

**Boston
Scientific**

Advancing science for life™



CRYOABLATION
RENAL CELL CARCINOMA

Advancing Innovation

Boston Scientific is committed to creating a world where we can treat any condition with minimal intervention. This commitment includes the world's leading technology in cryoablation.

- Real time ablation zone monitoring
- Flexibility of needle options to tailor your treatment
- Precise control allows you to sculpt—the optimal ablation zone
- Progressive cryoablation software platform simplifies procedure
- Advanced technology drives innovative capabilities

Cryoablation has the clear merit of physically demonstrating its tissue effects through the radiologically demonstrable iceball that is induced around the clustered cryoprobes and this permits the ablation to be carefully assessed during the course of the procedure.

- BREEN DJ ET AL. 2013¹

Oncologic outcomes of image guided renal cryoablation for RCC are competitive with those of partial nephrectomy and are associated with a low complication rate.

- BREEN DJ ET AL. 2018²

Percutaneous cryoablation was associated with a high disease-specific survival (94%) and better overall survival compared with partial or radical nephrectomy.

- MORKOS J, ET AL., 2020³



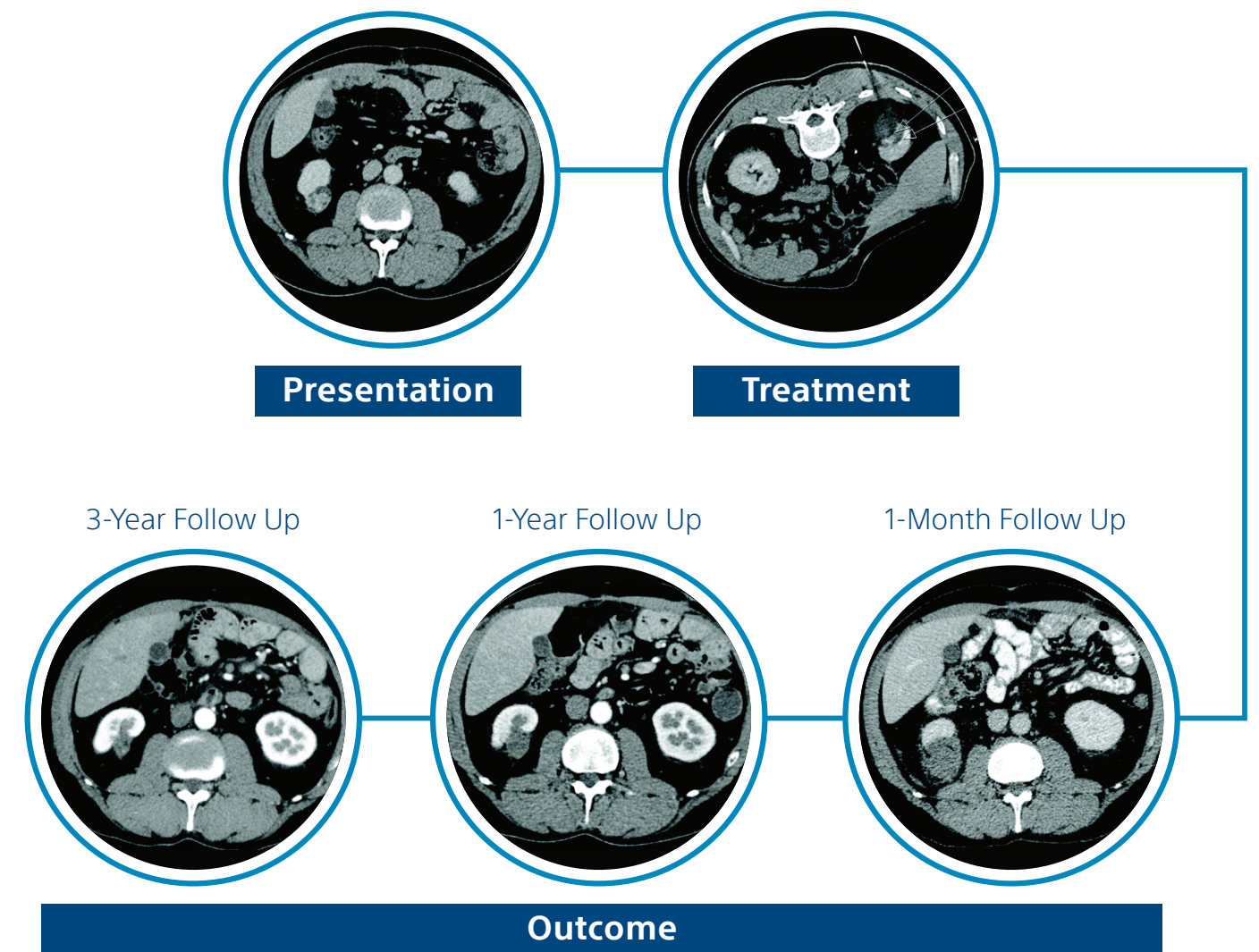
Kidney Cryoablation

An established, proven therapy that gives you visibility and control

Overview

