



Prostate and Renal Cryoablation

CLINICAL REVIEW GUIDE 2010

The information contained in this booklet is being provided for informational purposes only and does not contain all available published data on cryotherapy.

No specific claims (e.g. treatment of prostate cancer) are being made.

INTRODUCTION

As cryosurgery continues to grow as a therapy for cancer ablation, it is important to continue to review the published literature. The International Society of Cryosurgery (ISC) is pleased to present this clinical review guide which focuses on prostate studies with long term follow-up and renal studies published within the past two years.

In order to facilitate quick review, the summaries are presented in tabular format. The data primarily reflect the current version of cryosurgery (argon-based), but some long term follow-up data are included for patients that were treated with the old version of cryosurgery (nitrogen-based).

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KEY TERMS

- ASTRO criteria for biochemical failure of treatment for prostate cancer
 - 3 consecutive increases in PSA
- Phoenix (ASTRO II) criteria for biochemical failure of treatment for prostate cancer
 - PSA Nadir + 2 ng/mL
- BDFS
 - Biochemical Disease-Free Survival
- DSS
 - Disease-Specific Survival
- L, M, H
 - Low, Moderate and High Risk Patients according to the D'Amico classification system for prostate cancer
- Nadir
 - Lowest post-treatment PSA level
- Radiographic efficacy
 - No signs of tumor with contrast-enhanced CT or MRI

FULL GLAND PROSTATE DATA HIGHLIGHTS

- Timeframes up to 10 years³
- Over 6,000 patients studied¹⁻⁸
- Overall BDFS = 73%-90%¹⁻⁸
- Return to potency as high as 51% after 4 years³
 - Utilized active rehabilitation
- Rectal injury $\leq 0.5\%$ ^{1,3,5-8}
- Incontinence $< 8\%$ ^{1,4-8}
- Favorably compares to external beam radiation therapy²

FULL GLAND PROSTATE DATA SUMMARY

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2010 <i>J Urology</i> ¹	Dhar, <i>et al</i> (COLD Reg)	31.8	4099	5	75%	ASTRO (3 cons ↑)	0.4%	3.1%	32% (12 mo)
2010 <i>Cancer</i> ²	Donnelly, <i>et al</i>	100	117	7	73%	Phoenix (Nadir + 2)	N/A	N/A	29%
2008 <i>Urology</i> ³	Cohen, <i>et al</i>	147±33	370	10	80% (L) 74% (M) 46% (H)	Phoenix (Nadir + 2)	N/A	N/A	N/A
2008 <i>IBJU</i> ⁴	DiBlasio, <i>et al</i>	39.8	78	5	83%	ASTRO (3 cons ↑)	N/A	7.7%	26%
2007 <i>Urology</i> ⁵	Ellis, <i>et al</i>	20.4±14.7	416	4	84% (L) 82% (M) 69% (H)	ASTRO (3 cons ↑)	0.0%	4.0%	51% (48 mo)
2005 <i>Cancer</i> ⁶	Prepelica, <i>et al</i>	35	65	6	82% (H)	ASTRO (3 cons ↑)	N/A	3.1%	N/A
2002 <i>Urology</i> ⁷	Bahn, <i>et al</i>	68	590	7	92% (L) 89% (M) 89% (H)	ASTRO (3 cons ↑)	<0.1%	4.3%	5% (Unaided)
2001 <i>Urology</i> ⁸	Long, <i>et al</i>	24±16.5	975	5	76% (L) 67% (M) 41% (H)	>1.0 ng/mL	0.5%	7.5%	7% (Unaided)

SALVAGE PROSTATE DATA HIGHLIGHTS

- Timeframes up to 7 years¹²
- Over 1,000 patients studied^{1,9-14}
- Overall BDFS = 42%-69%^{1,9-14}
 - 42% BDFS study used unusual definition of 2 consecutive rises in PSA⁹
 - 42% BDFS study still showed 96% disease-specific survival⁹
- Return to potency for largest study = 40%¹
- Rectal injury $\leq 2.2\%$ ^{1,10,11,14}
- Incontinence $\leq 13\%$ ^{1,10,11,14}

SALVAGE PROSTATE DATA SUMMARY

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2010 <i>J Urology</i> ¹	Dhar, <i>et al</i> (COLD Reg)	38.5	594	5	69%	ASTRO (3 cons ↑)	1.5%	12% (12 mo)	40% (12 mo)
2009 <i>J Urology</i> ⁹	Pisters, <i>et al</i>	66	56	5	42% (BDFS) 96% (DSS)	2 cons ↑	N/A	N/A	N/A
2008 <i>J Urology</i> ¹⁰	Ismail, <i>et al</i>	33.5	100	5	73% (L) 45% (M) 11% (H)	ASTRO (3 cons ↑)	1%	13%	14%
2005 <i>Pros Can PD</i> ¹¹	Donnelly, <i>et al</i>	N/A	46	2	58%	>1.0 ng/mL	2.2%	4.3%	85%
2003 <i>Clin Pros Ca</i> ¹²	Bahn, <i>et al</i>	N/A	59	7	69%	>1.0 ng/mL	N/A	N/A	N/A
2002 <i>J Clin Oncol</i> ¹³	Izawa, <i>et al</i>	57.6	131	5	57% (L) 23% (H)	Phoenix (Nadir + 2)	N/A	N/A	N/A
2002 <i>Rvw Urology</i> ¹⁴	Katz, <i>et al</i>	N/A	38	3	65%	Nadir + 0.3 ng/mL	0.0%	7.9%	N/A

