Initial Experience Performing In-office Ultrasound-guided Transperineal Prostate Biopsy Under Local Anesthesia Using the PrecisionPoint Transperineal Access System

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OBJECTIVE To describe our procedural technique and initial outcomes performing in-office transperineal prostate biopsies using the PrecisionPoint Transperineal Access System (Perineologic, Cumberland, MD).

PATIENTS AND METHODS Following institutional review board approval, we retrospectively reviewed the records of men who underwent an in-office transperineal prostate biopsy using the PrecisionPoint device. Records were reviewed for baseline characteristics, biopsy results, and postbiopsy complications.

RESULTS Between January 4, 2017 and August 23, 2017, 43 men underwent an in-office transperineal prostate biopsy using the PrecisionPoint Transperineal Access System. Patients had a median serum prostate specific antigen level of 6.1 ng/mL (range 0.8-32.9). Of the 43 biopsies, 12 (27.9%) were performed for active surveillance of low-risk prostate cancer and 31 (72.1%) were performed for cancer screening. Overall, 21 (48.8%) men were found to have prostate cancer. Among those on active surveillance, cancer was detected in 8 of 12 (66.7%) patients, with 2 of 12 (16.7%) found to have Gleason ≥3 + 4 = 7 prostate cancer. Additionally, cancer was detected in 13 of 31 (41.9%) patients undergoing a biopsy for prostate cancer screening, with 5 (16.1%) found to have Gleason ≥3 + 4 = 7 disease. In total, 3 (7.0%) patients experienced a postbiopsy complication: 2 (4.7%) with urinary retention and 1 (2.3%) with gross hematuria requiring catheterization. No patient experienced an infectious complication despite omission of periprocedural antibiotics in all cases.

CONCLUSION The PrecisionPoint device allowed for the successful performance of in-office transperineal prostate biopsies under local anesthesia without the need for periprocedural antibiotics. We observed an acceptable cancer detection rate with no infectious complications. UROLOGY 115: 8–13, 2018. © 2018 Elsevier Inc.

It is estimated that upwards of 1 million prostate biopsies are performed annually in the United States.[1] Prostate biopsy is most commonly performed with ultrasound guidance via a transrectal approach. This procedure places men at risk of infectious complications due to the passage of needles through the rectal wall on their trajectory to the prostate. Complications such as cystitis, prostatitis, and epididymitis are reported in up to 7.0% of men undergoing a transrectal prostate biopsy and the rate of postbiopsy sepsis ranges from 0.3 to 3.1%.[2]

The performance of prostate biopsy using a percutaneous approach through the perineal skin greatly reduces the risk of infectious complications. Data from contemporary series of transperineal prostate biopsy have reported overall infectious complication rates of 0% to 1%.[3-6] In fact, in many of these series, periprocedural prophylactic antibiotics were omitted. However, unlike transrectal prostate biopsy, which can be performed in the office setting with only local anesthesia, transperineal prostate biopsy typically requires general or spinal anesthesia in order for patients to tolerate the required multiple needle passes through the perineal skin.[7] Additionally, this technique often requires the use of expensive stepper unit to ensure adequate needle alignment with the ultrasound probe. Alternative

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freehand approaches for performing transperineal prostate biopsy have also been described.[8-12] These techniques typically employ a common access needle or trocar to minimize the number of needle sticks to the perineal skin allowing for this procedure to be performed with the need for only local anesthesia. However, without a needle guide to ensure in-plane visualization of the biopsy needle, freehand methods are difficult to learn and perform. Thus, due to the aforementioned shortcomings, transperineal prostate biopsy has seen limited clinical adoption.

In August 2016, the United States Food and Drug Administration cleared a novel device, known as the PrecisionPoint Transperineal Access System (Perineologic, Cumberland, MD), for the performance of transperineal prostate biopsies.[13] The PrecisionPoint device employs a single access needle that minimizes the number of punctures to the perineal skin and serves to stabilize the biopsy needle in-plane with the ultrasound probe, thereby overcoming the limitations of freehand approaches. In an effort to minimize infectious complications from prostate biopsy, 2 urologists at our institution (M.A.E. and M.A.G.) adopted the PrecisionPoint device into routine clinical practice in early 2017. Herein, we describe our procedural technique and initial outcomes performing in-office transperineal prostate biopsies using the PrecisionPoint Transperineal Access System. This is the first report in the peer-reviewed medical literature describing the use of this novel device.

