

# PUBLICATION SUMMARY — RENAL

## Percutaneous Cryoablation of Renal Lesions with Radiographic Ice Ball Involvement of the Renal Sinus: Analysis of Hemorrhagic and Collecting System Complications

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### OVERVIEW

- Computed Tomography (CT)-guided percutaneous cryoablation of renal masses with iceball overlap of the renal sinus resulted in no cases of collecting system injury or serious hemorrhagic complications
- Tumor location is an important factor when cryoablation is being considered as an option for the treatment of small renal cell carcinoma (RCC). Central tumors involving or approaching the renal sinus pose a greater degree of technical difficulty because of concern of damage to vital structures
- Complications associated with radiofrequency ablation (RFA) near or in the renal sinus have been reported in numerous studies
- Centrally located lesions have been associated with a higher complication rate and higher recurrence rate after RFA, specifically with regard to collecting system injury and hemorrhage
- CT-guided imaging allows full evaluation of the location, extent of the radiographic iceball and visualization in detail of cryoablation zone proximity to the renal sinus

### OBJECTIVES

- This is a retrospective review to determine the incidence of collecting system and hemorrhagic complications resulting from CT-guided percutaneous cryoablation of renal tumors in which the radiographic iceball abuts or involves the renal sinus

### METHODS

- 107 patients (mean age 64 years) with renal masses suspicious of being RCC underwent 129 CT-guided percutaneous cryoablation procedures in a single institution from November 2005 to July 2009
- Radiographic iceballs that abutted or overlapped the renal sinus were classified as central; other lesions were classified as noncentral
- Hydrodissection was performed (n=14, 21%) to create space between the bowel and lesion using real-time CT fluoroscopic guidance
- Freeze, thaw, freeze cycle was initiated for 10, 8, 10 minutes and post procedural diagnostic CT was performed to assess the ice ball and to detect complications
- Medical records and follow-up images were retrospectively reviewed for hemorrhage requiring intervention and for evidence of collecting system injury
- The mean follow-up period was 9.3 months (range 0-45 months)

### RESULTS AND CONCLUSIONS

- The radiographic iceball was classified as central in 67 cases (52%). The mean sinus involvement was 6.2 mm (range 0-19 mm) for the central ablations, with 32% of the cases (41 ice balls) overlapping the renal sinus by  $\geq 6$  mm (mean 9.4 mm)
- Mean tumor size for central ablations was 2.5 cm  $\pm$  0.9 compared with 1.9 cm  $\pm$  0.8 for noncentral ablations ( $p < 0.001$ )
- The mean number of cryoprobes used for central ablations was 2.5 compared with 1.8 for noncentral ablations ( $p < 0.001$ )
- No cases of collecting system injury were identified for any ablation
- One hemorrhagic complication requiring intervention occurred in a noncentral ablation
- Recurrence rate was 6%. There was no significant difference between central and noncentral ablations with respect to recurrence

**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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