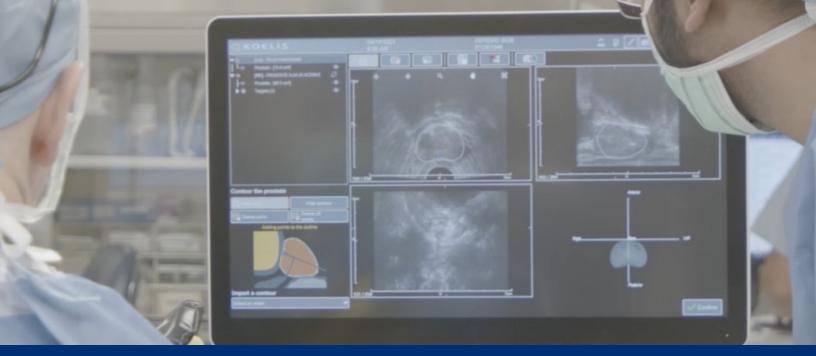


Transperineal White Paper



Are Transperineal Prostate Biopsies the Key to Minimizing Infection Risks?

A Global View



Prostate biopsies are a common method used for detecting prostate cancer at an early stage, with two specific approaches - transperineal (TPBx) and transrectal (TRBx) - which are currently among the most widely utilized.

Over the last 25 years, medical professionals have debated the individual merits of both transrectal and transperineal approaches for accessing areas of the prostate for biopsy samples. In particular, the issue of infection prevention has been discussed, and which of the two methods is more advantageous when it comes to protecting patients from infectious complications such as sepsis and antibiotic-resistant bacteria.

In recent years, the transperineal prostate biopsy approach has gained popularity as an alternative to the traditional transrectal biopsy method.¹ Inserting the biopsy needle through the perineum rather than through the rectal wall mucosa has been shown to have several clinical and procedural advantages. The transperineal method has gained significant attention, and a growing body of research highlights the distinct infection prevention benefits. In fact, in 2014, Grummet and colleagues performed a systematic review of the literature, one that encompassed 16 mutually exclusive series of TP biopsies that reported on infective complications. In a total of 6609 patients, only 5 (0.076%) were admitted to the hospital for sepsis.²

In the 10 years since Grummet's review, several other studies have been conducted worldwide, all directly highlighting the innate clinical advantages that transperineal biopsies offer for preventing infection and keeping patients safe. Here is a breakdown of but a few studies as it relates to infectious complications associated with prostate biopsy.

¹ Standards of Care Changing for Prostate Cancer Diagnosis? (Cleveland Clinic) https://consultqd.clevelandclinic.org/standards-of-care-changing-for-prostate-cancer-diagnosis

² Grummet, J. P., Weerakoon, M., Huang, S., Lawrentschuk, N., Frydenberg, M., Moon, D. A., O'Reilly, M., & Murphy, D. (2014). Sepsis and 'superbugs': should we favour the transperineal over the transrectal approach for prostate biopsy? BJU International, 114(3), 384-388. https://doi.org/10.1111/bju.12536 https://pubmed.ncbi.nlm.nih.gov/24612341/



2017: Australia

"Zero hospital admissions for infection after 577 transperineal prostate biopsies using single-dose cephazolin prophylaxis"

- WORLD JOURNAL OF UROLOGY

Between April 2013 and February 2016, **577 patients underwent transperineal prostate biopsies** with single-dose cephazolin prophylaxis. Ultimately, **0% of patients were reported to suffer from infection post-prostate biopsy**, with only one patient in total developing clinical prostatitis (which was later treated with oral antibiotics).³

2018: Greece

"Transrectal ultrasound-guided versus transperineal mapping prostate biopsy: complication comparison"

- REVIEWS IN UROLOGY

379 men from two institutions - 265 (69.6%) having had prior transrectal ultrasound-guided biopsies - underwent transperineal mapping prostate biopsies (TPMB) using a template, with biopsies taken at 5-mm intervals and fluroquinolone administered prior to and after the procedure. The study found **urinary tract infections were 5.4 times more common in transrectal prostate biopsies than TPMB, with the overall infection risk being 5.8 times greater in transrectal biopsies**, particularly when more than 12 cores were taken.⁴

