

BD TP Prostate Biopsy Evidence Compendium 2023



Contents

Procedure-experience with 400 Patients

| Introduction | 2 | Diagnostic Yield and Sample Accuracy | |
|---|----|--|--|
| Technique | 3 | Free-hand Transperineal Prostate Biopsy Provides Acceptable Cancer Detection and minimises Risk of Infection: Evolving Experience with a 10-Sector Template | |
| Ultrasound Guided, Freehand Transperineal Prostate Biopsy: An Alternative to the Transrectal Approach | 3 | | |
| Transperineal Prostate Core Needle Biopsy: A Comparison of Coaxial Versus Noncoaxial Method in a Randomised Trial | 5 | Transperineal Versus Transrectal Prostate Biopsy in the Diagno of Prostate Cancer: A Systematic Review and Meta-Analysis Transperineal Freehand Multiparametric MRI Fusion Targeted Biopsies Under Local Anaesthesia for Prostate Cancer Diagnos A Multicentre Prospective Study of 1014 Cases Freehand versus Grid-based Transperineal Prostate Biopsy: A Comparison of Anatomical Region Yield and Complications | |
| Complications Following Local Anaesthetic Transperineal Prostate Biopsies Without Antibiotic Prophylaxis: An Institution's Experience | 6 | | |
| Transperineal Prostate Biopsy: The Modern Gold Standard to Prostate Cancer Diagnosis | 9 | | |
| "Free-Hand" Transperineal Prostate Biopsy Under Local Anaesthesia: A Review of the Literature | 10 | How Many Cores Are Enough? Optimising the Transperineal Prostate Biopsy Template | |
| Transperineal Ultrasound-guided Prostate Biopsy: What the Radiologist Needs to Know | 12 | Economic Implications | |
| Patient Experience | 14 | The Clinical and Financial Implications of a Decade of Prostat Biopsies in the NHS: Analysis of Hospital Episode Statistics Data 2008-2019 | |
| Short Term Outcomes of Prostate Biopsy in Men Tested for Cancer by Prostate Specific Antigen: Prospective Evaluation within Protect Study | 14 | Economic Evaluation of Transperineal versus Transrectal Devices for Local Anaesthetic Prostate Biopsies | |
| Introduction of Free-hand MRI-guided Transperineal Prostate Biopsies as an Outpatient Procedure | 16 | | |
| Pain in Men Undergoing Transperineal Free-hand Multiparametric Magnetic Resonance Imaging Fusion Targeted Biopsies under Local Anaesthesia: Outcomes and Predictors from a Multicentre Study of 1,008 Patients | 18 | | |
| Transperineal Free-hand mpMRI Fusion-targeted Biopsies Under Local Anaesthesia: Technique and Feasibility from a Single-centre Prospective Study | 20 | | |
| Feasibility of Freehand MRI/US Cognitive Fusion Transperineal Biopsy of the Prostate in Local Anaesthesia as In-office | | | |

22

Introduction

Dear Reader,

24

24

26

28

30

32

34

34

36

Prostate cancer is the second most frequently diagnosed cancer, and the fifth leading cause of cancer death in men.¹ The diagnosis is confirmed via a tissue biopsy which can be performed by transrectal ultrasound-guided (TRUS) biopsy, or transperineal prostate ultrasound-guided (TPPUS) biopsy aided by multiparametric magnetic resonance imaging (mpMRI).²

Every year, it is estimated that over two million men undergo a prostate biopsy worldwide and given this large number, the preferred biopsy technique should be accurate and as safe as possible for the patient's well-being.² Historically, TRUS biopsy performed under general anaesthetic is the most widely adopted, however, TPPUS is gaining popularity in recent years owing to many benefits.²

TPPUS biopsy can be performed in a clinic setting under local anaesthesia and is shown to have a significantly lower rate of infectious complications, is better tolerated by patients, and is more economically viable compared to TRUS biopsies.^{3–5} The transperineal route may also forgo the requirement for antibiotic prophylaxis as the biopsy needle

Key definition

Transperineal prostate full freehand approach

A coaxial is inserted at two points on either side of the perineum mid-line. It is then advanced to the prostate with simultaneous targeted local anaesthesia (LA) infiltration to deeper structures (including pelvic muscles) using the integrated delivery needle without the trocar and under transrectal ultrasound guidance. Once in position, the trocar is removed, and the cannula can be used as an access sheath for prostate biopsies thus limiting tissue trauma and pain. The Marquee kit coaxial can be angled or repositioned to reach different areas without superficial or deep structure repuncture.

References:

- 1. Sung H, Ferlay J, Siegel RL, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021;71(3):209-249. doi:10.3322/caac.21660
- Studies. Journal of Urology. 2022;207(1):25-34. doi:10.1097/JU.00000000002251
- 4. Tambankar AS, Fl-Taii O, Vasdev N, Foley C, Popert R, Adshead J, The clinical and financial implications of a decade of prostate biopsies in the NHS: analysis of Hospital Episode Statistics data 2008–2019. BJU Int 2002(1):133-141. doi:10.1111/bju.15062 5. Bhatt NR, Breen K, Haroon UM, Akram M, Flood HD, Giri SK. Patient experience after transperineal template prostate biopsy compared to prior transrectal ultrasound guided prostate biopsy. Cent
- European J Urol. 2018;71(1):43-47. doi:10.5173/ceju.2017.1536
- 6. N. Mottet (Chair), P. Cornford (Vice-chair), R.C.N. van den Bergh, et al. European Association of Urology (EAU), European Association of Nuclear Medicine (EANM), European Society for Radiotherapy and Oncology (ESTRO), European Society of Urogenital Radiology (ESUR), International Society of Urological Pathology (ISUP), International Society of Geriatric Oncology (SIOG) Guidelines on Prostate Cancer 2023.: 2023 Update

is passed through an easily sterilised area of the skin.³ In light of the aforementioned clinical benefits, a 2021 update, and subsequent republications, to the European Association of Urology prostate cancer guidelines saw an important recommendation to use the transperineal biopsy technique.⁶

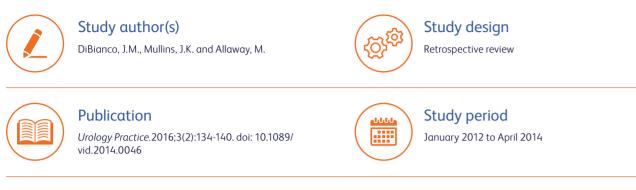
Becton Dickinson and Company (BD) is committed to supporting the use of the TPPUS biopsy technique. This evidence compendium was compiled to facilitate the reader in accessing the literature relevant to:

- Transperineal biopsy techniques
- Diagnostic yield and sample accuracy
- Patient experience
- Economic implications

All studies in this compendium were found via a literature search and the summaries are provided as a courtesy to you, the reader. All information in this summary was current as of April 2023 and BD is not liable for any inaccuracies thereafter.

Chomson A, Li M, Grummet J, Sengupta S. Transperineal prostate biopsy: A review of technique. *Transl Androl Urol.* 2021;9(6):3009-3017. doi:10.21037/tau.2019.12.40
 Castellani D, Pirola GM, Law YXT, et al. Infection Rate after Transperineal Prostate Biopsy with and without Prophylactic Antibiotics: Results from a Systematic Review and Meta-Analysis of Comparative

Ultrasound Guided, Freehand Transperineal Prostate Biopsy: An Alternative to the Transrectal Approach





Study objective

To assess the safety, feasibility, and early outcomes of a single urologist's experience with ultrasound guided FTPPBx as an alternative to TRUS biopsy



Study source

Medical records of patient population from the Department of Urology, George Washington University, School of Medicine, Washington, DC.



Study population

244 men undergoing prostate biopsy as part of a diagnostic evaluation or as part of active surveillance (AS) protocols



Study methods

- During the study period, 244 men underwent ultrasound guided freehand transperineal prostate biopsy (FTPPBx), with 274 procedures performed
- An intravenous line was placed, and a weight-based dose of cefazolin was administered
- Two pathologists analysed all biopsy specimens
- A retrospective review of medical records was carried out, including:
- Patient demographics, medical comorbidities, procedure details, and complications
- After data extraction, patients were de-identified before the analysis



Study limitations

The retrospective nature of this study, the single operator experience and the lack of a concurrent control population using a comparative technique limit the extrapolation of these observations to other patient settings

AS – active surveillance; DRE – digital rectal examination; FTPPBx – freehand transperineal prostate biopsy; PSA – prostate specific antigen; TRUS – transrectal ultrasound guided; TRPBx – transrectal prostate biopsy



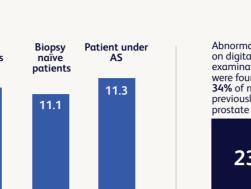
Key point

This technique allowed biopsy specimens to be obtained in a similar way to transrectal ultrasound-quided (TRUS) biopsy without major patient discomfort or morbidity and was free of major complications