LAPAROSCOPIC RENAL DATA HIGHLIGHTS

- Up to 7 years of follow-up²⁰
- Over 500 patients studied in last 2 years²⁰⁻²⁸
- Radiographic efficacy = 83%-100%²⁰⁻²⁸
- No significant renal impairment following the procedure³⁷
- Efficacy data suggest better outcomes from cryoablation than radiofrequency ablation²⁸

LAPAROSCOPIC RENAL DATA HIGHLIGHTS

Publication	Author	Method	Average Follow-Up (months)	Number of Patients	Radiographic Efficacy	Bleeding	Other Complications
2010 <i>J Urology</i> ²⁶	Aron, <i>et al</i>	Laparoscopic	96	80	90%	N/A	N/A
2010 <i>J Urology</i> ²⁰	Yoost, <i>et al</i>	Laparoscopic	13	45	83%	N/A	N/A
2010 <i>J Urology</i> ²¹	Tsivian, <i>et al</i>	Laparoscopic	20	163	96%	N/A	N/A
2009 <i>J Endourology</i> ²²	Malcolm, <i>et al</i>	Percutaneous Laparoscopic	30 39	20 52	95%* 96% *20% Retreat	0% 3.8%	N/A N/A
2009 <i>J Endourology</i> ²³	Badger, <i>et al</i>	Laparoscopic	22	27	100%	0%	7% (Major) 18.5% (Minor)
2008 <i>J Endourology</i> ²⁴	Derweesh, <i>et al</i>	Percutaneous Laparoscopic	25 25	26 34	89% 97%	3.8% 2.9%	23% 11.7%
2008 <i>ASR</i> ²⁵	Hinshaw, <i>et al</i>	Percutaneous Laparoscopic	14.5 14.6	30 46	100% 98%	0% 0%	13% 8.7%
2008 <i>J Urology</i> ²⁷	Finley, <i>et al</i>	Percutaneous Laparoscopic	11.4 13.4	18 19	95% 96%	11% 25%	11% 15%
2008 <i>J Urology</i> ²⁸	Weight, <i>et al</i>	Laparoscopic	6	139	90%	N/A	N/A

PERCUTANEOUS RENAL CLINICAL DATA HIGHLIGHTS

- Up to 3 years follow-up³³
- Over 300 patients studied in last 2 years^{22,24,25,27,32-36}
- Radiographic efficacy = 89%-100%^{21,23,27-31}
- Efficacy can be improved to 100% with second cryoablation of persistent disease³⁶
- Mean increase of creatinine = 0.1 mg/dL (range -0.4 – 2.0)³³
- Fewer complications compared to laparoscopic renal cryoablation²⁷

PERCUTANEOUS RENAL CLINICAL DATA HIGHLIGHTS

Publication	Author	Method	Average Follow-Up (months)	Number of Patients	Radiographic Efficacy	Bleeding	Other Complications
2009 <i>J Endourology</i> ²²	Malcolm, <i>et al</i>	Percutaneous Laparoscopic	30	20	95%*	0%	N/A
			39	52	96% *20% Retreat	3.8%	N/A
2008 <i>J Endourology</i> ²⁴	Derweesh, <i>et al</i>	Percutaneous Laparoscopic	25	26	89%	3.8%	23%
			25	34	97%	2.9%	11.7%
2008 <i>AJR</i> ²⁵	Hinshaw, <i>et al</i>	Percutaneous Laparoscopic	14.5	30	100%	0%	13%
			14.6	46	98%	0%	8.7%
2008 <i>SIR</i> ³²	Georgiades, <i>et al</i>	Percutaneous	7	40	100%	4%	18%
2008 <i>J Urology</i> ³³	Atwell, <i>et al</i>	Percutaneous	13.3	80	96%	2.7%	3.6%
2008 <i>J Urology</i> ²⁷	Finley, <i>et al</i>	Percutaneous Laparoscopic	11.4	18	95%	11%	11%
			13.4	19	96%	25%	15%
2008 <i>SIR Podium</i> ³⁴	Saad, <i>et al</i>	Percutaneous	6.4	32	94%	6.2%	3.1%
2008 <i>SIR Podium</i> ³⁵	Auon, <i>et al</i>	Percutaneous	15.6	65	94%	N/A	4%
2008 <i>SIR Poster</i> ³⁶	Gibson	Percutaneous	11	27	89%	0%	0%

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