



Technical Note

Perirectal hydrogel spacer placement prior to prostate radiation therapy using a probe-mounted needle guide

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ABSTRACT

In this report we describe our successful adoption of a single-use, probe-mounted, needle guide for perirectal hydrogel spacer placement prior to radiation therapy for prostate cancer. Use of this device eliminates the need for a mechanical stepper unit and facilitates perirectal hydrogel placement by ensuring alignment of the injection needle with the ultrasound probe.

Main text

Introduction

Bowel toxicity is a common side effect of radiation therapy for the treatment of prostate cancer [1,2]. This is in part due to the close proximity of the rectum to the prostate, placing men at risk for radiation-induced proctitis. To minimize this complication, a variety of methods for creating separation between the prostate and rectum have been developed [3–5]. One commonly used method involves injecting an absorbable polyethylene glycol hydrogel in the perirectal space [6]. The currently recommended method for performing this procedure involves the use of a mechanical stepper-stabilizer unit [7,8]. One challenge associated with use of a stepper unit for perirectal hydrogel placement is the fact that the injection needle is not coupled to the ultrasound probe making it difficult to maintain visualization of the needle tip throughout the procedure. This same issue, which exists when performing freehand transperineal prostate biopsy procedures, has been addressed with the introduction of probe-mounted needle guides that ensure in-plane alignment of the biopsy needle with the ultrasound probe [9–13]. Herein, we describe our successful adoption of one such needle guide for perirectal hydrogel spacer placement prior to radiation therapy for prostate cancer.

Patients and methods

Description of needle-guide

To overcome the challenges of needle visualization when performing perirectal hydrogel spacer placement using a mechanical stepper unit, we have adopted the use of a probe-mounted needle guide known as the PrecisionPoint Transperineal Access System (PPTAS; Perineologic, Cumberland, MD). The PPTAS is a disposable single-use device comprised of 3 main components: a clamp/rail subassembly, a needle carriage with five aperture holes, and a 15-gauge access needle. The assembled PPTAS is clamped to a side-fire transrectal ultrasound probe with the access needle aligned with the linear ultrasound array (Fig. 1A). The device is positioned on the probe so that the ends of the clamp/rail subassembly can be pressed against the perineal skin. The needle carriage is designed to slide freely along the rails, allowing the user to insert and remove the access needle from the perineal skin with ease (Fig. 1B–C). The PPTAS, is compatible with all biplanar transrectal probes currently manufactured by BK Medical (Peabody, MA) and with simple modification can also be used with similarly designed probes from Hitachi Healthcare (Tokyo, Japan) [9]. We and others have previously reported excellent outcomes with use of the PPTAS for performing transperineal prostate biopsy with and without MRI guidance [9–13].

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Procedural technique

The patient is placed in low lithotomy position and after prepping the skin the ultrasound transducer with the attached probe-mounted needle guide is inserted into rectum. A small area of skin several millimeters anterior to the anus along its midline is anesthetized with ~5 cc of 1% lidocaine. If the patient is to also undergo fiducial marker placement, the areas of skin overlying the lateral edges of the prostate are also anesthetized. A spinal needle is next passed through the access needle in each area of anesthetized skin and is used to inject 1% lidocaine into the deeper subcutaneous tissues and pelvic floor muscles at the apex of the prostate. A total of ~30 cc of 1% lidocaine is typically required to achieve adequate anesthesia.

Once the patient is anesthetized, the access needle of the PPTAS is engaged into the perineal skin. For patient requiring fiducial marker placement, the markers are inserted first followed by the hydrogel spacer. In these cases, three separate skin punctures are made, whereas in cases of just hydrogel insertion only a single midline puncture is needed. During all steps of the procedure, the access needle is typically maintained in the second lowest aperture hole. However, the needle may be raised or lowered depending on the anatomy of the patient. All remaining steps for hydrogel placement are performed as if one were using a stepper unit [7,8].

Data collection

After obtaining institutional review board approval, we retrospectively reviewed the electronic medical records of consecutive patients who underwent perirectal hydrogel spacer placement with SpaceOAR (Boston Scientific, Marlborough, MA) using the PPTAS probe-mounted needle guide. Patient images were evaluated to measure the distance created between the posterior capsule of the prostate and the anterior rectal wall. Measurements were obtained at the apex, mid, and base of the gland. When available, measurements were made using MRI studies. In cases where an MRI was not available, ultrasound images were instead evaluated. Paired pre- and post-procedure measurements were compared with the Wilcoxon signed-rank test. As additional measures of procedural success, the symmetry of gel placement at the mid-gland as well as frequency of rectal wall infiltration was determined as previously described [14,15]. Postprocedure complications were graded using the Clavien-Dindo system [16,17].

