

Safety, Feasibility and Oncologic Efficacy of Treatment for Small Renal Masses Using an Innovative Liquid Nitrogen-Based Cryogenic Device

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INTRODUCTION AND OBJECTIVE

The current gold standard treatment of small renal masses (SRMs) is Nephron-Sparing Surgery (NSS). Cryoablation (laparoscopic or percutaneous) is preferred in patients with multiple comorbidities and technically complex lesions, who are not good candidates for surgery. We investigated the safety, efficacy, and oncologic outcomes of cryoablation using new liquid nitrogen based cryogenic device in patients with early-stage (T1a) SRMs

PATIENTS

Patients (n=74)

- Number of Lesions _____ **78**
- Mean Age _____ **69 Years**
- Male/ Female Ratio ___ **53 (72%) Men / 21 (28%) Female**
- Mean Lesion size (Range) _____ **2.35 cm (0.9-4.2)**
- Mean R.E.N.A.L. score _____ **6.53**
- Endophytic Lesion _____ **16%**
- Baseline Renal Function (Serum Creatinine) _ **1.01 mg/dl**

METHODS

Patients with enhanced SRMs ≤ 4.0 cm diagnosed by cross sectional imaging (CT or MRI) are included in this study.

An interventional radiology team performed percutaneous cryoablation in patients under sedation/light general anesthesia using ProSense™ (IceCure Medical Ltd, Caesarea, Israel) innovative Liquid Nitrogen technology. Two freezing cycles with intervening passive thaw were used to freeze the target tissue.

Patients underwent imaging, laboratory, and clinical surveillance every 3 months during Year 1 and annually thereafter. Oncologic success was indicated by a reduction in lesion size and lack of enhancement on CT or MRI.



