Salvage Cryoablation for Radiorecurrent Prostate Cancer: Initial Experience at a Regional Health Care System

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Perm J 2019;23:18-153

E-pub: 04/04/2019

https://doi.org/10.7812/TPP/18-153

ABSTRACT

Context: Local recurrence after radiotherapy for prostate cancer remains challenging to treat effectively. Although oncologic control is highest with salvage prostatectomy, the procedure is associated with substantial morbidity.

Objective: To identify factors associated with successful salvage cryoablation for radiorecurrent prostate cancer.

Design: We retrospectively reviewed the medical records of patients who underwent salvage cryoablation at our institution between 2005 and 2015. All patients had biopsy-proven local recurrence after radiotherapy. Patients with seminal vesicle invasion or metastases were excluded. Complete follow-up was obtained for all patients.

Main Outcome Measures: Primary study endpoint was biochemical progression-free survival based on the Phoenix criteria.

Results: Seventy-five patients underwent salvage cryotherapy. Mean patient age was 69.3 years. The overall biochemical salvage rate was 50.7% at a median follow-up of 3.9 years. The following factors were independently associated with successful cryotherapy: Precryotherapy Gleason score of 3 + 3 or 3 + 4, low precryotherapy prostate-specific antigen (PSA), low precryotherapy PSA density, longer time to PSA nadir after radiotherapy, and low postcryotherapy PSA nadir. A postcryotherapy PSA nadir of 0.5 ng/mL or less was associated with a biochemical progression-free survival of 79.7% at 3 years and 64.7% at 5 years, whereas a postcryotherapy PSA nadir above 0.5 was associated with a biochemical progression-free survival of 5.6% at 3 years and 0% at 5 years ($p < 0.0001$).

Conclusion: Approximately 50% of the patients achieved biochemical salvage with cryoablation at 5 years. Nadir PSA after salvage was the strongest predictor of biochemical progression-free survival in our cohort.

INTRODUCTION

Local recurrence after radiotherapy for prostate cancer remains a challenge to treat effectively. Although oncologic control is highest with salvage prostatectomy, the procedure is associated with substantial morbidity.[1-5] By comparison, both cryoablation and high-intensity focused ultrasonography are options that offer the patient a chance of salvage and that minimize collateral damage.[6-9] In our health care system, complete follow-up data on this patient cohort were obtained, including use of androgen deprivation therapy (ADT) and serum testosterone levels. Herein, we present our series of cryoablation in the setting of radiorecurrent prostate cancer focusing on factors associated with treatment success.

METHODS

All patients who underwent salvage cryoablation between October 2005 and July 2015 in our regional health care system were retrospectively reviewed after obtaining institutional review board approval. All patients had biopsy-proven local recurrence after external beam radiotherapy (EBRT) or brachytherapy. Biopsies are typically performed at least 18 to 24 months after radiation therapy (RT). Indications for biopsy included the following: An increase in the prostate-specific antigen (PSA) value above the nadir level with 3 consecutive increases, or a PSA increase of 2 points above the nadir in the absence of 3 consecutive increases.

Metastatic disease was ruled out with computed tomography or magnetic resonance imaging and bone scan. Patients with metastatic disease, a negative prostate biopsy, or biopsy-proven seminal vesicle invasion were excluded from treatment. All procedures were performed at 2 centers by fellowship-trained urologic oncologists. Double freeze-thaw cycles were performed using Galil (Galil Medical, Arden Hills, MN) or Endocare (Cryocare CS, Endocare/Healthtronics Inc, Austin, TX) cryotherapy systems according to the principles previously described by Finley et al.[10] The following variables were culled and analyzed: 1) patient demographics; 2) RT data, including modality (EBRT or brachytherapy), pre-RT PSA, pre-RT biopsy Gleason score and D'Amico risk group, use of ADT, post-RT PSA nadir, time to post-RT PSA nadir; and 3) precryotherapy data, including PSA, PSA doubling time (PSA-DT), precryotherapy Gleason score and D'Amico risk group, prostate volume, ADT use, postcryotherapy PSA nadir, time to postcryotherapy PSA nadir, and time to PSA failure. Statistical analysis was performed using statistical software (SAS/STAT Version 9.2, SAS Institute, Cary, NC).

The primary study endpoint was biochemical progression-free survival (biochemical PFS), based on the Phoenix criteria (PSA nadir + 2). The secondary endpoints included functional outcomes and complications, development of metastases, initiation of hormone therapy, and death. Multivariate analysis with the Kaplan-Meier method and receiver operating curve analysis were used.