PATIENTS AND METHODS

Device Description and Setup

The PrecisionPoint Transperineal Access System is comprised of 3 components: a rail/clamp subassembly, a needle carriage with 4 apertures, and a 15 gauge access needle (Fig. 1A). The components of the PrecisionPoint device are provided by the manufacturer in a sterile single-use kit.

The assembled device is clamped to a side-fire transrectal ultrasound transducer such that the access needle is in-line with the linear ultrasound array (Fig. 1B). The needle carriage is intended to slide freely on the rail system such that the access needle can pierce the perineal skin while maintaining alignment with the ultrasound transducer. The distal portions of the rails are used to stabilize the assembly against the perineal skin.

The choice of ultrasound probe is of paramount importance to the success of this procedure. Although the device's clamp has several locking positions allowing for its use with a wide range of ultrasound probes, the ideal transducer has a linear array that is long enough to visualize from just beyond the perineal skin to the apex of the prostate. This is the same type of probe that is commonly used for brachytherapy seed placement or prostate cryoablation. It is not possible to perform the procedure with an end-fire probe or a side-fire probe with a short linear array.

Although the manufacturer states that the device is intended to be used with a side-fire transrectal probe for the BK ProFocus 2202 ultrasound, at our institution we routinely perform biopsies using a bk3000 ultrasound unit with a model E14CL4b biplanar transducer (BK Ultrasound, Peabody, MA). We have also performed a number of these biopsies using a Hitachi HI VISION Avius ultrasound with a EUP-U533 transducer (Hitachi Aloka Medical, Ltd., Wallingford, CT). Due to the narrow diameter of this probe, we have found that placement of a small collar of polyvinyl chloride tubing is required to stabilize the PrecisionPoint device (Supplementary Fig. S1). Additionally, we have found that with either ultrasound probe, a small piece of Coban self-adherent wrap (3M, St. Paul, MN) can be placed around the neck of the probe to minimize rotation of the PrecisionPoint device.

Procedural Technique

In preparation for the procedure, the patient is placed in low lithotomy position on a standard medical exam table equipped with heel stirrups. Paper tape is used to elevate the scrotum away from the perineum and the skin is cleaned using a ChloraPrep applicator containing 2% chlorhexidine gluconate in 70% isopropyl alcohol (Becton, Dickinson and Company, Franklin Lakes, NJ).

Once the patient is prepped, the ultrasound transducer with the attached PrecisionPoint device is inserted into rectum and used to visualize the prostate. At this point the

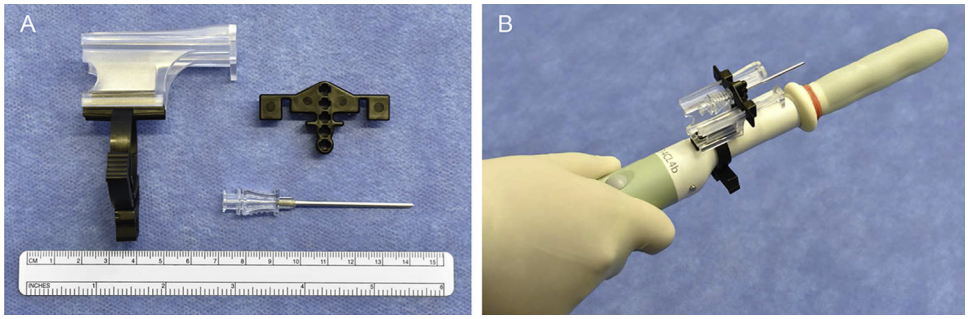

Figure 1. Images of the PrecisionPoint Transperineal Access System (Perineologic, Cumberland, MD). (**A**) The device is comprised of 3 components: a rail/clamp subassembly, a needle carriage with 4 apertures, and a 15 gauge access needle. (**B**) The assembled PrecisionPoint device clamped to an E14CL4b transrectal side-fire ultrasound probe (BK Ultrasound, Peabody, MA). (Color version available online.)