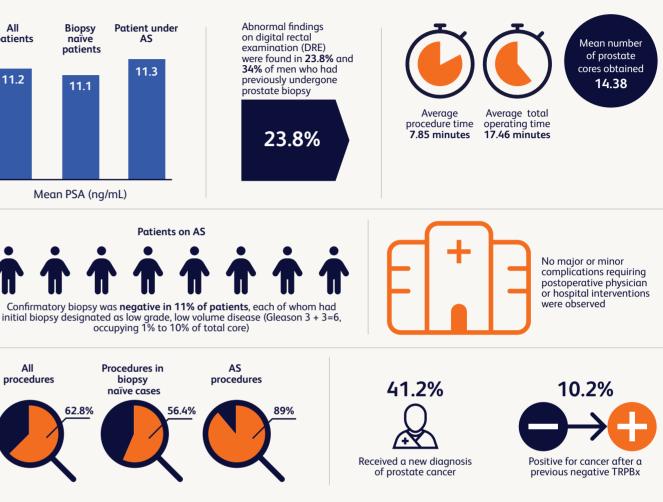


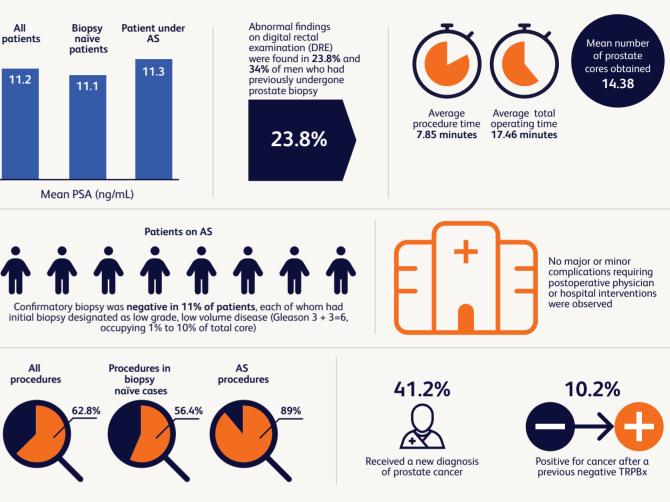
Study conclusions

- Safety, feasibility, and cost of ultrasound-guided FTPPBx were favourable and comparable to those of TRUS biopsy performed in a similar clinical setting
- This technique did not require any bowel preparation, prophylactic antibiotic pre-treatment, additional specialised equipment, operator, or facility time
- No significant morbidity, major complications, or post-biopsy sepsis was found
- Ultrasound-guided FTPPBx should be evaluated further with prospective, randomised studies to determine the comparative effectiveness of this technique



Study findings





Transperineal Prostate Core Needle Biopsy: A Comparison of Coaxial Versus Noncoaxial Method in a Randomised Trial



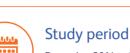
Study author(s)

Publication

10.1007/s00270-016-1437-8

Babaei Jandaghi, A., Habibzadeh, H., Falahatkar, S., Heidarzadeh, A., and Pourghorban, R.

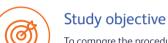






NI/A

Study source



To compare the procedural time and complication rate of coaxial approach with those of noncoaxial technique in transperineal prostate biopsy

Cardiovasc Intervent Radiol. 2016:39(12):1736-1742. doi:



Study population

240 patients who were referred to the radiology department for prostate biopsy following an elevated prostate-specific antigen (PSA) level, or a suspicious digital rectal examination were considered for enrolment



Study methods

- Patients were randomly assigned into two groups at a 1:1 ratio
- The first group underwent transperineal biopsy with a coaxial Tru-Cut needle (18-gauge, 17-gauge coaxial), the second group underwent transperineal biopsy with a noncoaxial 18-gauge needle; both groups' biopsies were performed using the fan-technique and were carried out under ultrasound guidance by a single interventional radiologist
- Fourteen specimens were obtained from each patient
- The following information was recorded;
 - » PSA level before the procedure
 - » Duration of procedure
 - » Level of pain associated with procedure using VAS
 - » Follow up assessment complications, fever within 48 hours after procedure, haematuria, incision site bleeding, meatal bleeding within 7 days after biopsy, urinary retention, dysuria, or hospitalisation
- Final diagnoses were made by a single pathologist according to the pathological result of the specimens
- Gleason score in patients with prostate cancer was recorded
- Mean time of procedure, mean visual analogue scale (VAS) score, and complication rate were compared between the two groups

Study limitations

- Small study population
- There are still no available data in the literature regarding the difference in the adequacy of specimens obtained between coaxial and noncoaxial techniques in transperineal prostate biopsy
- Total number of needle passes in each patient was not recorded
- There was a significant difference between the two groups in PSA level in this study
- Size of prostate data was not considered

BPH – benign prostatic hyperplasia; PSA - prostate-specific antigen; VAS – visual analogue scale



| | Whole study | First group | Second group | |
|----------------------------|------------------|-----------------|-----------------------------------|-----------|
| Mean PSA | 20.8 ±38.9 ng/mL | 14.8±26.9 ng/mL | 27.5 ±48.1 ng/mL | (P=0.018) |
| Mean time of the procedure | 27 ±8 min | 19 ±2 min | 34 ±4 min | (P<0.001) |
| Experienced pain | | 9 patients | 21 patients | (P=0.02) |
| Fever | 0 patients | 0 patients | 0 patients | |
| Rate of haematuria | | 0% | 4.2% | (P=0.029) |
| Incision site bleeding | | 0% | 34.4% | (P<0.001) |
| Meatal bleeding | | | Higher but not significantly | (P=0.059) |
| Urinary retention | | 0% | 4.2% | (P=0.029) |
| Dysuria | | | More common but not significantly | (P=0.078) |
| Hospitalisation | Not needed in | n any patients | | |

32% 21% diagnoses in Benign prostatic hyperplasia (BPH) Prostate whole study cancer



Final

Key points

- haemorrhage from biopsy site, and urinary retention than the noncoaxial technique
- The procedural time was significantly shorter in the first group (P<0.001)
- In the first group, pain occurred less frequently (P=0.002), with a significantly lower VAS score being experienced (P<0.002)



Study conclusion

Transperineal prostate biopsy using a coaxial needle is a faster and less painful method with a lower rate of complications compared with conventional noncoaxial technique



• The coaxial technique took less time, was less painful to patients, and had lower rates of haematuria,

Complications Following Local Anaesthetic Transperineal Prostate Biopsies Without Antibiotic Prophylaxis: An Institution's Experience



Study author(s)

John. J.B., MacCormick, A., MacDonagh, R., Speakman, M.J., Vennam, R. and Burns-Cox, N.



Publication

Study objective

Journal of Clinical Urology. 2022;15(5):385-390. doi: 10.1186/s13037-021-00303-8



Study period Local anaesthetic transperineal prostate biopsy (LATPPB) performed between September 2019 and July 2020

Study source

N/A

(**ଟ**) To report a UK institution's experience with local

anaesthetic (LA) TPPB, and to report the 30-day complication rate for patients undergoing LATPPB, including a large cohort that did not receive antibiotic prophylaxis



• A total of 313 consecutive LATPPB were maintained in the database:

- 149 patients underwent biopsies WITH prophylactic Antibiotics from September 2019 to January 2020
- 164 patients underwent biopsies WITHOUT prophylactic antibiotics from January 2020 to July 2020

Study methods

- Patients with suspected prostate cancer for whom biopsy is clinically appropriate are offered LATPPB using transrectal (TR) ultrasound guidance as standard at the authors institution
- Pre-procedure multiparametric magnetic resonance imaging (Mp-MRI) of the prostate is routinely performed at the authors institution
- Transperineal prostate biopsies (TPPB) are performed under LA as a day case by either one nurse specialist or one of two consultant urologists, all with extensive experience in performing prostate biopsies (PB)
- General anaesthesia cases comprised 0.9% of cases over the study period and is offered to patients if LA is poorly tolerated or based on patient preference
- The freehand procedure is used, with LA infiltrated through the perineum
- Routine pre-procedure antibiotic prophylaxis was discontinued halfway through the study period, following consultation with the hospital trust's microbiology department
- For those receiving prophylaxis, one dose of oral ciprofloxacin 750mg was administered two hours before biopsy
- Intramuscular gentamicin was used if ciprofloxacin was contraindicated

Study limitations

- There is a low risk of underreporting complications due to patients seeking treatment at different hospitals
- The study does not describe the personal experiences of patients since they were not directly surveyed following the procedure
- · Patient-reported outcome measures were not included, which is an important area for future research
- The clinicians who performed the biopsy in this case series were experienced in the technique, and the complication rate could be higher if performed by less experienced individuals or those who perform the procedure less frequently

CDR - cancer detection rate; GA - general anaesthesia; LA- local anaesthetic; LATPPB - local anaesthetic transperineal prostate biopsy; mpMRI – multiparametric magnetic resonance imaging; TP – transperineal; TPPB – transperineal prostate biopsy; TR – transrectal

Reference: 1. Kum F, Elhage O, Malivil J, et al. Initial outcomes of local anaesthetic freehand transperineal prostate biopsies in the outpatient setting. BJU Int 2020; 125: 244–252.

