



# Prostate and Renal Cryoablation

## CLINICAL REVIEW GUIDE

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.

*This Clinical Review Guide is made possible by a grant from Endocare, Inc.*



# 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 studies with 2-10 year perspectives for prostate cancer and 0.5 - 7 year perspectives for renal cancer.

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).

The ISC would like to thank Endocare, Inc. for its help in sponsoring the development of this clinical review guide.

Franco Lugnani, MD  
President  
International Society of Cryosurgery  
Casa di Cura Salus  
Via Bonaparte 4  
34100 Trieste  
Italy  
Email: [info@lugnani.com](mailto:info@lugnani.com)

# TOTAL GLAND CLINICAL DATA HIGHLIGHTS

- Timeframes up to 10 years<sup>1,2</sup>
- Over 5,000 patients studied<sup>1-7</sup>
- Overall BDFS = 80%-90%<sup>1-7</sup>
  - Lowest efficacy from 2001 study included old technology<sup>7</sup>
- Return to potency > 50% after 4 years<sup>3</sup>
  - Increased using Ellis' rehabilitation approach<sup>3</sup>
- Rectal injury  $\leq 0.5\%$ <sup>1,3,5-7</sup>
- Incontinence < 5% for post-2001 studies<sup>1,3-6</sup>
- Favorably compares to other treatments<sup>7,11,12</sup>

# TOTAL GLAND CLINICAL DATA SUMMARY

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2008 <i>J Urology</i> <sup>1</sup>	Katz, <i>et. al</i> (COLD Reg)	29.7±25.7	2558	10	89% (L) 84% (M) 80% (H)	ASTRO (3 cons ↑)	0.2%	1.6%	41% (24 mo)
2008 <i>Urology</i> <sup>2</sup>	Cohen, <i>et. al</i>	147±33	370	10	80% (L) 74% (M) 46% (H)	ASTRO II (Nadir + 2)	N/A	N/A	N/A
2007 <i>Urology</i> <sup>3</sup>	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> <sup>4</sup>	Prepelica, <i>et. al</i>	35	65	6	82% (H)	ASTRO (3 cons ↑)	N/A	3.1%	N/A
2002 <i>Urology</i> <sup>5</sup>	Donnelly, <i>et. al</i>	50	76	5	75% (L) 89% (M) 76% (H)	>1.0 ng/mL	0.0%	1.3%	47% (36 mo)
2002 <i>Urology</i> <sup>6</sup>	Bahn, <i>et. al</i>	68	590	7	92% (L) 89% (M) 89% (H)	ASTRO II (3 cons ↑)	<0.1%	4.3%	5% (Unaided)
2001 <i>Urology</i> <sup>7</sup>	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 CLINICAL DATA HIGHLIGHTS

- Timeframes up to 10 years<sup>9</sup>
- Close to 900 patients studied<sup>8-14</sup>
- Overall BDFS = 40%-69%<sup>8-14</sup>
  - 40% BDFS still had 80% disease-specific survival<sup>9</sup>
- Potency for largest study = 38%<sup>8</sup>
- Rectal injury  $\leq 2.2\%$ <sup>8,10,14</sup>
- Incontinence for largest study = 6.3%<sup>8</sup>

# SALVAGE CLINICAL DATA SUMMARY

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2008 <i>J Urology</i> <sup>8</sup>	Pisters, <i>et. al</i> (COLD Reg)	N/A	413	5	59%	ASTRO (3 cons ↑)	0.8%	6.3% (12 mo)	38%
2008 <i>J Urology</i> <sup>9</sup>	Hamoui, <i>et. al</i>	95	110	10	40% (DFS) 80% (DSS)	ASTRO II (Nadir + 2)	N/A	41%	N/A
2008 <i>J Urology</i> <sup>10</sup>	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> <sup>11</sup>	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> <sup>12</sup>	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> <sup>13</sup>	Izawa, <i>et. al</i>	57.6	131	5	57% (L) 23% (H)	ASTRO II (Nadir + 2)	N/A	N/A	N/A
2002 <i>Rvw Urology</i> <sup>14</sup>	Katz, <i>et. al</i>	N/A	38	3	65%	Nadir + 0.3 ng/mL	0.0%	7.9%	N/A

# PARTIAL GLAND CLINICAL DATA HIGHLIGHTS

- Timeframes up to 10 years<sup>17</sup>
- Over 500 patients studied<sup>15-19</sup>
- Overall BDFS = 80%-93%<sup>15-19</sup>
- Return to potency > 70% after 1 year<sup>15-19</sup>
  - Ranges as high as 89%<sup>19</sup>
- Rectal injury  $\leq$  0.3%<sup>15-19</sup>
- Incontinence < 4%<sup>15-19</sup>
  - Several studies report no incontinence in cases in which no prior treatment of the prostate had occurred<sup>17-19</sup>