2019: Canada

"Transperineal prostate biopsies using local anesthesia: experience with 1,287 patients. Prostate cancer detection rate, complications, and patient tolerability"

- JOURNAL OF UROLOGY

Beginning in October 2016, transperineal prostate biopsies were performed using local anesthesia in 1,287 patients. There were no documented cases of urosepsis or mortality, and the postbiopsy infection rate was low (0.3%), occurring in only four patients (including one with a febrile urinary infection and three with negative urine cultures, all treated with antibiotics). The study found that the transperineal approach, without using quinolone antibiotics, significantly reduces post-biopsy complications, particularly sepsis.⁵

- 3 Pepdjonovic, L., Tan, G. H., Huang, S., Mann, S., Frydenberg, M., Moon, D., Hanegbi, U., Landau, A., Snow, R., & Grummet, J. (2017). Zero hospital admissions for infection after 577 transperineal prostate biopsies using single-dose cephazolin prophylaxis. World Journal of Urology, 35(8), 1199-1203. https://doi.org/10.1007/s00345-016-1985-1 https://pubmed.ncbi.nlm.nih. gov/27987032/
- 4 Skouteris, V. M., Crawford, E. D., Mouraviev, V., Arangua, P., Metsinis, M. P., Skouteris, M., Zacharopoulos, G., & Stone, N. N. (2018). Transrectal Ultrasound-guided Versus Transperineal Mapping Prostate Biopsy: Complication Comparison. Reviews in Urology, 20(1), 19-25. https://doi.org/10.3909/riu0785 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6003299/
- 5 Stefanova, V., Noakes, J., Buckley, R., Flax, S., Spevack, L., Hajek, D., Tunis, A., Lai, E., Loblaw, A., Golda, N., Persaud, B., Spevack, K., Peltz, J., Deif, H., Jacobs, I., Margau, R., Raphael, S., Morton, G., Cheung, P., et al. (2019). Transperineal Prostate Biopsies Using Local Anesthesia: Experience with 1,287 Patients. Prostate Cancer Detection Rate, Complications and Patient Tolerability. The Journal of Urology, 201(6), 1121-1126. https://doi.org/10.1097/JU.00000000000156 https://pubmed.ncbi.nlm.nih.gov/30835607/



2019: Taiwan

"Comparisons of cancer detection rate and complications between transrectal and transperineal prostate biopsy approaches - a single center preliminary study"

- BMC UROLOGY

238 patients were divided into two groups, with 130 patients undergoing local anesthetic transperineal prostate biopsies and 108 receiving transrectal prostate biopsies. In the transperineal biopsy group, 0% experienced post-biopsy sepsis, with 2.2% diagnosed with UTI and 0.7% with prostatitis. In contrast, 12% of patients in the TR group developed post-biopsy UTI, and 6.4% were admitted to the ER with post-biopsy fever and sepsis.⁶

2020: Switzerland

"Feasibility of freehand MRI/US cognitive fusion transperineal biopsy of the prostate in local anaesthesia as in-office procedureexperience with 400 patients"

- PROSTATE CANCER AND PROSTATIC DISEASES

Between January 2015 and May 2019, **400 patients (median age 66) underwent office-based freehand transperineal prostate biopsy**. Among them, 118 patients received two doses of 500 mg fluoroquinolone, 105 received a single dose, and 177 patients received no antibiotic prophylaxis. **0 infectious complications, including sepsis, occurred.** The article concludes that the technique's elimination of infectious complications makes it a feasible alternative to the transrectal approach for urological offices.⁷

