Renal Ablation Lesion Selection and Minimizing Adverse Events

Introduction

Interventional oncology can be a valuable part of an interventional radiologist’s (IR’s) practice and it may be difficult to decide, if just starting an interventional oncology (IO) service line, where to begin. One consideration may be percutaneous ablation, as the access techniques are familiar to anyone with an IR background. Within the realm of ablation, percutaneous renal ablation is a well-established procedure with multiple algorithms already published regarding practice improvement. In order to effectively incorporate this into one’s practice, it is important to know the background of ablation for renal cell carcinoma and ways to measure the successful implementation of renal ablation into one’s practice.

It has been estimated that approximately 70,000 Americans are diagnosed with kidney cancer yearly. Due to increasing availability and improvement in quality of imaging, renal cell carcinoma (RCC) is now more frequently diagnosed incidentally and at an earlier stage, many times at a size amenable for percutaneous ablation.\(^1\,^2\)

In 2019, the Society of Interventional Radiology (SIR) published a position statement on the role of percutaneous ablation for RCC in which it made multiple recommendations regarding the safety and efficacy of the image-guided procedure.\(^3\) In summary, the panel recommended percutaneous ablation over active surveillance and as a safe and effective alternative to surgical intervention for small, stage 1a renal tumors (level of evidence: C, strength of recommendation: moderate).

Following SIR publication, the updated American Urologic Association (AUA) guidelines in 2021 incorporated percutaneous ablation as a recommendation, taking precedence over partial nephrectomy in patients with solitary kidney, bilateral tumors, known genetic predisposition, chronic kidney disease, and proteinuria. Additionally, the National Comprehensive Cancer Network (NCCN) guidelines in 2022 included percutaneous ablation as an equal alternative to partial nephrectomy in selected T1a patients.

Given the multidisciplinary support, this is an important time for IRs to become highly proficient and effective members of the multidisciplinary team. The goal of this toolkit, which was developed by SIR’s Practice Improvement and Change Committee (PICC), is to provide IRs with the tools to start an image-guided percutaneous kidney ablation practice as well as measure the quality of care so that best outcomes can be achieved.
Data collection planning

In the early stage of project development, the IR should consider what type of data they will be analyzing throughout the process. Data collection planning will ensure that collected data will be useful and reliable for performance improvement without excessive resource investment, either cost or time.4

When determining what data to collect consider the following:

- Why are we collecting the data?
- What data analysis tools will be used to display the data (e.g., run chart, control chart)?
- What type of data is needed?
- Where in the process can we get this data and from whom?

Keep in mind that the goal is to collect data with minimum effort, minimum chance for error, and with periodic audits to ensure accuracy and completeness.

CASE STUDY

Dr. Smith is an interventional radiologist who has spent a substantial amount of time and effort growing her interventional oncology practice. While she believes her patients are overall doing well, she wants to embark upon a quality improvement (QI) project to study this more objectively. She plans to study outcomes of her patients, look for any areas for improvement, and then implement changes, as appropriate.

She considers the following potential areas of study:

- Analyze consult notes to determine use of tools such as the mRENAL nephrometry score when guiding conversations regarding ablation outcomes and complication rates. Assess baseline, potentially incorporate more standardized use of the nephrometry score, and then track future use.

- Analyze a group of 50 consecutive ablation procedures for adverse events. Assess adverse events and correlate with nephrometry score. Correlate rates of adverse events with SIR guidelines. Implement an action plan to address any complication rates that are close to or above guideline thresholds and/or those that are outliers compared to the rest of her complication rates. Analyze outcomes for the next 50 patients and compare pre- and post-intervention data.

- Incorporate the use of a patient decision aid/structured educational material and assess whether this has an impact on patient understanding, procedural choice and overall patient experience.

- Measure number of referrals received for ablations of renal masses over 1 year and analyze the number and type of referrals, time to initial clinic visit from referral, time to procedure if deemed indicated, and number of patients who have received appropriate follow-up imaging.

It is important for interventional radiologists to be able to design and implement quality improvement projects relating to procedures they perform, including image-guided percutaneous ablation.
Current evidence and analysis

RENAL and mRENAL nephrometry scores

The RENAL nephrometry score was developed for surgical resection and is a standardized method for characterizing the complexity of renal masses. It was developed using images from CT (although MRI can also be used) and has been shown in some studies to predict percutaneous ablation treatment success and adverse events. A modified RENAL (mRENAL) nephrometry score was proposed for radiofrequency ablation (RFA) and demonstrated improved prognostic value for recurrence after RFA relative to the RENAL nephrometry score. These scoring systems differ only in how they assign points based on tumor diameter and location.

