

Multidisciplinary Approaches to Cancer Symposium

## Optimal Treatment of Small Renal Masses(SRM), Surgery, SBRT, or Ablation

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November 11/11/2022

#### Disclosures

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• Grant/Research Support from Aravive, Inc., and EMD Serono

• Consultant for Deka Biosciences, EMD Serono, Exelixis, and Pfizer.

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This presentation has been peer-reviewed and no conflicts were noted.

## Small Renal Masses(SRM)



### • Small Renal Mass(SRM)

- Renal Cell Cancer(RCC)
- 79,000 NEW CASES-est (2022)
- 13,900 DEATHS-est (2022)
- Stage at Presentation

Stage 1 and 2 ,Localized	65%
Stage 3, Regional Disease	17%
Stage 4, Metastatic	19%





SEER Cancer Stats 2022

#### NCCN GUIDELINES®



<sup>a</sup> Imaging with and without contrast is strongly preferred, such as a renal protocol.

<sup>b</sup> Biopsy of small lesions may be considered to obtain or confirm a diagnosis of malignancy and guide surveillance or ablative techniques, cryosurgery, and radiofrequency ablation strategies.

c If metastatic disease is present or the patient cannot tolerate ureteroscopy.

<sup>d</sup> See Principles of Surgery (KID-A\*).

<sup>e</sup> Stereotactic body radiotherapy (SBRT) may be considered for medically inoperable patients with Stage I kidney cancer (category 2B), with Stage II/III kidney cancer (both category 3).

See Follow-up (KID-B).

9 No single follow-up plan is appropriate for all patients. Follow-up should be individualized based on patient requirements.

\*Available online, in these guidelines, at NCCN.org.

#### Size Matters-SRM

#### Table 1. Tumor Size and Proportion of RenalCell Carcinomas

Size	Malignant	Benign	
0 – < 1 cm	43 (54%)	37 (46%)	
1 – < 2 cm	132 (78%)	38 (22%)	
2 – < 3 cm	266 (78%)	75 (22%)	
3 – < 4 cm	285 (80%)	71 (20%)	
All sizes (0–4 cm)	726 (77%)	221 (23%)	

Adapted from Frank et al. J Urol. 2003.[75]

#### Table 2. Risk of Metastatic Renal Cell Carcinoma (RCC) and Benign Lesion Based on Tumor Size

lumor Size	Benign Pathology	Metastatic (M1) RCC
< 1 cm	35%-45%	<1%
–2 cm	20%-25%	<1%
2–3 cm	15%-20%	<1%
}–4 cm	15%-20%	2%
1–5 cm	10%	2%–3%
5–6 cm	10%	5%–10%
}–7 cm	5%	5%–10%
≥ 7 cm	5%	15%–20%

Adapted from Thompson et al. J Urol. 2009.[76]

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## Optimal Treatment of Small Renal Masses(SRM)-Surgery

Clayton Lau, MD

Urology/Urologic Oncology

#### Kidney Cancer, Version 3.2022, NCCN Clinical Practice Guidelines in Oncology

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#### Kidney Cancer, Version 3.2022, NCCN Clinical Practice Guidelines in

#### Oncology



School of Medicine; | <sup>32</sup> Robert H. Lurie Comprehensive Cancer Center of Northwestern University; | <sup>33</sup> National Comprehensive

### Partial Nephrectomy

- NSS is Preferred Surgical Option for SRM
- Recurrence rate 1.9% (Wood, et al, U Urol 2018)
- Metastatic free rate 95.2% for T1 lesions at 10 years (Lane, et al J Urol 2013)
- Done Robotically, Same Day Discharge(SDD)
- Can do on T2 or select T3 lesions (Bertolo, et al, Eur Uro Onc 2019)





## Case for Partial Nephrectomy

- Gold standard for NSS for RCC
- Can treat large lesions
- Can treat central tumors or those near the collecting system or ureter
- Can treat Cystic Renal Cell Cancer
- Hard to Salvage Ablation and SBRT Failures, May Necessitate Radical Nephrectomy