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Keywords: cryoablation, cryotherapy, prostatic neoplasms, radiorecurrent prostate cancer, radiotherapy, salvage therapy

RESULTS

Seventy-five patients underwent salvage cryotherapy; 70 received whole-gland cryoablation, and 5 underwent hemiablation. Mean patient age was 69.3 years (range = age 54.7-84.6 years). Mean prostate volume was 26.1 mL (range = 9.5-67.0 mL). Fifty-eight patients underwent EBRT, and 16 underwent brachytherapy. The RT modality data were missing for 1 patient (Table 1). The overall biochemical salvage rate was 50.7% (38/75 patients) at a median follow-up of 3.9 years (range = 0.1-9.5 years).

A precryotherapy PSA level of less than 4.0 ng/mL was associated with a 62.0% biochemical PFS at 5 years and 51.7% at 7 years, whereas a precryotherapy PSA level of 7 ng/mL or higher was associated with a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years (p = 0.033, Figure 1). The following factors were associated with successful cryotherapy (Table 2): A precryotherapy Gleason score of 3 + 3 or 3 + 4 (p = 0.040, Figure 2), precryotherapy PSA (5.1 ng/mL vs 6.9 ng/mL, p = 0.009), precryotherapy PSA density (0.2 ng/mL^2 vs 0.3 ng/mL^2, p = 0.012), time to nadir after RT (25.6 months vs 15 months, p = 0.004), and postcryotherapy PSA nadir (0.2 ng/mL vs 2.7 ng/mL, p < 0.0001). The PSA-DT was not predictive of failure (20.1 months vs 21.3 months, p = 0.954). A postcryotherapy PSA nadir of 0.5 ng/mL or less was associated with a biochemical PFS of 79.7% at 3 years, 64.7% at 5 years, and 50.2% at 7 years. A postcryotherapy PSA nadir above 0.5 was associated with a biochemical PFS of 5.6% at 3 years and 0% at 5 years (Figure 3). Postcryoablation mean time to biochemical failure was 22.9 months (range = 1.1 months - 74.7 months).

Hormone therapy use before and after cryotherapy was fully captured in all patients. Four patients underwent a single dose of leuprolide acetate (Lupron) as neoadjuvant hormone therapy before cryotherapy. All 4 of these patients had castrate levels of testosterone at the time of cryotherapy (range = 12 ng/dL -3 3 ng/dL).

Table 1. Baseline precryotherapy characteristics of salvage and failure groups

Characteristic	Salvage (n = 38)	Failure (n = 37)	Total (N = 75)	p value
Age at cryotherapy, y				
Mean (SD)	69.0 (6.60)	69.6 (5.34)	69.3 (5.98)	0.8821
Median	69.9	68.9	69.1	
Range	54.7-84.6	55.7-82.7	54.7-84.6	
Prostate volume, mL				
Mean (SD)	26.9 (10.43)	25.2 (10.35)	26.1 (10.35)	0.3790
Median	23.0	23.4	23.0	
Range	12.5-67.0	9.5-53.8	9.5-67.0	
Type of RT, no. (%)				
Brachytherapy	5 (13.2)	11 (29.7)	16 (21.3)	0.1889
EBRT	32 (84.2)	26 (70.3)	58 (77.3)	
Missing	1 (2.6)	0 (0)	1 (1.3)	
RT with ADT, no. (%)				
No	32 (84.2)	24 (64.9)	56 (74.7)	0.0541
Yes	6 (15.8)	13 (35.1)	19 (25.3)	
D'Amico risk at time of cryotherapy, no. (%)				
Missing	1 (2.6)	4 (10.8)	5 (6.7)	0.3725
High	6 (15.8)	10 (27.0)	16 (21.3)	
Intermediate	22 (57.9)	16 (43.2)	38 (50.7)	
Low	9 (23.7)	7 (18.9)	16 (21.3)	

ADT = androgen deprivation therapy; EBRT = external beam radiotherapy; RT = radiation therapy; SD = standard deviation.

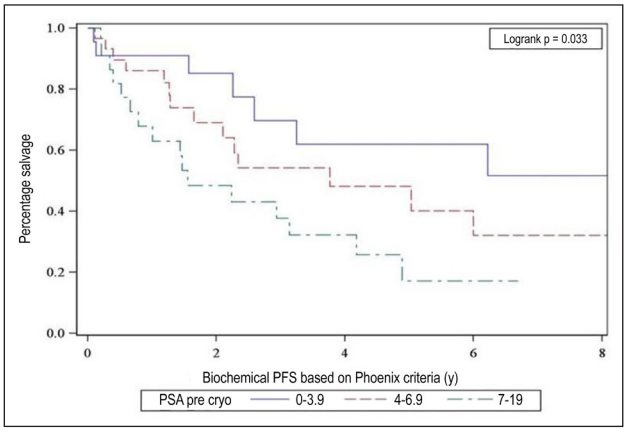

Figure 1. Association of precryotherapy (pre cryo) prostate-specific antigen (PSA) level (ng/mL) with biochemical progression-free survival (PFS), based on the Phoenix criteria (Phoenix_years on x-axis). A PSA level below 4.0 ng/mL was associated with a 62.0% biochemical PFS at 5 years and 51.7% at 7 years, whereas a precryotherapy PSA level of 7 ng/mL or more was associated with a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years.