The RENAL and mRENAL scores are based on the five most reproducible features of a solid renal mass on contrast-enhanced cross-sectional imaging. The features are (R) radius (tumor size as maximum diameter in cm), (E) exophytic/endophytic properties of the tumor, (N) nearness of the deepest portion of the tumor to the collecting system or renal sinus in millimeters, (A) anterior (a)/posterior (p) descriptor, and the (L) location relative to the polar line. The suffix “x” is assigned if an anterior or posterior designation is not possible. An additional suffix “h” is used to designate a hilar location if the tumor abuts the main renal artery or vein. The “a/p/x” descriptor is determined from axial imaging. All components except for the (A) descriptor are scored on a scale of 1–3. The numerical components are added to yield a score that corresponds to one of three complexity categories. For example, lesions with RENAL score of 10–12 are five times more likely to have a complication following partial nephrectomy compared to low complexity lesions. Please refer to the tables and figure for further clarification:

### Table 3. RENAL and mRENAL Score Calculation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>1 Point</th>
<th>2 Points</th>
<th>3 Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>R (maximum diameter)</td>
<td>≤ 4 cm</td>
<td>&gt; 4 cm and &lt; 7 cm</td>
<td>≥ 7 cm</td>
</tr>
<tr>
<td>mR (maximum diameter, modified scoring for mRENAL)</td>
<td>≤ 3 cm</td>
<td>&gt; 3 cm and &lt; 4 cm</td>
<td>≥ 4 cm</td>
</tr>
<tr>
<td>E (percent exophytic)</td>
<td>≥ 50%</td>
<td>&lt; 50%</td>
<td>Entirely endophytic</td>
</tr>
<tr>
<td>N (nearness of tumor to collecting system)</td>
<td>≥ 7 mm</td>
<td>&gt; 4 mm and &lt; 7 mm</td>
<td>≤ 4 mm</td>
</tr>
<tr>
<td>L (location relative to polar lines)</td>
<td>Entirely above upper pole or below lower pole</td>
<td>Lesion crosses polar line</td>
<td>&gt; 50% of mass is across polar line, or Mass is entirely between polar lines, or Mass crosses axial renal midline</td>
</tr>
</tbody>
</table>

Note—Calculation of RENAL and mRENAL scores is presented. The RENAL score is the sum of the R, E, N, and L scores, and the mRENAL score is the sum of the mR, E, N, and L scores. mRENAL = modified RENAL.

“This article was published in Analysis of the RENAL and mRENAL Scores and the Relative Importance of Their Components in the Prediction of Complications and Local Progression after Percutaneous Renal Cryoablation, Journal of Vascular and Interventional Radiology, Volume 28, Issue 6, 2017, Pages 860-867, Mouli et al., Table 3, Copyright SIR (2016).”
Assigning location (L) score. Solid lines delineate polar lines. In image 1, L = 1 because masses are above or below polar lines. In image 2, L = 2 because masses cross polar lines. In image 3, L = 3 because mass “a” crosses polar line > 50%; “b” crosses axial midline; and “c” is located between polar lines.


Mouli et al. found that the mRENAL score was predictive of adverse events following renal cryoablation with endophytic location being the only individual component of the RENAL and mRENAL scores associated with adverse events. Complexity as measured by either scoring system was not associated with local progression; only diameter >3 cm was associated with increased risk of local progression. Gahan et al. similarly found that for RFA, the only component of the mRENAL score predictive of recurrence-free survival was the modified size component. Other studies have also found that tumor size, rather than the total RENAL score, appeared to be the factor most associated with local recurrence following percutaneous microwave ablation. Although high-complexity masses may be difficult to treat primarily, once properly treated, tumor size may be the only relevant risk factor for recurrence following cryoablation. Mouli et al. suggest that the mRENAL score could supplant the RENAL nephrometry score as an improved composite score for risk stratification of potential complications. Patients with endophytic masses should be counseled about potential complications. Similarly, patients with larger lesions are more likely to require repeat ablation.

