

Best Practice Statement on Cryosurgery for the Treatment of Localized Prostate Cancer

Babaian RJ, Donnelly B, Bahn D, Baust JG, Dineen M, Ellis D, Katz A, Pister L, Rukstalis D, Shinohara K, and Thrasher JB
American Urological Association Education and Research, Inc.

J Urol 2008, 180: 1993-2004

HIGHLIGHTS

- AUA Practice Guidelines Committee and Board of Directors consensus opinion is
 - Primary cryosurgery is an option for clinically organ-confined prostate cancer of any grade with a negative metastatic evaluation
 - Salvage cryosurgery can be considered as a treatment option for men who failed radiation therapy
- HRQL – Cryosurgery (compared to brachytherapy) has superior AUA symptom scores at three months for irritative and obstructive symptoms

BACKGROUND

- The 2007 AUA Guideline for Management of Clinically Localized Prostate Cancer did not include cryosurgery in data meta-analysis
- Prostate cryosurgery can result in acceptable HRQL-based outcomes with a reduced cost when compared to other local therapeutic options
- Technological advances provide real-time control of ice ball formation for ablation precision and minimized harm to adjacent tissue

OBJECTIVE

- To develop an AUA Best Practice Statement (BPS) addressing use of cryosurgery for prostate cancer for primary applications, salvage applications and subtotal applications
- To suggest, based on scientific principles, specific procedural requisites which should be followed

METHODS

- AUA convened a Panel of 11 prostate treatment experts to review selected publications and, through a consensus process, to develop panel recommendations
- Medline search performed for publications from 2000 through 2008
- BPS document peer reviewed, approved by AUA Practice Guideline Committee

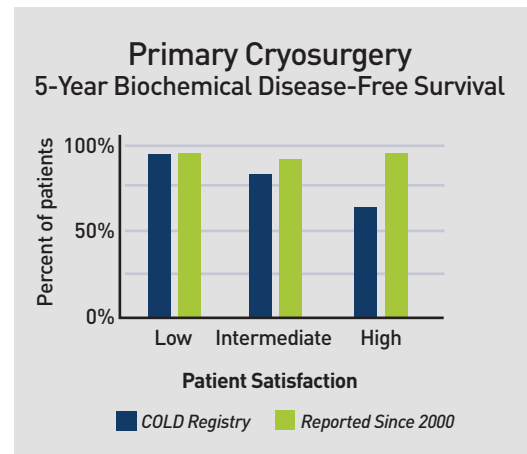
RESULTS AND DISCUSSION

Procedural requisites to maximize destructive effects of cryosurgery

- Employ rapid freeze rate to -40° nadir temperature
- Monitor tissue temperatures to evaluate status of freezing zone and protection of critical structures
 - Thermocouples
 - Hyperechoic ultrasound images
- Slowly thaw tissue
- Use double freeze-thaw cycles

Primary cryosurgery – Cryoablation is an appropriate option (Evidence Level II-2/3)

- Patient selection
 - Documented cancer clinically confined to prostate
 - Best results in patients with PSA levels less than 10 ng/mL
- HRQL – Cryosurgery has superior AUA symptom scores at three months for irritative and obstructive symptoms
- Outcomes – Disease free biochemical outcomes at 5 years (COLD registry, Phoenix definition): low risk patients – 91%; intermediate risk patients – 78%; high risk patients – 62%; survival rates reported since 2000: 92%, 89% and 91% respectively
- Complication – Erectile dysfunction is the primary complication; penile rehabilitation following cryoablation may result in potency rate of 41.4% at one year, 51.3% at four years
- Relative contraindication – Prior history of TURP



Salvage Cryosurgery – Cryosurgery can be considered as a treatment option (Evidence Level II-3)

- Patient selection
 - Men who failed radiation therapy
 - PSA \leq 4 ng/mL, a long PSA doubling time
 - Pathologic evidence of locally recurrent disease without clinical evidence of metastatic disease
 - No evidence of seminal vesicle invasion
- Technical considerations
 - Radioactive seeds visualized under TRUS may appear similar to tip of cryoneedles: place needles in sagittal plane so needle length is visualized
 - Reduced space (less than 5mm) between anterior rectal wall and posterior capsule: terminate freezing when leading edge of ice ball extends just beyond the capsule
- Outcomes – Biochemical failure-free rates: 74% at one year (Han); 66% at one year (de la Taille)
- Complications – Erectile dysfunction, incontinence, rectal pain
- HRQL – Return to preoperative levels by 24 months in all domains except urinary and sexual functioning
- Relative contraindication – Prior TURP

Subtotal Prostate Cryosurgery – Theoretical potential, but limited clinical experience (Evidence Level III)

CONCLUSIONS

- Clinical evidence documents 7-8 year biochemical disease free results following prostate cancer cryosurgery
- Technological advances over last 15 years improved morbidity profile in all aspects

www.galilmedical.com

Galil Medical

4364 Round Lake Road
Arden Hills, MN 55112
877.639.2796 Phone

