NYU Langone Health

Department of Urology

Case of the Month

Management of Men with Rising PSA After Radical Prostatectomy

Case 1:

An African-American man in his fifties with hyperlipidemia, hypertension, and morbid obesity presented in late 2005 with an elevated PSA of 10.6 ng/ml. A subsequent prostate biopsy demonstrated Gleason 3+4 adenocarcinoma of the prostate in 4 of 12 systematic biopsy cores. After discussing treatment options, the patient elected radical prostatectomy, and in early 2006, he underwent an open radical prostatectomy and pelvic lymph node dissection. His recovery was uneventful. Pathology revealed a Gleason 3+4, pT3b, N0, Mx prostate cancer with negative surgical margins. He regained continence, but erectile dysfunction persisted with partial erections after the operation.

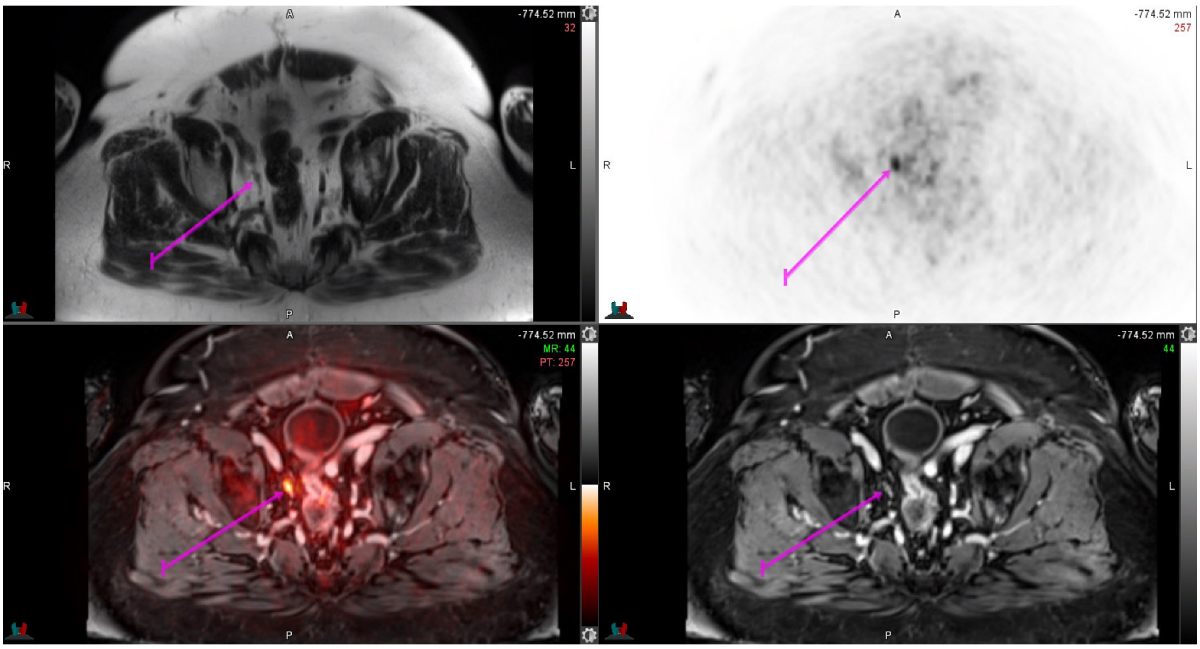
His PSA kinetics after the surgery are presented in Table 1. His initial PSA nadir was 0.03 ng/ml one month post-operative, but the PSA rose to 0.20 ng/l by mid-2006 and 0.37 ng/ml by the end of 2006.

Table 1.