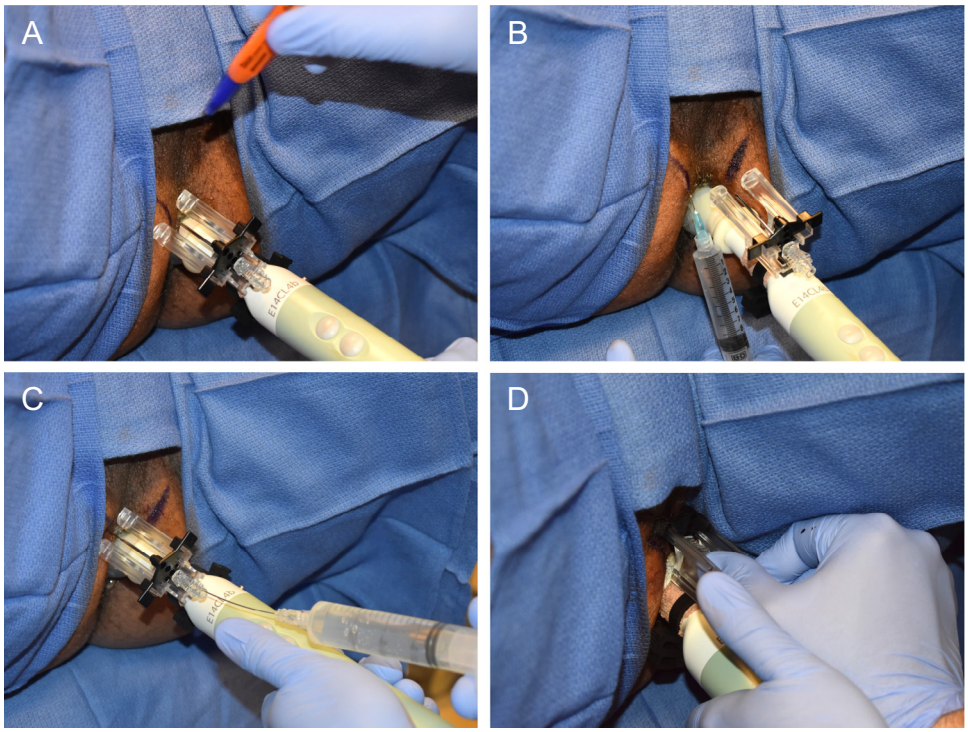

Figure 2. Key procedural steps when performing prostate biopsies using the PrecisionPoint Transperineal Access System. (**A**) With the access needle positioned several millimeters away from the skin surface, the perineum marked to note the lateral boundaries of the prostate. (**B**) A 25 gauge needle is used to raise a wheal of 1% lidocaine in the area of the 2 marks. (**C**) A spinal needle is passed through the access needle of the PrecisionPoint device and additional anesthetic is injected along a tract extending from the perineal skin to the prostatic apex. Of note, the access needle is not inserted in the perineal skin but rather serves to stabilize the spinal needle in plane as it punctures the perineal skin. (**D**) Once the patient is fully anesthetized, the access needle is engaged into the perineal skin. (Color version available online.)

access needle is not engaged into the skin but rather is positioned several millimeters away from the perineum so that it can be used as an external gauge of the rotational angle of the linear ultrasound array. In the axial plane the midprostate is visualized and its bilateral lateral edges are identified. The perineal skin is marked to note the lateral boundaries of the prostate (Fig. 2A). A 25 gauge needle is then used to raise a wheal of 1% lidocaine in the area of the 2 marks (Fig. 2B). A spinal needle is next passed through the access needle and used to inject 1% lidocaine into the deeper subcutaneous tissues (Fig. 2C). For this step, we typically place the access needle through the bottom aperture of the needle carriage. Anesthetic is injected along a tract extending from the perineal skin to the prostatic apex. Of note, the access needle is still not engaged into the perineal skin but rather serves to simply stabilize the spinal needle in plane as it punctures the perineal skin. The same steps are repeated on the contralateral side. A total of 20 to 30 cc of 1% lidocaine is typically required for the procedure.