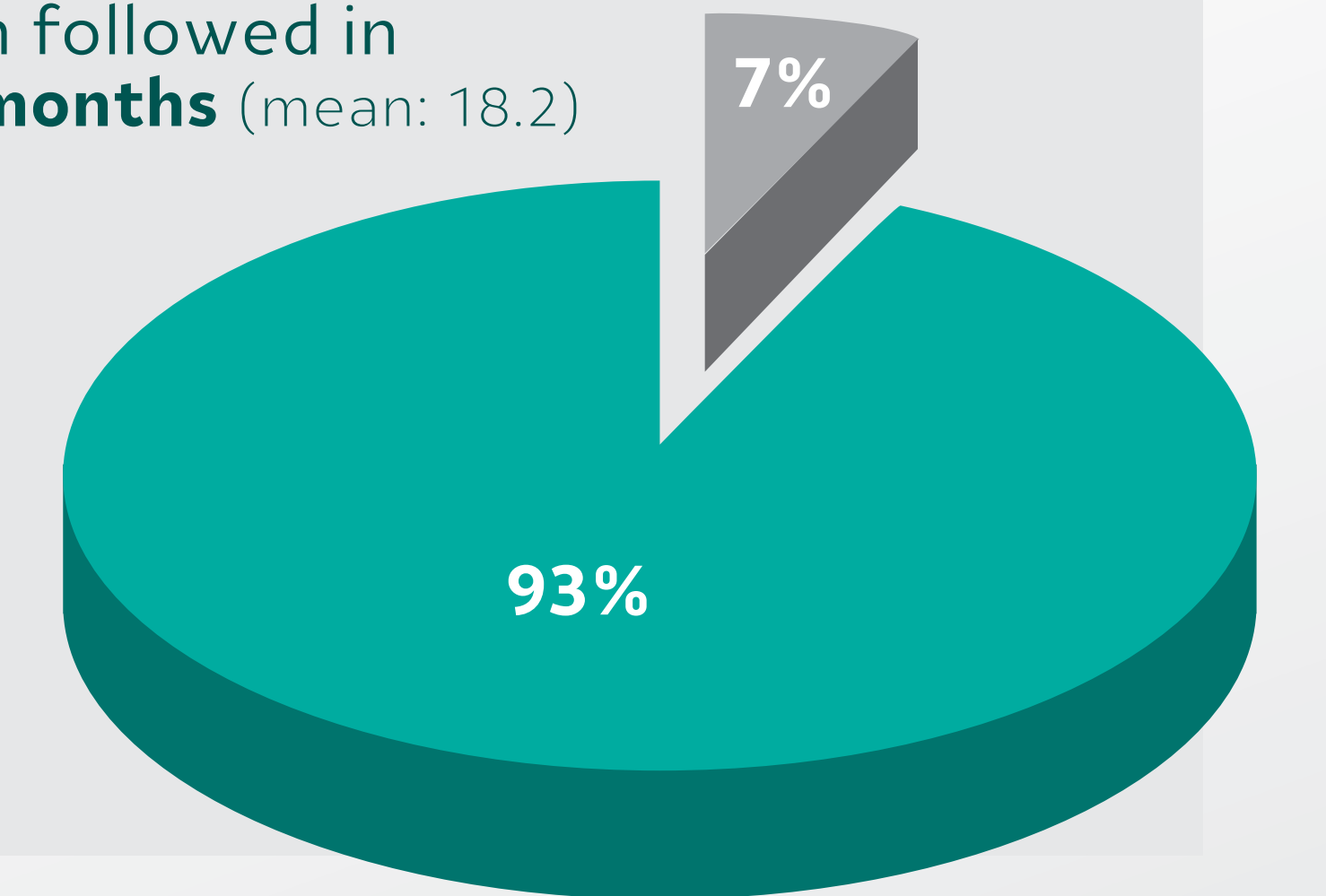
RESULTS

- **Success Rate* – 93%**
- Mean Time Of Ablation Cycle (Range) _____ **22 minutes (8-39)**
- Mean Duration Of Procedure (Range) ___ **50.5 minutes (23-152)**
- Mean Renal Function Decrease (Serum Creatinine) _ **0.04 mg/dl**
- Mean Serum Hemoglobin Decrease _____ **0.14 g/dl**
- Adverse Events (AE)** _____ **6 (8.1%)**

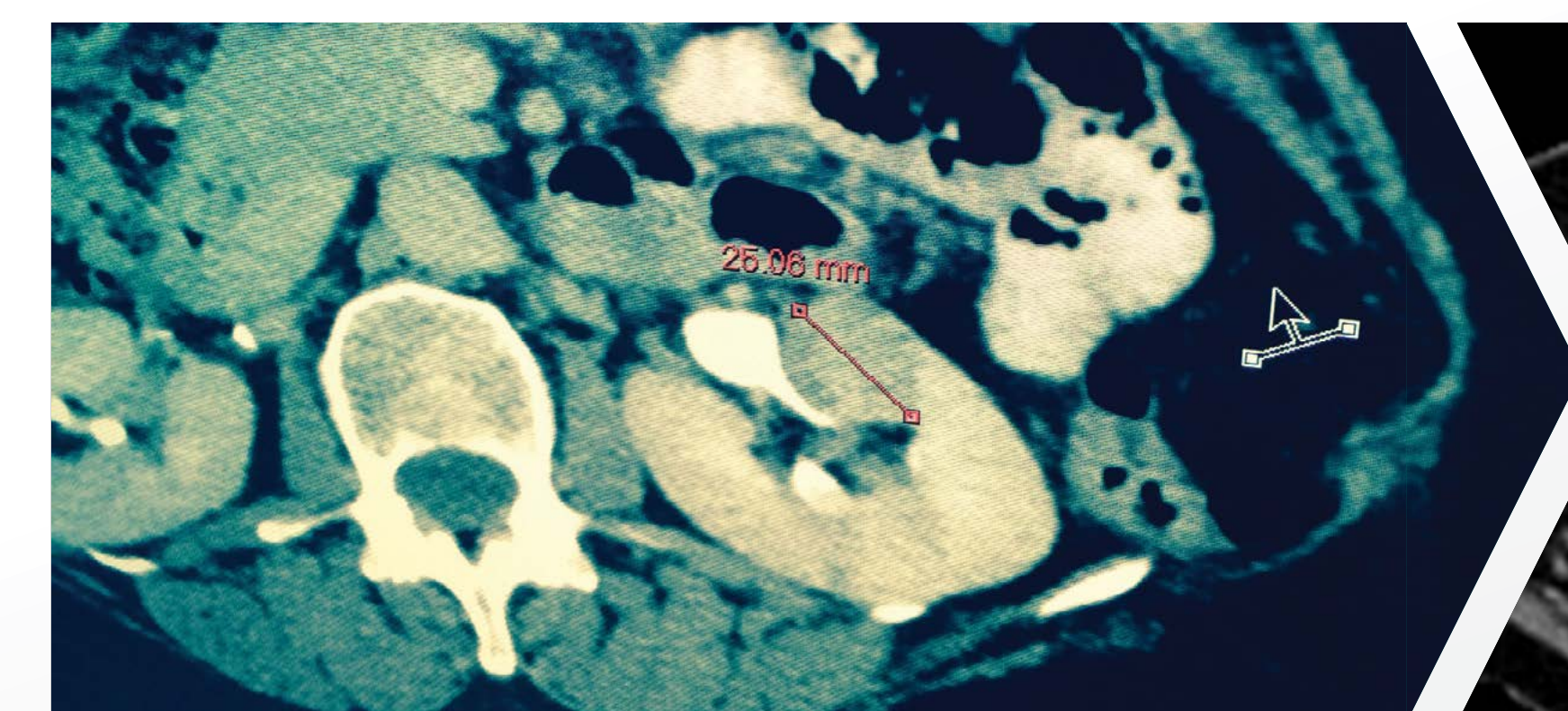
** Perinephric hematoma - 2, hematuria - 2, pain - 1, hydronephrosis - 1