Median number of biopsy cores taken <u>ዮዮዮዮዮዮዮዮዮጵ</u> ዮዮዮ 23 20 cores in patients who did not receive antibiotic prophylaxis prophylaxis Transperineal (TP) biopsies 0.64% The overall rate of hospital re-presentation requiring admission was 0.64% (2/313) The overall rate of hospital Both patients who developed re-presentation requiring complications required admission was 0.64% (2/313) admission

Study findings



• The study found a very low rate of complications following TPPB

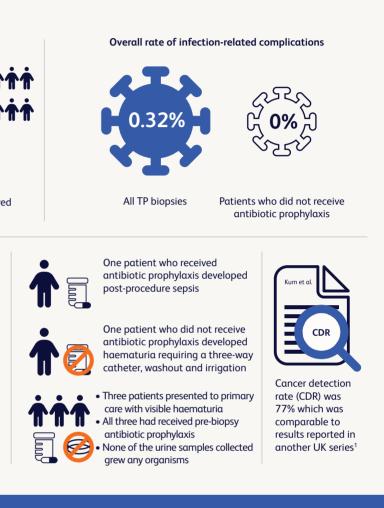
- The cohort of 164 patients undergoing PB without prophylactic antibiotics had a 0% rate of infection-related complications
- and promote antibiotic stewardship goals



Study conclusions

- There was a high rate of cancer detection and a very low complication rate
- Patients who did not receive antibiotic prophylaxis did not experience any infection-related complications
- The study provides additional evidence to support discontinuing routine prophylactic antibiotics before TPPB given the global rise of antibiotic resistance
- Results suggest that antibiotic prophylaxis can be safely discontinued in routine TPPB practice

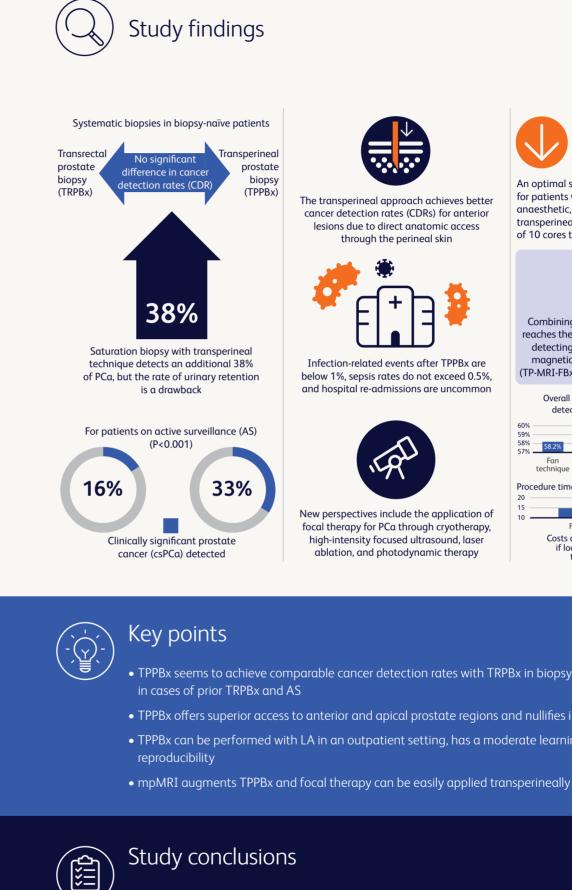
cores patients who received



• Discontinuing antibiotic prophylaxis for TPPB can contribute to the global effort to combat antibiotic resistance

Transperineal Prostate Biopsy: The Modern Gold Standard to Prostate Cancer Diagnosis





- The transperineal approach for prostate biopsy offers superior features when compared with TRPBx and is a fea-sible procedure in the inpatient and outpatient setting
- mpMRI offers an additional advantage to the transperineal approach
- Prospective studies directly comparing TRPBx and TPPBx with mpMRI targeted biopsies are needed to prove superiority of either concept



The transperineal approach achieves better cancer detection rates (CDRs) for anterior lesions due to direct anatomic access through the perineal skin



Infection-related events after TPPBx are below 1%, sepsis rates do not exceed 0.5%. and hospital re-admissions are uncommon



New perspectives include the application of focal therapy for PCa through cryotherapy, high-intensity focused ultrasound, laser ablation, and photodynamic therapy



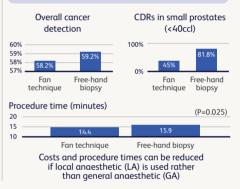
Side effects such as urinary retention, hematospermia, and hematuria decrease when taking <12 cores

An optimal setting to reduce pain for patients would include local anaesthetic, bilateral periprostatic transperineal block and a minimum of 10 cores taken





Combining targeted with systematic biopsies reaches the most accurate diagnostic power for detecting csPCa, and as such, transperineal magnetic resonance imaging-fusion biopsy (TP-MRI-FBx) use is rapidly increasing worldwide



• TPPBx seems to achieve comparable cancer detection rates with TRPBx in biopsy-naïve patients, but is superior

- TPPBx offers superior access to anterior and apical prostate regions and nullifies infectious complications
- TPPBx can be performed with LA in an outpatient setting, has a moderate learning curve and good

"Free-Hand" Transperineal Prostate Biopsy Under Local Anaesthesia: A Review of the Literature



Study author(s)

Szabo, R. J.



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Study design

Literature review of studies that included FTPPBx under LA with or without sedation and reported a CDR, and studies on the costs of post-prostate biopsy sepsis

Study period

Study source

NI/A

Literature published between 2000 and 2020

Publication Journal of Endourology.2021;35(4):525-543. doi: 10.1089/ end.2020.1093



Study objective

To compile and review summary tables from studies summarising cancer detection rate (CDR), patient experience, and complications between free-hand transperineal prostate biopsy (FTPPBx) under local anaesthesia (LA) with or without sedation, and to establish the cost of post-prostate biopsy sepsis



Study population

11,999 cases of FTPPBx under LA with and without sedation over 29 mutually exclusive studies (studies used come from: Italy, the People's Republic of China, the United States, Canada, the United Kingdom, Switzerland, Japan, Taiwan, Singapore, Hong Kong, Norway, and New Zealand)

Study methods

- PubMed and Embase search for 'transperineal prostate biopsy' as well as 'free-hand', 'freehand', and 'free hand' transperineal biopsy and supplemented through cross references and references found in various articles
- Weighted averages over multiple studies for each parameter were obtained, only data pertaining to FTPPBx under LA were extracted where possible
- Important complications were reported and classified depending on clinical interpretation of the authors of the articles

Study limitations

- Inclusion of studies where some intravenous sedation (IVS) and general anaethesia (GA) cases could not be completely separated from LA cases
- Absence of standardisation of FTPPBx techniques across different institutions elicited variation in biopsy patterns, numbers of cores sampled, and use or omission of antibiotic prophylaxis
- Some studies reported a small number of post-FTPPBx fevers along with a sepsis rate of zero, but did not clarify why these fevers were not classified as sepsis
- · Six of the studies included were recently published abstracts so may not contain adequate information to inform findings

AUR – acute urinary retention; CDR – cancer detection rate; csPCa – clinically significant prostate cancer; FTPPBx – free-hand transperineal prostate biopsy; GA – general anaesthesia; IVS – intravenous sedation; LA – local anaesthesia; PSA – prostate specific antigen; TRPBx – transrectal prostate biopsy; US – United States; VAS – visual analogue scale

Study findings



If FTPPBx under LA replaced TRPBx in the US, estimated annual savings would be \$341,676,800-\$752,540,000 through elimination of sepsis

Key points

- complications would be significant



Study conclusions

- Almost 12,000 cases of FTPPBx under LA have been reported in the literature reflecting increased acknowledgment of the superiority of this approach compared with TRPBx on safety, accuracy, and CDR of csPCa
- Procedural times for FTPPBx under LA and rate of AUR are slightly higher, but remain comparable when less than 16 cores were taken
- A change in standard of care from TRPBx to FTPPBx under LA would save healthcare systems millions of dollars annually
- Adoption of FTPPBx under LA may save lives

• Many centres around the world have adopted FTPPBx because it virtually eliminates sepsis, may improve detection rates of csPCa, and can be easily integrated into a normal clinical workflow using only LA

• If all urologists in the United States abandoned TRPBx for FTPPBx, the potential savings in health care costs of

Transperineal Ultrasound-Guided Prostate Biopsy: What the Radiologist Needs to Know





Study methods

anaesthetic utilising a free-hand ultrasound technique

33 papers were used to provide a comprehensive pictorial review of the TP biopsy procedure, pitfalls, and common post-procedural outcomes. The findings were split into 9 subsections.

