NYU Langone Health

Department of Urology

Case of the Month

Use of Salvage Partial Gland Cryoablation for Radio-Recurrent Prostate Cancer

Case Presentation

A man in his late 60s presented for evaluation and treatment recommendations for radio-recurrent prostate cancer.

Prostate Cancer History

Diagnosis

In June 2008, the patient was in his late 50s and in his usual state of health when he had an abnormal digital rectal examination (DRE) and a screening PSA of 4 ng/mL. A month later, a transrectal ultrasound-guided systematic 12-core prostate biopsy demonstrated a 28 cc prostate gland. The biopsy identified Gleason 4+4 prostate cancer—in 4 of 12 cores (left medial base [5%], left lateral base [80%], left lateral mid [25%], and left medial mid [50%]). Initial staging imaging with CT and bone scan was negative for metastatic disease.

At the time of diagnosis, the patient had a history of urinary calculi and hypothyroidism. His surgical history included an inguinal hernia repair and arthroscopic knee surgery. He was working as a paramedic and had no urinary or sexual function complaints.

The patient had no known family history of malignancy, and his father had died from cardiovascular disease.

Initial Curative Intent Treatment

After a review of his options, the patient elected to proceed with radiation therapy. He completed intensity-modulated radiation therapy (IMRT, 7740 Gy) in November 2008. He did not receive androgen deprivation therapy (ADT). He tolerated his therapy without significant side effects.

Post-Treatment Follow-Up

Following treatment, the patient underwent routine PSA monitoring. His PSA curve and PSA doubling time following a nadir of 0.3 ng/mL in May 2013 are illustrated in Figure 1.

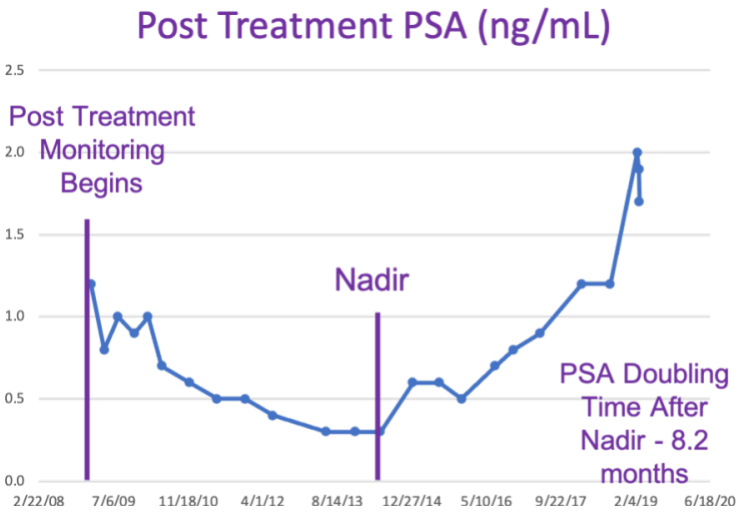

Figure 1. The patient's PSA course following intensity-modulated radiation therapy (IMRT) with nadir achieved in May 2013: post-nadir PSA rise and doubling time of 8.2 months in 2019.

In March 2019, about 11 years after his diagnosis, the patient's PSA doubling time was noted to be about 8.2 months. Repeat staging imaging at this time using conventional imaging (CT of the abdomen and pelvis and a bone scan) was negative for metastatic disease. A prostate MRI demonstrated a 30 cc prostate gland with a 17 mm x 10 mm PI-RADS 5 lesion in the left medial posterior base peripheral zone. No seminal vesical invasion, osseous lesions, or enlarged pelvic lymph nodes were identified.

In April 2019, the patient underwent an MRI-US fusion-targeted biopsy, which demonstrated prostate cancer in 1 of 12 systematic cores (left base, Gleason 4+4, 5 mm, 35%, cribriform pattern identified) and in 3 of 3 targeted cores obtained from the left mid posteromedial peripheral zone lesion (up to 8 mm of Gleason 4+4 [80%] with cribriform pattern again identified).

A fluciclovine F 18 (Axumin) PET CT obtained in May 2019 demonstrated intense radiotracer uptake in the left posterolateral prostate (SUV 7.2) and no evidence of uptake consistent with metastatic disease (Figure 2).

