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Clinical Outcomes Following Percutaneous Radiofrequency Ablation of Unilateral Aldosterone Producing Adenoma: Comparison to adrenalectomy

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Abstract

Purpose—To compare the efficacy of adrenal radiofrequency ablation (RFA) in treating unilateral aldosterone producing adenomas (APA) with adrenalectomy.

Materials and Methods—Between 04/2008–09/2013, 44 patients with adrenal venous sampling confirmed (lateralization index ≥ 4) unilateral APA underwent adrenal RFA (12/44 [27%]) or adrenalectomy (32/44 [73%]). Outcomes of patients treated with adrenal RFA (51 ± 11 years, 4/12 male) were compared to patients treated with adrenalectomy (50 ± 11 years, 19/32 male). Pre-treatment blood pressure ($145 \pm 19/94 \pm 13$ vs. $144 \pm 10/89 \pm 8$; $p=0.92$), number of anti-hypertensives (3.0 ± 1.3 vs. 2.7 ± 0.89 ; $p=0.38$) and serum potassium (3.2 ± 0.6 vs. 3.5 ± 0.6 mEq/L; $p=0.65$) of RFA and adrenalectomy patients were similar.

Results—Both RFA and adrenalectomy resulted in post-procedural normokalemia (RFA: 4.2 ± 0.1 mEq/L; $p=0.0004$ vs. adrenalectomy: 4.3 ± 0.6 mEq/L; $p<0.0001$) and normotension (RFA: $129 \pm 11/81 \pm 11$ mmHg; $p=0.02/0.001$ vs. adrenalectomy: $128 \pm 13/85 \pm 12$; $p<0.0001/p=0.07$) in all patients. Proportions of RFA and adrenalectomy patients cured of hypertension (2/12 (17%) vs. 12/32 (38%), $p=0.28$) or requiring fewer anti-hypertensives (7/12 (58%) vs. 13/32 (40%), $p=0.29$) was similar. RFA patients had a shorter length of stay (0.6 ± 0.8 d [Range: 0–2d] vs. 1.7 ± 1.4 d [0–7d], $p=0.01$) and lower intra-operative blood loss (1.2 ± 3 ml vs. 40 ± 85 ml, $p=0.01$) compared to adrenalectomy patients. Procedural complications occurred in 5/32 (15%) adrenalectomy patients (2 major, 3 minor) and in none of the RFA patients.

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Conclusion—RFA to treat APA can achieve clinical outcomes that approach adrenalectomy but result in shorter hospital stays. Larger, prospective trials are needed to validate these results.

Key terms

primary aldosteronism; adrenalectomy; radiofrequency ablation; adrenal nodule

INTRODUCTION

Primary aldosteronism (PA) is the most common cause of secondary hypertension, with a reported prevalence of 4.3% in the general hypertensive population and greater than 11% in patients referred to specialized centers^{1–3}. The Endocrine Society recommends adrenal venous sampling (AVS) as the gold standard study for lateralization of excess hormone production⁴. Unilateral production of excess aldosterone is most commonly due to an aldosterone producing adenoma (APA) or unilateral adrenal hyperplasia⁵. Clinical practice guidelines from the Endocrine Society recommend unilateral laparoscopic adrenalectomy for patients with documented unilateral PA¹.

Adrenalectomy results in a cure of hypertension (defined as normotension without the use of anti-hypertensive medications) in 21–72% (mean: 42%) of patients and improvement (normotension on same or reduced anti-hypertensive medications) in 18–68% (mean: 43%) of patients^{6,7}. Prior studies have shown the following to be associated with surgical cure: young age, fewer number of pre-procedure anti-hypertensive medications, higher pre-operative blood pressure, body mass index (BMI) <25 kg/m² and female sex^{6,8,9}. Outcomes after adrenalectomy are also dependent on whether AVS was utilized to determine laterality as well as the thresholds used to interpret results of the AVS^{10,11}. However, a report from the German Conn registry reported that less than 50% of patients with unilateral PA underwent adrenalectomy (15–46%)¹².

