Focal Ablative Therapies for Kidney Cancer

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Assistant Prof., Dept. of Surgery (Urology), University of Toronto

ICUC January 20th, 2017
Audience Question #1

• In managing SRMs I have referred a patient for a thermal ablative therapy (e.g. cryotherapy or radiofrequency ablation)
  – 1) True
  – 2) False
Audience Question #2

- I can summarize my feelings about cryo/RFA with the following statement:
  1. The whole field is a farce and we are hurting patients by offering this therapy.
  2. It should only be offered to patients who are sick/comorbid or elderly.
  3. It is overall safe, but higher recurrence rate than partial nephrectomy
  4. Cryo/RFA is the holy grail. I have stopped all kidney surgery and refer for thermal ablation.
## Faculty/Presenter Disclosures

<table>
<thead>
<tr>
<th>Company/Organization</th>
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<tbody>
<tr>
<td><strong>I am a member of an Advisory Board or equivalent with a commercial organization.</strong></td>
<td>Bayer, Janssen, Abbvie, Astellas</td>
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<tr>
<td><strong>I am a member of a Speakers bureau.</strong></td>
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<tr>
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<tr>
<td><strong>I hold a patent</strong> for a product referred to in the CME/CPD program or that is marketed by a commercial organization.</td>
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<tr>
<td><strong>I hold investments</strong> in a pharmaceutical organization, medical devices company or communications firm.</td>
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<tr>
<td><strong>I am currently participating in or have participated in a clinical trial within the past two years.</strong></td>
<td>SPARTAN (Janssen), Astellas/Janssen (Barrier-P), ARASENS (Bayer) Site-PI</td>
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</table>
Outline

• Review guidelines pertaining to SRM management
• Techniques:
  – Cryotherapy
  – Radiofrequency ablation
• Long-term oncologic outcomes
• Comparison to partial nephrectomy
• Complications

Special thanks to:
Dr. Michael Ordon
St. Michael’s Hospital Cryoablation Program
Localized RCC – TNM “Small renal mass’
Fuhrman Grading System

Fuhrman grade I
- Small cells (10um), round and uniform nuclei with inconspicuous or absent nucleoli

Fuhrman grade II
- Larger cells (15 um), irregular morphology with small nucleoli, visible at high magnification

Fuhrman grade III
- Larger cells (20um), irregular outlines, large and prominent nucleoli, visible at low magnification

Fuhrman grade IV
- Contains bizarre, multilobed nuclei, with heavy chromatin clumps

Sun et al., Eur Urology, 2009
Small Renal Mass (SRM)

- Contrast enhancing mass within kidney
- ≤ 4cm largest dimension
- N0,M0
- Incidental detection (asymptomatic)
- Now most common presentation for RCC
- ≈20% benign; ≈80% low grade
Histology of SRM’s

SOLID RENAL TUMORS: AN ANALYSIS OF PATHOLOGICAL FEATURES RELATED TO TUMOR SIZE

IGOR FRANK, MICHAEL L. BLUTE, JOHN C. CHEVILLE, CHRISTINE M. LOHSE, AMY L. WEAVER AND HORST ZINCKE

From the Departments of Urology (IF, MLB, HZ), Pathology (JCC), and Health Sciences Research (CML, ALW), Mayo Medical School and Mayo Clinic, Rochester, Minnesota

<table>
<thead>
<tr>
<th>Tumor Size (cm)</th>
<th>No. Benign (%)</th>
<th>No. RCC (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0–Less than 1.0</td>
<td>37 (46.3)</td>
<td>43 (53.8)</td>
</tr>
<tr>
<td>1.0–Less than 2.0</td>
<td>38 (22.4)</td>
<td>132 (77.7)</td>
</tr>
<tr>
<td>2.0–Less than 3.0</td>
<td>75 (22.0)</td>
<td>266 (78.0)</td>
</tr>
<tr>
<td>3.0–Less than 4.0</td>
<td>71 (19.9)</td>
<td>285 (80.1)</td>
</tr>
<tr>
<td>4.0–Less than 5.0</td>
<td>37 (9.9)</td>
<td>336 (90.1)</td>
</tr>
<tr>
<td>5.0–Less than 6.0</td>
<td>40 (13.0)</td>
<td>267 (87.0)</td>
</tr>
<tr>
<td>6.0–Less than 7.0</td>
<td>11 (4.5)</td>
<td>232 (95.5)</td>
</tr>
<tr>
<td>7.0 or Greater</td>
<td>67 (6.3)</td>
<td>998 (93.7)</td>
</tr>
</tbody>
</table>
# Histologic Grade of Clear Cell SRMs

