papers were ranked according to the grade of evidence as stated by Phillips and Sackett [11]. Meta-analyses of randomized clinical trials (RCTs) constitute the highest evidence (level 1a), followed by an adequately sampled, single RCT (level 1b); low-quality RCTs, prospective cohort studies, and high-quality case-control studies give level 2 evidence. A lower grade of evidence was provided by retrospective case-control studies or good-quality case series (level 3), whereas poor-quality case series, case reports, or expert opinion provide level 4 evidence [11].

3. Results

The search retrieved 196 records. Abstracts concerned with the issue of transperineal PBx numbered 68. The full texts of the 68 interesting articles

were reviewed. No level 1a evidence was retrieved and only two randomized trials (level 1b) were found [8,12]. Among those with level 2 evidence, most of the studies comparing different biopsy approaches or different core numbers used the same patients as internal controls [10,13-16]. Two further studies evaluated computer- or autopsy-based simulations of different approaches for PBx [7,17]. The remaining articles described non-controlled case series or case reports (level 3-4).

3.1. Preparation

No study specifically dealing with antibiotic prophylaxis, bowel preparation, or anticoagulant therapy suspension in transperineal PBx was retrieved.

Because the biopsy needle does not pass through the rectum, the transperineal approach should be considered a sterile procedure. For this reason, antibiotic prophylaxis should be recommended only for patients with a high risk of infection, such as diabetic or immunosuppressed patients, those with a poor general health status, cardiac prostheses, or cardiac valve pathologies, and those with an indwelling catheter or high postvoiding residual. In those patients, fluoroquinolones are indicated as first-choice antimicrobials. Alternatively, ampicillin, β -lactamase inhibitors, cephalosporins, or cotrimoxazole can be used as second-choice antibiotics. For patients with cardiac valve pathologies or prostheses, double antibiotic prophylaxis with ampicillin/vancomycin associated with aminoglycosides is indicated [18,19]. No univocal indication exists concerning the length of antibiotic prophylaxis in these patients. Similarly to what happens with the transrectal route, antibiotic usage should be prolonged for 3 d [20]. According to descriptive literature data, most of the centers performing transperineal PBx usually prescribe an antibiotic prophylaxis the day before the procedure; only some of them continue antibiotic usage for 2-3 d after the procedure [6,12,21]. In our clinical practice [13], we prefer to use antimicrobial prophylaxis in all patients scheduled for PBx. Our scheme includes a single-dose fluoroquinolone before the procedure. In our series, clinically significant urinary tract infections occurred in < 1% of cases. Only 3 patients (0.6%) of the 480 prospectively evaluated needed hospitalization for fever and urinary tract infections [13].

Roughly 80% of urologists will prescribe an enema as a preparation for transrectal PBx [22]. The reduction of the bacterial load on rectal mucosa may decrease procedure-related infections [23]. More recent data, from a Japanese PBx survey

including both transrectal and transperineal procedures (76% and 24%, respectively) report the use of a cleansing enema in only 44% of cases [6]. In transperineal biopsies, because the needle is not contaminated by fecal material, a preparation enema may be pointless. Nevertheless, currently it is preferable to perform an enema some hours before the procedure. In this way it is possible to reduce the discomfort due to the concomitant presence of the transrectal probe and fecal material in the rectum and to improve the quality of the ultrasound image [19].

As far as anticoagulant therapy is concerned, no specific study dealt with transperineal PBx. The few studies concerning transrectal PBx and suspension of anticoagulant therapy concluded there were no advantages in patients suspending aspirin ingestion before biopsy [24,25]. A recent meta-analysis confirmed such conclusions [26] and more recent data from a survey report 59% of United Kingdom urologists do not stop aspirin before PBx because the cerebrovascular risks of stopping aspirin outweigh the benefits on bleeding expected by aspirin discontinuation [27]. Similar conclusions have been drawn concerning with warfarin and other anticoagulants [28].

3.2. Transperineal biopsy technique

We retrieved 28 articles from 16 groups describing a transperineal PBx (Table 1). Five groups performed the biopsy through the guide of a brachytherapy template device, with one skin puncture for each single core, whereas 11 used a fan technique, using a common access for all the cores. All authors

performed this kind of biopsy in the dorsal lithotomy position (only 1 used the extended lithotomy [33]), exposing the perineum and executing TRUS as a preliminary procedure.