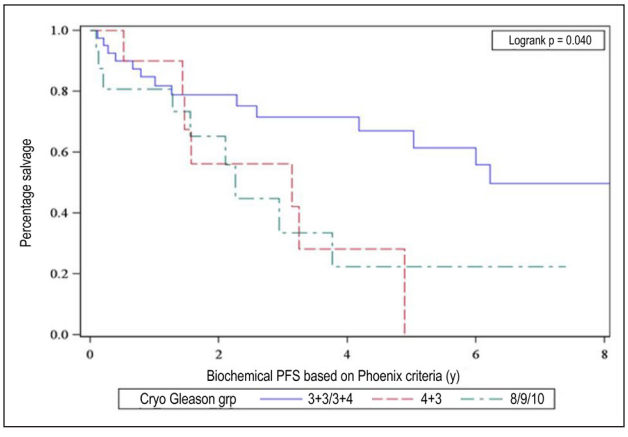

Figure 2. Association of precryotherapy Gleason score with biochemical progression-free survival (Phoenix_years on x-axis). Gleason score of 3 + 3/3 + 4 was associated with a 67.0% survival at 5 years and a 49.7% survival at 7 years, whereas a Gleason score of 8/9/10 was associated with a 22.4% survival at both 5 and 7 years.

Of the 37 patients in whom cryotherapy failed, 23 subsequently required ADT during our follow-up period (62.2%). Metastases developed in 10 patients (13.3%, 10/75 patients), all of whom were alive at the last follow-up.

Complications included 2 rectal fistulas (2.7%), 5 urethral strictures (6.7%), 19 patients with stress urinary incontinence requiring at least 1 pad per day (25.3%), and 1 death caused by a pulmonary embolism (1.3%). Sixty-nine patients were alive at last follow-up (92%). Among the 6 patients who died, only 1 death was attributed to metastatic prostate cancer (1.3% of 75 patients).

DISCUSSION

Radiorecurrent prostate cancer continues to pose a therapeutic challenge to the urologist, requiring a high degree of precision to balance oncologic control with functional outcomes. In this study, we followed a small cohort of patients with robust clinical follow-up to determine their response to salvage therapy. Few studies to date have complete data on androgen deprivation use or serum testosterone levels tied to PSA outcomes. We identified multiple independent predictors of successful salvage after cryoablation consistent with the findings of several other groups.[11,12] Most notably, we found a nadir PSA of 0.5 ng/mL or less after cryotherapy to be a strong predictor of biochemical PFS. In a similar study, Kovac et al[12] demonstrated that the best objective indicator of biochemical PFS in the setting of salvage cryotherapy was a PSA nadir less than 0.4 ng/mL. However, their study did not provide data on metastasis-free and overall survival rates. In our study, we observed a 13% metastasis rate and a 92% overall survival rate. Results of the current study reinforce the notion that postcryotherapy PSA nadir is a significant endpoint that may be used to predict those patients who will ultimately experience cryotherapy failure and will require hormone therapy. Thus, those patients who fail to achieve this nadir value should be monitored more closely after undergoing cryotherapy. Indeed, this also serves as useful information when counseling patients after salvage cryotherapy.

As previously demonstrated, precryotherapy PSA is an important predictor of successful salvage.[13,14] In our cohort, patients with a precryotherapy PSA below 4.0 ng/mL had a 62.0% biochemical PFS at 5 years and 51.7% biochemical PFS at 7 years. Those with a precryotherapy PSA level of 7 ng/mL or greater had only a 17.2% biochemical PFS at 5 years and a 0% biochemical PFS at 7 years. Similarly, Ng et al[14] reported that patients with a precryotherapy PSA below 4.0 ng/mL had a 5- and 8-year biochemical PFS of 56% and 37%, respectively. Those with a precryotherapy PSA above 9 had a 5- and 8-year biochemical PFS of 14% and 7%, respectively.[14] Thus, salvage cryoablation is most efficacious in patients who present with a low PSA at the time of initial consultation. This information should be used to encourage radiation oncologists to refer patients early after they observe RT failure, regardless of the definition of failure they choose to follow (ie, American Society for Radiation Oncology, Phoenix, Stuttgart).

