Acta Cardiol Sin 2020;36:160–167
Original Article
doi: 10.6515/ACS.202003_36(2).20190812C

Hypertension

Immediate Results and Long-Term Outcomes Following Percutaneous Radiofrequency Ablation of Unilateral Aldosterone-Producing Adenoma

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Background: The aim of this study was to evaluate early and long-term clinical and laboratory findings in patients with resistant hypertension secondary to aldosterone-producing adenoma (APA) treated with radiofrequency ablation (RFA).

Methods: From July 2009 to September 2017, eight adult patients underwent percutaneous computed tomography (CT)-guided RFA for APA. The safety, efficacy and complications of the procedure were determined. Blood pressure (BP), number of antihypertensive agents, serum potassium, plasma aldosterone and aldosterone-to-renin ratio (ARR) were analyzed before RFA and immediately, short-term and long-term after RFA.

Results: The technical success rate was 100%. Two patients developed minor complications but there were no major complications. Clinical improvement was achieved immediately and short-term after RFA. In the long-term (mean follow-up duration of 6.7 ± 2.1 years) there were significant improvements in systolic (from 162.3 mmHg ± 18.6 to 125 mmHg ± 16.1, p = 0.02) and diastolic (from 96.3 mmHg ± 12.7 to 68.5 mmHg ± 6.3, p = 0.02) BP, with a significant reduction in the number of antihypertensive agents (from 3.33 ± 0.82 to 1.33 ± 1.21, p = 0.02). Hypokalemia improved significantly (serum potassium from 2.16 meq/L ± 0.22 to 4.34 meq/L ± 0.54, p = 0.04). Although the plasma aldosterone level decreased significantly, ARR did not (from 100.7 ± 124.4 to 28.7 ± 30.7 ng/dL-per-ng/mL/h, p = 0.13). Hypertension was cured in 33.3% of the patients, and the BP of all patients was more easily controlled regardless of the plasma aldosterone and renin status.

Conclusions: CT-guided percutaneous RFA appears to be effective and safe to treat patients with APA, with clinical improvements in BP, reduced number of antihypertensive agents, and normalization of serum potassium level. These favorable outcomes persisted in short-term and long-term follow-up.

Key Words: Adrenal adenoma • Aldosterone • Hypertension • Radio-frequency ablation

INTRODUCTION

Aldosterone-producing adenoma (APA), also known as Conn's syndrome, is a curable cause of aldosterone-secreting benign adrenal neoplasms which can cause primary aldosteronism (PA). It is also a common cause of secondary hypertension, with a prevalence of 4~5% in patients with hypertension.[1-4] Laparoscopic adrenalectomy (LA) is currently recommended as the standard treatment for APA.[4,5] Even though LA has been shown to result in favorable clinical outcomes, it is still limited due to its relatively invasive nature, the need for general anesthesia, and prolonged operation time. Medical therapy is often recommended as an alternative for patients who are not candidates (e.g., those with a high body mass

Received: April 2, 2019 Accepted: August 12, 2019
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index, old age, or cardiopulmonary diseases) or reluctant to undergo surgery.[4] Hence, therapeutic options with lower invasiveness may be more appealing to such patients.

Image-guided percutaneous radiofrequency ablation (RFA) has emerged as a new treatment for APA, and it provides an alternative treatment option for patients at risk of a poor surgical outcome because of the minimally invasive approach. RFA works by delivering a high-frequency alternating current through a needle electrode, which generates frictional heat to destroy cells at a predictable temperature.[6] Previous studies have reported a high technical success rate ranging from 84~95%, and a lower rate of procedural morbidity with a minor complication rate of 7~18%, most of which were self-limited.[6-8] The efficacy of RFA has also been reported to be comparable with similar clinical achievement to LA and to result in a shorter hospital stay.[3,9] Although the safety, clinical outcomes and results of RFA have previously been reported, most previous studies have focused on short-term follow-up, and very few studies have reported long-term follow-up data of clinical improvements and recurrence in these patients. Therefore, this study focused on the efficacy and clinical outcomes of patients with unilateral APA treated with RFA immediately after the procedure, and in short- and long-term follow-up.

MATERIALS AND METHODS

This was a retrospective observational study in which we collected data from a single institution on patients who received computed tomography (CT)-guided percutaneous RFA for unilateral APA. This study was approved by our Institutional Review Board.