# PARTIAL GLAND CLINICAL DATA SUMMARY

Publication	Author	Average Follow-Up (months)	Number of Patients	Timeframe (years)	BDFS	Failure Basis	Rectal Injury	Incontinence	Potency
2008 <i>J Urology</i> <sup>15</sup>	Ellis, <i>et. al</i> (COLD Reg)	16.3±12.5	341	4	83%	ASTRO (3 cons ↑)	0.3%	1.6% (12 mo) 0% (24 mo)	51% (6 mo) 74% (36 mo)
2007 <i>Urology</i> <sup>16</sup>	Ellis, <i>et. al</i>	15.2±7.4	60	2	80% (1st) 93% (2nd)	ASTRO (3 cons ↑)	0.0%	3.6% (6 mo)	71% (12 mo)
2007 <i>Urology</i> <sup>17</sup>	Onik, <i>et. al</i>	43	55	10	90%	ASTRO (3 cons ↑)	0.0%	0.0%	85%
2007 <i>Urology</i> <sup>18</sup>	Lambert, <i>et. al</i>	28	25	3	88%	ASTRO II (Nadir + 2)	0.0%	0.0%	71%
2006 <i>Endourology</i> <sup>19</sup>	Bahn, <i>et. al</i>	70	31	6	93%	ASTRO (3 cons ↑)	0.0%	0.0%	89%

# LAP RENAL CLINICAL DATA HIGHLIGHTS

- Up to 7 years of follow-up<sup>20</sup>
- Over 500 patients studied in last 2 years<sup>20-26</sup>
- Efficacy = 85%-100%<sup>20-26</sup>
- No significant renal impairment following the procedure<sup>25</sup>
- Efficacy data suggest better outcomes from cryoablation than radiofrequency ablation<sup>22,25</sup>

# LAP RENAL CLINICAL DATA SUMMARY

Publication	Author	Method	Average Follow-Up (months)	Number of Patients	Radiographic Efficacy	Bleeding	Other Complications
2008 <i>J Urology</i> <sup>20</sup>	Aron, <i>et. al</i>	Laparoscopic	83	88	94%	N/A	N/A
2008 <i>J Urology</i> <sup>21</sup>	Finley, <i>et. al</i>	Percutaneous Laparoscopic	10.2 6.2	18 19	95% 96%	11% 21%	5.5% 5.3%
2008 <i>J Urology</i> <sup>22</sup>	Weight, <i>et. al</i>	Laparoscopic	6	139	90%	N/A	N/A
2007 <i>AUA Poster</i> <sup>23</sup>	Landman, <i>et. al</i>	Percutaneous Laparoscopic	16 7	53 35	96% 100%	0% 23%	0% 11.4%
2006 <i>Urology</i> <sup>24</sup>	Davol, <i>et. al</i>	Laparoscopic/ Open	36	40	85%	4%	10.4%
2006 <i>Urology</i> <sup>25</sup>	Hegarty, <i>et. al</i>	Laparoscopic/ Open	35	161	96%	3%	3.7%
2006 <i>Urology</i> <sup>26</sup>	Schwartz, <i>et. al</i>	Laparoscopic/ Open	10	84	96%	1.2%	3.6%

# PERC RENAL CLINICAL DATA HIGHLIGHTS

- Approaching from minimum 1.5 year follow-up up to 5 years<sup>23,27</sup>
- ~ 300 patients studied in last 2 years<sup>21,23,27-31</sup>
- Efficacy  $\geq 89\%$  (range 89-100%)<sup>21,23,27-31</sup>
- Efficacy can be improved to 100% with second cryoablation of persistent disease<sup>30</sup>
- Mean increase of creatinine = 0.1mg/dL (range -0.4 – 2.0)<sup>27</sup>
- Fewer complications compared to laparoscopic renal<sup>21,23</sup>

# PERC RENAL CLINICAL DATA SUMMARY

Publication	Author	Method	Average Follow-Up (months)	Number of Patients	Radiographic Efficacy	Bleeding	Other Complications
2008 <i>J Urology</i> <sup>27</sup>	Atwell, <i>et. al</i>	Percutaneous	13.3	80	96%	2.7%	3.6%
2008 <i>J Urology</i> <sup>21</sup>	Finley, <i>et. al</i>	Percutaneous Laparoscopic	10.2 6.2	18 19	95% 96%	11% 21%	5.5% 5.3%
2008 SIR Podium <sup>28</sup>	Saad, <i>et. al</i>	Percutaneous	6.4	32	94%	6.2%	3.1%
2008 SIR Podium <sup>29</sup>	Auon, <i>et. al</i>	Percutaneous	15.6	65	94%	N/A	4%
2008 SIR Poster <sup>30</sup>	Gibson	Percutaneous	11	27	89%	0%	0%
2007 AUA Poster <sup>23</sup>	Landman, <i>et. al</i>	Percutaneous Laparoscopic	16 7	53 35	96% 100%	0% 23%	0% 11.4%
2006 <i>J Urology</i> <sup>31</sup>	Permpong- kosol, <i>et. al</i>	Percutaneous	12.3	21	90%	9.5%	14.3%