ABLATE algorithm

An example of a structured approach to planning a renal ablation is the ABLATE algorithm, a systematic approach formed from the authors’ >10 years of experience in performing these procedures. This algorithm aggregates certain tumor characteristics which are identified on pre-ablation cross-sectional imaging, specifically, Axial tumor diameter (A), Bowel proximity (B), Location within the kidney (L), Adjacency to ureter (A), Touching renal sinus fat (T), and Endo vs. Exophytic (E) quality. Together, the assessment of each variable enables the early anticipation of technical challenges, thereby mitigating intra-procedural risk, promoting successful outcomes and minimizing adverse treatment events.

When considering axial tumor diameter, the authors suggest considering cryoablation for tumors less than 3 cm in size and performing prophylactic embolization for masses which are greater than 3 cm. In the setting of tumors which are located less than 1 cm from small or large bowel, hydro-dissection, pneumo-dissection and/or patient repositioning should be considered, in an effort to maximize the distance between lesion and bowel. Tumors which are located along the periphery
of the kidney must be carefully assessed, given the increased risk of damage to adjacent structures. Such considerations include a transhepatic approach for tumors located within the right anterolateral upper pole, and use of bowel displacement for anteriorly positioned lesions. Additionally, in the setting of tumors located less than 1 cm from the ureter, ureteral displacement or retrograde pyelo-perfusion should be considered to maximize protection of the ureter. In the setting of tumors which contact the renal sinus fat, cryoablation should be considered in favor of RFA.\textsuperscript{15,16} Lastly, while conventional methods of localization may be employed for exophytic tumors, endophytic tumors typically require the use of IV contrast during CT-guided ablation, ultrasound guidance and/or the use of fusion guidance.\textsuperscript{16}

**Adverse events**

Image-guided renal cell carcinoma ablation is a safe procedure with a low overall complication rate. Major adverse events, though rare, most commonly include hemorrhage, abscess and/or unintentional damage to adjacent structures. The most common adverse event identified during or immediately after the procedure is hemorrhage that is most often self-limiting. Several adverse events that can occur during or after renal mass image-guided tumor ablation are listed in the table below.\textsuperscript{17}

<table>
<thead>
<tr>
<th>Complication</th>
<th>Reported Rate\textsuperscript{*}</th>
<th>Threshold\textsuperscript{†}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemorrhage</td>
<td>3.5%–4.1%</td>
<td>5%</td>
</tr>
<tr>
<td>Hematuria</td>
<td>1%–2%</td>
<td>3%</td>
</tr>
<tr>
<td>Renal failure</td>
<td>0.5%–3%</td>
<td>5%</td>
</tr>
<tr>
<td>Urinoma or urine leak</td>
<td>0.5%–2.4%</td>
<td>4%</td>
</tr>
<tr>
<td>Ureteral or collecting system injury</td>
<td>0.4%–3.5%</td>
<td>5%</td>
</tr>
<tr>
<td>Bowel injury</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Infection/abscess</td>
<td>1%–4.9%</td>
<td>8%</td>
</tr>
<tr>
<td>Pneumothorax or pleural effusion</td>
<td>1.7%–3.9%</td>
<td>6%</td>
</tr>
<tr>
<td>Nerve injury</td>
<td>1%–3%</td>
<td>2%</td>
</tr>
<tr>
<td>Tract seeding</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
<tr>
<td>Skin injury</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
<tr>
<td>Cardiovascular complications</td>
<td>1.2%–5%</td>
<td>6%</td>
</tr>
<tr>
<td>Cerebrovascular complications</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

\textsuperscript{*}Rates reported in published studies.  
\textsuperscript{†}Threshold above which a review of the physician’s performance is warranted.

*This article was published in Society of Interventional Radiology Quality Improvement Standards on Percutaneous Ablation in Renal Cell Carcinoma, Journal of Vascular and Interventional Radiology, Volume 31, Issue 2, 2020, Pages 195-201.e3, Gunn et al., Table 4, Copyright SIR (2019).*

The threshold for major adverse events for percutaneous ablation of T1a RCC is 8%. When rates of major complications exceed 8% for T1a lesions, a review of the operator’s performance is warranted. For higher grade T1b lesions, the threshold for major complications is 19%. When rates of major complications exceed 19% for T1b lesions, a review of the operator’s performance is warranted.

**Renal ablation fishbone (Ishikawa) diagram:**

A successful renal ablation program must have good procedural and oncologic outcomes to be accepted as an alternative to nephron sparing surgery for early-stage renal carcinoma. Whether just starting a program or trying to improve an existing one, many factors may impact a practice’s results. These include factors related to patient comorbidities, lesion characteristics and/or ablation modality.