Patient selection

From July 2009 to September 2017, consecutive patients aged 20-80 years who had PA due to a unilateral APA smaller than 3 cm were recruited. PA was initially suspected in young patients with hypertension or resistant hypertension and unprovoked hypokalemia, and the diagnosis was usually made according to laboratory biochemical results (elevated plasma aldosterone level > 20 ng/dL and/or high plasma aldosterone-to-renin ratio (ARR) > 25 ng/dL-per-ng/mL/h or suppressed low renin level).[4,10] The test was performed in the morning in seated ambulatory patients. The diagnosis of APA was confirmed when a unilateral adrenal adenoma and a normal contralateral adrenal gland were detected on CT. We did not perform adrenal vein sampling due to its invasiveness and safety concerns, and because it is not a routine procedure in our department.

The exclusion criteria were: (i) bilateral or multiple adrenal tumors; (ii) other concomitant adrenal diseases such as Cushing syndrome or pheochromocytoma; (iii) a large tumor > 3 cm and potentially malignant tumors with evidence of heterogeneous contrast material enhancement on CT; (iv) uncorrected coagulopathy; (v) unfavorable tumor site (lesion closely located to the lung base, inferior vena cava or renal hilum); and (iv) patients who refused to undergo RFA.

A total of 26 patients were diagnosed with PA and unilateral APA during the study period, of whom eight received CT-guided percutaneous RFA. All patients were initially treated by a cardiologist or endocrinologist to optimize blood pressure control and hypokalemia before RFA.

CT-guided radiofrequency ablation

RFA procedures were performed in an inpatient setting. After the administration of general anesthetic, the patients were placed in the prone position. Under CT guidance, a single Cool-tip radiofrequency needle electrode (Covidien Boulder, CO, USA) with 2- or 3-cm tip exposure penetration was inserted into the adrenal adenoma using a posterior paraspinal approach. Once a successful puncture had been achieved, a standard 6- or 12-min cycle of ablation and impedance-control algorithm was applied.[11-17] Tissue destruction was achieved when the temperature threshold for cell death of 50-60 °C had been reached.[18] The extent and completeness of tumor ablation was then immediately assessed by CT, which also revealed possible bleeding complications. The ablation procedure was immediately halted if the SBP increased to over 180 mmHg or if any potentially life-threatening events developed. All of the procedures were performed under the supervision of an experienced interventional radiologist. Technical success was achieved in all patients who underwent a single RFA procedure as assessed by immediate post-procedural imaging (Figure 1).

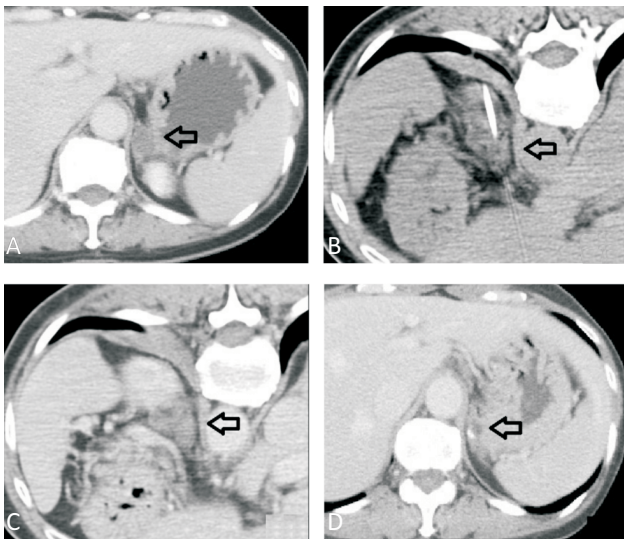

Figure 1. *Axial contrast-enhanced computed tomography (CT) images of a 56-year-old woman who presented with resistant hypertension and biochemically-confirmed primary aldosteronism. (a) CT image showing a 2.5-cm left aldosterone-producing adenoma (APA) (arrow). (b) CT-guided percutaneous radiofrequency ablation (RFA) with a paraspinal approach in the prone position – the arrow indicates the RFA needle in the adenoma. (c) Immediate post-RFA CT scan of the same left APA (arrow). (d) CT scan 6 years after RFA – the arrow shows partial calcification with a reduction in APA size.*

Outcome measurements

We recorded the rate of periprocedural complications, morbidity and mortality after RFA, and calculated the mean follow-up duration and long-term lost-to-follow-up rate. Clinical evaluations and biochemical markers were measured to assess the treatment response to RFA immediately post-ablation and in short- and long-term follow-up. These included; (i) blood pressure (BP) and the number of antihypertensive agents to determine whether hypertension had been cured or if it was persistent or worse; (ii) serum potassium level to assess the long-term resolution of hypokalemia; and (iii) plasma aldosterone level or ARR to evaluate the long-term resolution of PA and possible recurrence of the condition.

Statistical analysis

Statistical analysis was performed using SPSS software (version 18.0; SPSS Inc., Chicago, IL, USA). The Wilcoxon signed-rank test was used to compare differences between pre- and post-RFA measurements of BP, number of antihypertensive agents, serum potassium, plasma aldosterone and ARR at different follow-up times. A p value of < 0.05 was considered to indicate statistical significance.

RESULTS

During the study period, eight patients received CT-guided percutaneous RFA (five women, three men; mean age 54.3 years $\pm$ 13.5). The mean APA size was 1.9 cm $\pm$ 0.6. There were five (62.5%) left-sided APAs and three (37.5%) right-sided APAs. The mean plasma aldosterone level was 50.95 ng/dL $\pm$ 29.17, and the ARR was 93.63 ng/dL-per-ng/mL/h $\pm$ 71.24. The mean serum potassium level was 2.24 meq/L $\pm$ 0.28, and the lowest level was 1.9 meq/L. The mean systolic blood pressure (SBP) was 163.75 mmHg $\pm$ 16.01, and the mean diastolic blood pressure (DBP) was 97 mmHg $\pm$ 10.89 with appropriate medication (mean 3.25 $\pm$ 1.28 antihypertensive agents) control before ablation. The basic characteristics are summarized in Table 1.

Periprocedural complications

One patient had an intra-operative hypertensive crisis during the procedure. One minute after the ablation his BP reached 301/108 mmHg, and ablation was immediately ceased. His BP decreased to 150/77 mmHg within 3 minutes after the prompt administration of intravenous nitroglycerin, labetalol and nicardipine. No hypertensive crisis-related complications developed during or after ablation in this patient. Another patient had a mild retroperitoneal hematoma after RFA which was improved with conservative treatment without requiring drainage or surgical procedures. There were no major vascular injuries, visceral injuries, pneumothorax or cutaneous burns. There were no procedure-related deaths in this study.

Immediate post-ablation response

Complete clinical and biochemical outcomes of the eight patients were evaluated within 2 weeks after ablation to assess the rapid treatment response rate. BP was significantly well controlled (mean SBP 140.25 mmHg $\pm$ 12.79, $p = 0.0113$; DBP 84.25 mmHg $\pm$ 13.16, $p = 0.0116$). There was a slight reduction in the number of antihypertensive agents used (2.5 $\pm$ 0.93, $p = 0.0633$), and significant resolution of PA with a mean plasma aldosterone level of 5.2 ng/dL $\pm$ 4.08 ($p = 0.0117$) and ARR of 20.01 ng/dL-per-ng/mL/h $\pm$ 37.8 ($p = 0.0431$). The serum potassium level significantly increased (3.9 meq/L $\pm$ 0.8, $p = 0.011$) and normalized in almost all of the patients. The results are shown in Table 2 (Column A).

Short-term treatment success

The results at 3-6 months after RFA are shown in Table 2 (Column B). There was a significant improvement in BP control (mean SBP 130 mmHg ± 17.47, p = 0.0116; DBP 78.38 mmHg ± 13.7, p = 0.0117), normalization of serum potassium level (4.14 meq/L ± 0.67, p = 0.0115), and decrease in the number of antihypertensive drugs used (1.25 ± 1.04, p = 0.0269). Only one pa-

Table 1. Baseline characteristics of the eight patients with aldosterone-producing adenoma