Study limitations

Not included in paper

TP – transperineal; TRUS – transrectal ultrasound-guided

Study findings

Consent is key; patients should receive a patient information leaflet at the time of referral for biopsy, and a radiologist should detail the procedure and obtain informed consent on the day of the procedure. Equipment includes but is not limited to a lithotomy chair, ultrasound machine with biplane transrectal probe and three aana footswitch. Patient preparation should include fasting before the procedure, anticoagulants and antiplatelet medication stopped, and patient imaging reviewed. Antibiotic use as a prophylactic measure varies between institutions, the author's institution uses oral amoxicillin/ clavulanic acid to cover for skin contaminants. Patient positioning in the modified lithotomy bed allows for optimal positioning for comfort and relaxation of perineal musculature, and biopsy route access. Arthritis or prior surgery on hips, knees or back will impact tolerance of positioning and overall procedure. Analgesia – intravenous sedation can usually be avoided through conversation and distraction by nursing staff. Local anaesthetic used is commonly 1% lidocaine, with the volume varying across studies. Scrotum is taped back using and drape placed over knees, perineum is shaved, and the skin prepped with chlorhexidine. Instalagel is inserted into anus and rectum followed by the ultrasound probe, the footswitch is used to togale between transverse and lonaitudinal views. Local anaesthetic is administered to perineal skin, the prostate is imaged, and volume measurements taken. Spinal needle administers local anaesthetic to bathe neurovascular bundles of prostate capsule. Introducer needle is inserted to allow sampling of the periphery and transitional gland, biopsy needle is inserted and samples are obtained in a craniocaudal direction. 12 biopsy samples are taken, and opsite spray bandage used for puncture sites. Procedural artefacts can include air in the rectum and development of multiple hyperechoic foci throughout the prostate gland. Differentiation between these foci and the location of the biopsy needle can be challenging, particularly in transverse imaging. This can be overcome by toggling between the transverse and longitudinal planes to help locate the needle. For this reason, it may be helpful to biopsy targets before moving onto background nontargeted sampling biopsies.

procedure

Before procedure

Durina

Post

procedure

Key points

- TP biopsy can be performed safely as an outpatient procedure, under local anaesthetic
- TP biopsy can successfully replace TRUS biopsy in diagnosis of prostate cancer



Study conclusions

- TP biopsy is a safer and quicker procedure than TRUS biopsy, is well tolerated and favoured by the European Association of Urology
- This paper may be used as a guide to highlight techniques to aid in the transition to this technique

Patient taken to recovery, given a snack, and encouraged to drink plenty of fluids. Successful urination must occur before discharge, and nurses follow up with phone call the following day.

• TP biopsy reduces the risk of post-procedural sepsis versus transrectal ultrasound-guided (TRUS) biopsy

Short Term Outcomes of Prostate Biopsy in Men Tested for Cancer by Prostate Specific Antigen: Prospective **Evaluation within Protect Study**



Study author(s)

Rosario, D.J., Lane, J.A., Metcalfe, C., Donovan, J.L., Doble, A., Goodwin, L., Davis, M., Catto, J.W., Avery, K., Neal, D.E. and Hamdy, F.C.



Study design

A prospective cohort study (ProBE was a cohort study of ProtecT study)

Publication



BMJ. 2012;344:d7894. doi: 10.1136/bmj.d7894



NI/A

Between February 2006 and May 2008

Study period



- To measure the effect of adverse events after a first prostate biopsy in asymptomatic men having prostate specific antigen (PSA) testing
- To assess early attitudes to repeat biopsy
- To estimate the effect of adverse events from transrectal ultrasound-guided prostate biopsy (TRUS-Bx) on healthcare resource use
- To develop a simple classification system for consistent reporting of adverse events after prostate biopsy

Study population

- Of the 10,297 men offered TRUS-Bx within Protect, 1,753 attended for biopsy between February 2006 and May 2008 and were eligible to enter the ProBE study
- 1,147 (65%) of eligible men consented to participation in the ProBE study

Study methods

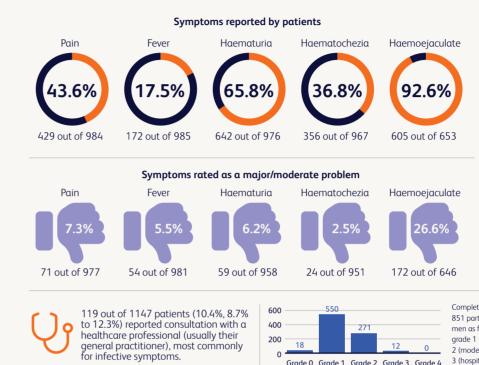
- Baseline data was assessed including weight, height, drug history, comorbidity, Hospital Anxiety and Depression Scale (HADS) score, and urinary, bowel, and sexual symptoms by using validated questionnaires
- Outpatient TRUS-Bx was carried out in the left lateral decubitus position under antibiotic cover by using a 10core lateral biopsy template
- Seven of the eight centres reported using periprostatic infiltration of local anaesthetic routinely before biopsy
- All men received antibiotic prophylaxis according to contemporary practice with a midstream specimen of urine sent for culture immediately before antibiotic administration
- Coumarin anticoagulant and clopidogrel treatment were discontinued up to 10 days before biopsy and advice sought as to appropriate substitutes if indicated
- Aspirin was continued at the discretion of the physician doing the biopsy
- Men were kept under observation after the biopsy until they voided, and urine was assessed for haematuria according to a four-point colorimetric scale
- Each centre provided its own post-biopsy written instructions and contact details

Study limitations

- The study cohort only included asymptomatic men aged 50-69 years who received a PSA test and a first prostate biopsy through the ProtecT study between February 2006 and May 2008, which may limit generalisability to men with urinary symptoms or clinically suspected prostate cancer
- The study was carried out over a limited period and sampled only approximately 11% of the ProtecT participants
- Non-responders to the single written invitation to attend for PSA testing sent out via general practices may not be represented in the study
- Each centre delivered its own information about the biopsy process, which may have influenced men's views
- There may have been recall bias in recording the duration of symptoms, as men were asked to summarise their experience over the previous four weeks in the 35-day questionnaire
- The main analyses required data with evaluable responses from both the seven-day and 35-day questionnaire assessments, which reduced the numbers and may have led to some degree of underestimation of the prevalence of adverse events
- Some of the reported symptoms may not have been related to the biopsy itself and may have inadvertently influenced a negative attitude to repeat biopsy

TRUS-Bx- transrectal ultrasound guided prostate biopsy; PSA - prostate-specific antigen; ProtecT- Prostate Testing for Cancer and Treatment; ProBE—Prostate Biopsy Effects; HADS – Hospital Anxiety and Depression Scale







Key points

- particularly pain at biopsy; differences are evident between centers carrying out the biopsies
- Very few men experience no symptoms at all after biopsy (2.1%)
- Most of those who did experience one or more symptom consider them to be of little consequence (64.6%)
- The remaining third experience adverse events that they consider to be a moderate or severe problem
- Pain, sepsis, or bleeding are the primary adverse events experienced by men during or after biopsy
- Men's attitude towards additional biopsies is significantly affected by their first biopsy, with pain experienced at biopsy and infective symptoms in the week after biopsy being strongly associated with a negative attitude towards repeat biopsy



Study conclusions

- One third of men reported moderate to severe biopsy-related symptoms after having their first TRUS-Bx for a high PSA
- One in 10 men had an unfavorable attitude towards repeat biopsy immediately after TRUS-Bx, rising to one in five later
- Adverse events in the seven days after biopsy were associated with this unfavorable attitude and affected younger men more
- Within 35 days of biopsy, 1.3% of men required admission to the hospital and a further 10.4% of men initiated a biopsy-related consultation with their general practitioner, urology department nurse, or other medical advice source, mostly for infective symptoms

BD TP Prostate Biopsy Evidence Compendium 2023 | Patient Experience

Would consider further biopsy a major or moderate proble



Immediately after biopsy 124 out of 1142 patients 10.9%. 95% confidence interval 9.2 to 12.8)



Immediately after biopsy 213 out of 1085 patients (19.6%, 17.4% to 22.1%)

A negative attitude to repeat biopsy was associated with unfavourable experience after the first biopsy, particularly pain at biopsy (odds ratio 8.2, P<0.001) and symptoms related to infection (7.9, P<0.001) and bleeding (4.2, P<0.001): differences were evident between centres (P<0.001)

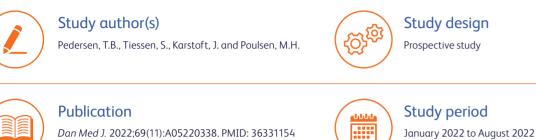


Grade of adverse event was associated with an unfavourable attitude to repeat biopsy (Kendall's τ-b ordinal by ordinal 0.29. P<0.001).

Complete data for all index symptoms at all time points were available in 851 participants. Symptoms and healthcare use could be used to arade these men as follows: grade 0 (no symptoms/contact) 18 (2.1%, 1.3% to 3.3%); arade 1 (minor problem/no contact) 550 (64.6%, 61.4% to 67.8%); arade 2 (moderate/major problem or contact) 271 (31.8%, 28.8% to 35.1%); grade 3 (hospital admission) 12 (1.4%, 0.8% to 2.4%); and grade 4 (death) 0.

• A negative attitude towards repeat biopsy is associated with an unfavorable experience after the first biopsy,

Introduction of Free-hand MRI-guided Transperineal Prostate Biopsies as an Outpatient Procedure





To describe the first Danish experience with multiparametric magnetic resonance imaging-guided transperineal ultrasonic biopsy (mpMRI-TP-Bx)



Study population

Study objective

143 men who were undergoing multiparametric magnetic resonance imaging-guided transrectal ultrasonic biopsy mpMRI-TRUS-Bx in the authors' hospital

Study source

Denmark

Odense University Hospital and University of Southern

Study methods

- Patients undergoing mpMRI-TRUS-BX were offered mpMRI-TP-BX instead
- Patients were placed in the lithotomy position with the scrotum elevated and a biplane ultrasound transducer was subsequently inserted into the rectum, visualising the prostate
- · Software registration with an integrated fusion system was used to fuse mpMRI prostate contours with ultrasonic imaging
- Three to five biopsy cores were taken per mpMRI lesion
- Immediately after the procedure, an 11-point visual analogue scale (VAS) was used to assess patient pain during and after the procedure (0: no pain to 10: severe pain)
- A week after the procedure, patients were asked to complete a questionnaire assessing post-procedural discomfort and complications
- Histopathology reports were registered
- P-values and 95% confidence intervals (CI) were calculated using a two-sides exact binomial test



Study limitations

Not included in paper

mpMRI-TP-BX – multiparametric magnetic resonance imaging-guided transperineal biopsy; mpMRI-TRUS-BX - multiparametric magnetic resonance imaging-guided transrectal ultrasonic biopsy; VAS – visual analogue score

Reference: 1. Borre M, Bentzen L, Hansen S et al. Dansk Prostata Cancer Database. Dansk Urologisk Cancer Gruppe. Årsrapport 2020. DaProCa, 2021:39.