The renal ablation toolkit offers suggestions on how to generate a QI project that can help by improving outcomes and minimizing adverse events. The fishbone diagram outlines any number of steps in the ablation pathway which may be explored individually or collectively to create a QI project to improve outcomes and minimize adverse events. By selecting topics from the diagram, PDSA (plan, do, study, act) cycles can be generated to allow comparison of existing results to those achieved after chosen changes have been instituted.
Renal Ablation Fishbone Diagram

**Comorbid Conditions**
- Diabetes
- Chronic Kidney Disease (CKD)
- Myocardial Infarction (MI)/Cardiac
- Allergies

**Number of Kidneys**
- Uninephric
- Two
- Transplant
- Horseshoe

**Biometrics**
- Age
- Weight

**Ablation Modality**
- Radiofrequency Ablation (RFA)
- Irreversible Electroporation (IRE)
- Cryotherapy
- Microwave

---

**Patient/lesion selection and minimizing adverse events**

**Tumor Stage**
- Ta
- T1a
- T1b

**Adjunctive procedures**
- Hydro/Air dissection
- Stent placement
- Embolization

**Tumor Scoring Systems**
- (MC)2 score
- Padua Predictions Score
- Percutaneous Renal Ablation Complexity (P-RAC) score
- Ablate
- Renal nephrometry

**Renal Mass Biopsy**

---

**Example PDSA For Renal Ablation Lesion Selection**

If increased scores correlate with adverse events, proceed with using ABLATE scoring in clinic visits to evaluate for adverse events and counsel patients and referring clinicians accordingly (consider future PDSA cycle to examine other interventions for reducing risk of adverse events in these populations, e.g., hydrodissection).

If adverse events are not correlated with increased ABLATE scores, re-examine adverse events and affected patients to assess for other correlative factors (e.g., comorbidities).

---

**ACT**

- Use pre-intervention score (i.e., ABLATE) to assess risk for adverse events.

**PLAN**

- Include ABLATE checklist/description as part of pre-intervention consult note template.

**STUDY**

- After ablation, record reported adverse events.

  - Compare to pre-intervention ABLATE scores and examine correlation between higher scores and increased number of adverse events.

**DO**

- Record pre-intervention ABLATE scores in database to compare to post-intervention adverse events.
Data analysis

After the QI project has been developed, data collection methods have been established and the results are ready for analysis, consider which of the following data analysis tools will best reflect the impact that the change has had on this patient population.

<table>
<thead>
<tr>
<th>Tool</th>
<th>Graph or chart</th>
<th>When to use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control chart</td>
<td><img src="image" alt="Control chart Image" /></td>
<td>If acceptable limits are clearly defined, a control chart should be used to show whether data points are within the upper control limits or lower control limits. They can help assess stability, monitor conditions that may require action and show consecutive run of results in any pattern.</td>
</tr>
<tr>
<td>Histogram</td>
<td><img src="image" alt="Histogram Image" /></td>
<td>To show the frequency or number of occurrences of a particular event, use a histogram.</td>
</tr>
<tr>
<td>Pareto chart</td>
<td><img src="image" alt="Pareto chart Image" /></td>
<td>Put a histogram in a descending order of frequency to show the root cause and corresponding number of defects contributed by them. The 80–20 rule, which the Pareto chart is based upon, states that 80% of the outcomes come from 20% of the sources.</td>
</tr>
<tr>
<td>Scatter diagram</td>
<td><img src="image" alt="Scatter diagram Image" /></td>
<td>To show relation between two variables, graph pairs of numerical data with a variable on each axis to identify relations. Correlations between variables can be seen if the points fall along a line or curve. Closer points to the line indicate stronger correlation.</td>
</tr>
<tr>
<td>Run chart</td>
<td><img src="image" alt="Run chart Image" /></td>
<td>Collect and chart data over an extended period to find trends or patterns in the process.</td>
</tr>
</tbody>
</table>

Ablation procedures are a valuable component of many interventional radiology practices and this toolkit provides a valuable framework for IRs to optimize their oncology service line. By conducting studies, employing PDSA cycles, and using tools like the fishbone diagram, interventional radiologists can systematically evaluate patient care at every step. This toolkit enables IRs to improve outcomes, minimize adverse events, and provide exceptional patient-centered care.
References:


