A prospective randomized pilot trial of stereotactic body radiation therapy vs. radiofrequency ablation for the management of small renal masses

IKCS 2021 #CTR13

Kapoor A ,[1] Mironov O,[2] Tajzler C,[1]Hoogenes J,[1] Cassim R,[1] Millan B,[1]
Matsumoto ED,[1] Swaminath A[3]

[1] Division of Urology, Department of Surgery, St. Joseph's Healthcare, Hamilton, ON, Canada
[2] Department of Diagnostic Imaging, St. Joseph's Healthcare, Hamilton, ON, Canada
[3] Department of Radiation Oncology, Juravinski Cancer Centre, Hamilton, ON, Canada

Introduction

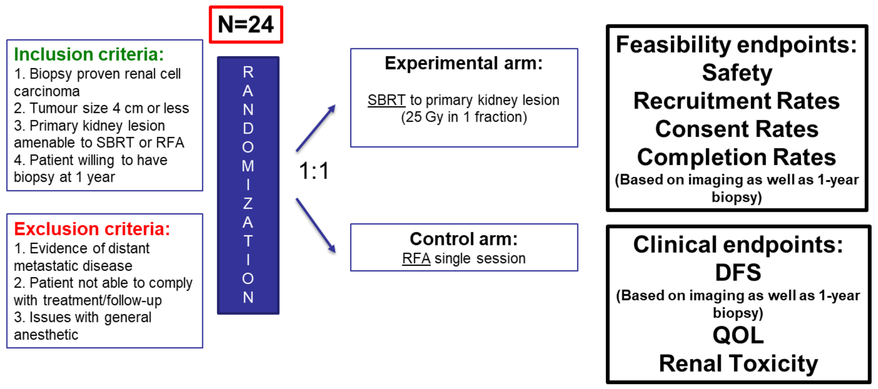
- While partial nephrectomy (PN) remains the standard of care for definitive management of small renal masses (SRMs; ≤4 cm), ablative technologies are an alternative to surgical management.
- **Radiofrequency ablation (RFA)** has been compared to PN showing cancer specific survival for PN and RFA to range between 95% to 100% at the pT1a stage.[1]
- **Stereotactic body radiation therapy (SBRT)** is an emerging treatment in the non-surgical management of SRMs. SBRT is locally effective and associated with low toxicity rates.[2]
- Currently, there is no high-level evidence comparing SBRT to RFA.

Objectives

- To determine the safety and toxicity of RFA vs. SBRT for SRMs
- To evaluate the feasibility of performing larger trial

Methods

- Prospective randomized parallel-controlled trial
- Eligible patients with biopsy-confirmed RCC scheduled for treatment of SRMs
- Patients randomized 1:1 to RFA or SBRT
- Recruitment goal N=24
- Single academic tertiary center
- Protocol: biopsy at baseline, imaging and follow-up at 3, 6, 9, 12 months post-procedure; biopsy and imaging at 12 months; 5-year follow-up
- RFA – performed percutaneously with two cycles of 8-minutes each.;150W of power to reach average ablative temperature of 105°C
- SBRT – single image-guided treatment 2 weeks following simulation session; total dose of 25 Gy



Results

- First patient recruited Jan 2020; last patient recruited July 2021
- 19 months to reach N=24
- 100% of eligible patients consented