<table>
<thead>
<tr>
<th>Tumor size (cm):</th>
<th>No. Clear Cell (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low Grade</td>
<td>High Grade</td>
</tr>
<tr>
<td>0.0–Less than 1.0</td>
<td>10 (90.9)</td>
<td>1 (9.1)</td>
</tr>
<tr>
<td>1.0–Less than 2.0</td>
<td>70 (88.6)</td>
<td>9 (11.4)</td>
</tr>
<tr>
<td>2.0–Less than 3.0</td>
<td>174 (93.6)</td>
<td>12 (6.5)</td>
</tr>
<tr>
<td>3.0–Less than 4.0</td>
<td>165 (81.3)</td>
<td>38 (18.7)</td>
</tr>
<tr>
<td>4.0–Less than 5.0</td>
<td>208 (77.6)</td>
<td>60 (22.4)</td>
</tr>
<tr>
<td>5.0–Less than 6.0</td>
<td>151 (69.3)</td>
<td>67 (30.7)</td>
</tr>
<tr>
<td>6.0–Less than 7.0</td>
<td>117 (60.9)</td>
<td>75 (39.1)</td>
</tr>
<tr>
<td>7.0 or Greater</td>
<td>308 (37.9)</td>
<td>505 (62.1)</td>
</tr>
</tbody>
</table>

Totals: 1,203 (Low Grade), 767 (High Grade)
Small Renal Mass (SRM)

• Dilemmas:
  1. To biopsy or not…
  2. To treat or not…
      • Active surveillance
  3. If treatment, what treatment?
      • Surgery vs. Ablative therapy (Cryo/RFA)
      • Partial nephrectomy vs. Radical nephrectomy
      • Open vs. Lap/Robotic
Guidelines
AUA: “Guideline for management of Clinical Stage I renal mass” (2009)

**INDEX PATIENT 1:**
Healthy; Clinical T1a

- **STANDARD–PN:**
  Complete surgical excision by PN is a standard of care and should be strongly considered.

- **STANDARD–RN:**
  Should be discussed as alternate standard of care if PN is not technically feasible as determined by the urologic surgeon.

- **OPTION–TA:**
  Cryoablation or RFA should be discussed as less-invasive treatment options, but local tumor recurrence is more likely, measures of success are not well defined, and surgical salvage may be difficult.

- **OPTION–AS:**
  AS with delayed intervention should be discussed as option for patients wishing to avoid treatment and willing to assume oncologic risk.

**INDEX PATIENT 2:**
Major comorbidities; Increased surgical risk; Clinical T1a

- **STANDARD–PN:**
  Complete surgical excision by PN is a standard of care and should be strongly considered.

- **STANDARD–RN:**
  Should be discussed as standard of care with increased risk of CKD and surgical complications in this patient.

- **RECOMMENDATION–TA:**
  Cryoablation or RFA should be discussed as less-invasive treatment options which may be advantageous in this high surgical risk patient, acknowledging the increased risk of local tumor recurrence compared to surgical excision.