3.2.1. Anesthesia

Even though no specific study compared different kinds of anesthesia for transperineal PBx, all authors agree with the need to perform some kind of anesthesia.

Among the authors performing PBx with the fan technique, some groups preferred spinal anesthesia, whereas others performed the biopsy under local anesthesia with a periprostatic nerve block. Regional differences exist: for example, Japanese authors prefer the locoregional approach, whereas Italian ones routinely use local anesthesia (Table 1). Among the groups performing a transperineal PBx with the guide of a brachytherapy template, most of them use a general or spinal anesthesia. More specifically, the execution of multiple punctures on perineal skin and multiple perineal paths for the brachytherapy template makes it almost impossible to perform adequate local anesthesia; on the contrary, as the fan technique implies the execution of only one or two skin punctures following the same perineal path, local anesthesia is feasible with good results. For the execution of the periprostatic nerve block and for the following biopsies, some authors use a double access situated on the two sides of the midline above the anus at a 45° angle from midline at about 1.5 cm from the anus [21], whereas other authors prefer a single transperineal access on the midline 1.5 cm above the anus [12]. Though presenting a theoretically higher risk of

Table 1 - Groups proposing an original transperineal prostate biopsy technique

Author	Region	Anesthesia	Template	Cores (range)	Set
Saitoh 1997 [29]	Japan	Spinal	No	12	First
Emiliozzi 2001 [21]	Italy	Local	No	12	First
Kojima 2001 [30]	Japan	Spinal	No	12	First
Igel 2001 [31]	USA	General/spinal	Yes	17	Repeat
Novella 2003 [12]	Italy	Local	No	14	First
Kawakami 2004 [32]	Japan	Spinal	No	14	First
Bott 2005 [33]	UK	General	Yes	24 (12-36)	Repeat
Pepe 2005 [34]	Italy	Local	No	12-18	First
Sato 2005 [9]	Japan	Spinal	Yes	22	Repeat
Watanabe 2005 [16]	Japan	Spinal	No	6 TP + 6 TR	First
Yamamoto 2005 [35]	Japan	General	No	12	First
Demura 2005 [36]	Japan	Spinal	Yes	30 (9-38)	Mixed
Luciani 2006 [37]	Italy	Local	No	12	First
Kawakami 2006 [38]	Japan	Spinal	No	14 TP + 12 TR	First
Takemasa 2006 [15]	Japan	Spinal	No	12	First
Moran 2006 [39]	USA	General	Yes	41	Repeat
Merrick 2007 [40]	USA	General	Yes	50	Repeat

TP = transperineal; TR = transrectal.

bulbar urethra and corpus spongiosus lesions, the median access reduces the risk of lesions to the bulbourethral arteries and perineal hematomas, thus improving the tolerability of the examination [12].

3.2.2. Fan technique

According to the conventional fan technique, biopsies are performed by repeatedly inserting the same biopsy needle through the anesthetized perineal path [21]. To minimize the invasiveness of the technique, a coaxial needle can be used with the aim of performing the several needle passages through the same path [12]. The coaxial needle makes the procedure easier and quicker, allowing the repeated introduction of the needle with low perineal trauma. The results of a prospective, randomized study comparing 51 patients undergoing conventional transperineal PBx and 51 patients undergoing transperineal PBx using the coaxial needle showed a reduction of pain during the biopsy and a better compliance for patients using the coaxial needle [12].

3.2.3. Template-guided stereotactic technique

With the aim of improving detection rates in patients with a previous negative biopsy or at high risk for prostate cancer, some authors proposed use

of the transperineal brachytherapy template device as a guide for the needle. This type of biopsy has been designed to perform saturation biopsy, being able to sample extensively the prostate with a higher tridimensional space control [31], but it has been used also for first-set biopsies [36,41]. The main disadvantage of this technique is the need for spinal or general anesthesia [42].

3.2.4. Number and location of cores

The optimal number and site of cores to be sampled in transperineal PBx is currently under debate [13]. Because the procedure is always preformed under anesthesia, the number of cores is usually higher than in the transrectal route, starting from 12 in the first set up to 50 in template saturation biopsies (Table 1).

Prostate cancer detection rates widely vary according to the population sampled (first or repeated biopsy), number of cores taken, prostate-specific antigen (PSA) value, and prostate volume (Table 2).