Once the lidocaine is administered, routine measurements are performed to determine the volume of the prostate. An aperture position is then chosen based on the height of the prostate and the intended area of biopsy. The access needle is engaged into the perineal skin (Fig. 2D). Tissue samples are obtained using a disposable 18 gauge × 20 cm biopsy gun (Bard Biopsy Systems, Tempe, AZ) under biplanar ultrasound guidance (Fig. 3). A total of 12 cores are obtained from the peripheral zone of the prostate. This is performed in the "fan" pattern described by Emiliozzi et al[8] and includes bilateral biopsies of the posterior medial, posterior lateral, and anterior sectors of the peripheral zone of the prostate (Fig. 4). For patients on active surveillance, an additional 2 cores are taken from the transition zone. During the course of the procedure, it is common to change aperture positions once per side of the prostate to ensure adequate sampling of the anterior and posterior sectors of the gland. On average, the procedure takes 10 to 15 minutes to complete (probe in to probe out time).

Data Collection

After obtaining institutional review board approval, we retrospectively reviewed the electronic medical records of consecutive patients who underwent a transperineal prostate biopsy using the PrecisionPoint Transperineal Access System. Abstracted variables included patient age, indication for biopsy, digital rectal exam findings, PSA level, prostate volume, ultrasound equipment used, number and locations of obtained cores, antibiotic use, volume of anesthetic administered, biopsy result including highest Gleason score, and post procedural complications.

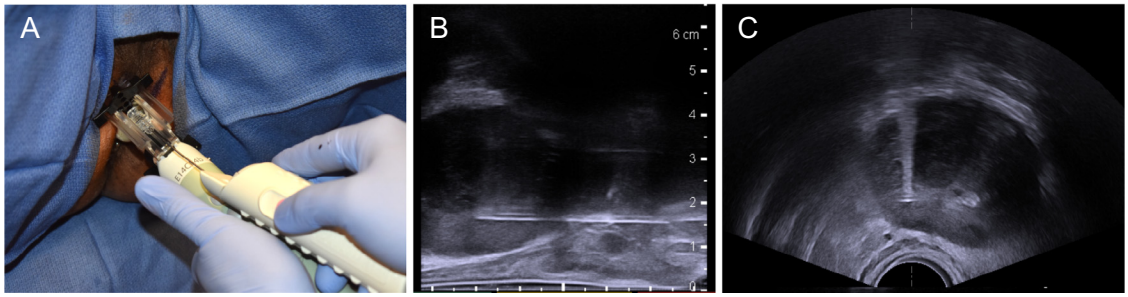

Figure 3. Biplanar ultrasound-guided biopsy of the prostate using the PrecisionPoint device. (**A**) Image of an 18 gauge biopsy needle being passed in-plane with the ultrasound probe through the access needle of the PrecisionPoint device. (**B**) Sagittal and (**C**) axial ultrasound images of the biopsy needle within the right posterior medial sector of the prostate. (Color version available online.)

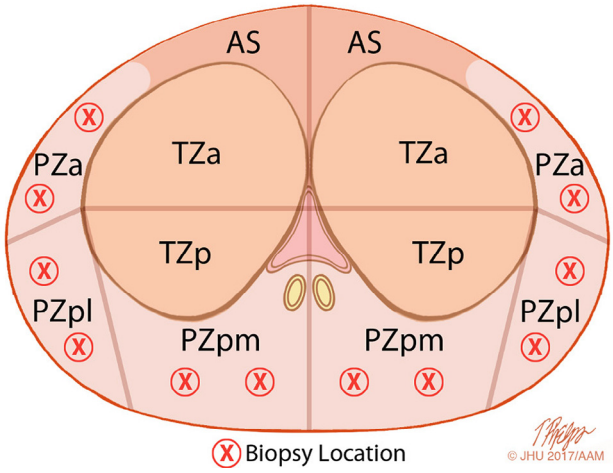

Figure 4. Standard 12-core biopsy template used with the PrecisionPoint device. Tissue samples are obtained bilaterally from the posterior medial (PZpm), posterior lateral (PZpl) and anterior (PZa) sectors of the peripheral zone of the prostate. For patients on active surveillance, an additional 2 cores are taken from the anterior (TZa) or posterior (TZp) transition zone. No cores are obtained from the anterior stroma (AS). (Color version available online.)