Date	PSA	Treatment/Imaging
2005	10.6	
2006		Radical Prostatectomy- Gleason 3 + 4,T3b,N0, negative margins
2006	0.03	
2006	0.20	
2006	0.37	
2007		Salvage EBRT, 66 Gy
2007	0.07	
2009	0.03	
2010	0.02	
2011	0.02	
2011	0.02	
2012	0.02	
2012	0.02	
2013	0.05	
2013	0.03	
2014	0.02	
2014	0.04	
2015	0.06	
2015	0.09	
2017	0.18	
2017	0.70	
2018	2.71	
2018	4.26	Bone scan negative

He elected for salvage radiotherapy and completed 66 Gy of external beam radiotherapy in Spring of 2007. His PSA subsequently nadired to 0.02 ng/ml and remained at that level until 2013, when it slowly started to rise. In mid-2017, the PSA began to rapidly rise to a level of 4.2 ng/ml by early 2018. A Tc-99 bone scan revealed uptake consistent with degenerative disease and known Paget's Disease, but an F18-fluciclovine PET/CT demonstrated concern for a solitary right external iliac lymph node metastasis (Figure 1). Of note, a 4.6 cm solid left renal mass was incidentally noted as well.

Figure 1.



In Spring of 2018, the patient underwent a salvage right-sided robotics-assisted laparoscopic pelvic lymph node dissection, inclusive of the site of suspicion for metastasis. Pathology revealed metastatic prostate cancer in early 2016 and subsequently his lymph nodes were removed. A subsequent renal CT that summer demonstrated two masses in the left kidney, and the patient underwent a robotics-assisted laparoscopic left radical nephrectomy and lymph node dissection. Pathology demonstrated a pT1b, N0, Mx clear cell renal cell carcinoma.

In follow-up, the patient's PSA has remained undetectable through early 2023. He has had no evidence of renal cancer recurrence.

Case 2:

A man in his fifties was referred to NYU Langone Health in August 2019 for a rising PSA after a previous radical prostatectomy. He had undergone an open radical prostatectomy in South America, in 2007 for Grade Group 2, pT3a, N0, Mx prostate cancer. Surgical margins were negative. His PSA began to rise by 2009 up to 0.66 ng/ml in 2009 (Table 2). He underwent salvage radiotherapy with standard dosing, though details of radiation therapy were not available. His PSA declined to 0.03 by 2010 but again began to rise. By fall of 2015, his PSA had risen to 1.85 ng/ml. A choline C-11 PET CT demonstrated no site of recurrence, and his PSA continued to rise (Table 2). By early 2018, his PSA rose to 3.67 ng/ml, and a repeat choline C-11 PET CT demonstrated uptake within a nodule adjacent to surgical clips.

Table 2.

Date	PSA	Treatment	Imaging
2007		Gleason 3+4 T3a, N0, (-) margins	
2008	0.01		
2009	0.28		
2009	0.43		
2009	0.66		
2010		Salvage pelvic RT	
2010	0.18		
2010	0.03		
2011	0.14		
2012	0.24		
2012	0.36		
2013	0.69		
2014	0.88		
2014	1.10		
2015	1.20		
2015	1.85		Choline PET negative
2016	1.65		
2016	2.23		
2017	2.65		
2018	3.67		
2018			Choline PET positive Avid nodule noted adjacent to metal clips
2018	3.22		
2019	2.69		PSMA PET positive for local recurrence
2019		Biopsy of nodule – GG4	

A follow-up Ga-68 PSMA PET CT demonstrated suspicion for local recurrence in the prostate bed (Figure 2). A visible nodule was then confirmed on subsequent MRI of the pelvis (Figure 3).

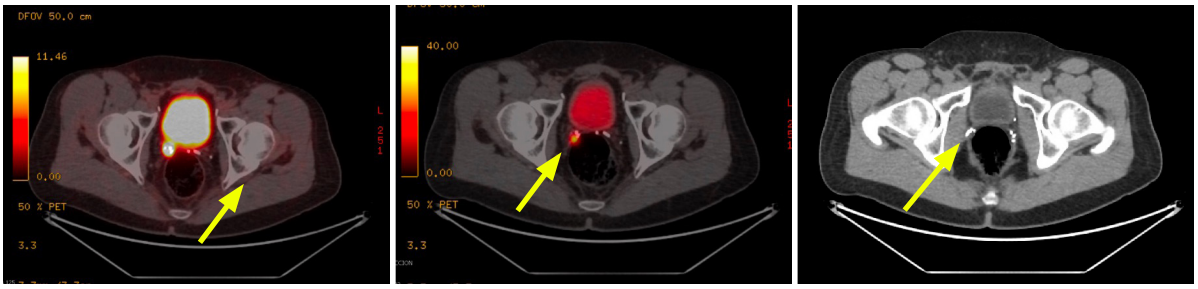


Figure 2.