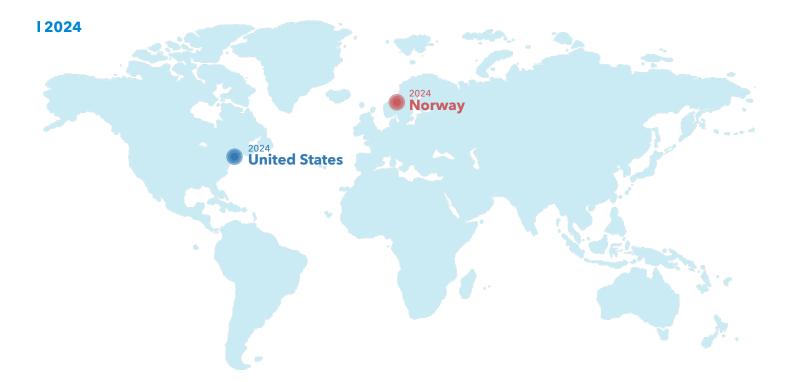
2023: China

"Transrectal versus transperineal prostate biopsy in detection of prostate cancer: a retrospective study based on 452 patients"

- BMC UROLOGY

A total of 452 patients underwent either transrectal or transperineal prostate biopsies between June 2017 and September 2021. In total, 4.1% of patients in the TR group developed fever. Conversely, only 1.0% in the transperineal group developed fever, with the article stating that statistically, **patients who received transrectal biopsies ultimately had a higher general infection rate than those who received transperineal biopsies.**⁸

- 6 Huang, G.-L., Kang, C.-H., Lee, W.-C., & Chiang, P.-H. (2019). Comparisons of cancer detection rate and complications between transrectal and transperineal prostate biopsy approaches a single center preliminary study. BMC Urology, 19(1), 1-8. https://doi.org/10.1186/s12894-019-0539-4 https://pubmed.ncbi.nlm.nih.gov/31660936/
- 7 Wetterauer, C., Shahin, O., Federer-Gsponer, J. R., Keller, N., Wyler, S., Seifert, H. H., & Kwiatkowski, M. (2020). Feasibility of freehand MRI/US cognitive fusion transperineal biopsy of the prostate in local anaesthesia as in-office procedure-experience with 400 patients. Prostate Cancer and Prostatic Diseases, 23(3), 429-434. https://doi.org/10.1038/s41391-019-0201-y https://pubmed. ncbi.nlm.nih.gov/31896767/
- 8 Lu, M., Luo, Y., Wang, Y., Yu, J., Zheng, H., & Yang, Z. (2023). Transrectal versus transperineal prostate biopsy in detection of prostate cancer: a retrospective study based on 452 patients. BMC Urology, 23(1). https://doi.org/10.1186/s12894-023-01176-y https://pubmed.ncbi.nlm.nih.gov/36709292/



2024: Norway

"Transitioning from transrectal to transperineal prostate biopsy using a freehand cognitive approach"

- BRITISH JOURNAL OF UROLOGY

Between June 2018 and May 2022, 1,915 patients underwent 2,337 prostate biopsy sessions (both transrectal and transperineal). All transrectal patients received antibiotics, while only 2.4% (25) of transperineal patients did. **Of the transrectal group, 54 (5%) experienced urosepsis.** In contrast, **there were no urosepsis cases in the transperineal group**, with only two instances of combined urinary retention and infection, both managed with a catether and oral antibiotics.⁹

2024: United States

"Complications Following Transrectal and Transperineal Prostate Biopsy: Results of the ProBE-PC Randomized Clinical Trial"

- THE JOURNAL OF UROLOGY

In a prospective, randomized clinical study of 763 men, **351 received transrectal biopsies with 1-day antibiotic prophylaxis, and 367 received transperineal biopsies** <u>without</u> routine prophylaxis. **Infectious complications occurred in 2.6% (9) of the transrectal group and 2.7% (10) of the transperineal group,** with fever being the most common issue (reported by 6 men). None developed sepsis. The authors concluded there was no significant different in infectious complications between the two biopsy methods.¹⁰

2024: United States

"Transperineal Versus Transrectal Magnetic Resonance Imaging-targeted and Systematic Prostate Biopsy to Prevent Infectious Complications: The PREVENT Randomized Trial"