In addition to precryotherapy PSA and Gleason score, we found that time to nadir after RT was also a significant predictor of successful salvage cryotherapy (25.6 vs 15 months, p = 0.004). In a cohort of 228 men who underwent primary EBRT for T1-T3 prostate cancer, Aref et al[15] also demonstrated that a longer time to nadir after RT was associated with better rates of biochemical disease-free survival.

Table 2. Factors associated with successful salvage

Factor	Salvage (n = 38)	Failure (n = 37)	Total (N = 75)	p value[a]
Precryotherapy Gleason score, no. (%)				
Missing	0 (0)	7 (18.9)	7 (9.3)	0.040
3 + 3	9 (23.7)	9 (24.3)	18 (24.0)	
3 + 4	18 (47.4)	5 (13.5)	23 (30.7)	
3 + 5	2 (5.3)	0 (0)	2 (2.7)	
4 + 3	4 (10.5)	7 (18.9)	11 (14.7)	
4 + 4	3 (7.9)	2 (5.4)	5 (6.7)	
4 + 5	1 (2.6)	6 (16.2)	7 (9.3)	
5 + 5	1 (2.6)	1 (2.7)	2 (2.7)	
Precryotherapy PSA, ng/mL				
Mean (SD)	5.1 (2.93)	6.9 (3.65)	6.0 (3.41)	0.009
Median	4.5	6.4	5.5	
Range	0.9-13.7	0.5-18.9	0.5-18.9	
Precryotherapy PSA density, ng/mL^2				
Mean (SD)	0.2 (0.16)	0.3 (0.17)	0.3 (0.17)	0.012
Median	0.2	0.3	0.2	
Q1, Q3	0.1, 0.3	0.2, 0.4	0.1, 0.4	
Range	0-0.7	0-0.7	0-0.7	
Precryotherapy PSA-DT, months				
Mean (SD)	20.1 (13.86)	21.3 (17.07)	20.7 (15.38)	0.954
Median	14.4	16.5	16.3	
Q1, Q3	11.1, 28.2	9.7, 24.4	10.5, 28.2	
Range	(3.8-67.8)	(6.1-83.9)	(3.8-83.9)	
Time to PSA nadir, months				
Mean (SD)	25.6 (19.46)	15.0 (9.55)	20.1 (15.92)	0.004
Median	21.7	11.8	15.6	
Range	1.0-93.6	1.6-43.3	1.0-93.6	
PSA value at postcryotherapy nadir, ng/mL				
Mean (SD)	0.2 (0.19)	2.7 (3.97)	1.4 (3.05)	< 0.0001
Median	0.1	0.8	0.2	
Range	0-1.0	0.1-18.9	0-18.9	

[a] With the exception of precryotherapy PSA doubling time, all factors shown were associated with successful salvage in a statistically significant fashion.

PSA = prostate-specific antigen; PSA-DT = prostate-specific antigen doubling time; Q = quartile; SD = standard deviation.

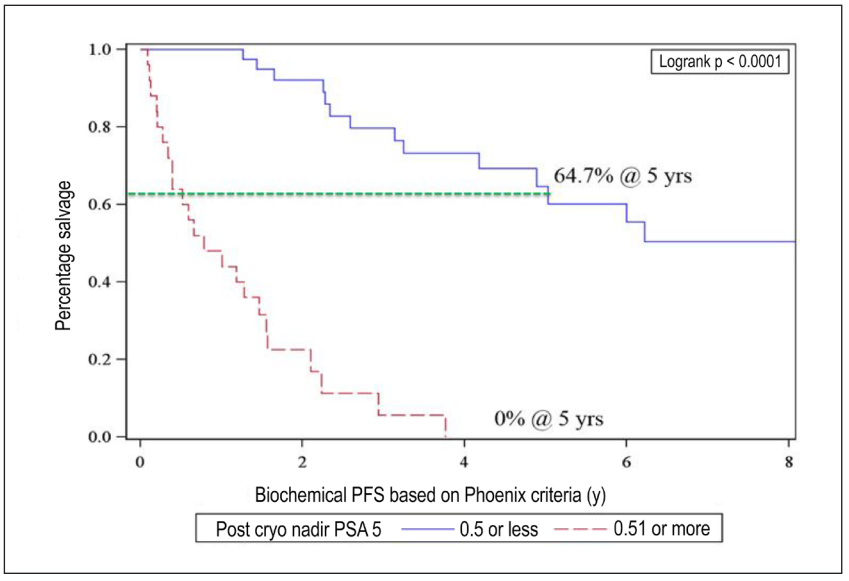

Figure 3. Association of postcryotherapy prostate-specific antigen (PSA) nadir (ng/mL) with biochemical progression-free survival, or PFS (Phoenix_y on x-axis). A PSA nadir of 0.5 ng/mL or less was associated with a biochemical PFS of 79.7% at 3 years, 64.7% at 5 years, and 50.2% at 7 years. A postcryotherapy PSA nadir above 0.5 was associated with a biochemical PFS of 5.6% at 3 years and 0% at 5 years.