Complications were categorized using the Clavien-Dindo system.[14,15]

RESULTS

Between January 4, 2017 and August 23, 2017, 43 men with a median age of 62 years (range 44-73 years) underwent an in-office transperineal prostate biopsy using the PrecisionPoint Transperineal Access System. Patients had a median PSA of 6.1 ng/mL (range 0.8-32.9 ng/mL) and a median prostate volume of 42.9 g (range 18.1-150.0 g). Additional details of the study cohort can be found in Supplementary Table S1.

Biopsies were performed following administration of 20-30 mL of 1% lidocaine to the perineal skin, deeper soft tissue of the perineum, and prostatic apex. In all cases, the procedure was well tolerated without need for additional anesthetic or anxiolytic agents. Additionally, periprocedural antibiotics were omitted in all cases.

Overall, 21 (48.8%) men were found to have prostate cancer. Among those on active surveillance, cancer was detected in 8 of 12 (66.7%) patients, with 2 of 12 (16.7%) reclassified to Gleason ≥3 + 4 = 7 prostate cancer. Among those men undergoing a biopsy for prostate cancer screening, cancer was detected in 13 of 31 (41.9%), with 5 of 31 (16.1%) found to have Gleason ≥3 + 4 = 7 disease.

The anterior peripheral zone of the prostate was sampled in all cases. Prostate cancer was detected anteriorly in 8 (18.6%) of the 43 patients. Additionally, cancer was detected exclusively in the anterior peripheral zone in 2 (4.7%) men.

In total, 3 (7.0%) patients experienced a postbiopsy complication, all of which were Clavien grade II. More specifically, 2 (4.7%) patients experienced urinary retention requiring urethral catheterization and 1 (2.3%) patient developed gross hematuria that also required catheterization. No patient experienced an infectious complication despite omission of periprocedural antibiotics in all cases.

COMMENT

We present our procedural technique and initial outcomes performing in-office transperineal prostate biopsies using the PrecisionPoint Transperineal Access System. In our retrospective series, we observed an overall cancer detection rate of 48.8% with a 7.0% incidence of minor complications, none of which were infectious in nature. These data appear to be in line with prior studies of prostate biopsy using both the transrectal and transperineal approaches[3-6]; however, our results were achieved in the office setting with need for only local anesthesia and without the use of antibiotics.

The omission of periprocedural antibiotics in our series is of particular note. As discussed earlier, the transperineal approach has the advantage of eliminating the passage of needles through rectum thereby preventing inoculation of bowel flora into the urinary tract. Published series evaluating transperineal prostate biopsy have shown that the rate of sepsis is ≤0.01%, with minor infectious complications

also being quite rare.[3-6] Thus, periprocedural antibiotic prophylaxis is not required with this method of prostate biopsy. In contrast, the rate of infectious complications related to transrectal prostate biopsy has been reported to be up to 7.0%, with sepsis rates ranging from 0.3 to 3.1%.[2] In an effort to prevent infectious complications, the American Urological Association recommends 24 hours of an oral fluoroquinolone or a single dose of intravenous or intramuscular cephalosporin prior to transrectal prostate biopsy.[2,16]

Despite the use of antibiotic prophylaxis with the transrectal approach, recent studies have reported increasing rates of infectious complications in parallel with a rising prevalence of multidrug resistant bacterial strains.[17,18] To combat this, urologists have been forced to adopt additional prophylactic measures. For example, some have advocated for augmenting oral antibiotic prophylaxis by adding a dose of intravenous and intramuscular antibiotics in addition to standard oral fluoroquinolone.[19,20] While this method has resulted in a significant decrease in the rates of hospital admissions, this can be a selective force for the emergence of resistant bacteria. Another strategy that has seen popular adoption is the use targeted antibiotics based on the results of prebiopsy rectal swab cultures.[21-23] While this is an effective method at reducing rates of postbiopsy sepsis, it continues to require antibiotic escalation placing patients at risk for antibiotic-related complications and the development of resistant organisms. Furthermore, the use of rectal cultures places a financial and administrative burden on the healthcare system. Transperineal prostate biopsy not only reduces infectious complications, but allows for improved antibiotic stewardship while potentially decreasing healthcare costs.