Study findings The cancer detection rate 6 CT· 74 5-8 Detection rate of cancer with an 69.2% International Society of Urological 5% CI: 61-76.7 Pathology score above 1 Detection rate of cancer for 37.7% patients who had previously CI: 76.3-94. undergone active surveillance Both Anterior part of the prostate only Target lesion



Posterior part of the prostate only

Key points

• Rates of post-biopsy infection were low following mpMRI-TP-BX • Patients generally reported a low pain score for during, immediately after, and one week after the procedure

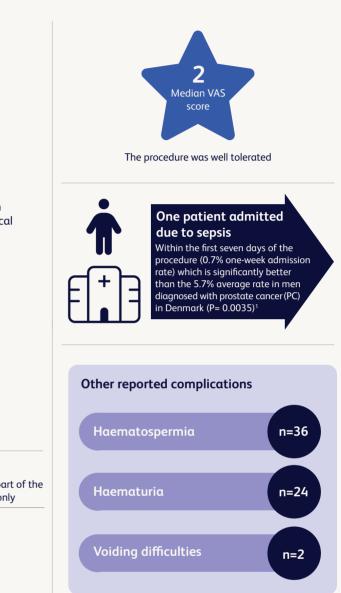


Study conclusions

location

• mpMRI-TP-BX is a safe and feasible procedure with a low risk of infection

- Despite being marginally more technically challenging than mpMRI-TRUS-BX, it offers improved patient safety



- Transperineal biopsies may readily be performed under local anaesthesia in an outpatient setting

Pain in Men Undergoing Transperineal Free-hand Multiparametric Magnetic Resonance Imaging Fusion Targeted Biopsies under Local Anaesthesia: Outcomes and Predictors from a Multicentre Study of 1,008 Patients



• To establish whether and how we can identify those experiencing severe pain, and to verify whether pain decreases clinically significant prostate cancer (csPCa) detection

Study population

1,327 (1008 included in the final analysis that all met the inclusion criteria and providing all follow-up data) consecutive men undergoing transperineal fusion biopsy (TPFBx) (target and systematic cores); indications to perform biopsy were a positive mpMRI performed due to elevated prostate specific antigen and/or suspicious digital rectal examination

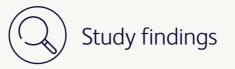
Study methods

- All TPFBxs were performed in an in-office setting using the same LA technique with 20mL 1% lidocaine
- Data were collected 1) before the procedure (baseline features); 2) during the procedure (pain and procedural timings; 3) immediately after the procedure, before patient discharge; and 4) at 40 days from the biopsy during the first clinical follow up
- Peri-procedural pain was evaluated using a 0 to 10 numeric rating scale (NRS)
- Pain scores were recorded at the time of 1) transrectal ultrasound (TRUS) probe insertion; 2) local anaesthesia (after the needle exit); and 3) prostate biopsy (after taking the last core)
- Patient anxiety was assessed before starting the procedure using the NRS; severe anxiety was defined as an NRS greater than 6
- Clinically significant PCa was defined as 1) ISUP greater than 1, or ISUP 1 having 3 or more positive cores or 1 core with more than 50% PCa involvement (D1) and 2) ISUP 2 or greater (D2)
- Complications were graded according to the Clavien-Dindo classification

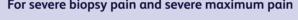
Study limitations

- Anxiety preventive measures should be tested through randomised control trials (RCTs) to investigate if they may improve procedural compliance and patient comfort in those with severe pain
- Pre-biopsy anxiety should be evaluated with validated instruments, in addition to NRS
- Absence of randomisation with the transrectal approach hampers comparisons on pain severity

BPH – benign prostatic hyperplasia; csPCa – clinically significant prostate cancer; ISUP – International Society of Urological Pathology; LA – local anaesthetic; mpMRI – multiparametric magnetic resonance imaging; NRS – numeric rating scale; RCT – randomised control trial; TPFBx – transperineal fusion biopsy; TRUS – transrectal ultrasound; US - ultrasound

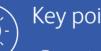














Study conclusions

• This paper develops a model that may be used to identify those at higher risk of severe pain and to test the effect of possible anxiety preventive measures in these patients

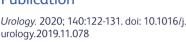
• Further studies are needed to validate the findings

BD TP Prostate Biopsy Evidence Compendium 2023 | Patient Experience

Transperineal Free-hand mpMRI Fusion-targeted Biopsies Under Local Anaesthesia: Technique and Feasibility from a Single-centre Prospective Study









To evaluate the feasibility of "in-office" full freehand transperineal fusion biopsy (TPFBx) under local anaesthetic (LA)

| Stud |
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dy source San Giovanni Battista Hospital, Turin, Italy

September 2016 to June 2018

Study population

Study objective

724 (actual number of men included is 459 – TPFBx= 279, transperineal systematic biopsy (TPSBx)= 180 – the additional number includes multiparametric magnetic resonance imaging (mpMRI) performed in and outside the centre) consecutive men undergoing either TPSBx (target and systematic cores) and TPSBx (systematic cores only)

Study methods

- Data collection was performed at four different time frames: (1) before the procedure; (2) during the procedure; (3) immediately after the procedure, before patient discharge; (4) at 40 days from the biopsy during the first clinical follow-up visit
- Urinary and erectile functions were assessed using International Prostate Symptom Score (IPSS) and International Index of Erectile Dysfunction (IIEF-5), respectively
- Periprocedural pain was determined using a 1-10 numeric rating scale (NRS); complications were graded according to the Clavien-Dindo Score
- All procedures were carried out in an in-office setting using the same LA technique
- Oral ciprofloxacin was administered twice daily for 3 days starting the day before the procedure; biopsies were collected using an 18-gauge, 22 mm depth standard coaxial needle
- All mpMRIs were reviewed by an experienced radiologist dedicated to prostate mpMRI and blind to clinical data using prostate imagine - reporting and data system (Pi-RADS) score and sectors

Study limitations

- The single-centre nature of the study requires that other researchers reproduce the findings
- It was unclear whether the findings of exceedingly high and low proportions of clinically significant prostate cancer (csCaP) and non-clinically significant prostate cancer (CaP) were derived from the transperineal (TP) approach and warrants further investigation
- The study includes both primary and secondary biopsy settings and external mpMRIs being performed with different protocols, so the cancer detection does not refer to a specific patient group

AUR – acute urinary retention; csCaP – clinically significant prostate cancer; IIEF-5 – International Index of Erectile Dysfunction; IPSS – International Prostate Symptom Score; LA – local anaesthetic; mpMRI – multiparametric magnetic resonance imaging; NRS – numeric rating scale; RCT - randomised control trial; TP - transperineal; TPFBx - transperineal fusion biopsy; TPSBx - transperineal systematic biopsy



- Mean procedural time of TPFBx was 19.1 minutes, higher than TPSBx (P<0.001)
- The procedure was well tolerated
- The maximum experience mean pain being 4.7 NRS points
- Pain was highest at the time of LA
- Pain during prostatic sampling was slightly higher for TPFBx (P=0.03)



Acute urinary retention (AUR) was the only major complication that occurred (which occurred in only 3 patients out of 459) (Clavien 3a)

Key points

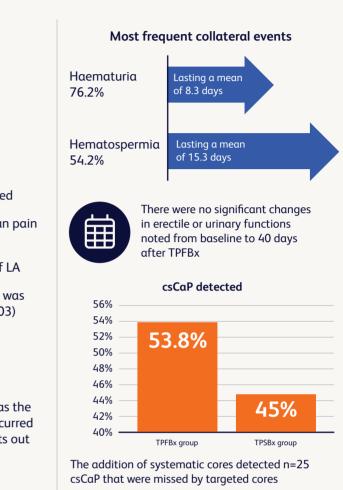
- cores has superior detection
- dysfunction and good csCaP detection
- The addition of systematic cores identified approximately one in five men having csCAP that would have been missed by targeted cores



Study conclusions

- Transperineal mpMRI-targeted biopsies under LA are feasible, yield high tolerability and have low complication rates in an in-office setting
- The addition of systematic cores remains recommended in the study
- Further studies are needed to confirm the findings of the study due to it being a single-centre study

BD TP Prostate Biopsy Evidence Compendium 2023 | Patient Experience



• Transperineal mpMRI-targeted biopsies under LA are feasible in an in-office setting; target and systematic • Complication rates are low including negligible urinary retention and risk of infection, no impact on erectile

Feasibility Of Freehand MRI/US Cognitive Fusion Transperineal Biopsy of the Prostate in Local Anaesthesia as In-office Procedure-experience with 400 Patients





Study objective

To assess safety and tolerability of transperineal prostate biopsy (TPPBx) performed using local anaesthesia (LA)