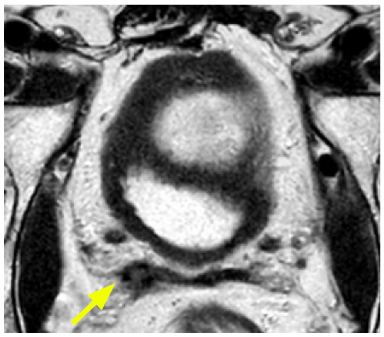


Figure 3.

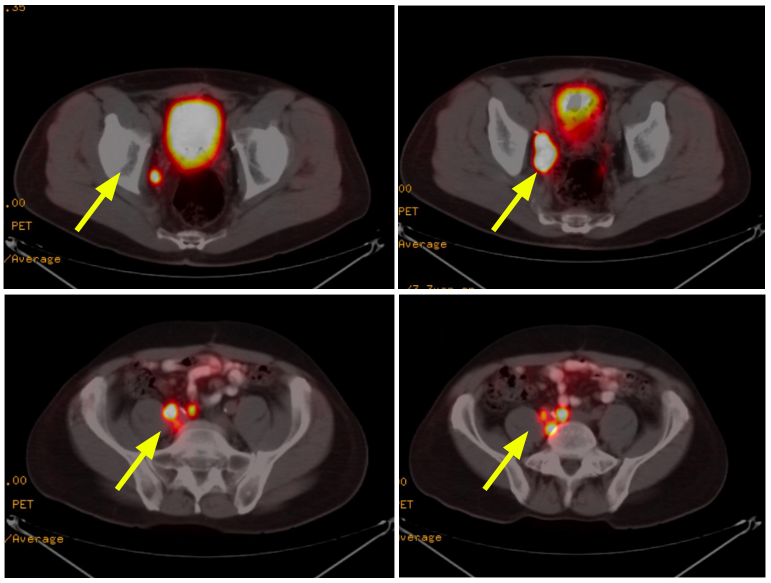


Figure 4.

The patient underwent a robotics-assisted re-resection of the surgical bed from the seminal vesical pedicle through the right prostate pedicle with excision of pre-rectal fascial onto the right neurovascular bundle. Pathology confirmed the presence of grade group 5 prostate cancer intermingled with nerves, blood vessels, and surgical clips. Surgical margins were negative.

The patient's recovery from surgery was uneventful, and three months post-operatively, his PSA declined to 0.02 ng/ml but then began to rise shortly after that. A follow-up Ga68 PSMA-PET in early 2021 demonstrated recurrent, suspicious pelvic lymphadenopathy (Figure 4), and androgen deprivation therapy was initiated.

Discussion

The management of men with rising PSA after radical prostatectomy has been a critical decision process for practicing urologists for more than three decades. In most historical cohorts of surgically treated localized prostate cancer, approximately 35% of men experience a biochemical relapse in the course of their follow-up. While the management strategy has evolved over the past years, as improved methods of PSA measurement and patient evaluation have emerged, individualizing treatment remains a challenge, typically based upon risk assessment and disease localization.

As the conventional management of biochemical relapse has generally been empiric pelvic radiotherapy, the early literature regarding the topic focused on the debate regarding immediate adjuvant radiation therapy for men with high-risk pathologic features versus salvage radiation therapy at the time of biochemical relapse. Two large trials, SWOG 8794 and EORTC 22911, largely informed early practice.[1,2] In both these trials, men with high-risk, non-metastatic prostate cancer, defined as clinical stage ≥ T3 and/or margin positive, were randomized to immediate adjuvant radiotherapy or observation with a plan for salvage therapy at the time of relapse. The trials demonstrated improved biochemical progression-free survival, reduced clinical progression/relapse, and delay in initiation of androgen-deprivation therapy among men receiving immediate adjuvant radiotherapy. A subsequent follow-up analysis of the SWOG 8794 trial also showed improved survival among men receiving adjuvant radiation therapy (HR 0.72, 95% CI 0.55,0.96; p=0.023).[3]

While suggestive of improved outcomes in men with high-risk pathology, both the trials suffered from a lack of baseline risk stratification, with broad inclusion criteria, and a lack of standardized protocol for timing of intervention in the salvage arm. As such, early salvage radiotherapy remained a standard practice in the United States for many years.

