

Article Review

Author	Journal or Book	Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Chin JL, Pautler S, Mouraviev V, et al	<i>Abstract</i>	2000	Case series	PSA levels and serial biopsy at 3,6,12, and 24 months	118 patients All < 78yrs of age Karnofsky status > 90 > 2 years post radiation Negative CT and bone scans Followup 3-60 months	51.6% PSA < 0.5 26.9% PSA 0.5- 5.0 21.5% PSA > 5.0 5.3% at least one core-biopsy post-op 3.5% overall positive 22% were deemed clinical or biochemical failure Pre-cryo predictive factors: PSA > 5 Prostate size > 40gms Stage > T3a Gleason > 7	Limited statistical analysis. Abstract Unclear of time frame of DFS Attempt at defining s subpopulation most likely to benefit from this procedure.

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De la Taille, A, Hayek O, Benson MC, et al	<i>Urology</i>	2000	Case series	Biochemical recurrence-free survival (defined as PSA < 0.1 ng/ml)	43 patients between October 1994-April 1999. Mean age 69.4 years (48.1-83.6) Mean PSA 7.07 26 pts Stage T1-T2 All patients had biopsy-proven recurrent prostate cancer. Patients had received 3 months of combined hormonal therapy before cryosurgery. Mean followup 21.9 months (1.2 - 54). Patients underwent serial DRE and serum PSA testing 1 month after cryosurgery and then every 3 months for 18 months.	60% patients PSA nadir < 0.1 37% PSA < 4.0 3% PSA < 10 DFS 79% at 6 months 66% at 12 months PSA nadir > 0.1ng/ml was an independent predictor of PSA recurrence Complications: Incontinence 9% Obstruction 5% Urethral stricture 5% Rectal pain 26% Urinary infection 9% Scrotal edema 12% Hematuria 5% No patients died of prostate cancer or developed metastatic diseases, during the study period.	Short followup Limited statistical analysis reported All cryosurgeries were performed by a single physician. Technique was different for the first 25 patients. Patients underwent hormonal therapy, which makes it somewhat more difficult to discern the true effect of the cryosurgery.

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Greene GF, Pisters LL, Scott SM, et al	<i>The Journal of Urology</i>	1998	Case series	Biochemical failure Incidence of positive biopsies. (Disease progression was defined as a PSA increase greater than 2 ng/ml from the nadir or biopsy proven local recurrence.)	146 patients who underwent salvage cryotherapy Median followup 21 months (3-47 months) with serum PSA and DRE. Sextant biopsies performed. Patients received salvage cryo between 7/92-3/95. 37 patients received hormonal therapy.	40% of patients, PSA decreased to undetectable level within 3 months. 78% who underwent biopsy were negative for cancer. 10% in whom PSA nadir was 0.5 ng/ml or less, and 37% with higher PSA, had positive biopsy.	PSA nadir is a better prognostic indicator of biochemical/biopsy-proven failure than posttreatment PSA. Authors suggest that PSA nadir of 0.5 ng/ml or less should be achieved after cryosurgery. Limited statistical analysis provided.
Lee F, Bahn DK, and Badalament RA.	<i>unpublished abstract</i>		Case series	Biochemical failure (defined as maintenance of PSA < 0.1) Complications: Incontinence BOO/TUR Rectal injury Perineal pain	56 patients with radiation therapy failure; from Feb 1993- Jan1999. Patients followed for a median of 12 months (range 3-72 months) Patients separated into risk groups: low, moderate, high	DFS: 56% low risk 44% moderate risk 14% high risk	Unpublished material. Used actuarial data. No statistical analysis performed.

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Perrotte P, Litwin MS, McGuire EJ, et al	<i>The Journal of Urology</i>	1999	Retrospective survey	Modified UCLA Prostate cancer index Incontinence Pain Impotence Tissue sloughing Voiding symptoms Also, cryotherapy treatment parameters	150 patients with recurrent adenocarcinoma of the prostate who underwent salvage cryosurgery between 7/92-4/95 were surveyed. Age range 45-81 years Prior treatment included radiation therapy in 90 patients, combination of radiation, hormone therapy, and systemic chemotherapy in 22 patients. 112 (74%) were returned. Mean followup: 16.7 months (range 0.5-31.5)	Incontinence, perineal pain, tissue sloughing, and AUA symptoms score greater than 20 were associated with lack of an effective urethral warming catheter. Impotence was higher in the double freeze-thaw cycle group. 27% patients completely dry post treatment. 44% patients chronic perineal pain/discomfort Overall satisfaction was 33%.	Study primarily discussed incidence of events, which can significantly affect quality of life. Authors do point out complications can be significant, but urethral warming can reduce these complications. Of note, urethral warming is routinely used nowadays. Authors do point out that although cryotherapy is not better than salvage prostatectomy in terms of quality of life, it is not worse either. Specifically, note that incontinence rate was similar to salvage prostatectomy. Long time since completion of study to publication.

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Pisters LL, Perrotte P, Scott SM, et al	<i>Journal of Clinical Oncology</i>	1999	Case series	<p>Predictors of failure: Tumor stage and grade at initial diagnosis Type of prior therapy Stage/Grade of locally recurrent tumor # of positive biopsy cores at recurrence Precryo PSA level</p> <p>Disease free survival rate</p> <p>PSA < 0.1ng/mL was considered undetectable</p>	<p>145 patients, with locally recurrent adenocarcinoma of the prostate, undergoing salvage cryotherapy from 1992- 1995 (failure defined as increasing PSA level > 2ng/ml above postcryo nadir, or positive post- treatment biopsy.</p> <p>108 patients XRT only 37 patients combo of XRT, hormonal therapy, systemic chemo</p> <p>110 patients underwent biopsy</p>	<p>Patients with precryo PSA <10 ng/mL and history of XRT only, disease free survival at 2 years was 74%.</p> <p>For patients with PSA > 10, DFS was 28%. P<.00001 Gleason < 8, DFS 58% Gleason > 9 DFS 29% p<0.04 PSA < 10, DFS 74% for pts with prior history of XRT only, and 19% for patients with hormonal therapy + XRT p< 0.002</p>	<p>Article gives possible criteria for patients who salvage cryo is unlikely to work: Patients failing initial radiation therapy with a PSA > 10 ng/ml and Gleason score >9 are unlikely to be salvaged. Patients failing initial hormonal therapy and XRT are less likely to be successfully salvaged than patients failing radiation therapy alone.</p> <p>Authors note that DFS is 35-50% for patients after salvage prostactectomy</p> <p>Short study period Data reported actuarially</p> <p>Conducted at a single center.</p>