- EUROPEAN UROLOGY

A 2024 multi-center study compared infectious complications between **transperineal prostate biopsies** <u>without</u> **antibiotic prophylaixs and transrectal biopsies with targeted prophylaxis.** Among 658 participants, 328 underwent transperineal biopsies and 330 underwent transrectal biopsies. **Infections were reported by 1.4% of the transrectal group, while 0% of the transperineal group reported any infections.** No patients in the study experienced sepsis.¹¹

- 9 Honoré, A., Moen, C. A., Juliebø-Jones, P., Reisaeter, L. A. R., Gravdal, K., Chaudhry, A. A., Rawal, R., Sandøy, A., & Beisland, C. (2024). Transitioning from transrectal to transperineal prostate biopsy using a freehand cognitive approach. BJU International, 133(3), 324-331. https://doi.org/10.1111/bju.16237 https://pubmed.ncbi.nlm.nih.gov/38009392/
- 10 Mian, B. M., Feustel, P. J., Aziz, A., Kaufman, R. P., Bernstein, A., Avulova, S., & Fisher, H. A. G. (2024). Complications Following Transrectal and Transperineal Prostate Biopsy: Results of the ProBE PC Randomized Clinical Trial. The Journal of Urology, 211(2), 205-213. https://doi.org/10.1097/JU.00000000003788 https://pubmed.ncbi.nlm.nih.gov/37976319/
- 11 Hu, J. C., Assel, M., Allaf, M. E., Ehdaie, B., Vickers, A. J., Cohen, A. J., Ristau, B. T., Green, D. A., Han, M., Rezaee, M. E., Pavlovich, C. P., Montgomery, J. S., Kowalczyk, K. J., Ross, A. E., Kundu, S. D., Patel, H. D., Wang, G. J., Graham, J. N., Shoag, J. E., et al. (2024). Transperineal Versus Transrectal Magnetic Resonance Imaging-targeted and Systematic Prostate Biopsy to Prevent Infectious Complications: The PREVENT Randomized Trial. European Urology. https://doi.org/10.1016/j.eururo.2023.12.015 https://pubmed.ncbi.nlm.nih.gov/38212178/

TP PIVOT PRO THE **SAARTER** APPROACH TO PROSTATE BIOPSIES

For clinicians dedicated to enhancing patient safety, research underscores the advantage of the transperineal approach in reducing infection risks. Moreover, opting for the freehand technique minimizes perineal puncture sites compared to grid-based methods, lowering the incidence of adverse outcomes like infection and bleeding.¹² Just as important as choosing the right prostate biopsy method, is choosing the right tools to perform it with.

CIVCO's TP Pivot Pro disposable needle guide was designed with clinicians, for clinicians to enable a freehand, minimally invasive approach to ultrasound-guided transperineal biopsies. TP Pivot Pro is the first transperineal biopsy guide to grant access to the full prostate gland with its unique pivoting function. Allowing needle angulation of +/- 20 degrees from the initial parallel path, TP Pivot Pro enables access to the entire prostate, including the anterior zone where prostate cancer is frequently diagnosed, without the need to remove the needle from the guide or patient.

Additionally, TP Pivot Pro improves stability through secure attachment to a range of biplane probes, helping ensure needle visualization, as the needle is kept within the imaging plane. Together, these features allow for both easier access to varying anatomies and more control during the procedure, enabling clinics to achieve better workflow. While the traditional transrectal biopsy method comes with infectious complication risks, the freehand minimally invasive transperineal biopsy can offer a safer, more precise alternative with easier access to all zones of the prostate. To learn more about how TP Pivot Pro can transform the safety of your prostate biopsies and help to prevent infection, visit civco.com/tp-pivot-pro.

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¹² Panzone J. Byler T. Bratslavsky G. & Goldberg H. (2022). Transrectal ultrasound in prostate cancer: current utilization integration with Mpmri Hifu and other emerging applications. Cancer Management and Research 1209-1228. https://pubmed.ncbi.nlm.nih.gov/35345605/