Figure 1. Randomization

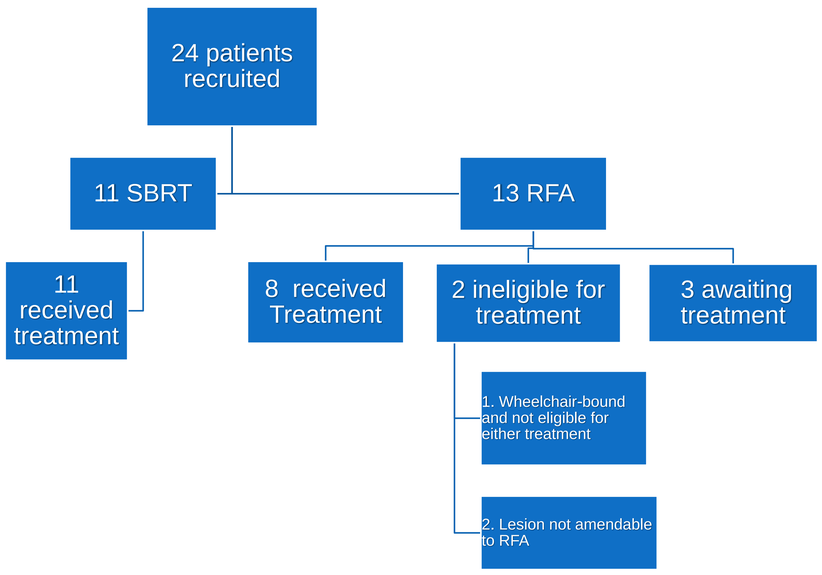
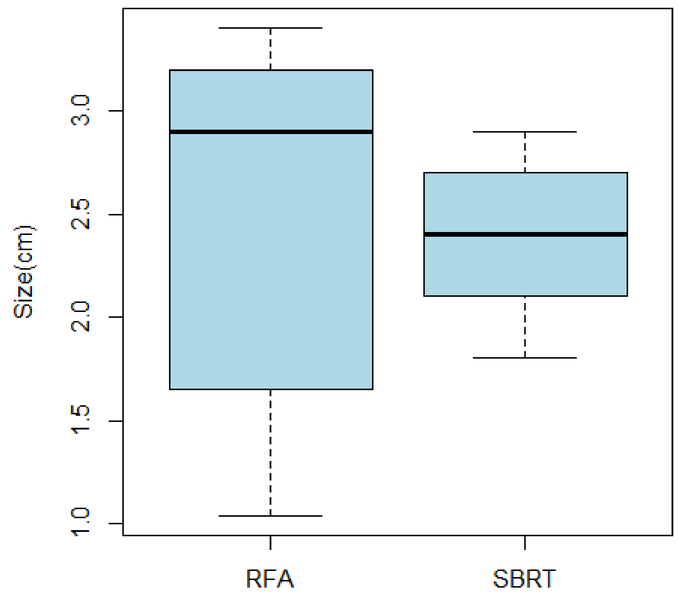


Table 1. Patient and treatment characteristics

Characteristic	All (N=24)	SBRT (n=11)	RFA (n=8)
Age [median(range)]	67 (53.85)	67 (59,61)	67 (62,75
Sex (male)	17	8	8
Race	Caucasian=23 Other=1	Caucasian=10 Other=1	Caucasian=8
Baseline pathology	ccRCC=17 pRCC (1)=6 chromophobe=1	ccRCC=7 pRCC (1)=3 chromophobe=1	ccRCC=5 pRCC (1)=3
Stage of disease	T1a = 24	T1a = 11	T1a = 8
Procedure length in minutes (mean, ± SD)	15.5±7.4	21.3 ± 6.2	10.5 ± 3.9

- 1 SBRT patient had grade 2 pain flare-up
- 2 SBRT patients underwent12-month biopsy demonstrating no residual tumor
- 2 patients (1 SBRT, 1 RFA) have had repeat imaging at 9 months demonstrating no recurrence or metastatic disease

Figure 2. Tumor size defined as largest reported dimension on cross-sectional imaging



Conclusions

- A larger prospective randomized parallel-controlled trial of RFA vs. SBRT is feasible and safe
- Minimal adverse events noted thus far
- Results have shown good oncological control at follow-up biopsy and imaging
- COVID-19 pandemic slowed recruitment rate due to decreased research activity at our center
- Plan to launch a large multicenter trial

ClinicalTrials.gov identifier: NCT03811665

References

1. Pierorazio PM, Johnson MH, Patel HD, Sozio SM, Sharma R, Iyoha E, Bass EB, Allaf ME. Management of renal masses and localized renal cancer: Systematic review and meta-analysis. J Urol. 2016 Oct;196(4):989-99.
2. Correa RJM, Louie AV, Zaorsky NG, Lehrer EJ, Ellis R, Ponsky L, Kaplan I, Mahadevan A, Chu W, Swaminath A, Hannan R, Onishi H, Teh BS, Muacevic A, Lo SS, Staehler M, Siva S. The emerging role of stereotactic ablative radiotherapy for primary renal cell carcinoma: A systematic review and meta-analysis. Eur Urol Focus. 2019 Nov;5(6):958-969.