Unilateral APA can also be treated with percutaneous radiofrequency ablation (RFA) of the adrenal gland under computed tomography (CT)-guidance (Figure 1)¹³. Multiple reports document the technical and clinical success of RFA in the treatment of functional adrenal tumors^{13–16}. This study compares outcomes of RFA vs. adrenalectomy in treating AVS-confirmed unilateral APA.

MATERIALS AND METHODS

Institutional review board approval was obtained with waiver of informed consent. The study was conducted at two tertiary care institutions in the northeastern United States located in the same city, with one serving as a regional clinical and surgical referral center for adrenal disorders and the second serving as a regional referral center for AVS and RFA of adrenal adenomas. All patients were referred for AVS by endocrinologists after confirmation of aldosterone excess (serum aldosterone to renin ratio [ARR] ≥ 25 and a positive oral salt or saline loading test)¹. There was no significant difference between the pre-operative characteristics of patients undergoing adrenalectomy or RFA (Table 1).

Inclusion and exclusion criteria

All patients referred for AVS at the AVS referral center were reviewed for study eligibility. AVS was performed using a standard technique, as previously described¹⁷. In patients with a selectivity index (SI = plasma cortisol in adrenal vein/plasma cortisol in inferior vena cava) greater than 2 in non-stimulated samples of each adrenal vein, a lateralization index (LI; [plasma aldosterone of dominant adrenal vein/plasma cortisol of dominant adrenal vein]/[plasma aldosterone of non-dominant adrenal vein/plasma cortisol of non-dominant adrenal vein]) was calculated in post-ACTH samples¹. Unilateral PA was defined as patients with a LI > 4.0, per published guidelines¹. Patients were excluded if adrenal veins were not successfully catheterized (SI < 2), if the patient did not have an identifiable nodule on cross-sectional imaging, the LI was less than 4 or if the patient was lost to follow-up (Figure 2). Between April 2008 and September 2013, 44 patients fit study criteria and underwent RFA or adrenalectomy for unilateral APA.

Treatment for primary aldosteronism

An adrenal nodule, satisfying size (< 4 cm) and enhancement criteria for adrenal adenoma, was present on cross-sectional imaging in 44 patients. All AVS patients were offered RFA treatment but the decision for RFA vs. adrenalectomy was made by the patient and referring endocrinologist. 32/44 (72%) patients underwent adrenalectomy and 12/44 (27%) underwent RFA. All patients undergoing RFA had an adrenal nodule on the same side as the biochemical lateralization by AVS (Maximum diameter: 15.5 ± 5 mm [10–30 mm]). Laparoscopic adrenalectomy was performed in all surgical patients; however one patient was converted to an open adrenalectomy. All lateralized patients at the surgical referral center (21/21) underwent adrenalectomy. Adrenalectomy was performed in 11/23 (48%) patients at the RFA referral center and the rest underwent RFA (12/23, 52%).

Percutaneous CT-guided RFA was performed using a previously described technique¹³. Patients were positioned in the prone or lateral decubitus position as required in a CT gantry. General anesthesia was induced with endotracheal intubation and an arterial line was placed for real time blood pressure monitoring. Under CT guidance, a single monopolar radiofrequency electrode, 17G, 15cm long with a 3cm active tip, internally cooled with ice cold water in a closed system (Cool-Tip; Covidien Healthcare, Dublin, Ireland) was inserted percutaneously into the nodule in the adrenal gland (Figure 3). The duration of ablation was precisely 12 minutes in each case, per manufacturer protocol using a pulsed technique, with estimated power ranging between 50 and 150W. Fat stranding was usually seen in the peri-adrenal fat surrounding the entire nodule while the ablation was being performed and also persisted on subsequent imaging (Figure 4). Post-procedure contrast-enhanced CT scan was performed in 12/12 cases. Technical success was defined as successful electrode access to the nodule and completion of the ablation treatment with lack of enhancement of adrenal nodule. Intra-operative hypertensive urgency was defined as an acute elevation of systolic blood pressure greater than 180 mmHg.