However, they examined this relationship only in the setting of RT and not salvage cryotherapy. The utility of this value in the setting of salvage cryotherapy has not previously been reported in the literature, to our knowledge. Again, we believe that this is very useful information for not only the urologist but also for the referring radiation oncologist when counseling patients who are considering salvage cryotherapy.

The PSA-DT has previously been shown to accurately predict biochemical failure after RT in both the primary and salvage settings.[16,17] Spiess et al[18] demonstrated that a presalvage cryotherapy PSA-DT of 16 months or less was associated with a higher risk of failure (p = 0.06). In our cohort, however, PSA-DT was not predictive of failure on the basis of our statistical analyses. However, this is likely owing to the fact that both groups in our study had a relatively long mean PSA-DT (20.1 vs 21.3 months, p = 0.95). Thus, no significant conclusions could be drawn from this information.

In a retrospective study consisting of 797 men treated with salvage cryotherapy, Spiess et al[19] reported a biochemical failure rate of 66% with a median follow-up of 3.4 years; biochemical failure was defined as a total serum PSA level above 0.5 ng/mL in this study. Pisters et al[20] reported a 5-year biochemical disease-free rate of 54.5% using the Phoenix definition. In our study, we report a comparable overall salvage rate of 50.7% at a median follow-up of 3.9 years using the Phoenix definition (range = 0.1-9.5 years).

Salvage cryotherapy is associated with inherent morbidity and complications caused by retraumatization of previously damaged tissue. Nevertheless, we believe that it is a relatively safe procedure if performed by a trained specialist. The most devastating complication, rectal fistula, occurred in 2 of our patients (2.7%). The occurrence of this complication is reportedly low in the literature, ranging from 0% to 3.4%.[20-28] In 19 of our patients, urinary incontinence developed after cryotherapy (25.3%), which was defined as needing 1 or more pads daily. A review of the literature indicates a wide range of occurrence of this complication, ranging anywhere from 4.3% to 95%.[20,22-28] Lastly, we had 1 death in our cohort as a result of a perioperative pulmonary embolism. Overall, our results indicate that salvage cryotherapy is an effective treatment option with a low morbidity and mortality rate.

We recognize that our study has several limitations. First and foremost, the retrospective design of this study comes with its own innate biases. Additional limitations include our relatively short length of follow-up and small sample size. Furthermore, results from our single-institution study may not be generalizable to a greater patient population. We also recognize a lack of data regarding potency in our cohort. Nevertheless, our data were obtained from a fully captured medical record system in a single integrated health care system. Unlike much of the literature regarding cryotherapy that comes from the heterogeneous multi-institutional Cryo On-Line Data Registry, we feel that our data are more robust and consistent. It is important to note that data from the Cryo On-Line Data Registry are variable among different institutions and represent dissimilar operative techniques.[12] In contrast, our entire cohort came from a single health care system using standardized operative techniques. In our review of the relevant literature, we did find another retrospective single-institution study that demonstrated that presalvage PSA and presalvage Gleason score were the best predictors of early recurrence in the setting of salvage cryotherapy.[29]

CONCLUSION

We identified several statistically significant predictors of success that can be used to guide both the urologist and radiation oncologist in counseling patients before and after salvage cryotherapy. Overall, 50% of the patients achieved biochemical salvage with cryoablation. Multiple independent predictors of success were identified, including low Gleason score, low precryotherapy PSA and PSA density, and longer time to PSA nadir after RT. Importantly, patients who achieved a postcryotherapy PSA nadir of 0.5 ng/mL or less had significantly improved biochemical PFS rates. Nadir PSA after salvage cryotherapy was the strongest predictor of biochemical PFS in our cohort. ❖

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgments

Kathleen Louden, ELS, of Louden Health Communications performed a primary copy edit.

How to Cite this Article

Safavy S, Jabaji RB, Lu SM, et al. Salvage cryoablation for radiorecurrent prostate cancer: Initial experience at a regional health care system. Perm J 2019;23:18-153. DOI: https://doi.org/10.7812/TPP/18-153

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