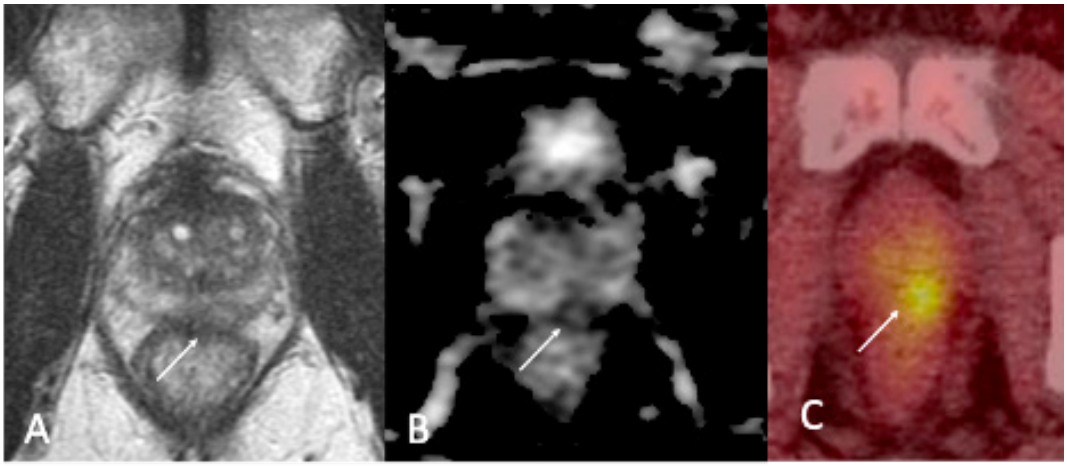

Figure 2. Prostate MRI: (A) axial T2 image, PI-RADS 5 lesion, prostate volume 30 cc, (B) apparent diffusion coefficient (ADC) map with corresponding region of restricted diffusion, (C) fluciclovine F 18 prostate-specific membrane antigen (PSMA) PET demonstrating uptake in the left posterior prostate, SUV 7.2.

At this time, the patient noted no urinary complaints (IPSS 5, QoL score 1). He reported moderate erectile dysfunction (SHIM score 8), which responded to PDE-5 inhibitors. He was then referred to NYU Langone Health Department of Urology for further evaluation of salvage treatment options for radio-recurrent localized prostate cancer.

Evaluation and Treatment at NYU Langone

On exam, the patient was found to be a normal, well-developed adult male. No inguinal, scrotal, or penal abnormalities were noted. DRE demonstrated a small, flat prostate (<30 cc) without discrete nodules, induration, or tenderness. A repeat serum PSA was found to be 2.13 ng/mL. A review of the patient's prior imaging and pathology report confirmed the previous findings.

After discussion of salvage treatment options for radio-recurrent prostate cancer, which included continued monitoring with serial PSA, salvage prostatectomy, salvage brachytherapy, and salvage ablation treatment as well as the potential side effects and expected cancer control outcomes with each approach, the patient elected to pursue salvage cryoablation.

Transperineal Pretreatment Planning Biopsy

In order to optimize the treatment strategy for salvage ablation, the patient underwent a pretreatment transperineal prostate biopsy for further characterization of the extent of radio-recurrent disease. This pretreatment biopsy was performed under sedation via a transperineal approach and more extensively sampled the prostate than his prior diagnostic biopsy. In total, 22 zones were sampled in this biopsy to assess extent of disease. Sampling from the periprostatic tissue posterior to the left prostate was also obtained to assess for extraprostatic extension. The template employed for this biopsy was derived from Barzell's zones and is illustrated in Figure 3.

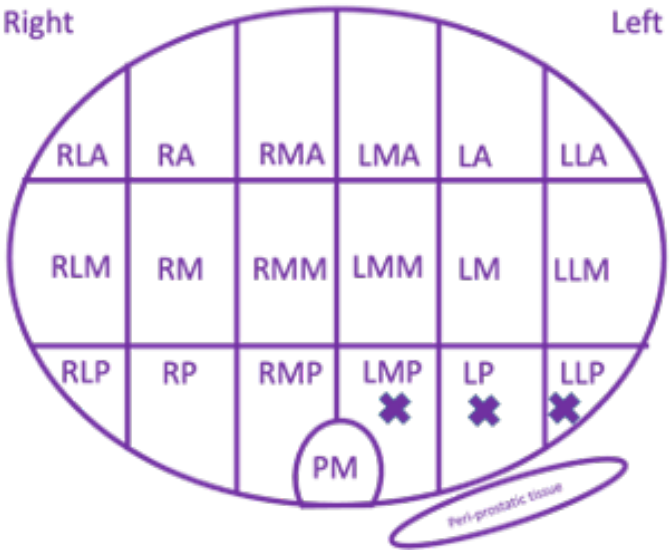

Figure 3. Transperineal pretreatment planning biopsy zones. Zones positive for cancer are marked with an "X." LA = left anterior; LLA = left lateral anterior; LLM = left lateral mid; LLP = left lateral posterior; LM = left mid; LMA = left medial anterior; LMM = left medial mid; LMP = left medial posterior; LP = left posterior; PM = posterior midline; RA = right anterior; RLA = right lateral anterior; RLM = right lateral mid; RLP = right lateral posterior; RM = right mid; RMA = right medial anterior; RMM = right medial mid; RMP = right medial posterior; RP = right posterior.

