Evidence Table

Clinical Area: Cryoablation of renal tumors.
Keywords: Kidney, neoplasm, laparoscopy, cryoablation.

Study Type: Case series.
Study Aim: To determine the intermediate-term benefits and effects of laparoscopic cryoablation for the treatment of renal tumors.

Outcomes:
- **Primary**: Cryolesion diameter and histopathological evidence of freedom of tumor cells.

Design
- **Number of subjects**: N=32 patients with 34 renal tumors.
- **Description of study population**: This series included patients who had a laparoscopic renal cryoablation at one of two institutions: Cleveland (27 patients) and Florida (5 patients). Their ages ranged from 35-93 with a mean of 65.4 years. The mean tumor size was 2.3 cm, 55% were on the right kidney, and 45% on the left. The serum creatinine ranged from 0.7-2.2 with a mean of 1.2. Eleven (34%) patients had a previous renal procedure.
- **Inclusion criteria**: Enhancing renal mass size \(< 4\) cm, peripherally located, and circumscribed.
- **Exclusion criteria**: Not discussed.
- **Consecutive patients?**: Not discussed.
- **Intervention**: All patients underwent a laparoscopic cryoablation of the tumors. This was approached either retroperitoneally (in 69% of the patients) or transperitoneally (31%) depending on the location of the tumor. For both approaches, the kidney was first mobilized, and the overlying fat excised for histologic examination. Doppler ultrasonography was then made for the kidney and tumor, followed by a needle biopsy of the tumor, and renal cryoablation using a cryoprobe under ultrasound and laparoscopic control. A double freeze-thaw cycle was performed aiming at creating an ice ball, at a lethal temperature, extending 1 cm beyond the tumor edge. The mean surgical time was 2.9 hours, and the mean cryoablation time starting from the first freeze to the end of the second freeze (not include the second thaw) was 15.1 minutes.
- **Source of outcome data (e.g. patient self-report, doctor report, lab results)**: Follow-up was done radiologically with magnetic resonance imaging (MRI) on day 1 and 1,2,3,6, and 12 months after the procedure. 1-3 core needle biopsies were taken from the tumor site, under the direction of computed tomography, at 3 or 6 months after the cryoablation. Telephone interviews with the patients were made by one of the investigators to check on and obtain data on their convalescence.
- **Length of follow-up**: The follow-up duration ranged from 7 to 23 months with a mean of 16.2 months.
- **Completeness of follow-up**: 24 (75%) patients completed 1 year of follow-up.

Validity
- **Is the study type appropriate for the questions being asked?** No, a randomized controlled trial would be the ideal type of study.
- **Were patients similar with respect to baseline characteristics?** Not discussed.
- **Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?** The procedure was performed in two centers (Cleveland and Florida). The protocol for the procedure was the same, but it is not discussed if the same or different surgeons performed it. Radiologic data were only available for the patients treated in the Cleveland institution.
- **Was the process of observation likely to affect the outcome?** The outcome measures were mainly objective, however the procedure was performed in two different institutions, and the authors do not discuss if the results were interpreted independently at each center. Radiologic data were not available for the 5 patients who underwent the procedure in Florida.
- **Did an objective observer assess outcomes and were outcome measurements consistent?** An expert radiologist interpreted the MRI findings. The assessment of the other outcome measures was not discussed.
- **Was follow-up duration appropriate?** Not for determining the long-term outcomes for the procedure.
Conclusions regarding validity of methods:
This is a small case series with potential selection and observational biases. It is not discussed if the patients included in the study were consecutive, there were no definitive exclusion criteria, and the follow-up radiological data were available only for the patients treated in the Cleveland center.

Results:

Radiological data*

\[ \begin{array}{lll}
\text{Mean cryolesion diameter} & \% \text{ size reduction} \\
\text{One day after the procedure} & 3.5 \text{ cm} & \\
1 \text{ month post procedure} & 3.2 \text{ cm} & 8\% \\
2 \text{ months postprocedure} & 2.7 \text{ cm} & 23\% \\
3 \text{ months postprocedure} & 2.1 \text{ cm} & 40\% \\
6 \text{ months postprocedure} & 1.8 \text{ cm} & 48\% \\
\end{array} \]

At 12 months (n=20):

- No residual cryolesion 5 (25%)
- Cryolesion size reduced 15 (75%)
  (Mean size reduction 66%)

* Radiologic data was available only for the patients treated in the Cleveland center.

Histologic data: (n=23):
No evidence of cancer was observed for all 23 patients who underwent a biopsy at 3 or 6 months postoperatively.

Adverse effects:
There were 2 postoperative complications, one case of peripheral hematoma, and one case of herpes esophagitis.

Authors’ Conclusions:
The authors concluded that the results of cryoablation of small renal masses in selected patients are encouraging yet they noted that the technique is still in development, and that long-term follow-up is needed to determine its efficacy.

Reviewer’s Conclusions:
The study is a small case series with potential selection and observation biases. The follow-up duration was not long enough to determine the long-term efficacy of the cryoablation. Patients were followed up for a mean of 16.2 months yet no histopathologic studies were performed after 6 months from the procedure. Further large randomized trials with long-term follow-up are needed to compare cryoablation to other alternatives, and determine its benefit.