In follow-up, more recently, three randomized trials (RAVES, GETUG-AFU 17, and RADICALS-RT) comparing adjuvant radiation with early salvage radiation, performed at a PSA of 0.1-0.2 ng/ml, have been published.[4,5,6] All three studies observed no difference in event-free/progression-free survival, thus verifying that if patients are carefully monitored, avoidance of adjuvant radiotherapy appears safe for most patients with high-risk pathology. Importantly, only 39% of men in the pooled observation arms of these trials required salvage radiotherapy.[7] As such, more than half of men with high-risk pathology will demonstrate durable disease control with surgery alone.

In evaluating the likelihood of favorable response to salvage radiotherapy, a retrospective multi-center evaluation has previously shown several factors to be predictive of durable response. Men most likely to respond well included those with Gleason score < 8, no seminal vesical invasion, > 12-month disease-free interval after primary therapy, PSA doubling time > 10 months, and pre-radiation therapy PSA of < 2.0 ng/ml.[8] Though men with favorable risk parameters appear most likely to respond to salvage radiotherapy, the benefit, with regard to improvement in survival, appears to be greatest among men with adverse risk features predicting a low likelihood of response. Trock and colleagues demonstrated a three-fold improvement in prostate cancer-specific survival among those undergoing salvage radiotherapy. Still, interestingly the survival advantage was limited to men with PSA doubling time < 6 months.[9] In other words, those least likely to respond were most likely to benefit.

This paradoxical observation is most likely attributed to the very variable natural history of prostate cancer, with only 1/3 of men with biochemical relapse after surgery exhibiting metastatic relapse within ten years of follow-up.[10] Interestingly, the vast majority of those who develop

metastases demonstrate PSA doubling time < 8 months.[11] As such, several attempts to improve outcomes among men with biochemical relapse and high-risk clinical characteristics have ensued, including the addition of 6-24 months of androgen deprivation therapy and wide-field radiation to include pelvic nodes. A predominant limitation in the treatment of men with biochemical relapse has been the inability to reliably localize sites of recurrence, and this is particularly concerning in higher-risk patients with adverse clinical characteristics, such as a rapid PSA velocity, in whom occult metastatic disease is more likely.

With the advent of prostate cancer-selective radiotracers to be utilized in positron emission tomography (PET), the ability to accurately stage and localize high-risk and recurrent prostate cancer has vastly improved. In particular, Ga-68 PSMA PET and F-18 DCF-Pyl PET (targeted to PSMA) allow for increased sensitivity in the detection of metastatic prostate cancer as compared to conventional imaging modalities such as bone scan and cross-sectional imaging.[12, 13] The increased sensitivity of PSMA PET does allow for the detection of lymph node, visceral, and bone metastases at earlier disease stage than conventional imaging, but in the relapse setting, the sensitivity and detection rate is highly dependent upon the PSA level at the time of evaluation.[13] In assessing men with relapse after radical prostatectomy, the while the positive predictive value of the test is quite high, the sensitivity for detection of disease remains low in the range of PSA at which men are typically considered for salvage treatment.

Among men who do demonstrate evidence of recurrence on PSMA PET, metastasis-directed therapy (MDT) has been considered as a novel treatment paradigm in men with limited metastatic disease (oligo-metastasis) in which metastatic sites are either resected or treated with stereotactic body radiotherapy (SBRT). In the case of metastases limited to pelvic lymph nodes, as in the case of our first patient, salvage lymph node dissection remains a viable option. To date, limited studies of MDT have demonstrated that durable disease control is rare but that delay in clinical progression and the need for androgen-deprivation therapy (ADT) can generally be achieved.