- **RECOMMENDATION–AS:**
  Should be offered as an acceptable approach which can delay or avoid the need for intervention in this high-risk patient.
EAU Guidelines - Ablative Therapy

• **Indications**
  – small, incidentally found, renal cortical lesions in *elderly* patients;
  – *genetic predisposition* for developing multiple tumours
  – *bilateral* tumours
  – *solitary kidney* at high risk of complete loss of renal function following surgical tumour resection
# EAU Guidelines - Ablative Therapy

## Recommendations

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>GR</th>
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</thead>
<tbody>
<tr>
<td>Patients with small tumours and/or significant co-morbidity who are unfit for surgery should be considered for an ablative approach, e.g. cryotherapy and radiofrequency ablation</td>
<td>A</td>
</tr>
<tr>
<td>Pre-treatment biopsy has to be carried out as standard.</td>
<td>C</td>
</tr>
<tr>
<td>Other image-guided percutaneous and minimally invasive techniques, such as microwave ablation, laser ablation, and high-intensity focused ultrasound ablation are still experimental in character. The experience obtained with radiofrequency ablation and cryoablation should be considered when using these related techniques.</td>
<td>B</td>
</tr>
</tbody>
</table>
• Thermal ablative therapy:
  – Attractive approach in elderly and infirm
  – Ensure biopsy prior
  – Local recurrence up to 14%
  – Laparoscopic approaches unnecessary
  – Complications relatively uncommon
  – Good oncologic efficacy in carefully selected patients
  – Salvage surgery usually requires nephrectomy
NCCN Guidelines Version 2.2017
Kidney Cancer

INITIAL WORKUP

- H&P
- CBC, comprehensive metabolic panel
- Urinalysis
- Abdominal ± pelvic CT\textsuperscript{a} or abdominal MRI\textsuperscript{a}
- Chest x-ray
- If clinically indicated
  - Bone scan
  - Brain MRI\textsuperscript{a}

STAGE

Stage I (pT1a)

PRIMARY TREATMENT\textsuperscript{c}

- Partial nephrectomy (preferred)
  - or
- Radical nephrectomy (if partial not feasible or central location)
  - or
- Active surveillance in selected patients
  - or
- Ablative techniques in selected patients

FOLLOW-UP\textsuperscript{d}
(category 2B)

Follow-up
(See KID-B)
Relapse
See F Therap

- Primary treatment
  - For Stage I (pT1a), the option for ablative techniques was revised: "Ablative techniques in selected patients for non-surgical candidates"
Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline


January 17, 2017.

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Small Renal Mass (≤4cm T1aN0M0 lesion)

- Renal Tumor Biopsy when results may alter management
  - Benign → Surveillance
  - No biopsy, Non-diagnostic or cancer

Does the patient have significant comorbidities and/or limited life expectancy?

- Yes → Perform patient-specific quantitative assessment to determine if active surveillance is appropriate
  - Yes³ → Life expectancy <5 years or high risk for anesthesia or intervention
    - No → Is the SRM amenable to nephron-sparing treatment?

- No → Can Ablation completely treat lesion?
  - Yes → Energy Ablation
  - No → Biopsy (if none previous)

- Yes → Radical Nephrectomy

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1 Repeat biopsy can be considered
2 Intensity of surveillance varies from active to watchful waiting based on life expectancy and biology of the tumour.
3 Relative indications for surveillance include high risk of ESRD if treated, SRM < 1 cm or life expectancy < 10 years
4 Referral to surgeon or center with expertise should be considered
5 Ideally performed in a minimally invasive manner
6 Referral to a nephrologist should be considered for patients with CKD or progressive CKD after treatment especially if associated with proteinuria.
Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline


January 17, 2017

THE BOTTOM LINE

Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline

Key Recommendations

Recommendation 3.2: Percutaneous thermal ablation should be considered an option for patients who possess tumors such that complete ablation will be achieved. A biopsy should be obtained before or at the time of ablation (type: evidence based; evidence quality: intermediate; strength of recommendation: moderate).

An oncologist would provide an optimal and safe approach. The historical notion that ablation should be limited to unfit and vulnerable patients with SRMs who are rejected for surgical intervention should be discouraged because, as described above, those patients may be better served with active surveillance.
Fig. 1 Change in renal procedures over time: percentages indicate the proportion that each individual modality constitutes with respect to the total annual renal procedures. RFA, radiofrequency ablation.
Why Ablation?