The pretreatment biopsy demonstrated Gleason 4+5, Gleason grade (GG) 5, in the left lateral posterior, left posterior, and left medial posterior zones. GG 5 cancer of up to 8 mm was detected in these zones. No disease was detected posterior to the urethra in the posterior midline zone, and sampling of the periprostatic tissue posterior to the left prostate was noted to be benign fibromuscular tissue. Based on these results, the decision was made to proceed with salvage partial gland cryoablation.

Salvage Partial Gland Cryoablation

The cryoablation procedure was performed under anesthesia in an ambulatory surgical suite. Cryoablation was performed using Endocare V-Probe cryoprobes, which were advanced percutaneously into the prostate transperineally under ultrasound guidance (HealthTronics). Six V-probes were placed into the left posterior hemi-prostate. In a similar fashion, 6 thermocouple probes were placed at treatment boundaries to provide intraoperative temperature assessment of treatment margins.

Two freeze-thaw cycles were used and treatment margin temperatures of at least –20° C were achieved in both cycles. The patient was discharged with a Foley catheter; he successfully passed a trial of void on post-op day 3.

Post-Treatment Course

The patient's post-ablation MRI and PSA trend 4 years post ablation are shown in Figure 4. His surveillance biopsies at 6 months and at 2 years found no evidence of cancer in the ablation zone or in the remainder of his prostate. He remains continent. He has initiated intracorporeal injection therapy for erectile dysfunction, with adequate response.

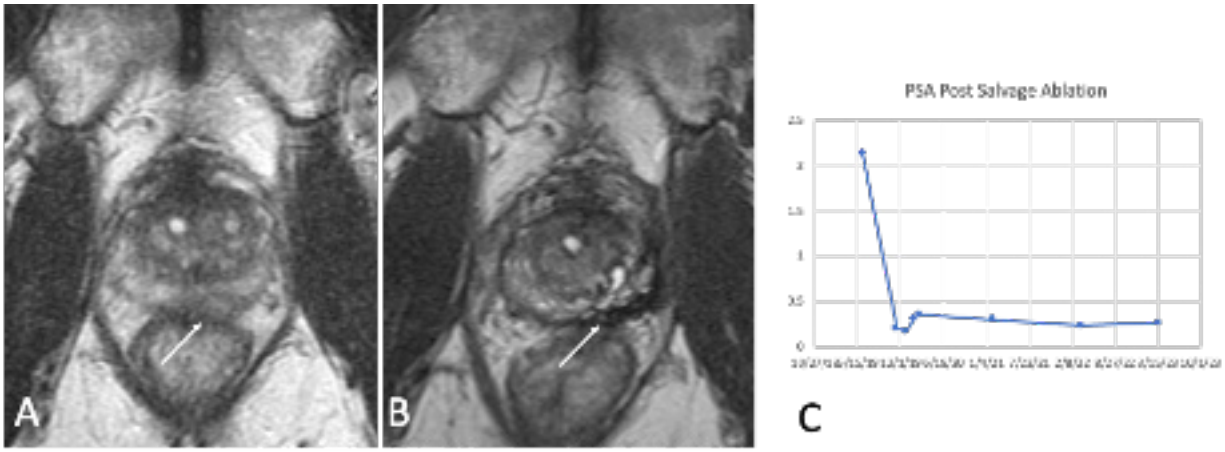

Figure 4. Post-ablation imaging and PSA: (A) pretreatment MRI, (B) 4-year post-ablation MRI demonstrating no evidence of tumor, (C) PSA course post ablation.