#### Meta-analysis of outcomes for patients with clinical T1 renal masses according to treatment approach

	RADICAL NEPHRECTOMY*	PARTIAL NEPHRECTOMY*	RADIOFREQUENCY ABLATION	CRYOABLATION	ACTIVE SURVEILLANCE
Number of patients	6,235	6,418	745	644	390
Median age (years)	63	60	70	66	68
Median tumor size (cm)	5.4	3.0	2.7	2.6	2.2
Median follow-up (months)	58	47	19	17	29
Urologic complication rate (%)	1.3	6.3	6.0	4.9	NA
Local recurrence-free survival rate (%)	98.1	98.0	87.0	90.6	NA
Metastatic recurrence- free survival rate (%)	89.8	96.7	97.8	95.3	97.7
Reduction in renal function and potential impact on cardiovascu- lar morbidity	High	Minimal	Minimal	Minimal	None

Cambell et al, Practice Guidelines Committee of AUA for Management of Clinical T1 Renal MASS. juROL 2009



## Cytoreductive SBRT for Primary Renal Cell Carcinoma

An Alternative to Nephrectomy and Ablation

Savita Dandapani, MD, PhD

Radiation Oncology

#### • Introduction: Cytoreductive SBRT

a)

b)

- High precision, high dose, high conformability, and low treatment frequency
- Recommended for treatment of bone & brain metastases in RCC, and for local tx of limited sites of progression for pts on immunotherapy (ASCO Guidelines 2022)
- Has been used in cases of inoperable primary RCC since 1999 (Qian et al. 2003)
- Less invasive than cytoreductive/partial nephrectomy
- Less invasive than cryoablation and radiofrequency ablation (no need for percutaneous or laparoscopic access to tumor)
- Immunomodulatory
- Retains renal function



c

- (a) CTV and PTV of a patient at first treatment.
- (b) Relative dose distribution, with the prescription isodose (100% in blue), at the periphery of the PTV.
- (c) Relative dose distribution to the target in sagittal view
- (Svedman et al. 2008)



#### • Favorable Toxicity Profile

- In multiple dose-escalation trials (up to 70 Gy), no DLTs were observed
- Adverse events above G2 are uncommon
- Main adverse events include fatigue and gastrointestinal toxicities (abdominal pain, diarrhea, distension, nausea)

#### Lapierre et al. 2022

Recent dose-escalation prospective trial with 12 pts showed no  $G \ge 3$  toxicities

	8 Gy x 4	8 Gy x 5	10 Gy x 4	12 Gy x 4
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Table 4Acute toxic effects (within 3 months of treatment completion) (N = 12)

Toxic effect	Patients, No. (%)			
TOXIC CITCC	Grade 1	Grade 2	Grade ≥3	
Fatigue	5 (41.7)	0	0	
Abdominal pain	2 (16.7)	0	0	
Diarrhea	2 (16.7)	0	0	
Nausea	0	0	0	
Abdominal distension	1 (8.3)	0	0	
Gastritis	0	1 (8.3)	0	
Colitis	0	0	0	
Hematuria	0	0	0	
Rash	0	0	0	
Occlusive syndrome	0	0	0	

Lapierre et al. 2022. Safety and Efficacy of Stereotactic Ablative Radiation Therapy for Renal Cell Cancer: 24-Month Results of the RSR1 Phase 1 Dose Escalation Study. PRC

Cytoreductive SBRT for Primary Renal Cell Carcinoma

#### • SBRT Retains Renal Function

- Median decrease in eGFR due to SBRT for primary generally does not exceed 10 mL/min
  - Systematic review random effects estimate = -7.7 ml/min (Correa et al. 2019)
- Radical nephrectomy = over -20 mL/min (Patel et al. 2017)
- eGFR decrease for thermal ablation or partial nephrectomy are not significantly different in systematic reviews, and appear to be similar to decreases post-SBRT
- However, eGFR decrease after treatment is correlated with tumor size and the volume of the ablation region
- SBRT allows treatment of larger tumors compared with partial nephrectomy or thermal ablation

Cytoreductive SBRT for Primary Renal Cell Carcinoma



#### • SBRT Retains Renal Function

Cytoreductive SBRT for Primary Renal Cell Carcinoma

## Efficacy of SBRT for Primary RCC

 Favorable local control (90-100%) up to 5 years post-SBRT in multiple prospective & retrospective studies