- Minimal impact on renal function\textsuperscript{1}
- Less blood loss versus surgery\textsuperscript{2}
- Day procedure or overnight hospital stay\textsuperscript{3}
- Fewer complications $\rightarrow$ less morbidity $\rightarrow$ rapid return to everyday life\textsuperscript{4}
- May be suitable for patients who cannot tolerate general anesthesia\textsuperscript{5}
- Partial would be tough

\textsuperscript{1}Raman, Can J Urol, 2008
\textsuperscript{2}Haramis, Laparoendosc Adv Surg Tech 2011
\textsuperscript{3}Haber, BJU Intl 2011; Mues, World J Urol 2010; Weld, BJU Int’l 2005
\textsuperscript{4}Desai, Urology, 2005
\textsuperscript{5}Gupta, J Urol 2006; Allaf, Radiol 2005
Ablative Therapy- Indications

- Small tumours
  - ≤3cm
- Patients who are high surgical/anesthetic risk
- Specific clinical scenarios:
  - Renal insufficiency
  - Solitary kidneys
  - Bilateral tumours
  - Partial nephrectomy technically challenging
  - Recurrent tumours 2° to hereditary disorders such as VHL
Cryotherapy
Cryotherapy

• Intracellular ice:
  – Direct trauma to organelles and plasma membrane

• Extracellular ice:
  – Depletes water & osmotic gradient → Membrane rupture

• Thawing phase: water back into cells
  – Edema & further membrane rupture

• End product:
  – Coaggulative necrosis, apoptosis, fibrosis
Cryotherapy

- Probe(s) inserted to tumor
  - Historically lap, now percutaneously
- Argon gas (most common)
- Target temp: -40°C
- 5-10mm overshoot on margins
- 8-10 min freeze/thaw cycle x 2
- Can monitor ice ball radiographically
Radiofrequency Ablation (RFA)
RFA

- Radiofrequency energy (450 – 1200 KHz)
  - Vibrates ions, molecular friction → heat
- Heat causes protein denaturation and membrane disruption → apoptosis & necrosis
- Target temp: 105°C
- Treat 5-8 minutes depending on size
- Zone of treatment based on probe choice, placement and duration
- Monitoring challenging (no ice ball to watch)
  - Temp- or impedance-based
  - May see bubbles on U/S or loss of enhancement on CT
Outcomes
Treatment success

- Post-cryo and post-RFA look very different
  - Cryo: 50% reduction in size after 1 year
  - RFA: minimal reduction, but fibrotic halo (75% of cases)
- Routine biopsy: problematic
  - Pathology difficult to interpret
  - Architectural preservation for up to 6 months: false positive
  - Positive biopsy doesn’t correlate with clinical recurrence
- Radiographic: the accepted standard
  - CT or MRI at 1-3 months post
  - Lack of contrast enhancement = success
Defining outcomes & challenges

- Define? Re-biopsy vs. CT scan
- Does retreatment count?
- No biopsy prior? What if benign?
- Does local recurrence matter?

- No biopsy prior? Unknown benign masses
- Death from competing risks (historically unhealthy patients)
- Need long follow-up
- Need big numbers
Local recurrence

• Is different than: “Incomplete Ablation”
  – Persistent contrast enhancement immediately after ablation
  – Usually immediate re-treatment
• New contrast enhancement in lesion that had no enhancement post-treatment
• Biopsy can corroborate new enhancement
• Any growing lesion, considered local recurrence
Incomplete ablation and re-treatment
Oncoologic Outcomes (Long Term)

Cryoablation

- Tanagho et al. 2014
  - Laparoscopic and Percutaneous Cryotherapy (267 pts)
  - Mean F/U 39.8 months
    - 5-yr Disease Free Survival 83%
    - 5-yr Cancer Specific Survival 96.4%
    - 5-yr Overall Survival 77.1%

- Georgiades et al. 2014
  - Percutaneous Cryotherapy (134 pts)
  - Median F/U around 3.5 yrs
    - 5-yr Disease free survival 97%
    - 5-yr Cancer Specific Survival 100%
    - 5-yr Overall Survival 97.8%
Oncologic Outcomes (Long Term)

Radiofrequency Ablation

- Psutka et al. (2013)
  - 185 patients
  - Median F/U 6.43 yrs (0.5-13.4)
    - Disease Free Survival 88.6%
    - 5-yr Cancer Specific Survival 99.4%
    - 5-yr Metastasis-Free Survival 99.4%

- Olweny et al. (2012)
  - Compared RFA (37pts) vs. PN (37pts)
  - Median follow-up was 6.5 yr vs. 6.1 yr (p = 0.68)
    - 5-yr RFS was 91.7% versus 94.6% (p = 0.96)
    - 5-yr DFS was 89.2% versus 89.2% (p = 0.78)
    - 5-yr CSS was 97.2% versus 100% (p = 0.31)
Ablation vs. Partial Nephrectomy

VS.