Study population

400 patients who had undergone office-based TPPBx using local anaesthesia performed by a single surgeon



Study methods

 Demographic and clinical data, such as antibiotic prophylaxis, multiparametric magnetic resonance imaging (mpMRI) findings and number of biopsies, as well as histopathologic findings were extracted by chart review

Study source

Uro Merian, Basel, Switzerland

- 308 (77%) of the patients has undergone mpMRI
- The standard random biopsy template comprised of 12 biopsy cores using the fan-technique with patients in lithotomy position
- A single puncture and trocar-like access sheath introduction technique was used during the biopsy
- The first 118 (29.5%) patients in this cohort have received two doses of 500 mg oral fluoroquinolone, one dose was taken in the evening before the biopsy and the second dose was taken 1 hour before the procedure
- The next 105 (26.2%) patients received only one single dose of 500 mg oral fluoroquinolone 1 hour before the biopsy
- The remaining 177 (44.3%) patents received no antibiotic prophylaxis, unless otherwise indicated
- A visual analogue scale (VAS) ranging from 0 to 10 was used to record pain perceived by the patients during the procedure
- The Clavien-Dindo grading system was used to classify clinically relevant complications, including urinary retention and infectious complications post-biopsy



Study limitations

- The study is limited to its retrospective design
- The single centre data and lack of control group limited the generalisation and comparability of this study

FTPPBx – freehand transperineal prostate biopsy; LA – local anaesthesia; mpMRI – multiparametric magnetic resonance imaging; PSA – prostate-specific antigen; TPPBx – transperineal prostate biopsy; TRPBx – transrectal prostate biopsy; US – ultrasound; VAS – visual analogue scale

Median age 66 (range, 49-86) Median PSA concentration (range, 0.3–1400) Median PSA density (range, 0–31.1) Median prostate volume 40 mL



(range 6-150)





There was a significant correlation of age with perceived pain: older men perceived less pain than younger

individuals (P<0.01)

Key points

- detection rate
- Median pain score (2.0) recorded by patients was low
- 54.8% of men who had undergone previous TRPBx rated TPPBx as the less painful procedure



Study conclusions

- alternative to the TRPBx
- The single-puncture and trocar-like access sheath introduction technique may have diminished tissue trauma and bacterial exposition

BD TP Prostate Biopsy Evidence Compendium 2023 | Patient Experience

None of the patients required:

Additional analgesics

Local anaesthesia

Interruption to procedures due to discomfort or pain

54.8% of men who had undergone previous transrectal prostate biopsy (TRPBx) rated TPPBx as the less painful procedure 35.7% reported no difference, 9.5% preferred TRPBx than TPPBx



The applied freehand magnetic resonance imaging (MRI)/ultrasound (US) cognitive fusion TPPBx yielded an overall higher than expected cancer detection rates compared to other reports

FTPPBx in local anaesthesia is a safe, effective, and well tolerated outpatient procedure with a high cancer

• Elimination of infectious complications and high accuracy makes the TPPBx technique a feasible

Free-hand Transperineal Prostate Biopsy Provides Acceptable Cancer Detection and Minimises Risk of Infection: Evolving Experience with a 10-Sector Template



Study author(s)

Ristau, B.T., Allaway, M., Cendo, D., Hart, J., Riley, J., Parousis, V. and Albertsen, P.C.



A retrospective review

Study source



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Publication





NI/A



- To determine whether freehand transperineal prostate
- biopsy (FTPPBx) achieves cancer detection rates comparable to historic transrectal prostate biopsy cohorts
- To determine infectious and other complications associated with FTPPBx



Study population

- Prospectively collected single institution experience of 1,000 consecutive men undergoing FTPPBx for elevated serum PSA (\geq 4.0 ng/mL), abnormal digital rectal examination, or on an active surveillance protocol
- For men who underwent multiple FTPPBx, only the initial biopsy was included in the analysis (n=116)

Study methods

- All procedures were performed in an outpatient surgery centre
- Intravenous sedation was administered for 873 patients and sedation was omitted in favour of LA in 127 patients
- Single dose cephalexin was administered early in the cohort but not for the remaining 400 patients
- Men were positioned in the dorsal lithotomy position
- Prostate volume was calculated using the ellipsoid volume calculator
- Prostate specific antigen (PSA) density was calculated as the PSA divided by prostate volume
- Clinically significant cancer was defined as Grade Group 2 or higher

Study limitations

- The retrospective design and accrual within a single institution which may limit its applicability to other populations
- The study population is primarily Caucasian, potentially limiting generalisability to other racial groups
- The number of biopsy cores was not standardised

FTPPBx - freehand transperineal prostate biopsy; LA - local anaesthesia; PSA - prostate specific antigen; TRPBx - transrectal prostate biopsy; UTI – urinary tract infection





Key points

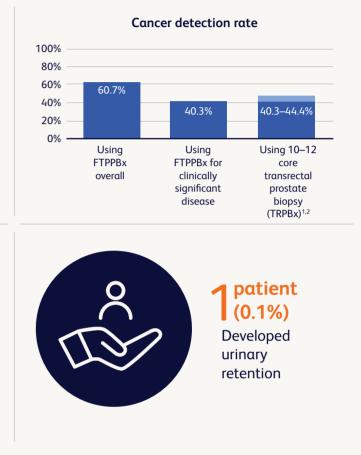
- FTPPBx approach
- detection rate comparable to the traditional TRPBx technique References: 1. Presti JC, O'DOWD GJ, Miller MC, Mattu R, Veltri RW. Extended peripheral zone biopsy schemes increase cancer detection



Study conclusions

Cancer detection rates are comparable to traditional TRPBx, and the FTPPBx approach eliminates the need for antibiotic prophylaxis

BD TP Prostate Biopsy Evidence Compendium 2023 | Diagnostic Yield and Sample Accuracy



• Elimination of antibiotic prophylaxis with no increase in infectious risk remains a major advantage of the

• Using an access device that permitted an accurate 10-sector template sampling procedure achieves a cancer

rates and minimize variance in prostate specific antigen and age-related cancer rates: results of a community multi-practice study. The Journal of urology. 2003 Jan;169(1):125-9. 2. Gore JL, Shariat SF, Miles BJ, Kadmon D, Jiang N, Wheeler TM, Slawin KM. Optimal combinations of systematic sextant and laterally directed biopsies for the detection of prostate cancer. The Journal of urology. 2001

Transperineal Versus Transrectal Prostate Biopsy in the Diagnosis of Prostate Cancer: A Systematic Review and Meta-analysis



Study author(s)





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Study design
A systematic review
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Publication

World J Surg Oncol. 2019;17(1):31. doi: 10.1186/s12957-019-1573-0



Study period Literature search included papers published between 2002 and 2017



Study objective

To compare the diagnosis rate and complications of transperineal prostate biopsy (TPPBx) versus transrectal prostate biopsy (TRPBx)



Study population

- Male patients in journals included the following inclusion criteria:
- A randomised control study (RCT) study, cohort study, or case-control study
- Studies comprised of patients who underwent prostate biopsy
- The intervention method included the transperineal (TP) approach and transrectal (TR), the number of cores and the guidance method remained the same
- The final case outcome included a diagnosis of prostate cancer (PCa) or complications of the two approaches
- The studies provided odds ratios (ORs) or relative risks (RRs) with 95% confidence intervals (CIs), or adequate evidence to estimate them
- Seven observational studies and four RCTs were included, the 11 studies were from Italy, China, and Japan
- Total population in the meta-analysis reached 2569 with 1644 for the TP approach and 1634 for the TR approach

Study methods

- The search was conducted in PubMed, Scopus, Web of Science, and Chinese National Knowledge Infrastructure (CNKI) databases, papers were limited to the English or Chinese language
- The author's last name and country, publication year, patient age, prostate volume, PSA level, biopsy method, and covariates in the analysis
- · For this study, RR and OR were alternatively extracted for the largest number of cofounders
- RR was used in all studies to estimate the diagnosis accuracy of TPPBx and TR approaches

Study limitations

- Only 4 RCTs (which represent the gold standard methodology of clinical trial) were included
- Selection and compatibility problems could not be avoided for cohort studies
- Xiang et al. could not rule out the possibility that the conclusions may be affected by potential publication bias mainly due to language limitations

CIs - confidence intervals; CNKI - Chinese National Knowledge Infrastructure; ORs - odds ratios; PCa - prostate cancer; PSA - prostate-specific antigen; RCT – randomised controlled trial; RRs – relative risks; TP – transperineal; TPPBx – transperineal prostate biopsy; TR – transrectal; TRPBx – transrectal prostate biopsy

RR 0.94. 95% CI 0.81-1.10

TP

Study findings

The general RR from RCT and observational studies showed no significant difference between TP and TR approaches on diagnosis accuracy

However, TP was associated with significantly higher pain (RR=1.83, 95% CI 1.27-2.65)



Key points

- fever (RR = 0.26, 95% CI 0.14-0.28)
- However, TP was associated with significantly higher pain
- No significant difference was found in the acute retention of urine and haematuria between the two approaches
- For patients who are prone to infection (including those with diabetes, prostatitis, and urinary catheterisation) the TP approach was recommended to avoid sepsis and severe fever after the procedure
- The TP approach significantly decreased risk of complications
- The TR approach had significantly higher risk of infection than the TP approach
- The TP approach was confirmed to be superior in detecting tumours in the transitional zone and apex of the prostate confirmed to be superior in detecting tumours in the transitional zone and apex of the prostate