Results

Between November 15, 2018 and January 30, 2020, 48 patients underwent perirectal hydrogel spacer placement using the probe-mounted needle guide. Of these patients, 29 (60.4%) also underwent fiducial marker placement. All procedures were performed under local anesthesia by a single urologist (M.A.G.) with experience performing transperineal prostate biopsies using the PPTAS [9–11]. Prior to using

this device for hydrogel placement, this urologist had performed 8 procedures in the standard fashion using a stepper unit.

All 48 procedures of hydrogel placement performed with the probe-mounted needle guide were successfully completed. A total of 35 (72.9%) patients had paired pre- and post-procedure imaging. Patients with available paired imaging experienced a statistically significant increase in the distance between the rectum and the prostate (median ~1 cm at all 3 measured locations, Supplemental Table 1). Hydrogel symmetry and degree of rectal wall infiltration could be evaluated in 32 (66.7%) patients with available post-procedure MRI studies (Fig. 2). Symmetric spacer placement was observed in 20 (62.5%) cases. Moderate rectal wall infiltration (<25% rectal wall circumference) was observed in 1 (3.1%) patient and significant rectal wall infiltration (≥25% rectal wall circumference) was observed in another (3.1%). In total, 2 of 48 (4.2%) patients experienced a post-procedure complication, with 1 (2.1%) developing a skin abscess managed with incision and drainage (Grade I), and 1 (2.1%) experiencing a urinary tract infection managed with intravenous antibiotics (Grade II). Notably, both patients underwent fiducial marker placement at the time of their procedure.

Discussion

We present our technique and initial outcomes performing perirectal hydrogel spacer placement under local anesthesia using a single-use, probe-mounted, needle guide. All procedures were successfully completed and well tolerated. Using this method, we observed a statistically significant increase in the distance between the rectum and the prostate along the entire length of the prostate gland. Median separation distances (~1 cm), frequency of symmetrical hydrogel placement (62.5%), incidence of moderate to severe rectal wall infiltration (6.3%), and number and severity of complications (4.2%, all grade ≤2) were consistent in all regards with previously reported studies that employed a mechanical stepper unit for perirectal hydrogel placement prior to radiation therapy [7,14,15,18,19].

Use of a probe-mounted needle guide for perirectal hydrogel spacer placement offers the key advantage of coupling of the working needle to the ultrasound probe. This ensures continuous visualization of the needle tip during the entirety of the procedure. Without this, the user must spend considerable effort to locate the needle during the various steps of the procedure. Loss of visualization of the needle has the potential to lead to serious procedural complications such as rectal injury or intravascular hydrogel injection [20].

One shortcoming of using the PPTAS for perirectal spacer placement is that it introduces the challenge of needing to hold the ultrasound probe with one hand at all times during the procedure. In contrast, a mechanical stepper frees both hands of the user to allow for preparation of the hydrogel or other procedure-related tasks. To overcome this limitation introduced by the PPTAS, we now prepare the hydrogel components prior to initial placement of the ultrasound probe. Additionally, we have learned how to stabilize the probe and working needle

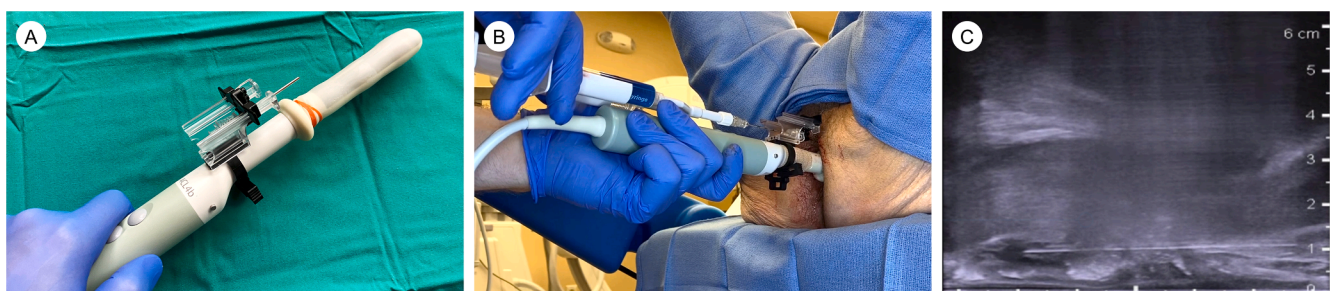


Fig. 1. Perirectal hydrogel spacer placement with the single-use PrecisionPoint Transperineal Access System. (A) The assembled device is clamped to a biplanar transrectal ultrasound probe. (B) The access needle is engaged in the perineal skin 2–3 mm above the anus. The physician passes the needle of the hydrogel's delivery system through the needle guide. (C) Transverse ultrasound image showing the hydrogel being injected between the posterior prostate and rectal wall.