UHN Princess Margaret Cancer Centre
Comparison of Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses

July 23, 2014

R. Houston Thompson a,*, Tom Atwell b, Grant Schmit b, Christine M. Lohse c, A. Nicholas Kurup b, Adam Weisbrod b, Sarah P. Psutka a, Suzanne B. Stewart a, Matthew R. Callstrom b, John C. Cheville d, Stephen A. Boorjian a, Bradley C. Leibovich a

- Retrospective cohort: 1424 cT1 masses

<table>
<thead>
<tr>
<th>Feature</th>
<th>PN, n = 1057</th>
<th>RFA, n = 180</th>
<th>Cryoablation, n = 187</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at treatment, yr, mean (median; IQR)</td>
<td>60.1 (62; 52–69)</td>
<td>70.7 (72; 64–78)</td>
<td>71.6 (72; 65–79)</td>
<td>&lt;0.001</td>
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<td>Serum creatinine, n = 1387, mean (median; IQR)</td>
<td>1.1 (1.0; 0.9–1.2)</td>
<td>1.3 (1.1; 1.0–1.4)</td>
<td>1.1 (1.0; 0.9–1.3)</td>
<td>&lt;0.001</td>
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<tr>
<td>Charlson score, n = 1418, mean (median; IQR)</td>
<td>1.2 (1.0; 0–2)</td>
<td>2.1 (1; 0–3)</td>
<td>2.0 (2; 0–3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Tumor size, cm, mean (median; IQR)</td>
<td>2.5 (2.4; 1.8–3.1)</td>
<td>2.1 (1.9; 1.5–2.5)</td>
<td>2.9 (2.8; 2.4–3.4)</td>
<td>&lt;0.001</td>
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Subset with RCC

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<th>Cryoablation, n = 187</th>
<th>p value</th>
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<tbody>
<tr>
<td>Histology, no. (%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clear cell</td>
<td>560 (67)</td>
<td>38 (52)</td>
<td>73 (68)</td>
<td>0.019</td>
</tr>
<tr>
<td>Papillary</td>
<td>153 (18)</td>
<td>20 (27)</td>
<td>20 (19)</td>
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<tr>
<td>Chromophobe</td>
<td>55 (7)</td>
<td>3 (4)</td>
<td>1 (1)</td>
<td></td>
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<tr>
<td>Collecting duct</td>
<td>1 (&lt;1)</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>Not indicated</td>
<td>67 (8)</td>
<td>12 (16)</td>
<td>14 (13)</td>
<td></td>
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<tr>
<td>Grade, no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
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<tr>
<td>Not indicated</td>
<td>7 (1)</td>
<td>16 (22)</td>
<td>22 (20)</td>
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<tr>
<td>1</td>
<td>173 (21)</td>
<td>24 (33)</td>
<td>26 (24)</td>
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<tr>
<td>2</td>
<td>568 (68)</td>
<td>31 (42)</td>
<td>51 (47)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>84 (10)</td>
<td>2 (3)</td>
<td>9 (8)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>4 (&lt;1)</td>
<td>0</td>
<td>0</td>
<td></td>
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Comparison of Partial Nephrectomy and Percutaneous Ablation for cT1 Renal Masses

R. Houston Thompson*a,*, Tom Atwellb, Grant Schmitb, Christine M. Lohsec, A. Nicholas Kurupb, Adam Weisbrodb, Sarah P. Psutkaa, Suzanne B. Stewarta, Matthew R. Callstromb, John C. Chevilled, Stephen A. Boorjiana, Bradley C. Leibovicha