At NYU Langone Health, we have been interested in utilizing PSMA PET imaging to define new treatment paradigms for men with limited metastatic burden, both in the primary treatment setting and among men with recurrence after primary therapy. Using advanced robotic techniques, we have been able to perform salvage node dissections directed to conventional regions or atypical regions (mesorectal fat or presacral space) as directed by the PET imaging. Similarly, we have approached local recurrences, in the bed of prostatectomy, surgically when feasible, as in the case of Case 2.

Two studies have evaluated the outcomes of metastasis-directed therapy. In the Surveillance or metastasis-directed Therapy for oligo-metastatic Prostate cancer recurrence (STOMP) trial, men with oligo-metastatic recurrence were randomized to surveillance or MDT by surgery or SBRT with a plan for ADT at the time of clinical progression or symptomatic progression.[15] ADT-free survival improved from 13 months (80% CI, 12 to 17 months) to 21 months (80% CI, 14 to 29 months) with addition of MDT at a median follow-up of 3 years. In the ORIOLE randomized phase II trial of observation or SBRT for oligo-metastatic recurrent hormone-sensitive prostate cancer, and demonstrated similar improvement in progression-free survival, with a delay of androgen-deprivation therapy.[16] To date, no trials have demonstrated an improvement in overall survival, but the observed outcomes have prompted great interest in larger phase III studies of MDT in men with recurrent oligo-metastatic prostate cancer.

While the predictors of durable response to MDT remain unclear, there has been growing interest in baseline mutational status as predictor of response and improved progression-free survival.[16] In Case 1, the prolonged interval since primary therapy, along with maximal loco-regional therapy, may have increased the likelihood that the observed nodal recurrence was isolated to that observed on PSMA PET. Even in this case, it is important to note that though the PET scan demonstrated one lymph node, on pathology, lymph node metastases were identified.[3] In Case 2, despite a favorable PSA response to the local resection, previous maximal loco-regional therapy, and a prolonged interval since primary therapy, the disease rapidly recurred, illustrating the shortcomings of PSMA PET in identifying all sites of disease in many patients. Nonetheless, we believe the addition of baseline PSMA PET staging in men with recurrence after primary therapy offers the opportunity to improve outcomes among men who are most likely to benefit from salvage therapy but least likely to respond durably to empiric pelvic radiation.

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Case of the Month

Samir S. Taneja, MD

Dr. Taneja is the James M. Neissa and Janet Riha Neissa Professor of Urologic Oncology in the Department of Urology and professor in the Department of Radiology at NYU Grossman School of Medicine; professor of in the Department of Biomedical Engineering at NYU Tandon School of Engineering; and leader of the Genito-Urologic Program in the Perlmutter Cancer Center, director of the Division of Urologic Oncology, and vice chair of the Department of Urology at NYU Langone Health.

Dr. Taneja is a nationally renowned opinion leader in the treatment and research of prostate cancer. He has conducted extensive laboratory research on androgen receptor transcriptional activation and the relationship of the androgen receptor to prostate cancer growth. For the past 15 years, his clinical research interest has been in prostate cancer diagnostics, with particular focus on the application of imaging in the detection, risk stratification, and therapy of prostate cancer. He pioneered the clinical application of pre-biopsy prostate MRI and techniques of MRI-targeted biopsy and is a widely recognized innovator in the emerging field of prostate cancer focal therapy. He contributed to the establishment of standards for use of prostate MRI and targeted biopsy, serving on the Society of Abdominal Radiology Prostate Cancer Disease-focused Panel, the Appropriate Use Criteria Committees of the Society of Nuclear Medicine and Molecular Imaging and the American College of Radiology, and the AUA Committee for establishing an AUA Prostate MRI Standard Operating Procedure.

Dr. Taneja received the 2023 American Urological Association Distinguished Contribution Award for "creative and notable contributions in prostate cancer imaging, biopsy, and treatment." He is the author of more than 250 articles, 25 book chapters, and 5 textbooks, and he is the editor of *Taneja's Complications of Urologic Surgery: Prevention and Diagnosis*, one of the most widely read textbooks in American urology.

Department of Urology

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Locations subject to change.

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+NYU Langone Ambulatory Care Center East 38th Street
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