Correa et al. 2019 reported an estimated LC of 97% in a systematic review incl.
 26 studies

Generally,

o 5-year PFS >50%

o 5-year disease-specific survival >90%

o 5-year OS ~70%

Larger tumor size associated with poorer outcomes

Cytoreductive SBRT for Primary Renal Cell Carcinoma

### IROCK Pooled Analysis (Siva et al. 2017)

- 9 institutions
- N=223 (Single-fx n=118; Multi-fx n = 105)
- Median f/u = 2.6 yrs
- Larger tumor size and tx w/ multi-fx SBRT associated with:
  - o Poorer PFS (HR 1.16, p<.01; HR 1.13, p=.02)
  - Poorer cancer-specific survival (HR 1.28, p<.01; HR 1.33, p=.01)
- Single-fx cohort had 1 local failure, multi-fx cohort had 2 (p=.60)



Cytoreductive SBRT for Primary Renal Cell Carcinoma

	At 2 years	At 4 years
LC	97.8%	97.8%
Cancer-specific survival	95.7%	91.9%
PFS	77.4%	65.4%

## Tumor Response to SBRT for Primary RCC

 Slow and continuous tumor response, with some patients showing transient progression in the short term, followed by long term ablation



Cytoreductive SBRT for Primary Renal Cell Carcinoma

#### Funayama et al. 2019

- Prospective trial; N=13
- SBRT: 6 or 7 Gy x 10 (higher dose selected if dose constraints satisfied)
- Mean f/u = 48.3 months (11-108)
- Tumor response
  - o Slow but continuous decrease in size
  - 3 cases showed transient progression in the short term
  - o Median duration to PR or CR was 22.6 months
- 2-yr OS = 91.7%
- 3-yr OS = 71.3%
- 3-yr LC = 92.3%

Host SBRT (year)

Cytoreductive SBRT for Primary Renal Cell Carcinoma

#### SBRT vs. Nephrectomy vs. Ablation

#### Grant et al. 2020

- Retrospective article by MDACC comparing outcomes for primary RCC treated with SBRT, ablation or surgery from 2004-2014, using the National Cancer Database
  - SBRT = RT in 5 fx or less to a total biological effective dose (BED) of 72 or more)
  - o Ablation (Abl) = cryoablation or thermal ablation
  - Surgery (SRG) = partial or total nephrectomy
- SBRT with BED>100, ablation and nephrectomy have similar survival outcomes.
- Advantages of SBRT compared to ablation/nephrectomy:
  - Can treat tumors >4 cm or tumors located near the renal pelvis (contraindications for interventional radiology–guided tumor ablation)
    - In this analysis, nearly 40% of SBRT tumors were >4 cm, vs. 12% of ablated tumors
  - o Noninvasive treatment with no associated anesthesia risk or prolonged recovery time
  - o Convenience (treatment generally completed in ≤5 days)
  - Immunomodulatory effects, may augment immunotherapy



**Table 5**Cox proportional hazards regression for overallsurvival by propensity score stratification in quintiles\*

HR	(95% CI)	P value
1		
0.20	(0.19, 0.20)	<.001
0.32	(0.31, 0.33)	<.001
0.52	(0.37, 0.74)	<.001
0.85	(0.55, 1.32)	.64
0.32	(0.18, 0.56)	<.001
	HR 1 0.20 0.32 0.52 0.85 0.32	HR (95% CI) 1 0.20 (0.19, 0.20) 0.32 (0.31, 0.33) 0.52 (0.37, 0.74) 0.85 (0.55, 1.32) 0.32 (0.18, 0.56)

Cytoreductive SBRT for Primary Renal Cell Carcinoma

## SBRT to Primary Tumor shows immunomodulatory effects

#### Singh et al. 2017 pilot study

- 16 Gy x1 SBRT to primary lesion + CN 4 weeks later for mRCC pts
- 14 pts
- SBRT-treated tumors had:
  - ↑ expression of the immunomodulatory molecule calreticulin and tumor-associated antigens (CA9, 5T4, NY-ESO-1, and MUC-1)
  - ↑ Ki67+ (proliferating) CD8+ T cells and FOXP3+ cells in tumors and at the tumor– stromal interface