3-yr Local Recurrence Free:
- Partial Nx: 98%
- RFA: 98%
- Cryotherapy: 98%

3-yr MFS
Cryo = 100%
PN = 99%
RFA = 93%

Only 4 RFA pts had mets
Radiofrequency Ablation Versus Partial Nephrectomy for Clinical T1a Renal-Cell Carcinoma: Long-Term Clinical and Oncologic Outcomes Based on a Propensity Score Analysis

Xiaofeng Chang, MD,* Tieshi Liu, MD,* Fan Zhang, MD,* Changwei Ji, MD, Xiaozhi Zhao, MD, Wei Wang, MD, and Hongqian Guo, MD

JOURNAL OF ENDOUROLOGY
Volume 29, Number 5, May 2015

• Propensity score matched retrospective review of 90 patients

<table>
<thead>
<tr>
<th>5-year outcome</th>
<th>RFA</th>
<th>Partial</th>
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<tbody>
<tr>
<td>Recurrence-free survival</td>
<td>95.4</td>
<td>97.7</td>
</tr>
<tr>
<td>Disease-free survival</td>
<td>86.7</td>
<td>88.5</td>
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<tr>
<td>Mets-free survival</td>
<td>95.5</td>
<td>95.5</td>
</tr>
<tr>
<td>Cancer-specific survival</td>
<td>95.6</td>
<td>97.7</td>
</tr>
<tr>
<td>Overall survival</td>
<td>90.2</td>
<td>93.2</td>
</tr>
</tbody>
</table>

No significant differences

Mean % Decline in GFR: -12% vs. -26.9%; p=0.001

Conclusions: In the propensity-score matched cohort of patients with clinical T1a RCC, we observed that RFA was an effective treatment option that provided comparable 5-year oncologic outcomes and better preservation of renal function than PN.

UHN Princess Margaret Cancer Centre
Tumor Size – Size Matters

• 3cm appears reproducible cut-point
  – Best et al., J Urol 2012
    • 3cm cut-point: 5-year DFS 98% vs. 79%
  – Zhang et al., J Endourol 2016
    • 3cm cut-point: 5-year DFS 98.2% vs. 84.3%
  – Psutka et al., Eur Urol 2013
    • 4cm cut-point: 5-year DFS 92.3% vs. 76.2%
  – Whitson et al, BJU Int 2012
    • For every 1cm increase: 1.5x Recurrence
    • Median tumor size: 2.6cm

It is feasible to ablate at >3cm, but must acknowledge higher local recurrence rate
Complications
Complications

• Related to size, complexity (nephrometry score)
• 5% major urological complications
  – Ureteral injury/urinary fistula/stricture (1-2%)
  – Bleeding:
    • Perinephric hematoma <5%; Hematuria <3%
    • Transfusion rates: 0.3 – 2%
• 5% major non-urological complications
  – Pain, paresthesia (1-3.5%)
    • New probe technology lessens this
  – Pneumothorax/hemothorax (2%)
  – Colon injury (1.3%)
Nuanced issues

• Tumour location
  – Heat sink
  – Colon injury
  – Urothelial injury

• Tumour size
  – Failure rate
Tumour location

- **Central tumour**
  - Heat sink (blood vessels, collecting system):
    - Leads to viable tumor at edge
  - Calyceal injury/urine leak
  - Consider cryotherapy
  - Retrograde and irrigation

- **Inferomedial**:
  - Ureter injury/stricture
  - Retrograde and irrigation

- **Anterior**:
  - Bowel injury
  - Hydrodissect bowel away
  - Lateral decubitus

- **Posterior**:
  - Neuropraxia
  - Hydrodissect kidney away
  - Consider Cryotherapy
Conclusions

• Thermal therapies increasingly utilized
• Guidelines relaxing: not just for “elderly & infirm”
• Clear advantages:
  – Blood loss, complications, renal function etc.
• Local recurrence: 5-15%
  – But retreatment a possibility
• Metastases & cancer-specific survival:
  – Studies are confounded, and still too immature
  – Appears thermal therapy not significantly inferior to PN
• Cryo and RFA essentially interchangeable
  – Save for some nuances of tumour location