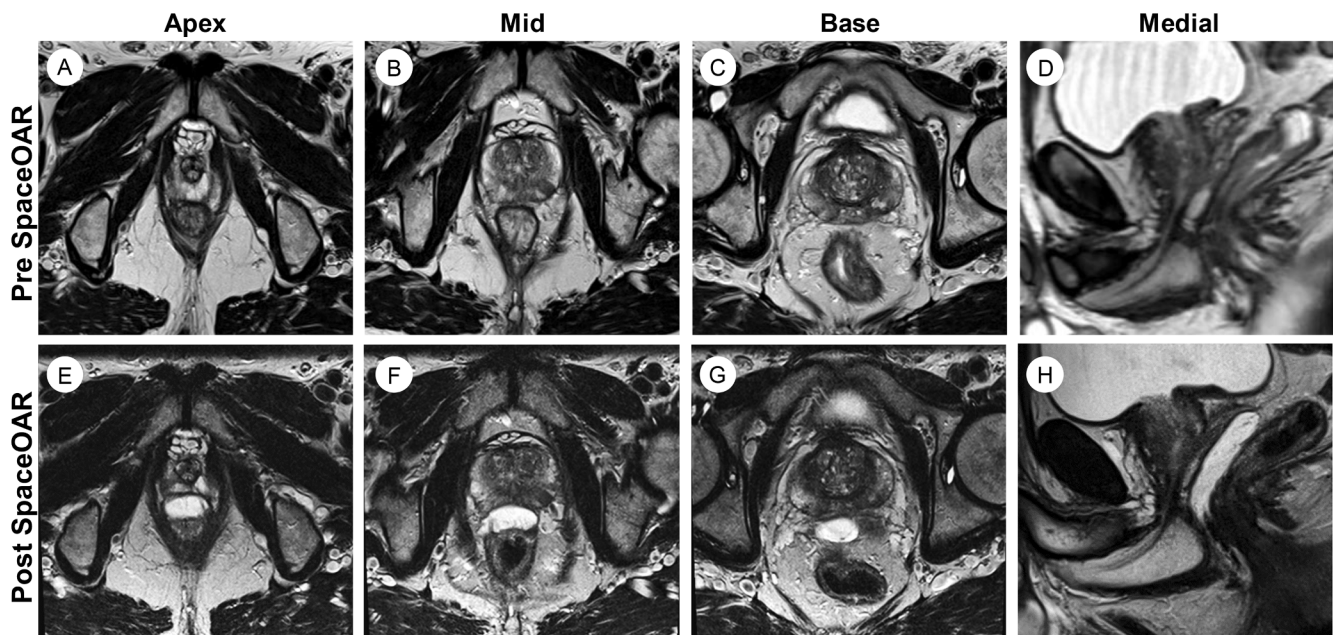


Fig. 2. Representative images of (A–D) pre- and (E–H) post- hydrogel placement with the probe-mounted needle guide. The prostate is elevated from the rectum without skewing or rectal wall infiltration of the hydrogel.

with one hand, freeing the other hand to exchange syringes during the procedure (Supplemental Video 1).

A second potential benefit of the PPTAS is elimination of the need to purchase a mechanical stepper unit which typically cost >\$10,000. Use of the PPTAS, which costs ~\$250 per device, allows physicians to begin performing perirectal spacer placement without a significant upfront capital outlay. We acknowledge, however, that for many practices the additional expense of this disposable device may increase the overall long-term costs associated with this procedure. This concern, however, may be balanced by the fact that the PPTAS eliminates the need for manual disinfection of the stepper unit, a process that can be time consuming for staff, freeing them to perform other tasks. Additionally, this device eliminates any costs associated with maintenance and repair of a stepper unit.

In conclusion, we demonstrate the safety and technical feasibility of perirectal hydrogel spacer placement using a single-use, probe-mounted, needle guide. This device, which was originally designed for performing transperineal prostate biopsies, couples the injection needle to the ultrasound probe thereby offering the benefit of continuous visualization of the needle tip during hydrogel placement.

Data sharing agreement

Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

Disclosure statement

Dr. Gorin is a paid consultant to Perineologic, maker of the PrecisionPoint Transperineal Access System. All other authors have no relevant disclosures.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ctro.2021.05.003>.

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