- Supported by major guidelines, including, National Comprehensive Cancer Network (NCCN), American Urological Association (AUA), European Association of Urology (EAU), Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
- Comparable oncologic outcomes to resection/LPR, with lower complication rate and shorter hospital stay^{2,3,4,5}
- Over 27 years of published data⁶
- Improved outcomes vs Radiofrequency Ablation (RFA)^{6,7,8}
- Suitable for use in traditionally 'unablatable' tumor locations:
 - Into the collecting system^{9,10}
 - Near critical structures²
 - Effective in T1a and T1b tumors*^{2,4,11,12,13}

Cryoablation of 3 cm Exophytic Right RCC



Images courtesy of Dr Alex King, University Hospital Southampton, Southampton, UK

*A recent study by Breen et al. demonstrated that on multivariable analysis, there was no significant difference between outcomes from cryoablation of T1a vs T1b RCC tumors in terms of treatment efficacy, complication rates or recurrence-free survival. Earlier studies, while showing efficacy in both T1a and T1b tumors, have shown a lower rate of efficacy in the T1b disease.

Outcomes of Kidney Cryoablation vs Other Therapies

Safety: Cryoablation in the Renal Sinus⁹

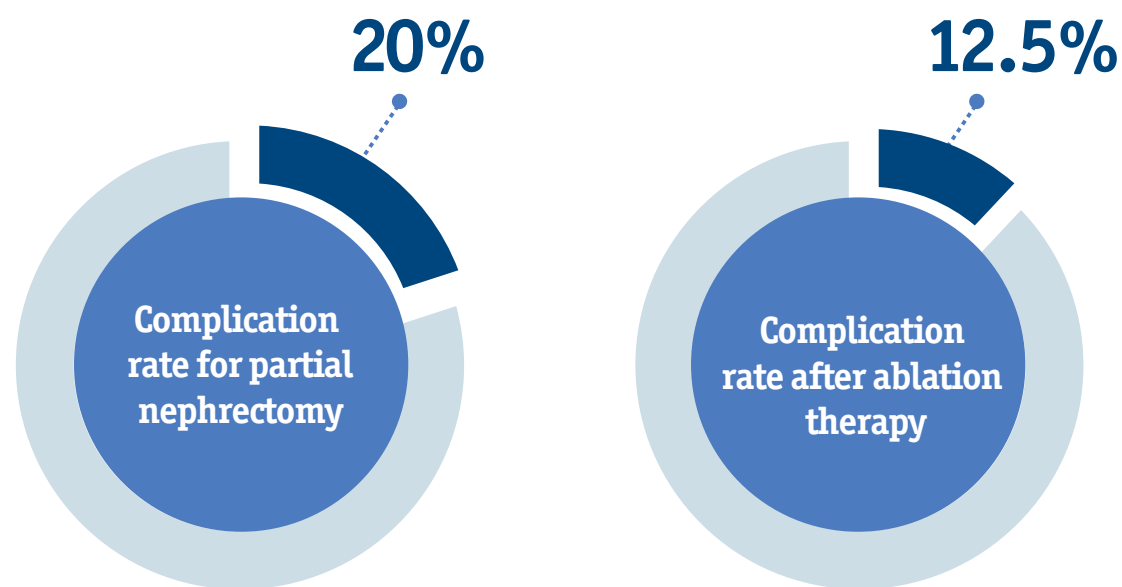
In 129 cryoablation procedures, 52% of which involved iceball overlap of the renal sinus, there were no injuries to the collecting system.



