



Salvage Cryotherapy is an Effective and Efficacious Treatment Option with a Curative Intent for Radiorecurrent Prostate Cancer^{1, 2, 3}

Well-defined Patient Selection Criteria

- **AUA 2008⁴ and NCCN 2011⁵ Guidelines:**
 - PSA <10 ng/mL
 - Life expectancy of >10 year
 - A long PSA doubling-time of ≥ 16 months
 - Absence of seminal vesicle invasion
 - A positive biopsy and a negative metastatic evaluation

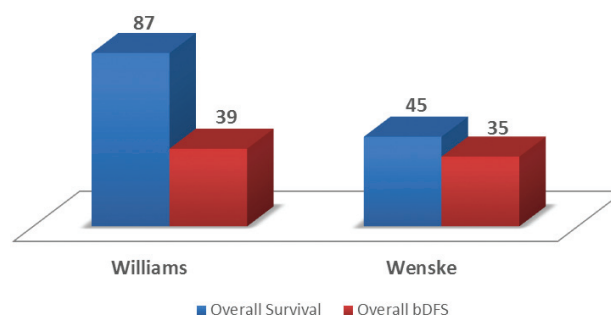
Better Definition of an Ideal Salvage Cryoablation Patient

- **Strong predictors for a positive salvage cryoablation (CSA) treatment outcome:**
 - Low pre-salvage PSA | PSA <4 ng/mL^{1,4}
 - Post-salvage nadir PSA <0.6 ng/mL indicates favorable biochemical progression-free survival (bPFS)⁶
 - Post-salvage nadir PSA >0.1 ng/mL indicates a likelihood of early disease recurrence^{1,7}
- **Patients with a higher risk profile:**
 - Post-salvage nadir PSA >2.5 ng/mL⁶, or
 - Pre-salvage biopsy Gleason PSA score ≥ 7 ⁶
- **Time to reach normal PSA:**
 - Post-salvage nadir PSA 0.2 ng/mL at 2.6 months (10-year data)³
 - Post-salvage nadir PSA 0.17 ng/mL at 4.3 years⁶
 - Biochemical failures for salvage cryoablation (SC) tend to occur before 3 years¹

Excellent Oncological Outcome and Local Control

- High local control | 17.6% positive post-salvage biopsy⁷
- Low risk of metastases | 10-year metastatic-free survival rate at 82%⁷
- Prolonged patient lives | 45 - 87% of patients alive after 10 years^{3, 7}
- Reduced risk of dying from prostate cancer (PCa) | 35 - 39% disease-free survival (bDFS) after 10 years^{3, 7}

10-Year Overall Survival and Disease-Free Survival (%)

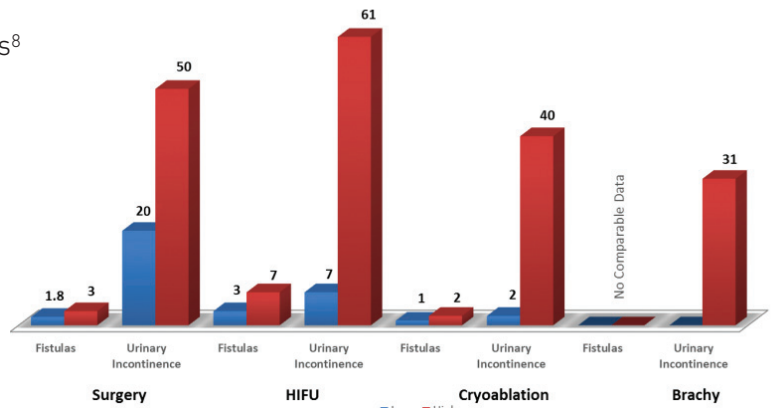


Williams⁷ | Single-center | 1994 - 2004
Total patients | 176
> 10 yr. follow-up | 30% (52 patients)

Wenske³ | Single-center | 1994 - 2011
Total patients | 328
> 10 yr. follow-up | 11% (36 patients)

Minimal Morbidities and Complications

- Less morbidities than other salvage treatment options⁸
- High likelihood of preserving urinary continence with the use of Multi-Point Thermal Sensors (MTS™) | 2.6 - 5% urinary incontinence^{2, 3}
- Low complications | 1 - 2% rectourethral fistula^{2, 3}
- Few side-effects compared to hormone therapy⁹