Comment

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Local Recurrence Following Primary Radiation Therapy

Treatment of prostate cancer with radiation therapy via external beam or brachytherapy offers men a noninvasive option for managing localized prostate cancer. The National Cancer Care Network (NCCN) and the European Association of Urology (EAU) include radiation therapy with or without ADT as a primary treatment recommendation for men diagnosed with low-, intermediate-, and high-risk disease depending on patient life expectancy, disease characteristics, comorbidities, and patient preference.[1,2]

Rates of biochemical failure and local disease recurrence following radiation therapy vary depending on disease characteristics (e.g., stage), radiation technique, inclusion of ADT, and time from treatment. The current American Society for Therapeutic Radiology and Oncology (ASTRO)-Phoenix criteria define biochemical recurrence following external beam radiotherapy (EBRT) as a PSA rise equal to or greater than 2 ng/mL above the nadir PSA achieved.[3] Grimm et al. conducted a comparative analysis of PSA-free survival outcomes for patients with low-, intermediate-, and high-risk prostate cancer who underwent radical therapy. The authors compiled data from 18,000 patients treated with prostatectomy, EBRT, or brachytherapy, with or without ADT. The primary endpoint of the study was biochemical failure, defined as a detectable or rising PSA level following treatment. The authors reported biochemical survival rates for intermediate-risk disease of 65% to 88% at 5 years and 48% to 62% at 10 years. For men with high-risk disease, these rates decreased to 40% to 60% at 5 years and 20% to 45% at 10 years.[4]

Whether the post-treatment PSA meets the ASTRO-Phoenix criteria or, as in the case described here, the PSA kinetics raise concern for disease recurrence, an investigation into the potential source of recurrence is required. Given that men with an isolated, early local recurrence could potentially benefit from local salvage therapy, accurate localization of disease recurrence is critical.

Ruling Out the Presence of Metastatic Disease

Conventional staging imaging modalities such as CT and 99mTc bone scan have limited sensitivity in diagnosing and localizing recurrence at the lower PSA levels associated with biochemical failure. The recent introduction of molecular imaging using PSMA coupled with a radiolabel such as 18F offer improved staging imaging through whole-body PET imaging.[5] In a recent prospective evaluation of PSMA PET staging at the time of biochemical failure, Fendler et al. reported an overall detection rate of 75%, with a positive prediction value of 0.92.6 They also reported a direct relationship between cancer detection and level of PSA at time of recurrence, with cancer detection rates ranging from 38% for PSA <0.5 ng/mL, 57% for PSA 0.5 to <1.0, 84% for PSA 1.0 to <2.0 ng/mL, 86% for PSA 2.0 to <5.0 ng/mL, and 97% for PSA 5.0 ng/mL.[6]

Improving Localization of Radio-Recurrent Disease Using MRI

While PSMA PET improves the ability to identify those with local recurrence by ruling out metastatic disease, multiparametric MRI (mpMRI) of the prostate has improved disease localization, risk stratification, and treatment planning for disease recurrence within the prostate gland itself. The utility of mpMRI in the primary management setting has been well documented.[7,8]

As in the primary setting, the sensitivity and specificity of mpMRI for detection and localization of radio-recurrent disease enable the localization of recurrent disease foci.[9,10] Whereas pre-biopsy mpMRI allows men to avoid the risks associated with unnecessary biopsy, this imaging modality also guides biopsy and improves the diagnostic accuracy.[9] Furthermore, the success of targeted biopsy in localizing disease has provided the foundation for partial gland treatment strategies such as focal cryoablation and focal high-intensity focused ultrasound (HIFU).[11]

Managing Local Recurrence of Prostate Cancer Following Radiation Therapy

The local management of radio-recurrent prostate cancer involves several options and poses increased clinical challenges as compared to primary management. Repeat radiation to the prostate is not recommended because of the potential for increased side effects to surrounding tissue and the higher probability that locally recurrent prostate cancer cells may have developed radio-resistance via hypothesized mechanisms including alterations in DNA repair and cell cycle pathways, epithelial-mesenchymal transition, activation of survival signaling pathways, and survival of cancer stem cells.[12,13] Subsequently, the options in this setting include salvage radical prostatectomy, salvage ablation, salvage radiation (stereotactic body radiotherapy [SBRT], low-dose-rate and high-dose-rate brachytherapy), ADT, systemic therapy, and surveillance or observation.[14,15]

Valle et al. recently summarized the oncologic and functional outcomes following local salvage treatment options for radio-recurrent prostate cancer.[16] The results of this review are shown in Table 1.

Table 1. Salvage treatment outcomes[16*]

Salvage Therapy	2-Year bRFS	5-Year bRFS	Severe GU Toxicity	Severe GI Toxicity	*P* value
Salvage RP	72% (66-78)	53% (46-59)	21% (16-26)	1.5% (0.4-3.2)	Reference
Salvage Cryo	66% (59-72)	57% (49-65)	15% (8-23)	0.9% (0.9-1.8)	0.2-0.5
Salvage HIFU	**52% (45-59)**	46% (37-55)	23% (17-30)	0.8% (0.1-2.1)	**<0.001**
SBRT	58% (46-69)	56% (37-73)	**5.6% (1.4-12)**	0.0% (0.0-1.2)	**<0.001**
HDR brachytherapy	77% (69-83)	58% (52-64)	**9.6% (6.0-13.9)**	**0.0% (0.0-0.3)**	**0.002/0.003**
LDR brachytherapy	79% (72-85)	53% (43-63)	**9.1% (5.2-14)**	2.1% (0.6-4.0)	**0.001**

*Adapted from Valle LF, Lehrer EJ, Markovic D, et al. A systematic review and meta-analysis of local salvage therapies after radiotherapy for prostate cancer (MASTER). Eur Urol. 2021;80(3):280-292.