Cytoreductive SBRT for Primary Renal Cell Carcinoma

#### Radiation induces dynamic changes to the T cell repertoire in RCC

#### Chow et al. 2020

- Primary tumors from RCC patients after nephrectomy-only (control) and SBRT plus nephrectomy (SBRT) specimens were analyzed by bulk RNA sequencing.
- Serial blood samples to analyze T-cell repertoire post-SBRT
- After SBRT, there is a **window of expansion of T-cell activity** in tumors between 2- and 4-weeks post-treatment
- Significant upregulation of immune-related pathways in SBRT-treated RCC
- Significantly increased clonality of the intratumoral T-cell repertoire
- Strong evidence suggests that the immune activity of tumors determines the patient's response to cancer immunotherapy



Cytoreductive SBRT for Primary Renal Cell Carcinoma

### Immune Cell Infiltration in RCC & OS



Cytoreductive SBRT for Primary Renal Cell Carcinoma

## Neutrophil:Lymphocyte Ratio



- Neutrophil:lymphocyte ratio inversely correlated to % change in tumor size at 1 yr (r<sup>2</sup>=0.45. p<.001)
  - o SBRT-induced immune stimulation directly contributes to tumor response
  - Increase neutrophils in PB associated w/ chronic inflammatory state; decreased lymphocytes associated with reduced immune response to cancer

Cytoreductive SBRT for Primary Renal Cell Carcinoma



• SBRT may facilitate deferral of systemic tx initiation for oligometastatic RCC

#### Tang et al. 2021

- Phase II trial at MDACC
- N=30
- All pts had ccRCC and had prior nephrectomy
- Median f/u = 17.5 mo (13.2-24.6)
- LC = 97%
- 1-yr PFS = 64%
- 1-yr OS = 100%
- 1-yr systemic tx-free survival = 82%

Cytoreductive SBRT for Primary Renal Cell Carcinoma

## • SBRT for Oligoprogression Delays Systemic Treatment Escalation for Metastatic RCC

- Patients who progress at limited sites while on systemic tx may benefit from local therapy with SBRT, as it delays the need to switch systemic tx
- COH experience (retrospective, ASCO 2022)
  - N=23 (15 on immunotherapy, 7 on targeted therapy, 1 on combination)
  - Median time from SBRT to onset of new systemic tx = 13.4 mo (0.5-37.7)
- Phase II study at UT Southwestern (Hannan et al. 2021)
  - N=20
  - Median f/u = 10.4 months (5.8-16.4)
  - LC = 100%
  - Primary objective: extend ongoing systemic therapy by >6 mo in >40% of pts
    - Achieved in 14 pts (70%)
  - Median time from SBRT to onset of new systemic tx or death = 11.1 mo (4.5-19.3



Hannan et al. 2021.

Cytoreductive SBRT for Primary Renal Cell Carcinoma

# Does SBRT+IOT Improve Outcomes for Primary RCC? SAMURAI (NRG-GU012)

- Open to accrual
- Arm 1: standard IOT
- Arm 2: SBRT to primary (14Gy x 3) + standard IOT
- Randomization 2:1 (favoring SBRT arm)
- Accrual goal = 240

- Standard IOT options:
  - o Nivolumab + ipilimumab
  - o Pembrolizumab + axitinib
  - o Avelumab + axitinib
  - o Nivolumab + cabozantinib
  - o Pembrolizumab + lenvatinib

### Other Ongoing Studies

- CYTOSHRINK (NCT04090710) → phase 2, multicenter, randomized controlled trial evaluating upfront cytoreductive SBRT to primary kidney in mRCC with combination Ipi/Nivo in patients who are deemed CNineligible.
- Liu, Peking Univ (ChiCTR1800015118) → Preoperative SBRT combined with surgical treatment for RCC and inferior vena cava tumour thrombus
- Hannan, UT Southwestern (NCT02141919) → SBRT for biopsy-proven and growing small renal tumors
- Kaplan, Beth Israel Deaconess Medical Center (NCT01890590) → A Phase II Study of Cyberknife Radiosurgery for RCC
- Trans Tasman RadOnc Group (NCT02613819) → Focal Ablative STereotactic Radiosurgery for Cancers of the