*45 lesions have been followed in 42 patients for ≥ 12 months (mean: 18.2)

■ Treatment Success
■ Treatment Failure



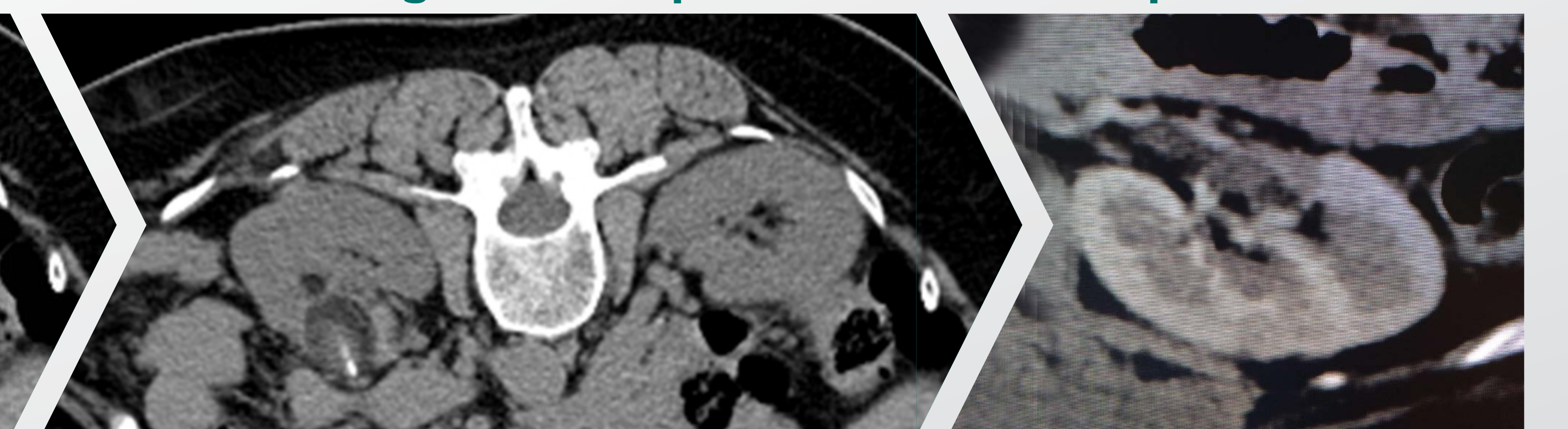
Baseline of Tumor



Biopsy during procedure



Iceball tumor engulfment in procedure Follow up



CONCLUSIONS

Cryoablation of SRMs using ProSense™ device is safe, effective and without serious AEs.