Study conclusions

- TPPBx has the same diagnosis accuracy of TRPBx
- TPPBx is safer and more valuable because it poses a significantly lower risk of infection and rectal bleeding

BD TP Prostate Biopsy Evidence Compendium 2023 | Diagnostic Yield and Sample Accuracy

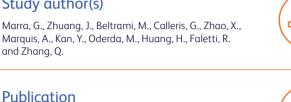
TR RR 1.01. 95% CI 0.87-1.18

• The TP approach significantly protected the patients from rectal bleeding (RR=0.02, 95% CI 0.01-0.06) and

Transperineal Freehand Multiparametric MRI Fusion Targeted Biopsies Under Local Anaesthesia for Prostate Cancer Diagnosis: A Multicentre Prospective Study of 1014 Cases



Study author(s)



BJU Int. 2021;127(1):122-130. doi: 10.1111/bju.15121



Study objective

- To assess the outcomes of multiparametric magnetic resonance imaging (mpMRI) transperineal targeted fusion biopsy (TPFBx) under local anaesthetic (LA) by:
- Analysing the accuracy of TPFBx demonstrated through clinically significant prostate cancer (csPCa) detection and.
- Evaluating pain, complications, the need to add systemic cores, variation of urinary and erectile function, procedural timing, and final concordance with final prostatectomy for those undergoing surgery



Study population

1327 consecutive patients with positive mpMRI undergoing TPFBx under LA at two tertiary referral institutes (1014 patients were included in the data)

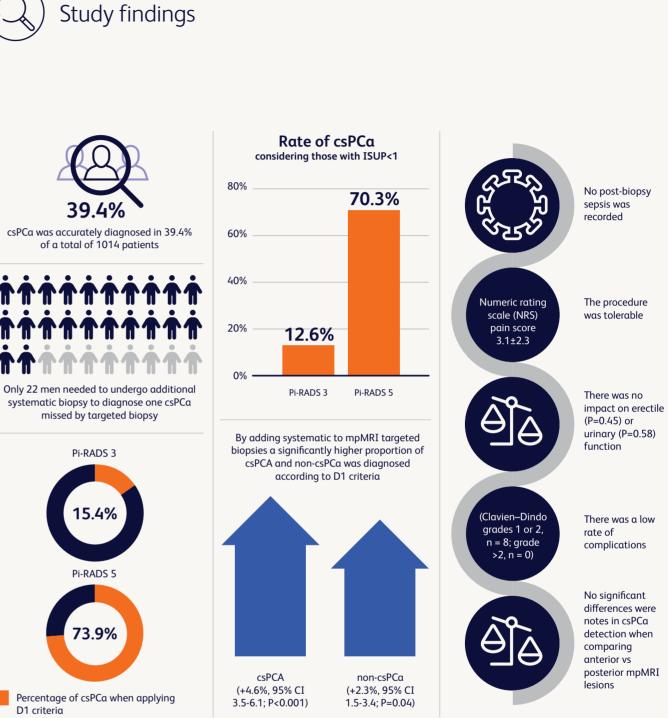
Study methods

- Baseline data of general and urological history, comorbidity status, pain, peri-procedural complications, procedural timings were collected before the procedure
- Data on the early onset of complications were collected immediately after the procedure prior to patient discharge
- Data were collected on pathology, complications, and functional outcomes 40 days after the biopsy during the first clinical follow-up visit
- csPCa was defined as: International Society of Urological Pathologists (ISUP) grade >6 or ISUP grade 6 with >50% involvement of PCa in a single core or >2 cores (D1); or ISUP grade >1 (D2)
- A minimum of 10 systematic cores were taken in the posterior peripheral zone
- Prostate imaging-reporting and data system (Pi-RADS) scale was assigned each lesion is assigned a score from 1 to 5 indicating the likelihood of clinically significant cancer

Study limitations

- Non-randomised design excluding a TR cohort
- There was a relatively high number of different operators performing the procedure
- Having the procedure performed by experienced operators only would have improved results
- The inclusion of different mpMRI protocols and a minority of mpMRI procedures performed outside the referral centres enhance the generalisability of the results

csPCa - clinically significant prostate cancer; ISUP - International Society of Urological Pathologists; LA - local anaesthetic; mpMRI - multiparametric magnetic resonance imaging; PCa - prostate cancer; Pi-RADS - prostate imaging-reporting and data system; RP - radical prostatectomy; NRS - numerical rating scale; Society of Urological Pathologists; TPFBx – transperineal targeted fusion biopsy





TPFBx under LA yielded good csPCa detection and was feasible, guick, well tolerated, and safe



Study conclusions

• Infection risk of the technique was negligible

San Giovanni Battista Hospital, Turin, Italy and Drum Tower Hospital Nanjing, China

Study design

Study period

Study source

September 2016 to May 2019

cohort

Non-randomised design excluding a transrectal (TR)

BD TP Prostate Biopsy Evidence Compendium 2023 | Diagnostic Yield and Sample Accuracy

• Additional of systematic to target cores improves csPCa detection but may not be required for all men

Freehand versus Grid-based Transperineal Prostate Biopsy: A Comparison of Anatomical Region Yield and Complications





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Publication J Urol, 2021:206(4):894-902. doi: 10.1097/ JU.000000000001902



Study period The grid-based (GB) method was performed from 2014 to 2018 and the freehand (FH) technique was performed from 2018 to 2020

Study objective

To compare the efficacy and complication rates of the FH method with those of standard GB method



Study population

• Cohort of men that underwent the GB method was 174

• Cohort of men that underwent the FH method was 304

Study methods

- TPB cases, including indications, prostate specific antigen (PSA), lesion volumes, magnetic resonance imaging (MRI) findings, and biopsy core counts and templates were maintained in a prospective database
- Additional retrospective chart review was performed to verify pathology results and patient characteristics, and to assess for postprocedure complications which were graded using the Clavien-Dindo method
- All biopsies were performed by a single urologist
- For clinically significant cancer detection analysis, patients were separated into two cohorts and comparisons made in each prostate sector
- Patients who have had previous negative biopsy with persistent clinical suspicion of prostate cancer (PCa)
- Patients who were previously diagnosed with low-grade PCa and under active surveillance
- Multivariable logistic regression analysis identified predictors of ≥Gleason grade group (GGG)-2 PCa detection in each prostate sector
- Primary biopsies, evaluations for radiation recurrence, and patients on neoadjuvant therapy trials were excluded

Study limitations

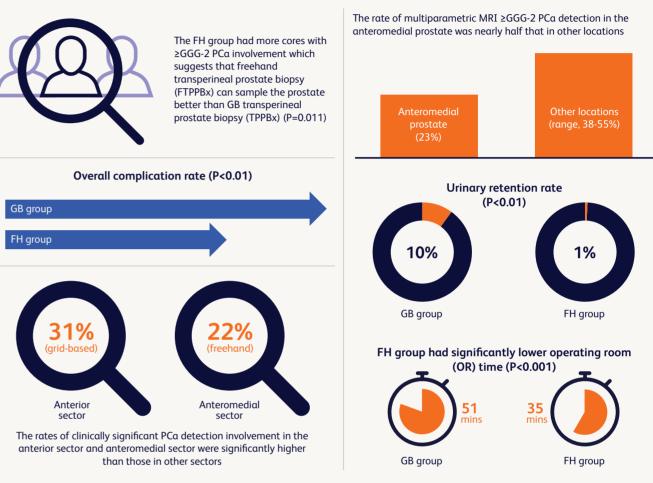
The study was limited by its retrospective, single-centre, single surgeon, non-randomised design

FTPPBx – freehand transperineal prostate biopsy; GB – grid-based; GGG-2 – Gleason grade group; FH – freehand; MRI – magnetic resonance imaging; OR – operation room; PCa – prostate cancer; PSA – prostate-specific antigen; TPPBx - transperineal prostate biopsy



Study findings

suggests that freehand transperineal prostate biopsy better than GB transperineal





Key point

FTPPBx demonstrates a cancer yield equivalent to that of GB TPPBx



Study conclusions

- urinary retention, and reduced anaesthesia needs
- FTPPBx allows for greater needle trajectory control and reduced unnecessary sample of the transition zone
- Given MRI's low PCa detection rate in anterior segments, patients with rising PSA levels and prior negative biopsies/patients on active surveillance might benefit from FTPPBx to maximise detection accuracy
- The FH group had more cores with ≥GGG-2 PCa involvement (P=0.011) which suggests that FTPPBx can sample the prostate better than GB TPPBx

BD TP Prostate Biopsy Evidence Compendium 2023 | Diagnostic Yield and Sample Accuracy

• FTPPBx shows significant benefits as the procedure has no risk of sepsis, significantly reduced risk of

How Many Cores Are Enough? Optimising the **Transperineal Prostate Biopsy Template**



Study author(s)

Publication

Schaufler, C., Daigle, R., Singhaviranon, S., Gjertson, C.K., Albertsen, P.C. and Ristau, B.T.