Patient No.	Year of RFA treatment	Age	Gender	Co-morbidity	Positive family history of hypertension	Location	Size (cm)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Lowest serum K (meq/L)	Plasma aldosterone level (ng/dL)	ARR (ng/dL-per-ng/mL/h)
1	2009	63	Female	CKD stage 3b, OSA	Nil	Left	1.3	150	92	2.5	56.5	7.4
2	2009	29	Female	Nil	Nil	Left	2.3	166	110	2.1	79.3	54.69
3	2009	51	Female	Lymphoma, ICH	Father	Left	2.6	170	100	2.2	36.6	9.97
4	2011	56	Female	Dyslipidemia, bladder cancer	Nil	Left	2.5	144	90	2.1	23.1	88.85
5	2012	55	Male	Dyslipidemia	Nil	Right	2.3	160	103	2.1	107.4	51.39
6	2013	76	Male	CAD, HF, dyslipidemia, CKD stage 3b	Father, mother	Left	1.1	157	76	2.2	44.4	317.14
7	2014	58	Male	Ischemic stroke, DM, dyslipidemia	Elder brother	Right	1.7	197	107	1.9	35	38.89
8	2017	46	Female	Nil	Father, grandmother	Right	1.7	166	98	2.8	25.3	180.71
Mean		54.3 ± 13.5					1.9 ± 0.6	163.75 ± 16.01	97 ± 10.89	2.24 ± 0.28	50.95 ± 29.17	93.63 ± 71.24

ARR, aldosterone-to-renin ratio; BP, blood pressure; CAD, coronary artery disease; CKD, chronic kidney disease; DM, diabetes mellitus; HF, heart failure; ICH, intracranial hemorrhage; K, potassium; OSA, obstructive sleep apnea; RFA, radiofrequency ablation.

Table 2. Comparison of the mean parameters of the patients before and after RFA at different time points

	Column A				Column B				Column C			
	Immediately post-RFA (within 2 weeks)				Short-term follow-up (3-6 months) after RFA				Long-term follow-up (mean 6.7 years ± 2.1)			
	No. of patients	Before RFA	Immediately post-RFA	p value	No. of patients	Before RFA	Short-term follow-up	p value	No. of patients	Before RFA	Long-term follow-up	p value
Systolic BP (mmHg)	8	163.75 ± 16.01	140.25 ± 12.79	0.0113	8	163.75 ± 16.01	130 ± 17.47	0.0116	6	162.33 ± 18.64	125 ± 16.16	0.0273
Diastolic BP (mmHg)	8	97 ± 10.89	84.25 ± 13.16	0.0116	8	97 ± 10.89	78.38 ± 13.7	0.0117	6	96.33 ± 12.79	68.5 ± 6.35	0.0277
No. of antihypertensive drugs	8	3.25 ± 1.28	2.5 ± 0.93	0.0633	8	3.25 ± 1.28	1.25 ± 1.04	0.0269	6	3.33 ± 0.82	1.33 ± 1.21	0.0235
Serum K level (meq/L)	8	2.24 ± 0.28	3.9 ± 0.8	0.011	8	2.24 ± 0.28	4.14 ± 0.67	0.0115	5	2.16 ± 0.22	4.34 ± 0.54	0.0431
Plasma aldosterone level (ng/dL)	8	50.95 ± 29.17	5.2 ± 4.08	0.0117	6	36.82 ± 12.4	11.22 ± 8.19	0.0464	5	53.28 ± 32.65	14.03 ± 3.98	0.0431
ARR (ng/dL-per-ng/mL/h)	8	93.63 ± 71.24	20.01 ± 37.8	0.0431	4	59.24 ± 82.23	97.47 ± 189.32	0.715	5	100.73 ± 124.44	28.73 ± 30.74	0.138

Statistical method: Wilcoxon signed-rank test.

ARR, aldosterone-to-renin ratio; BP, blood pressure; K, potassium; No., number; RFA, radiofrequency ablation.

tient used the same number of medications after the procedure; however the dose was reduced by half as early as 1 week after ablation. There was no evidence of increased BP or hypokalemia in any of the patients. Although the plasma aldosterone level significantly decreased (11.22 ng/dL ± 8.19, p = 0.0464), the mean ARR increased (97.49 ng/dL-per-ng/mL/h ± 189.32; p = 0.715) due to one patient who had recurrent PA.

Long-term follow-up

The mean follow-up duration was 6.7 years ± 2.1. One patient received RFA in 2017, so the follow-up period was not long-term. Another patient was lost-to-follow-up. Therefore, six of the eight participants were evaluated for long-term outcomes. Five of these patients had complete clinical and biochemical data, but one did not have long-term biochemical data due to clinical improvement and normotensive status without medical control. These data are shown in Table 2 (Column C).