Clinical follow-up

Clinical follow-up was available in all 44 patients (346 ± 390 days [9–1408 days]). Patients were divided into the following categories based on changes in anti-hypertensive medication

post-adrenalectomy or RFA: cured (defined as normotensive patients not requiring any anti-hypertensive medications post-treatment); reduced number of medications, (defined as patients requiring fewer number of anti-hypertensive medications post-treatment); and reduced dosage of medications (defined as patients requiring a lower dose but same number of anti-hypertensive medications). Patients who did not meet any of these three response criteria were classified as non-responders. Definitions of cure after RFA was consistent with standardized reporting guidelines on RFA use for hormonally-active benign tumors¹⁸.

Intra-procedural complications were graded using Society of Interventional Radiology quality improvement guidelines¹⁹. Early readmissions (less than 30 days after discharge) were categorized as procedure-related or not procedure-unrelated.

Statistical Analysis

All continuous variables were reported as mean $\pm$ standard deviation. All categorical variables were reported as percentages. Continuous data was compared using a two-sample non-paired Student's t-test. Categorical data was analyzed using Fischer's exact test or Pearson's chi-square test. Statistical analysis was performed using Matlab (Mathworks, Natick, MA). A value of $p < 0.05$ was considered statistically significant.

RESULTS

Procedure characteristics

Intra-procedural time between the two groups was similar (158 ± 42 minutes for RFA, 168 ± 69 minutes for adrenalectomy, $p=0.64$). All adrenalectomies were initiated as laparoscopic procedures but 1/32 was converted to an open procedure. Intra-operative blood loss did not require blood transfusion in any patient in both groups but patients in the adrenalectomy group had more blood loss (1.2 ± 3 ml in RFA vs. 40 ± 85 ml in adrenalectomy, $p=0.01$). Hypertensive urgency occurred in 8/12 (67%) of RFA patients (Duration: 7 min [2–15 min]) and 3/32 (9%; 12 min [6–15]) of adrenalectomy patients ($p=0.0001$). All 12 RFA patients required intra-operative blood pressure control (anti-hypertensives in 12/12 and magnesium sulphate in 7/12) but only 3/32 adrenalectomy patients required the same. Patients undergoing RFA were more likely to have a same day discharge (7/12 [58%] vs. 1/32 [3%], $p=0.0001$) and had a shorter length of stay (0.6 ± 0.8 days [Range: 0–2 days] vs. 1.7 ± 1.4 days [0–7 days], $p=0.01$).

No intra-operative or peri-operative complications occurred in RFA patients. No patients suffered end organ damage or escalation of care (other than the use of intra-operative medications) due to hypertensive urgency in either group. In adrenalectomy patients, 5 patients had intra-operative complications including 3 minor complications (self-limiting liver and spleen laceration and damage to a renal cyst) and 2 major complications (damage to the pancreatic duct requiring drain placement and a liver laceration that resulted in an early readmission). Two adrenalectomy patients with normal pre-operative serum potassium also developed post-operative atrial fibrillation with rapid ventricular rate requiring intensive care unit admission although it is unclear if this was procedure related.

Clinical outcomes

Clinical follow-up was available in 12 patients undergoing RFA (463±470 days after treatment) and 32 patients undergoing adrenalectomy (299±339 days after treatment). Both RFA and adrenalectomy resulted in normokalemia, a significant decrease in systolic blood pressure as well as the number of anti-hypertensives required by each patient (Table 2). The proportion of patients cured of hypertension or patients requiring reduced number or dose of anti-hypertensive medications in the RFA and adrenalectomy groups were similar (Table 2).

Following discharge, two RFA patients (2/12, 17%) developed acute symptoms, one with flank pain at the site of treatment requiring supportive care for one week and one with nausea, vomiting and abdominal pain and CT scan showing no acute findings who required a readmission for observation. Five adrenalectomy patients (5/32, 15%) developed acute, post-discharge symptoms, one patient had flank pain at the site of treatment lasting one week, one had incisional pain lasting one month, one patient with a liver laceration had nausea, pain and rising liver function tests requiring a readmission for observation, one patient had nausea and vomiting requiring an emergency room visit with a negative abdominal CT and one patient developed a drug rash requiring readmission. Overall, two adrenalectomy patients and one RFA patient were readmitted with all readmissions occurring within 7 days of discharge.