Urol Oncol. 2022;40(5):191.e1-191.e7. doi: 10.1016/j. urolonc.2021.11.026



Study design

biopsy (TRUS-B)

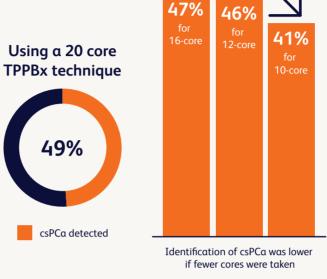
A prospective monitoring study



- To develop an optimal systematic template for TPPBx based
- Primary outcome was detection of clinically significant prostate cancer (csPCa), defined as clinically significant grade group 2 (≥GG2) and secondary outcome was detection of clinically insignificant PCa grade group 1 (GG1)



Study findings



12-core TP-B cohort



More clinically significant cancers were detected in the 12-core TP-B cohort (P<0.001)



Key point

More csPCa were detected using the 20-core template compared to the 10-core template for both the whole cohort (49% vs. 41%, P=0.02) and the biopsy naïve subset (48% vs 40%, P=0.05)



Study conclusions

• A 20-core TP-B systematic biopsy detected a greater number of csPCa compared to a 10-core TP template

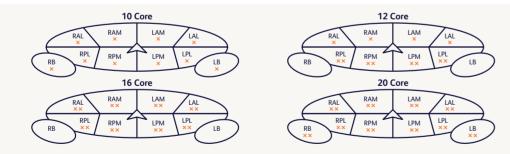
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• A minimum of 12-core systematic TP biopsy template was decided to be optimum
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Study population 200 consecutive free-hand TPPBx on men undergoing a 20 core TPPBx including those who

- Were biopsy naïve (n =117)
- Had elevated PSA with prior negative biopsy (n = 18)
- On active surveillance (n = 65)

Study methods

Templates comprised on 10, 12, 16 and 20-cores were created



LAL – left anterior lateral; LAM – left anterior medial; LB – left Base; LPL – left posterior lateral; LPM – left posterior medial; PCa – prostate cancer; PSA – prostate specific antigen; RAL – right anterior lateral; RAM – right anterior medial; RB – right base; RPL – right posterior lateral; RPM – right posterior medial

• An institutional cohort of 10-12 core TRUS-B (n = 170) was used to compare prostate cancer detection between techniques

• Cancer detection rates were compared between templates



- The study is limited to a single centre which may reduce generalisability to other populations
- TPPBx data were obtained prospectively and transrectal (TR) data were obtained retrospectively
- Variations in the performing urologist and diagnosing pathologist between patients potentially introduces measurement bias

csPCA - clinically significant prostate cancer; CZ - central zone; GG - grade group; TPPBx - transperineal prostate biopsy; TRUS-B – transrectal ultrasound-guided prostate biopsy; TR – transrectal

BD TP Prostate Biopsy Evidence Compendium 2023 | Diagnostic Yield and Sample Accuracy



12-core TRUS-B series

The Clinical and Financial Implications of a Decade of Prostate Biopsies in the NHS: Analysis of Hospital Episode Statistics Data 2008-2019



Study author(s)

Tamhankar, A.S., El-Taji, O., Vasdev, N., Foley, C., Popert, R., and Adshead, J.



Study design Retrospective evaluation of prospectively maintained

pseudonymised dataset



Publication

BJU Int. 2020;126(1):133-141. doi: 10.1111/bju.15062



Study period Data between April 2008 and March 2019



Study objective

To evaluate the clinical and financial implications of a decade of prostate biopsies performed in the UK National Health Service (NHS) through the transrectal (TR) vs the transperineal (TP) route



Study population

Patients who had undergone TR or TP prostate biopsy

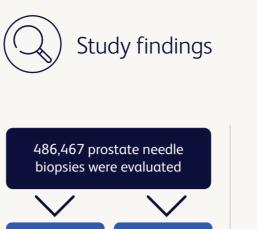
Study methods

- Hospital episode statistics (HES) recorded procedure-specific codes were used to identify patients
- Patients were included if they had received transperineal prostate biopsy (TPPBx) or transrectal prostate biopsy (TRPBx)
- All patients who were readmitted or attended accident and emergency (A&E) 28 days following procedure were identified to classify for subgroup analyses
- NHS 'payment by results' Healthcare Resource Group tariffs for 2013 were used to calculate financial costs for procedure specific complications
- Data were descriptively analysed to summarise patient characteristics

Study limitations

- Lack of:
- Standardisation of technique across hospitals
- Standardised reporting of all post-procedure events
- Details of demographics for stratification of complication rates
- Information on patients who may have had TRPBx and gone on to have a TPPBx within 12 months
- Information on the exact days of hospitalisation for each group according to the type of event
- Difficulty in assessing functional outcomes of biopsies
- Errors may have occurred through misreporting codes

A&E – accident and emergency; HES – hospital episode statistics; NEL – non-elective; NHS – National Health Service; TPPBx – transperineal prostate biopsy; TRPBx – transrectal prostate biopsy; UK – United Kingdom; UTI – urinary tract infection



ΤP

98,588

0.31%

0.96%

1.17%



The main reason for readmission for TR and TP cohorts was infective complications and urinary retention, respectively



Rates of sepsis have more than doubled for TR biopsies in the last 2 years compared to the previous decade



Non-elective (NEL) readmissions for TP have reduced in the last 2 years compared to the TR group



TR

387,879

0.53%

0.77%

1.16%

Key point

Sepsis

Jrinary tract

infections (UTIs)

Real

General

infection

There is sufficient evidence for the advantages of the TP route over the TR route including reduced infections and burden of expenditure, and the potential for savings in upstream and downstream costs if performed under local anaesthetic



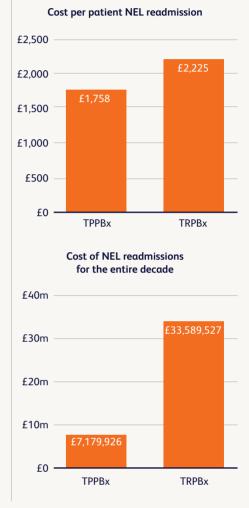
Study conclusions

• TPPBx is superior to TRPBx, with reduced infectious complications and sepsis rates, and equivalent to TRPBx for NEL admission rates

- TPPBx shows dramatic savings in costs for management of complications and readmissions
- The proportion of TPPBx has rapidly increased to 32.8% of all prostate biopsies and, if performed under general anaesthetic, will increase cost
- Switching all prostate biopsies to a local anaesthetic would lead to upstream and downstream savings







Economic Evaluation of Transperineal versus Transrectal **Devices for Local Anaesthetic Prostate Biopsies**



Publication

Pharmacoecon Open. 2021;5(4):737-753. doi: 10.1007/ s41669-021-00277-4



UK

Study source

Study objective 6

To estimate the cost effectiveness of transperineal ultrasound-guided biopsy (TPUSBx) devices compared with transrectal ultrasound-guided biopsy (TRUSBx) in the diagnosis of prostate cancer from the perspective of the UK National Health Service (NHS), and to estimate the value of further research in the area

Study population

Men suspected of having prostate cancer



Study methods

- A decision model was developed comprising a decision tree with Markov models at terminal nodes
- Design of the model mirrors the current clinical diagnostic pathway for men presenting in primary care for suspected prostate cancer; TPUSBx is added as a comparator strategy in place of TRUSBx, as well as the cost and consequences of adverse events associated with TRUSBx
- This model allowed comparison of the expected lifetimes costs (based on NHS unit cost sources for 2018-2019) and quality adjusted life years (QALYs) (based on UK lifetable statistics) accrued with TPUSBx and TRUSBx
- Data informing the decision model were taken from a prospective case series representing the first rigorous data on the safety, acceptability, and cost effectiveness of the Cambridge prostate biopsy (CamPROBE) device
- A 'value of information' analysis was conducted to guide direction of further research, using parameters calculated for relevant patient populations of England over 10 years



Study limitations

Pertaining to the quality of data:

- The observed difference in consumable costs is driven by a small sample of biopsies conducted in one centre this may not be generalisable to other settings
- Comparative data is needed to establish the difference in infection rate between the two techniques, as probability of infection is uncertain
- Diagnostic accuracy was assumed to be equal between transrectal and transperineal biopsies, but as the distributions are modelled independently, sensitivity and specificity can vary according to current levels of uncertainty
- No costs for training or the impact of any learning curve were included

CamPROBE - Cambridge prostate biopsy; ICER - incremental cost-effectiveness ratio; NHS - National Health Service; QALY - quality adjusted life year; TPUSBx – transperineal ultrasound-guided biopsies; TRUSBx – transrectal ultrasound-guided biopsy; UK – United Kingdom

Study findings **TPUSBx per-procedure device** acquisition cost Below £81 Yields an incremental cost-effectiveness ratio (ICER) below £20.000 per OALY gained Below £41 Yields cost neutrality There is value in future research on: Diagnostic accuracy Incidence of of TPUSBx versus iatrogenic infection transrectal biopsies and sepsis Key points effective compared with TRUSBx, as long as the per-procedure acquisition cost is below £81



Study conclusions

on men with intermediate-risk disease

• TPUSBx has the potential to be cost effective, with the greatest value of future research being randomised comparisons of the diagnostic accuracy and risk of infection • Future economic modelling should consider non-template TPUSBx, as well as biomarker tests

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• Subject to a number of assumptions and based on current information, it is estimated that TPUSBx is cost • Future research should focus on comparative diagnostic accuracy and infection risk, focusing particularly

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