There were statistically significantly improvements in SBP 125 mmHg ± 16.16 (p = 0.0273), DBP 68.5 mmHg ± 6.35 (p = 0.0277), serum potassium level 4.34 meq/L ± 0.54 (p = 0.0431) and plasma aldosterone level 14.03 ng/dL ± 3.98 (p = 0.0431), however there was no significant reduction in ARR (28.73 ng/dL-per-ng/mL/h ± 30.74, p = 0.138). One patient had recurrent PA with an elevated ARR (82.92 ng/dL-per-ng/mL/h), however she achieved clinical improvement with a stable BP without antihypertensive drug control.

There were improvements in SBP and DBP, a reduction in the number of antihypertensive agents, and normalization of serum potassium and aldosterone levels after the procedure (Figure 2). The mean serum ARR

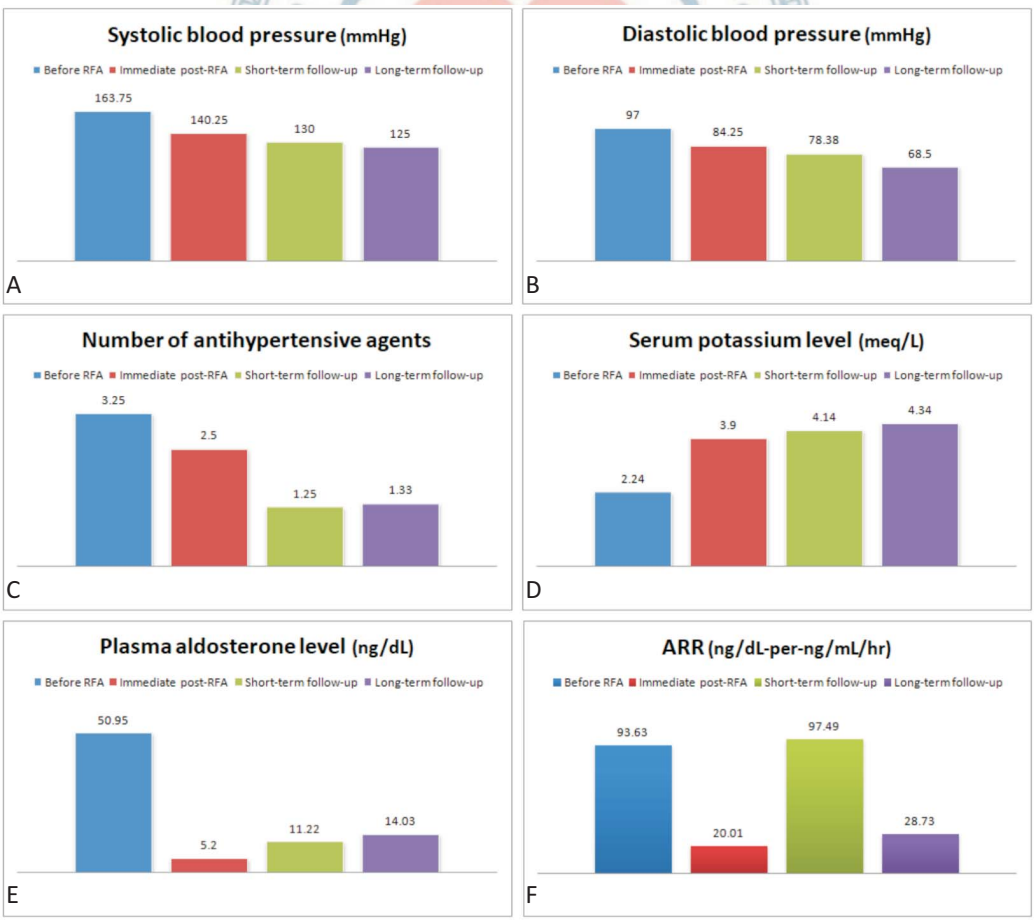

Figure 2. *Serial changes of the mean values of systolic blood pressure (a), diastolic blood pressure (b), number of antihypertensive agents used (c), serum potassium (d), plasma aldosterone (e) and plasma aldosterone-to-renin ratio (ARR) (f) before radiofrequency ablation (RFA), immediate after RFA, and in short- and long-term follow-up.*

was elevated in short-term follow-up as one patient with recurrent PA had a high ARR.