In patients undergoing their first PBx for a PSA between 4 and 10 ng/ml (Table 3), fan PBx yields a positive result in 27–45%; template PBx is rarely used in the first set, providing detection rates approximating 50%, whereas it is frequently used as a saturation sampling method in patients repeating PBx, providing a 22–43% rate of prostate cancer

Table 2 - Features of the transperineal prostate biopsy published series

Author	Patients	Cores (range)	PSA range	Median PSA	Median prostate volume	Negative DRE	First set	Template	Detection rate
Igri 2001 [31]	88	17	NR	13.1	NR	NR	0%	Yes	43%
Emiliozzi 2001 [21]	141	12	4.1–5000	8	NR	NR	100%	No	51%
Kojima 2001 [30]	541	12	NA	NR	NR	68.8%	100%	No	24%
Emiliozzi 2003 [10]	107	6TR + 6TP	4–240	8.2	NR	NR	100%	No	40%
Forano 2004 [41]	113	18.2 (9–33)	4–10	NR	NR	88.5%	23.9%	Yes	43%
Emiliozzi 2004 [8]	72	12	4–10	NR	NR	71%	100%	No	49%
Kawakami 2004 [12]	289	14	2.5–40	10.7	47	81.4%	100%	No	36%
Boit 2005 [33]	60	24 (18–36)	4.5–35.7	12.8	54	93%	0%	Yes	38%
Demiara 2005 [36]	371	20.1 (9–38)	NR	NR	42.5	63.6%	84.1%	Yes	49%
Pinkstaff 2005 [43]	210	21.212–41	NR	13.4	NR	NR	0%	Yes	37%
Ficarra 2005 [13]	480	14	2.5–20	7.6	41.6	67.3%	100%	No	44%
Pepé 2005 [34]	372	12–18	NR	NR	NR	76.1%	NR	No	42.7%
Sasoh 2005 [9]	128	12	2.4–170	10.3	43.9	98.5%	0%	Yes	22.7%
Watanabe 2005 [14]	402	6TR + 6TP	0.6–460	NR	NR	67.8%	100%	No	48.5%
Yamamoto 2005 [35]	300	12	2.5–20	7.25	38.3	35.1%	100%	No	36%
Moran 2006 [39]	180	41	0.8–40.1	8.1	46.5	NR	0%	Yes	38%
Kawakami 2006 [38]	321	14TP + 12TR	0.9–38	6	36	82%	100%	No	34%
Luciani 2006 [37]	122	12	> 0	16.3	38	100%	100%	No	75%
Rocco 2006 [44]	63	12	0.2–9.1	1.2	NR	NR	100%	No	17.2%
Takenaka 2006 [15]	247	12	3.2–99	9.4	39.2	75.3%	76.6%	No	39.7%
Merrick 2007 [40]	102	50	NR	8.3	78.6	NR	1%	Yes	42%
Kawakami 2007 [14]	235	14TP + 12TR	5.8–2.2 (I.q.)	8.3	41	82%	0%	No	37%

PSA = prostate-specific antigen; DRE = digital rectal examination; TP = transperineal; TR = transrectal; NR = not reported; NA = not available
I.q. = interquartile range.

Table 3 – Cancer detection rates in patients undergoing the first transperineal prostate biopsy for 4–10 ng/ml PSA

Author	Patients	Cores (range)	Template	Detection rate
Emiliozzi 2001 [21]	97	12	No	45%
Kojima 2001 [30]	541	12	No	40.8%
Emiliozzi 2003 [10]	70	6TP + 6TR	No	30%
Emiliozzi 2004 [8]	72	12	No	45%
Kawakami 2004 [32]	148	14	No	27%
Furuno 2004 [41]	86	18 (9–33)	Yes	49%
Ficarra 2005 [13]	389	14	No	42.4%
Watanabe 2005 [16]	180	14TP + 12TR	No	33.9%
Yamamoto 2005 [35]	134	12	No	31%

PSA = prostate-specific antigen; TP = transperineal; TR = transrectal.

diagnoses. Such detection rates are usually higher than in transrectal saturation biopsies, reportedly between 13% and 41% [45]. Probably, this might be justified by the higher precision in sampling all prostatic zones and in particular the anterior part of the gland [41].