Significant p-values after Bonferroni correction appear in bold.

Abbreviations: bRFS = biochemical recurrence-free survival; cryo = cryoablation; GI= gastrointestinal; GU = genitourinary; HIFU = high-intensity focused ultrasound; HDR = high-dose-rate; LDR = low-dose-rate; RP = radical prostatectomy; SBRT = stereotactic body radiotherapy.

Overall, this review indicates that these salvage local therapies have similar rates of oncologic control but they have varying degrees of impact on urinary and sexual function.

Given the risks of toxicity associated with salvage therapy, techniques that can limit the impact of these treatments warrant consideration. The use of a targeted intra-prostate treatment, such as partial gland ablation or focal therapy, represents an emerging strategy for prostate cancer management. This strategy aims to selectively treat or ablate tissue containing clinically significant disease while preserving the surrounding healthy, or non-malignant, tissue. From an oncologic standpoint, this strategy is employed in some form for nearly every other solid malignancy. However, the application to prostate cancer has been historically limited by the inability to accurately localize disease within the gland itself. As stated earlier in this case study, mpMRI ushered in a revolution in the localization of prostate tumors and has opened the door to prostate treatments that can potentially reduce treatment-related side effects such as urinary incontinence and erectile dysfunction.[17-20] Efforts to develop and employ primary partial gland treatments are ongoing in many environments, including at NYU Langone. This experience has spurred progress in the use of partial gland treatment in the management of radio-recurrent prostate cancer.

Salvage Partial Gland Cryoablation

Salvage partial gland cryoablation is a technique that adapts the principles used in primary partial gland cryoablation.[20,21] Although the treatment approach is similar, the post-radiation setting carries a higher risk for side effects such as urinary incontinence and rectal fistula development. In view of this, the cryoablation energy is often deployed with a smaller and more focal treatment volume, and at a slower rate. The purpose of these adjustments is to limit the thermal impact on surrounding tissue and thus mitigate the risk of serious side effects.

The reported outcomes of focal salvage cryoablation remain limited. However, emerging data provide optimism for the success of this approach. Using data from the Cryo On-Line Data (COLD) Registry, Li et al. reported biochemical disease-free survival rates of 46.5% at 5 years in 91 patients treated with focal salvage cryoablation along with complication rates comparable to whole gland salvage ablation.[23] de Castro Abreu et al. reported a small series of cases of salvage focal cryoablation compared to salvage whole gland ablation that demonstrated no new onset of incontinence or fistulas in the focal treatment arm.[24] For comparison, Chin et al. recently reported recurrence rates ranging from 15.6% to 57.6% in a systematic review of whole gland salvage cryoablation in 11 studies on 2,101 patients over a follow-up range of 9 to 297 months.[25] Haj-Hamed et al. performed a review focusing on the use of focal salvage treatments for radio-recurrent prostate cancer.[26] They reported on limited data comparing whole gland salvage cryoablation to focal salvage cryoablation and noted a lower side effect profile for focal salvage therapy.

Successful salvage focal cryoablation requires careful patient selection and meticulous treatment application.[27] Assessing treatment success following salvage cryoablation presents challenges similar to those associated with primary partial gland ablation. Monitoring with serial PSA and MRI provides essential clinical endpoints; however, data guiding the frequency and interpretation of these endpoints remain limited. Ongoing work at NYU Langone aims to further characterize and strengthen these endpoints through the use of routine post-treatment tissue evaluation with prostate biopsy.

Conclusion

The management of radio-recurrent prostate cancer presents unique challenges and requires a tailored approach. Advances in imaging techniques, such as mpMRI, have facilitated the localization of recurrent disease and enabled the development of focal salvage therapies, including cryoablation. These focal therapies have shown promising oncologic outcomes and reduced side effects compared to whole gland salvage treatments; however, further research is needed to establish optimal monitoring protocols and strengthen clinical endpoints. Continuing efforts at NYU Langone and similar institutions are vital for refining the understanding of these treatments and ultimately improving the care and quality of life for patients with radio-recurrent prostate cancer.

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Case of the Month

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Department of Urology

NYU Langone Health

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