# GLOSSARY

- ASTRO criteria for biochemical failure
  - 3 consecutive increases in PSA
- ASTRO II (Phoenix) criteria for biochemical failure
  - 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
- Lap Renal
  - Laparoscopic Renal Cryoablation
- Nadir
  - Lowest post-treatment PSA level
- Perc Renal
  - Percutaneous Renal Cryoablation
- Radiographic efficacy
  - No signs of tumor with contrast-enhanced CT or MRI

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Aron M (Cleveland Clinic)  
Atwell TD (Mayo Clinic, Rochester, MN)  
Auon HD (Wayne State University, Detroit, MI)  
Bahn DK (Prostate Institute of America, Community Memorial Hospital, Ventura, CA)  
Badalament R (Crittenton Hospital, Rochester, MI)  
Chinn DO (Alhambra Hospital, Arcadia, CA)  
Clayman RV (University of California, Irvine)  
Cohen JK (Drexel University, Philadelphia, PA)  
Davol PE (Geisinger Health System, Danville, PA)  
Desai MM (Cleveland Clinic)  
Dineen M (Atlantic Urological Assoc, Daytona Beach, FL)  
Donnelly BJ (University of Calgary)  
Ellis DS (Urology Associates of N Texas, Arlington)  
Finley DS (Long Beach Memorial Medical Center, CA)  
Gibson MA (Eastern Virginia Medical School, Norfolk)  
Gill IS (Cleveland Clinic)  
Greski J (Crittenton Hospital, Rochester, MI)  
Hamoui O (Tampa, FL)  
Hegarty NJ (Cleveland Clinic)  
Ismail M (Guildford, UK)  
Izawa JI (MD Anderson Cancer Center, Houston, TX)  
Jones JS (Cleveland Clinic)  
Katz AE (Columbia University, NY)  
Kauok JH (Cleveland Clinic)  
Kavoussi LR (Long Island Jewish Medical Center, NY)  
Kumar A (Crittenton Hospital, Rochester, MI)  
Lambert EH (Columbia University, NY)  
Landman J (Columbia University, NY)  
Lee F (Karmanos Cancer Center, Detroit, MI)  
Link RE (Baylor University, Houston, TX)  
Littrup PJ (Karmanos Cancer Center, Detroit, MI)  
Long JP (Tufts-New England Medical Center, Boston, MA)  
Lugnani F (ISC Trieste, Italy)  
Macaluso JN Jr (Urological Institute of New Orleans)  
Manny TB Jr (University of Texas SW Medical School, Dallas)  
Onik G (Celebration Health/Florida Hospital)  
Permpongkosol S (Johns Hopkins University, Baltimore, MD)  
Pisters LL (MD Anderson Cancer Center, Houston, TX)  
Prepelica KL (Columbia University, NY)  
Rukstalis KL (Geisinger Health System, Danville, PA)  
Saad NEA (Washington University, St Louis, MO)  
Schwartz BF (Southern Illinois University, Springfield, IL)  
Scionti S (Coastal Carolina Urology, Hilton Head, SC)  
Shingleton B (Louisiana State University, Shreveport, LA)  
Shinohara K (University of California, San Francisco)  
Silverman P (Prostate Institute of America, Community Memorial Hospital, Ventura, CA)  
Solomon SB (Memorial Sloan-Kettering Cancer Center, NY)  
Weight CJ (Cleveland Clinic)  
Wiegard L (MD Anderson Cancer Center, Houston, TX)

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# ISC OVERVIEW

The International Society of Cryosurgery (ISC) was founded in 1974 to promote continuing medical education in the field of cryosurgery from an experimental and clinical point of view. The overall aim of the ISC is to continue to develop and expand membership of the society.

The headquarters of the Society are based in Casa di Cura Salas, Trieste, Italy. The Society corresponds with approximately 700 members worldwide. Membership is open to anyone who has a professional interest in research and education in the fields of cryosurgery, cryobiology, cryopreservation and other disciplines related to the use of low temperature in medicine.

A major world congress (autumn) is held in different continents every 2 years with a wide-ranging scientific program covering all areas of cryosurgery and cryobiology. The Society also recognizes significant scientific achievements by younger researchers via special awards.

Apart from the main meeting, the ISC organizes regional activities and meetings in each continent (Europe, Asia and Far East, Americas, Australasia, Africa and Middle East). These meetings are organized by members of the ISC Board who are based on the respective continent. These activities can be viewed at [www.societyofcryosurgery.org](http://www.societyofcryosurgery.org).

The Society produces a biannual publication Cryosurgery which is available at [www.societyofcryosurgery.org](http://www.societyofcryosurgery.org) and covers all aspects of cryosurgery and cryobiology.

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Casa di Cura Salus  
Via Bonaparte 4  
34100 Trieste  
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*This Clinical Review Guide is made possible by a grant from Endocare, Inc.*