Kidney (FASTRACK II) - phase II study

- University Health Network, Toronto (NCT03747133) → SABR for Renal Tumors
- Chu, Sunnybrook Health (NCT03108703) → Assessment of QoL and Outcomes With SBRT for RCC (AQuOS-RCC)
- Dandapani, City of Hope (NCT05371132) → Evaluating the Immune Response to XRT (ELIXR)
  - mRCC cohort (accrual goal = 8, 3 pts accrued so far)
  - Using CD8 ImmunoPET (ImaginAb) <sup>89</sup>Zr-Dfcrefmirlimab

Cytoreductive SBRT for Primary Renal Cell Carcinoma

## Thank you!

Cytoreductive SBRT for Primary Renal Cell Carcinoma

Savita Dandapani, MD, PhD

CITY OF HOPE



#### Optimal Management of Small Renal Masses

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#### Small Renal Masses

- T1a: Confined to kidney <4 cm</p>
- T1b: Confined to kidney > 4cm and < 7 cm</p>



## • Ablation: To Freeze or To Fry

- Andrews Eur Urol 2019
  - 1798 patients with >6 year follow up
    - 5 year Cancer specific Survival
      - Cryo- 100%
      - RFA- 96%
      - Partial Nephrectomy-99%



## Ablation or Surgery?

#### Pierorazio et al. Journal of Urology 2016

- $\circ$  Meta-analysis of 107 studies
  - No Difference
    - Cancer specific survival
    - Metastasis free survival
    - Secondary local recurrence free survival
    - Overall survival
  - Complications
    - Shorter length of stay
    - Less blood loss/transfusion
    - Lower rates
      - Infection
      - Ureteral injury
      - Urine leak
      - Acute kidney injury
      - Cardiovascular
      - Wound complications
      - Subsequent intervention



#### Radiation

Less invasive?

- Up to 20% of small renal masses may be benign
- Standard of care for tissue sampling
- Renal Function
  - o Siva et al 2016
    - Mean decrease in GFR 14.5
    - Split renal function decline in treated kidney 53.9% to 43.9%

	Patients N	Events N	5-year estimated OS	(95% CI)	<i>P</i> value
All	200,839	40,489	0.82	(0.81, 0.82)	
Surgery	165,298	26,768	0.86	(0.86, 0.86)	<.001
Tumor ablation	17,196	4180	0.77	(0.76, 0.77)	
SBRT, BED <100	42	20	0.42	(0.25, 0.59)	
SBRT, BED ≥100	62	12	0.73	(0.56, 0.84)	
Observation	18,241	9509	0.43	(0.42, 0.43)	

Abbreviations: BED = biological effective dose; SBRT = stereotactic body radiation therapy.



#### Data

- Comparative Studies?
- o Retrospective Database Study
  - 165,298 Surgery
  - 17,196 Ablation
  - 104 SBRT



- 80 year old retired urologist with small left renal mass
  - PMHx:
    - Wheel chair bound
    - History of Myeloma and Amyloidosis, controlled on therapy
    - Stage 1 bladder ca x2 treated cystoscopically
  - CT 3 years prior showed a 0.8 cm non-specific lesion in left kidney
  - Repeat MRI shows mass now measures 1.8 cm





- 74 yo retired pediatrician
  - History of right lower pole RCC, resected >5 yrs ago
  - CKD stage 3, HTN, Afibb
  - 2.9 cm biopsy confirmed RCC





- 80 yo retired anesthesiologist
  - Incidental finding on MRI spine
  - DM2 (HgA1c- 7), Htn, hyperlipid
  - Remote history of breast cancer, treated



#### •Case 4

- 60 yo retired nurse
  - History of right RCC s/p radical nephrectomy
  - Lost to follow up for 5 years.
  - Now with 4 new lesions on left kidney
  - NI renal function. No comorbidities.

