

## 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<br>All < 78yrs of age<br>Karnofsky status > 90<br>> 2 years post radiation<br>Negative CT and bone scans<br><br>Followup 3-60 months | 51.6% PSA < 0.5<br>26.9% PSA 0.5- 5.0<br>21.5% PSA > 5.0<br><br>5.3% at least one core-biopsy post-op<br>3.5% overall positive<br><br>22% were deemed clinical or biochemical failure<br><br>Pre-cryo predictive factors:<br>PSA > 5<br>Prostate size > 40gms<br>Stage > T3a<br>Gleason > 7 | Limited statistical analysis.<br>Abstract<br>Unclear of time frame of DFS<br>Attempt at defining s subpopulation most likely to benefit from this procedure. |

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| De la Taille, A,<br>Hayek O, Benson<br>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.<br>Mean age 69.4 years (48.1-83.6)<br>Mean PSA 7.07<br>26 pts Stage T1-T2<br>All patients had biopsy-proven recurrent prostate cancer.<br>Patients had received 3 months of combined hormonal therapy before cryosurgery.<br>Mean followup 21.9 months (1.2 - 54).<br>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<br>37% PSA < 4.0<br>3% PSA < 10<br><br>DFS 79% at 6 months<br>66% at 12 months<br><br>PSA nadir > 0.1ng/ml was an independent predictor of PSA recurrence<br><br>Complications:<br>Incontinence 9%<br>Obstruction 5%<br>Urethral stricture 5%<br>Rectal pain 26%<br>Urinary infection 9%<br>Scrotal edema 12%<br>Hematuria 5%<br><br>No patients died of prostate cancer or developed metastatic diseases, during the study period. | Short followup<br>Limited statistical analysis reported<br>All cryosurgeries were performed by a single physician.<br>Technique was different for the first 25 patients.<br>Patients underwent hormonal therapy, which makes it somewhat more difficult to discern the true effect of the cryosurgery. |

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

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| Perrotte P, Litwin MS, McGuire EJ, et al | <i>The Journal of Urology</i> | 1999 | Retrospective survey | <p>Modified UCLA Prostate cancer index</p> <p>Incontinence<br/>Pain<br/>Impotence<br/>Tissue sloughing<br/>Voiding symptoms</p> <p>Also, cryotherapy treatment parameters</p> | <p>150 patients with recurrent adenocarcinoma of the prostate who underwent salvage cryosurgery between 7/92-4/95 were surveyed. Age range 45-81 years</p> <p>Prior treatment included radiation therapy in 90 patients, combination of radiation, hormone therapy, and systemic chemotherapy in 22 patients.</p> <p>112 (74%) were returned. Mean followup: 16.7 months (range 0.5-31.5)</p> | <p>Incontinence, perineal pain, tissue sloughing, and AUA symptoms score greater than 20 were associated with lack of an effective urethral warming catheter.</p> <p>Impotence was higher in the double freeze-thaw cycle group.</p> <p>27% patients completely dry post treatment. 44% patients chronic perineal pain/discomfort</p> <p>Overall satisfaction was 33%.</p> | <p>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.</p> <p>Long time since completion of study to publication.</p> |

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