RESULTS AND CONCLUSIONS						
	No of cases	Mean sinus involvement	Mean tumor size	Mean no. cryoprobes	Recurrence	Complications
Central	67	6.2 mm (32% ≥ 6)	2.5 cm ± 0.9	2.5	6%	0
Noncentral	62	NA	1.9 cm ± 0.8	1.8		1 (Hemorrhagic)
p value			<0.001	<0.001		

Complications and Quality of Life: a Meta Analysis¹⁴

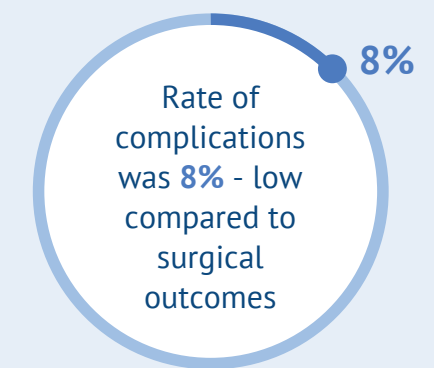
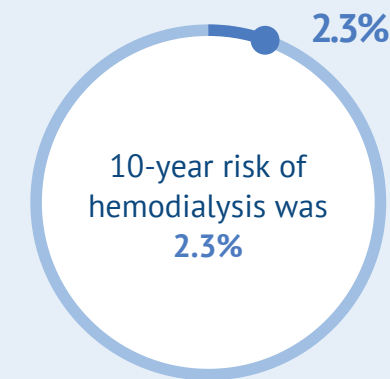
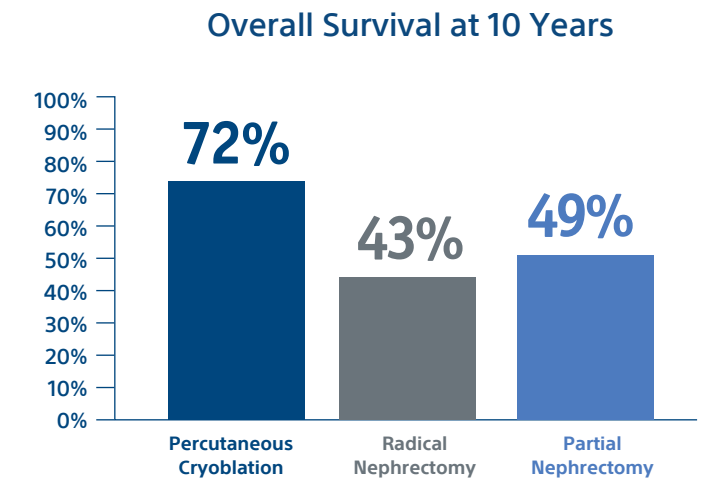
All cryoablation patients returned to baseline quality of life 12 months after procedure



Meta Analysis was of performed on 8 studies, with a combined total of 535 patients.

Cryoablation vs Partial and Radical Nephrectomy for cT1 RCC: a 10-Year Prospective Study³

Biopsy-proven renal cell carcinoma showed that percutaneous cryoablation was associated with a high disease-specific survival (94%) and better overall survival compared with partial or radical nephrectomy at 10 years, with (p < 0.001).



n = 143

Overall Survival: Cryoablation vs Heat-based Ablation in T1a RCC⁸

In propensity-score-matched patients:

