

UroCryo™ Ablation

CLINICAL DATA REVIEW

2015



Primary Prostate Data Summary

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2014 <i>J Urology</i> ¹	Levy, <i>et al</i> (COLD Registry)	> 60	891 (with nadir <0.4 ng/mL)	5	90% (L) 81% (M) 74% (H)	ASTRO II (Nadir + 2)	N/A	N/A	N/A
2012 <i>J Urology</i> ²	Levy, <i>et al</i> (COLD Registry)	> 60	1,280	5	N/A	N/A	0.2%	3.4%	33% (12 mo)
2010 <i>Cancer</i> ³	Donnelly, <i>et al</i>	100	122	7	73%	ASTRO II (Nadir + 2)	1% (≥ Grade 3)	1% (≥ Grade 3)	29% (36 mo)
2008 <i>Urology</i> ⁴	Cohen, <i>et al</i>	147	370	10	80% (L) 74% (M) 46% (H)	ASTRO II (Nadir + 2)	N/A	N/A	N/A
2007 <i>Urology</i> ⁵	Ellis, <i>et al</i>	20	416	4	84% (L) 82% (M) 69% (H)	ASTRO (3 cons ↑)	0.0%	4.0%	51% (48 mo)
2002 <i>Urology</i> ⁶	Bahn, <i>et al</i>	68	590	7	92% (L) 89% (M) 89% (H)	ASTRO (3 cons ↑)	<0.1%	4.3%	5% (Unaided)

Salvage Prostate Data Summary

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2012 <i>J Urology</i> ⁷	Spiess, <i>et al</i> (COLD Registry)	52	132	5	46%	ASTRO II (Nadir + 2)	0.7%	N/A	N/A
2008 <i>J Urology</i> ⁸	Hamoui, <i>et al</i>	95	110	10	40% (BDFS) 80% (DSS)	ASTRO II (Nadir + 2)	N/A	41%	N/A
2008 <i>J Urology</i> ⁹	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> ¹⁰	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> ¹¹	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> ¹²	Izawa, <i>et al</i>	58	131	5	57% (L) 23%(H)	ASTRO II (Nadir + 2)	N/A	N/A	N/A

Laparoscopic Renal Data Summary

Publication	Author	Average Follow-Up (months)	Number of Patients	Local Control	Bleeding Requiring Transfusion
2015 <i>Uro Onc</i> ¹³	Larcher, <i>et al</i>	48	174	95%	8%
2014 <i>Urology</i> ¹⁴	Kim, <i>et al</i>	71	145	84%	N/A
2014 <i>Urology</i> ¹⁵	Johnson, <i>et al</i>	98	92	91%	5%
2012 <i>Euro Uro</i> ¹⁶	Guillotreau, <i>et al</i>	44	220	89%	0%
2011 <i>J Endourology</i> ¹⁷	Klatte, <i>et al</i>	34	41	89%	0%
2010 <i>Urology</i> ¹⁸	Tsivian, <i>et al</i>	20	163	96%	1%
2010 <i>J Urology</i> ¹⁹	Aron, <i>et al</i>	96	80	90%	N/A

Key Terms

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

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