To date, six studies have compared schemes sampling a different core number, two using different patient samples [8,34] and four using internal controls [13–15,40]. Emiliozzi et al demonstrated an increasing detection rate with higher core numbers, particularly in patients with a PSA of 4–10 ng/ml (30% in 6-core transperineal biopsy vs. 49% in 12-core transperineal biopsy). Pepe et al confirmed these data comparing 12 versus 18 transperineal cores, with detection rates reaching 35% and 51%, respectively [34].

In the studies comparing different schemes through a recursive partitioning within the same patient population, Takenaka et al compared their complete scheme (12 cores) with the standard sextant, obtaining a 20% increase in diagnoses with the additional cores [15]. More detailed studies have been conducted by Ficarra et al in 2005 and by Merrick et al in 2007; both of them confirmed an increase in diagnoses proportional to the increase in core number, reaching 43.8% detection rates in a 14-core first biopsy series [13] and 42.1% in a 24-core repeat biopsy series [40]. These two studies report prostate volume as the strongest predictor for prostate cancer detection [13,40], highlighting the need to increase the number of cores in prostates > 50 cc [13].

Another variable to be taken into account for prostate cancer detection is the location of the cores. In studies coming from transrectal biopsy series, prostate cancer has been reported to be located in the peripheral zone in 85% of nonpalpable [46] and in 74% of palpable tumors [47].

On the other hand, transperineal PBx series demonstrate that up to 70% of prostate cancers are located in the anterior part of the prostate [32],

with a more frequent involvement of this area in nonpalpable cancers than in palpable ones [32,36] and in repeat biopsy than in the first set [9,41]. Moreover, the transitional zone is involved by cancer in up to 76% of patients with a positive result after a repeat biopsy with a transperineal template approach [31].

With this perspective, prostate sampling should include at least a minimum number of anterior cores in the first set, preferably in the far lateral peripheral zone (anterior horn). According to Ficarra et al, sampling this region with a single core per lobe provides an additional cancer diagnosis in 11% of cases [13].

According to these data, it seems reasonable to deduce that in the first transperineal biopsy setting a minimum of 12 cores should be taken, including the far lateral peripheral zone (anterior horn). Sampling of the transition zone might be omitted in these patients. On the other hand, repeat PBx should include a thorough sampling of the posterior and anterior zones, including transitional cores (Fig. 1). The brachytherapy template in repeat biopsy theoretically provides a more rational prostatic sampling, even though higher anesthetic support is necessary.

3.2.5. Comparing transperineal and transrectal PBx

Five studies have been identified comparing transrectal and transperineal PBx, all of them performing transperineal and transrectal PBx on the same patients (Table 4). The first one [7] was a simulation of transperineal (longitudinal) and transrectal (transverse) PBx conducted on radical prostatectomy surgical specimens. In this study, cancer had been initially diagnosed through transrectal biopsy. Nevertheless, 82.5% of the 40 analyzed cancers was redetected by sextant transperineal biopsy, whereas only 72.5% of cases was redetected by transrectal sextant biopsy. These experimental data were confirmed in clinical practice in 2003, when Emiliozzi et al studied 107 patients under-

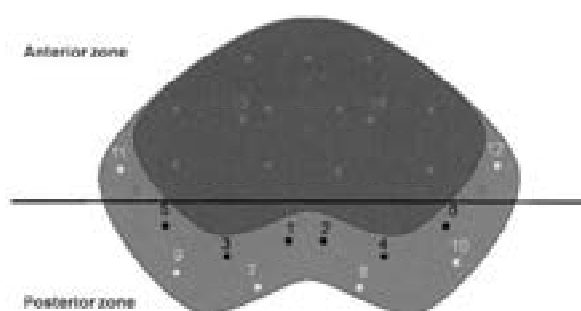


Fig. 1 – Number and location of cores in transperineal prostate biopsy. 1–6 (black) sextant cores; 7–12 (yellow) lateral sextant cores; 13–14 (orange) transition zone cores. Not numbered (pink) cores: possible additional cores in the anterior zone of the prostate.

going 12 biopsies using a combination of the transrectal (6 cores in the peripheral zone) and transperineal (6 cores in the peripheral zone) approach. The authors reported higher detection

rates for the transperineal technique. In particular, the study showed an overall cancer detection rate of 40%, with 38% imputable to transperineal 6-core biopsy and 32% due to 6-core transrectal approach. In the subset of patients with a PSA of 4–10 ng/ml, the detection rates of the transperineal and transrectal biopsy were 27% and 20%, respectively [10]. A nearly identical study was performed by Watanabe et al, with different results. In their study, the authors reported an overall detection rate of 48%, significantly lower than the one produced by the six transrectal cores (40%) or by the one produced by the transperineal ones (41.2%). This difference could be due to the different prostatic sampling (6 peripheral transrectal cores versus 4 peripheral and 2 transitional transperineal cores) [16].