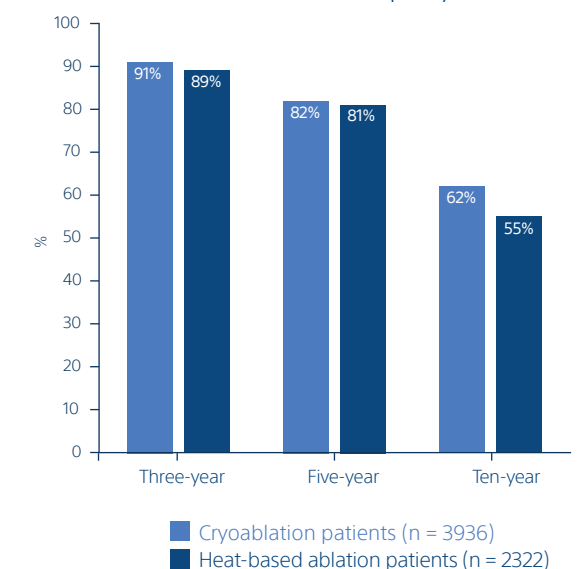
- Median overall survival (n = 2269 in each group) was **11.3 years** for cryoablation vs **10.4 years** for heat-based ablation (p = .016)*
- For tumors ≤2 cm (755 in each group), there was no significant **difference in median overall survival**

*Hazard ratio 1.175, 95% CI 1.03-1.341

Overall, cryoablation may be associated with longer overall survival compared with heat-based thermal ablation in cT1a RCC.

Kaplan-Meier Survival Estimates

Median Follow-up: 4 years



STUDY FOCUS:

Oncologic Outcomes Following Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses Kidney Cryoablation vs Other Therapies⁷

Retrospective review of prospectively maintained database comparing oncologic outcomes in 1,798 patients who underwent either Partial Nephrectomy (PN) Radiofrequency ablation (RFA), or Cryoablation (Cryo). Outcomes included:

- Local recurrence-free survival at 5 years
- Metastatic-free survival at 5 years
- Cancer-specific survival at 5 years
- Overall survival at 5 years

"For cT1a patients, clinically relevant differences between PN and ablation are unlikely and treatment choice should involve shared decision making"

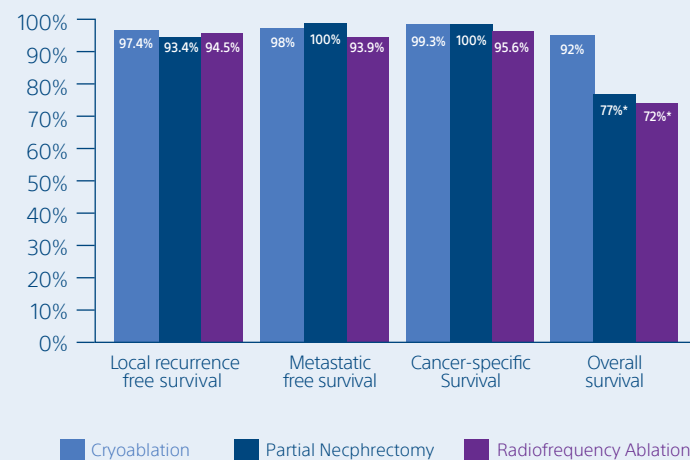
"Local recurrence, metastases, and death from RCC were not statistically significantly different among PN, RFA, and cryoablation for cT1a patients, and were not statistically significantly different between PN and cryoablation for cT1b patients."