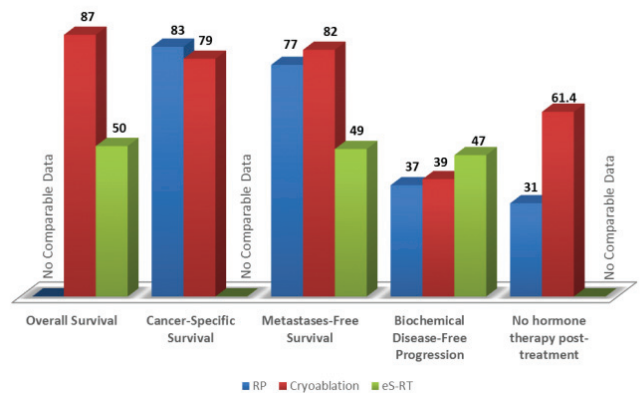


Source: Bjerkklund Johansen T.E.⁸

Comparable Oncological Outcomes Compared to Surgery

- CSA is an alternative to Radical Prostatectomy (RP) or surgery^{2, 8}:
 - Minimally invasive procedure
 - Technically less challenging
 - Less morbidity
 - Better cancer control
- CSA has better oncological outcome data and lower complication rate than salvage HIFU⁸
- NCCN 2011 Guidelines does not endorse hormone therapy for prostate biopsy-positive, non-metastatic local recurrences⁵
- The use of early adjuvant salvage radiation (eS-RT) or to delay S-RT in margin-positive disease is an ongoing debate⁸

10-Year Clinical Data on Salvage RP, Cryoablation and RT (%)



Source: Bjerkklund Johansen T.E. and Wenske S. (Cryoablation CSS data)^{3, 8}

* Overall survival and metastases-free survival data for eS-RT are 15-years data.

References

1. Finley DS and Belldgrun AS. Salvage cryotherapy for radiation-recurrent prostate cancer: outcomes and complications. *Curr Urol Rep.* 2011; 12(3): 209-215.
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3. Wenske S, Quarrier S and Katz A. Salvage cryosurgery of the prostate for failure after primary radiotherapy or cryosurgery: long-term clinical, functional, and oncological outcomes in a large cohort at a tertiary referral centre. *Eur Urol.* 2013; 64: 1-7.
4. Babaian RJ, Donnelly B and Thrasher JB, et. al. Best practice statement on cryosurgery for the treatment of localized prostate cancer. *J Urol.* 2009; 180: 1993-2004.
5. NCCN 2011 guidelines version 1.2012 prostate cancer. PROS-7.
6. Spiess PE, Levy DA and Jones JS, et. al. Predictors of biochemical failure in patients undergoing prostate whole-gland salvage cryotherapy: a novel risk stratification model. *BJUI* 2013; doi: 10.1111/j.1464-410X.2012.11695.
7. Williams AK, Marti'nez CH and Chin JL, et. al. Disease-free survival following salvage cryotherapy for biopsy-proven radio-recurrent prostate cancer. *Eur Urol.* 2011; 60: 405-410.
8. Bjerkklund Johansen TE, Witzsch U. and Greene D. Salvage treatment in prostate cancer: a clinical approach. *Expert Rev Anticancer Ther.* 2013; 13: 613-623.
9. Schwandt A and Garcia JA. Complications of androgen deprivation therapy in prostate cancer. *Curr Opin Urol* 2009; 19: 322-6.

Indications for Use

The Galil Medical Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures; various Galil Medical ancillary products are required to perform these procedures. Galil Medical Cryoablation Systems are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology, proctology and urology. These Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, and skin lesions) by the application of extremely cold temperatures.

A full list of specific indications can be found in the Galil Medical Cryoablation System User Manuals.

Contraindications There are no known contraindications.

Warnings / Precautions / Adverse Events

A thorough understanding of the technical principles, clinical applications, and risks associated with cryoablation procedures is necessary before using Galil Medical products to conduct cryoablation. Use of such products should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a Galil Medical Cryoablation System.

A full list of the warnings, precautions, and adverse events can be found by referencing the respective device Instructions for Use document or Cryoablation System User Manual.

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