A different scenario was proposed by Kawakami et al, one using a systematic transrectal (12 cores) and transperineal (14 cores) prostatic sampling in patients undergoing their first [38,48] or repeated biopsy [14]. In both cases, the route of sampling

Table 4 – Studies comparing transrectal versus transperineal prostate biopsy

Author	Patients	Cores	PSA range	Set	Detection rate (all)	Detection rate (TR)	Detection rate (TP)	p (TR vs. TP)	p (TP vs. all)
Via 2000 [7]	40	6TR + 6TP	NA	NA	NA	72.5%	82.5%	NR	NR
Emilioszi 2003 [10]	107	6TR + 6TP	4–240	First	40%	32%	38%	0.032	>0.05
Watanabe 2005 [16]	180	6TR + 6TP	4–10	First	48.5%	40%	41.3%	>0.05	0.019
Kawakami 2006 [38]	321	14TP + 12TR	0.9–38	First	34%	21.1%	NR	NR	NR
Kawakami 2007 [14]	235	14TP + 12TR	5.8–12.2 (Iq)	Repeat	37%	29.3%	30.2%	>0.05	>0.05

PSA = prostate-specific antigen; TP = transperineal; TR = transrectal; NA = not applicable; NR = not reported; Iq = interquartile range.

Table 5 – Major complications of transperineal prostate biopsy series

Author	Patients	Cores	Set	Severe hematuria	AUR	Fever	Hospitalization
Emilioszi 2003 [21]	141	12	First	NR	0.7%	0%	0%
Kojima 2001 [30]	679	12	First	2.6%	7.2%	5.2%	NR
Igel 2001 [31]	88	17 T	Repeat	3.4%	2.2%	1.1%	0%
Emilioszi 2003 [10]	107	6TP + 6TR	First	NR	0%	0%	0%
Novella 2003 [12]	103	14	First	NR	3%	1%	0%
Emilioszi 2004 [8]	107	12	First	NR	0%	0%	0%
Kawakami 2004 [32]	289	14	First	1%	0%	0%	1.4%
Buskirk 2004 [49]	157	12	First	NR	11%	NR	NR
Furuno 2004 [41]	113	18 T	Mix	NR	1%	0%	0%
Picarra 2005 [13]	480	14	First	0.4%	0.6%	0.6%	0.6%
Pepe 2005 [34]	372	18	NR	NR	4.3%	0.8%	NR
Watanabe 2005 [16]	402	6TR + 6TP	First	0.5%	0.5%	0.5%	NR
Bott 2005 [33]	60	24 T	Repeat	2%	NR	NR	NR
Demura 2005 [36]	371	20 T	Repeat	1.6%	1.6%	0%	0
Pinkstaff 2005 [43]	210	21 T	Repeat	NR	11%	NR	NR
Sato 2005 [9]	128	18 T	Repeat	NR	3.2%	0.8%	0.8%
Kawakami 2006 [38]	321	12TR + 14TP	First	NR	0%	0.6%	0.6%
Moran 2006 [39]	180	41 T	Repeat	NR	30%	NR	NR
Merrick 2007 [46]	102	50 T	Repeat	1%	38%	NR	NR
Kawakami 2007 [14]	235	12TR + 14 TP	Repeat	0.4%	0.4%	0.8%	1.3%

AUR = acute urinary retention; TP = transperineal; TR = transrectal; T = template; NR = not reported; Iq = interquartile range.

seems not to affect the ability to detect prostate cancer (88% vs. 88% of the cancers in the first biopsy set and 79% vs. 82% in repeat biopsy), whereas the combination of the two techniques allowed detection of a significantly higher number of cancers, with an overall cancer diagnosis of 34% in case of first biopsy and of 37% in case of repeat biopsy [14,48].