One final advantage of the transperineal approach that is worthy of mention is the improved ability to sample the anterior peripheral zone of the prostate. Using the PrecisionPoint device, the anterior prostate was felt to be sampled in all cases. In total, cancer was detected in the anterior peripheral zone in 8 (18.6%) cases, with cancer detected exclusively in this region in 2 (4.7%) men. These data are notable, as it has long been appreciated that the anterior prostate is difficult to access with the transrectal approach and tumors arising from this location have a propensity for higher grade and stage.[24-27] Furthermore, anteriorly located tumors have been found to harbor the molecular hallmarks of a more aggressive cancer phenotype.[28] Thus, sampling of the anterior prostate is of critical importance and can be readily achieved with the transperineal approach.

Limitations of this study include its retrospective design and small sample size. Furthermore, there is no direct comparison with transrectal prostate biopsy. We are, however, encouraged by the ease of use of the PrecisionPoint device and the data generated thus far. At the present time we continue to use this device on a routine basis and have initiated a prospective cohort study to compare the safety and diagnostic yield of biopsies performed using the PrecisionPoint device versus standardly performed transrectal prostate biopsy.

CONCLUSION

The PrecisionPoint Transperineal Access System allowed for the successful performance of in-office transperineal prostate biopsies under local anesthesia without the need for periprocedural antibiotics. We observed a cancer detection rate in line with prior series as well as relatively few minor complications. In-office transperineal prostate biopsy using the PrecisionPoint device is a promising method for prostate cancer detection and should be explored further.

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APPENDIX

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.urology.2018.01.021.

EDITORIAL COMMENT

Prostate biopsy is one of the most common procedures performed by urologists with an estimated >2 million performed in the United States and Europe every year,[1,2] and is the gold standard for the diagnosis of prostate cancer. The majority of prostate biopsies in the United States are done in the office setting using the ultrasound probe through a transrectal approach. The proximity of the posterior prostate to the anterior rectal wall provides easy access the peripheral zone which is known to harbor >70% of malignancies.[3] However, this approach is associated with a significant risk of infectious complications, with rates ranging from 1 to 17.5% in the literature. Furthermore, the risk of serious infectious complications requiring hospitalization has been shown to be increasing over time,[4] likely as a result of the increased prevalence of fluoroquinolone-resistant *Escherichia coli*.[5] Partly in response to this, several centers are increasingly using the transperineal (TP) approach to prostate biopsy. Rather than using broad-spectrum prophylaxis, which contributes to antibiotic resistance, TP biopsies are often performed after a single prophylactic dose of first generation cephalosporin. Large series using this approach have reported sepsis rates approaching zero.[1] To date, TP biopsy has been mostly performed under general anesthesia, having important implications on health care resources, cost and time. Although the TP approach has been more widely adopted in other countries, in the United States it has been mostly reserved for special situations where the transrectal approach is either not possible or is unsafe. In recent years, several devices have been developed allowing TP prostate biopsies to be performed in the office, under local anesthesia, without the need for bulky, cumbersome, expensive equipment. The authors of this manuscript present their initial experience using 1 such device, and demonstrate the safety and feasibility of office TP prostate biopsy in a small number of men. What is now needed are studies in larger cohorts of patients demonstrating safety on a large scale using standardized reporting, patient tolerability using validated pain questionnaires and confirmation of the diagnostic accuracy for prostate cancer. Advances in prostate imaging (eg magnetic resonance imaging) aim to decrease the overuse of prostate biopsy, similarly modifications of the approach and instrumentation for prostate biopsy aim to decrease the morbidity of the procedure. These efforts will continue to shift the balance in favor of screening and diagnosis of prostate cancer, and will thus benefit the population on a large scale.

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