DISCUSSION

Although adrenalectomy is currently the standard of care for unilateral APA, efficacy of percutaneous RFA in treating functional benign adrenal tumors has been reported in multiple small studies^{13–16}. However, comparing efficacy of competing treatments in unilateral APA is challenging because pre-treatment patient characteristics and thresholds for AVS interpretation can influence outcomes after treatment^{9,11}. Establishing the role of RFA relative to adrenalectomy in treating APA requires direct comparisons of safety and efficacy in comparable cohorts. In the current study, outcomes after RF ablation and adrenalectomy for treatment of AVS-proven unilateral APA are compared.

In adrenalectomy and RFA cohorts with similar pre-treatment characteristics (age, sex, blood pressure, number of anti-hypertensives, obesity) and AVS profiles, efficacy in treating APA was similar. Both treatments reduced blood pressure and number of anti-hypertensive medications and increased serum potassium without need for potassium supplementation. Both techniques were equivalent in terms of the proportions of patients in the two cohorts who were cured (no anti-hypertensives needed), improved (needed reduced number or dose of anti-hypertensives) or did not respond to treatment. The proportion of non-responders in both groups was also similar (8% of RFA and 16% of adrenalectomy patients). Overall, this compares favorably with other reports of the proportion of non-responders after adrenalectomy (12–38%)^{7,15,20,21}. Theoretically, non-responders to RFA can potentially still undergo unilateral adrenalectomy in case treatment failure was due to incomplete ablation, although no patient in this cohort followed this clinical pathway. Additionally, compared to adrenalectomy, RFA requires the presence of a nodule on the affected adrenal gland¹³. This requirement makes this technique well suited for APA but unilateral adrenal hyperplasia may require adrenalectomy.

Although not statistically significant, a higher percentage of adrenalectomy patients were cured of hypertension compared to RFA. This could be related to more patients in the RFA group having underlying essential hypertension although no significant difference in age, sex or obesity was noted between the two groups. Another possibility is that RFA may treat the dominant nodule but the remaining gland may still have untreated hyperfunctioning tissue. However, studies have also reported and advocated the use of partial adrenalectomy or enucleation of APA^{22–24}. More recent studies, including a randomized control trial, report similar technical success and therapeutic outcomes for partial versus total adrenalectomy^{7,21}. One study reported recurrent hypertension in 2/29 (7%) of patients undergoing partial adrenalectomy²⁵. RFA may be similar to partial adrenalectomy; however, no recurrence occurred in the RFA cohort in this study. In light of these studies, the lower cure rate in RFA patients may be related to sample size limitations and not untreated hyperfunctioning adrenal tissue. Similar studies in larger patient cohorts are clearly needed to assess the cure rate after RFA.

The advantages of a percutaneous RFA technique over adrenalectomy include an ambulatory day procedure with same-day discharge for most patients, lower volume of blood loss and fewer instances of damage to adjacent organs, i.e., percutaneous RFA has a better safety profile compared to adrenalectomy. Yang et al recently reported the efficacy and outcomes of laparoscopic RFA compared to partial adrenalectomy with similar therapeutic effects of the two modalities but the benefits of a shorter operative time, less blood loss and a lower complication rate (16.7% vs. 26.9%) using laparoscopic RFA²¹. Complications of laparoscopic RFA in that study included paresthesia at the trocar site in one patient and a perinephric hematoma in one patient. More importantly, compared to the report of Yang et al where the length of stay ranged from 2–6 days, nearly 60% of patients undergoing percutaneous RFA in the current study had a same day discharge and no RFA patients suffered any complications, highlighting the advantages of percutaneous RFA over laparoscopic RFA.