Unfortunately, no study specifically assessed the differences in time consumption and in costs for these two techniques. Nevertheless, because the only differences are in patient preparation and position and the materials to be used are similar, it can be supposed that no substantial differences exist between transrectal and transperineal PBx.

In conclusion, though having a strong rationale, the transperineal approach has not convincingly been demonstrated to provide detection rates higher than transrectal biopsy. High-quality, comparative studies must be performed to assess which kind of biopsy provides better results.

3.3. Complications

Most of the series reporting on transperineal PBx provide data concerning the complications related to the procedure. According to those data, transperineal biopsy is a safe procedure. Major complications, such as severe hematuria, acute urinary retention, fever, and other problems requiring hospitalization are rare (Table 5). Considering that in transperineal PBx the needle does not pass through the rectum, fever occurs in 0–1% of cases. Only one series reports fever occurring in 5.2% of cases [30].

Minor complications are more frequent but, because they rarely need treatments, they are seldom reported. In particular, self-limiting hematuria occurs in percentages ranging from 8.6% [34] to 52% [12], hemospermia happens in up to 79% of patients [8], and perineal discomfort or perineal hematoma has lower percentages (1–6%) [12,21]. Unfortunately, only a few authors reported the methods used to collect data concerning complications.

4. Conclusion

Transperineal TRUS-guided PBx is a safe procedure, with high detection rates and low morbidity.

The specific preparation for transperineal biopsy has not been studied through prospective controlled studies. Because the infectious risk of this procedure seems to be low, a single-dose fluoroquinolone prophylaxis has been advised in patients with a

standard risk for infection. The execution of a cleansing enema is recommended, and anticoagulant therapy should be stopped only if the hemorrhagic risk exceeds the thrombotic risk.

At least local anesthesia with periprostatic nerve block should be performed. Particularly in repeat PBx or when using the brachytherapy template, some groups propose using spinal or (more rarely) general anesthesia.

Because 6-core schemes provide insufficient detection rates, at least 12 cores are usually taken in the first prostatic sampling. Repeat biopsy, with or without a brachytherapy template, should include more cores, with particular attention to the anterior zone of the prostate.

High-quality, randomized, controlled studies must be performed to support the available evidence that the transperineal approach provides better results than the transrectal one both in terms of complications and results.

Conflicts of interest

The authors have nothing to disclose.

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CME questions

Please visit www.eu-acme.org/europeanurology to answer these CME questions on-line. The CME credits will then be attributed automatically.

- Transperineal prostate biopsy:
 - Has to be performed without the guide of transrectal ultrasound (TRUS).
 - Cannot be performed without general anesthesia.
 - Has to be performed in selected centers only.
 - Has to be performed with some kind of anesthesia.
- In transperineal prostate biopsy, the template technique:
 - Requires multiple skin accesses and paths to take the cores.
 - Requires one or two skin accesses for all the cores.
 - Is the technique of implanting the seeds for brachytherapy at the same moment of prostate biopsy.
 - Has to be performed with three-dimensional ultrasound equipment.
- A good-quality first-set transperineal prostate biopsy:
 - Should include at least six cores.
 - Should sample the anterior far lateral aspects of the prostate (anterior horn).
 - Should include at least four cores from the transition zone.
 - The transition zone should be sampled only for prostate-specific antigen levels > 10 ng/ml.
- Comparing transperineal versus transrectal prostate biopsy:
 - There is a theoretical minor risk for infection in transperineal biopsy.
 - Detection rates are higher in transrectal procedures than in transperineal ones.
 - Transrectal biopsy requires a more difficult preparation.
 - Complication rates are higher in transperineal biopsy.
- To improve detection rates, it is advisable:
 - To increase the number of cores proportionally to prostate-specific antigen levels.
 - To decrease the number of cores proportionally to the transition zone volume.
 - To increase the number of cores proportionally to prostate volume.
 - To decrease the number of cores in patients undergoing repeat biopsy.
- In transperineal prostate biopsy, the cleansing enema:
 - Has the aim to reduce the bacterial load of the rectal mucosa.
 - Might improve TRUS images and reduce the discomfort during the procedure.
 - Is contraindicated.
 - Is rarely performed.

APPENDIX 1008B