Comparison of Oncologic Outcomes for T1a and T1b Patients at 5 Years

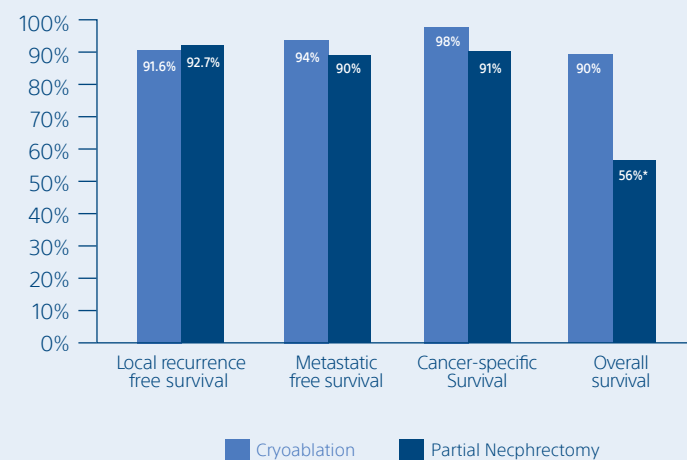
Kaplan-Meier survival estimates and propensity score-adjusted Cox models for 1,422 T1a patients who underwent either PN, RFA, or cryoablation with 5-year follow up.

Kaplan-Meier survival estimates and propensity score-adjusted Cox models for 376 T1b patients who underwent either PN, or cryoablation with 5-year follow up.

Comparison of Oncologic Outcomes for T1a Patients at 5 years



Comparison of Oncologic Outcomes for T1b Patients at 5 years



Differences in overall survival for cryoablation vs partial nephrectomy is likely due to selection bias. Ablation patients were older and had higher Charlson scores.

PROTOCOLS

Study Title	Percutaneous Cryoablation for Stage 1 Renal Cell Carcinoma: Outcomes from a 10-year Prospective Study and Comparison with Matched Cohorts from the National Cancer Database ³
Approach & Protocol	<p><i>Biopsy planned at the time of ablation unless patient had prior diagnostic biopsy. Objective to generate iceball extending 5mm beyond tumor margin. Baseline non contrast CT obtained with patient prone. If nontarget organ was within iceball, 22-gauge spinal needle inserted between RCC and that organ provided air and/or hydrodissection.</i></p>
Study Title	Image-guided Cryoablation for Sporadic Renal Cell Carcinoma: Three- and 5-year Outcomes in 220 Patients with Biopsy-proven Renal Cell Carcinoma ²
Approach & Protocol	
Study Title	Outcomes of Renal Tumors Treated by Image-Guided Percutaneous Cryoablation: Immediate and 3- and 5-Year Outcomes at a Regional Center ⁵
Approach & Protocol	<p>CT scans at 5 and 10 minutes to monitor iceball and assess complication.</p>
Study Title	Oncologic Outcomes Following Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses ⁴
Approach & Protocol	

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CRYOABLATION NEEDLES (IceSeed 1.5, IceSphere 1.5, IceSphere 1.5 CX, IceRod 1.5, IceRod 1.5 PLUS, IceRod 1.5 i-Thaw, IceRod 1.5 CX, IcePearl 2.1 CX and IceForce 2.1 CX) and ICEFX and VISUAL ICE CRYOABLATION SYSTEMS

INDICATIONS: The Galil Medical Cryoablation Needles and Systems are intended for cryoablative destruction of tissue during surgical procedures. The Cryoablation Needles, used with a Galil Medical Cryoablation System, are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology, and urology. Galil Medical Cryoablation 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 respective Galil Medical Cryoablation System User Manuals. **CONTRAINDICATIONS:** There are no known contraindications specific to use of a Galil Medical Cryoablation Needle. **POTENTIAL ADVERSE EVENTS:** There are no known adverse events related to the specific use of the Cryoablation Needles. There are, however, potential adverse events associated with any surgical procedure. Potential adverse events which may be associated with the use of cryoablation may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/coronary ischemia, arrhythmia, atelectasis, bladder neck contracture, bladder spasms, bleeding/hemorrhage, creation of false urethral passage, creatinine elevation, cystitis, diarrhea, death, delayed/non healing, disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT), ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, genitourinary perforation, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure, pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary insufficiency / failure, rectal pain, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, rectourethral fistula, scrotal edema, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPJ obstruction/injury, urethral sloughing, urethral stricture, urinary fistula, urinary frequency/urgency, urinary incontinence, urinary leak, urinary renal leakage, urinary retention/oliguria, urinary tract infection, vagal reaction, voiding complication including irritative voiding symptoms, vomiting, wound complication, and wound infection. **PI-719210-AA.**

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