RFA patients in this study had a significantly higher incidence of intra-procedural hypertensive urgency compared to adrenalectomy patients. Hypertensive urgency has been reported for both adrenal RF ablation and during adrenal surgery^{21,26}. In RFA patients, hypertensive urgency was short in duration (<15 min as determined by real-time intra-arterial blood pressure monitoring), easily reversed by intra-procedural medications and without any clinical sequelae. Traditionally, evaluation, management and clinical sequelae for hypertensive urgency are based on longer periods of exposure (>30 min), and so the clinical significance of transient hypertension in these patients is unclear. The prophylactic use of anti-adrenergic agents for several weeks prior to ablation in practice and existing literature for adrenal adenomas is variable^{16,27,16,26,14,21}. In consultation with the anesthesiology department peri-procedural rather than prophylactic control was adopted in this study. Multiple potential intra-procedural techniques are available to minimize the secondary intra-procedural hypertension such as real-time intra-arterial blood pressure monitoring in combination with intra-procedural anti-adrenergic medications and intermittent ablation protocols (stopping ablation during the initial hypertensive response until the blood pressure normalizes). Even though end-organ effects of ablation-induced hypertensive urgency are described, no patient had peri-procedural or long term effects of

ablation-induced hypertensive urgency. In the future, RFA for APA may become even safer by adding pre-treatment with an alpha-adrenergic antagonist to minimize catecholamine surges that may occur due to incidental ablation of normal adrenal medullary tissue.

Limitations to this study include a small sample size, which may be why there was a non-statistically significant difference in the number of patients cured and the number of non-responders for RFA and adrenalectomy groups. Although clinical response rates were similar in the two groups, neither histological evidence of adenoma necrosis nor biochemical evidence of PA cure was available in the RFA patients. Intra-procedural blood loss was subjectively estimated by the operating physician for both RFA and adrenalectomy, but clinically significant bleeding complications or blood transfusions were not found in either group. Due to multiple sources of referral, heterogeneity in the referred population and the non-randomized selection of patients for RFA and adrenalectomy may result in selection bias. Out-of-state referrals also resulted in 20% of patients being lost to follow-up. Finally, due to its retrospective nature, there are differences in the duration of follow-up available for the two techniques.

This study demonstrates that RFA can achieve similar clinical outcomes to adrenalectomy with lower procedural morbidity in treating patients with AVS-proven unilateral APA. Given this favorable comparison, prospective and ideally randomized studies comparing both techniques are needed to establish the role of RFA in treating unilateral APA.

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Figure 1.
Computed tomography axial image of a prone patient with primary aldosteronism showing a 17 mm right adrenal nodule (white circle).

Figure 2.
Flow chart showing patients included and excluded from the study.

Figure 3.
Intra-procedure computed tomography image of a prone patient showing placement of a cooled-tip radiofrequency probe into the nodule.

Figure 4.
Computed tomography axial image obtained 6 months after adrenal adenoma radiofrequency ablation showing peri-adrenal stranding and fat necrosis (white circle).

Table 1

Pre-procedure characteristics of patients with unilateral APA undergoing surgical adrenalectomy or RFA.

	RFA (n=12)	Adrenalectomy (n=32)	p
Age (years)	51±11	50±11	0.68
Male sex	4/12 (33%)	19/32 (59%)	0.18
Pre-operative BP (mmHg)	145±19/94±13	144±10/89±8	0.92
No. of medications (drugs)	3.0 ±1.3	2.7±0.89	0.38
Renal artery stenosis	None	None	-
Obesity (BMI >25)	3/12	14/32	0.31
Serum potassium (mEq/L)	3.2±0.6	3.5±0.6	0.65
Follow-up (days)	463±470	299±339	0.59

Table 2

Results and comparison of outcomes of RFA vs. surgical adrenalectomy in patients with unilateral APA

	RFA (n=12)		Surgery (n=32)		p
Cured patients					0.28
	2/12 (17%)		12/32 (38%)		
Reduced no. of medications					0.29
	7/12 (58%)		13/32 (40%)		
Reduced dose					0.29
	2/12 (17%)		2/32 (6%)		
Non-responders					1.00
	1/12 (8%)		5/32 (16%)		
<hr/>					
	Pre-Procedure	Post-Procedure	Pre-Procedure	Post-Procedure	p
Blood pressure (mmHg)	145±19/94±13	129±11/81±11	144±10/89±8	128±13/85±12	<0.0001/0.07
Potassium (mEq/L)	3.2±0.6	4.2±0.1	3.5±0.6	4.3±0.6	<0.0001
Number of anti-HTN (drugs)	3±1.3	1.75±1.6	2.7±0.88	1.1±1.1	<0.0001