DISCUSSION

Hypertension is one of the most common public health problems worldwide. High BP has a detrimental effect on endothelial function that can cause various end-organ damage.[19] APA can lead to clinical syndrome including resistant hypertension and hypokalemia. In this study, we evaluated the immediate post-ablation, short-term and long-term biochemical and clinical outcomes of RFA in the treatment of APA. The results showed significant improvements in SBP and DBP, a reduction in the number of antihypertensive agents used, and normalization of serum potassium and aldosterone levels. The mean serum ARR was elevated in short-term follow-up as one patient with recurrent PA had a high ARR. While RFA has previously been shown to be an effective treatment for APA,[3,7-9,17] this study demonstrated that its effectiveness was also sustainable without worsening the clinical status. In addition, RFA has previously been shown to have a short-term effect in treating APA,[6,11-15] however few studies have reported long-term outcomes with regards to reversing PA in APA.[6,11,12]

Mendiratta-Lala et al.[11] reported the use of RFA in 10 patients, however their study was limited by the short follow-up duration (median 17 months), and the fact that more than 50% of their follow-up biochemical data were missing. Szejnfeld et al.[12] retrospectively evaluated the use of RFA in nine patients, however they only reported short-term biochemical follow-up data. Although Yang et al.[16] evaluated biochemical parameters in 12 patients, the mean follow-up period (4.1 years) was still relatively short. A recent study by Liu et al.[17] included 36 patients with long-term follow-up (mean 6.2 years), and RFA was found to be an effective option with a sustainable treatment response in relieving PA. In addition, long-term treatment failure was found only in three (8%) patients during follow-up, and long-term recurrence was not a therapeutic concern. To the best of our knowledge, the current study has the longest follow-up duration (mean 6.7 years) for the evaluation of clinical and biochemical results.

Our results are consistent with previous adrenalectomy studies which indicated that RFA is as effective as surgery in resolving hypertension for APA. However, in contrast to surgery, RFA can be performed safely without high risks of major morbidity and mortality. Retroperitoneal hematomas, small pneumothoraces, and intraprocedural hypertensive crises are the most common self-limiting minor complications, none of which require aggressive interventions.[6,16,20] Due to its low invasiveness, RFA is a reasonable alternative for patients who are reluctant to undergo or are not candidates for surgery. There were no cases of major morbidity or mortality associated with RFA in this study, and only two (25%) patients developed minor complications (controlled intra-procedural hypertensive crisis and self-limiting retroperitoneal hematoma). Several techniques can be used to minimize intraprocedural hypertension crisis, such as real-time arterial BP monitoring, using intraprocedural antiadrenergic medications and intermittent ablation during the initial hypertensive response until BP normalizes.[3]

RFA has been reported to achieve long-term improvements in hypertension in up to 56% of patients, with rates of post-operative persistent hypertension ranging from 33-61%. In addition, 5-11% of patients have been reported to still have poor BP control or worsening hypertension after laparoscopic adrenalectomy, with 34-50% being cured of hypertension.[21-25] In the current study, two (25%) patients were cured of hypertension and no longer required medications in short-term follow-up, and two (33.3%) patients in long-term follow-up. All of the patients (100%) achieved good BP control in long-term follow-up. Although two patients were prescribed with one additional antihypertensive agent at the 43rd and 92nd weeks of follow-up, their BP was still better controlled with fewer drugs than before RFA. There were no cases of elevated BP.

The serum potassium level increased significantly from 1-2 weeks after RFA, and it remained normalized in long-term follow-up. This outcome is similar to previous study results.[11,12,16,17] The plasma aldosterone level was significantly decreased both in short- and long-term follow-up, but ARR was not (Figure 2f). One patient presented with recurrent PA in short-term with an increase in ARR from 180.71 to 381.4 ng/dL per ng/mL/hr. However, this patient received RFA treatment within one year, her clinical and biochemical follow-up was not in-

cluded in the long-term analysis. This influenced the elevation in ARR in short-term but not in long-term results. However, all of the patients achieved better BP control or were even normotensive with a reduction in the number of medications regardless of the plasma renin and aldosterone levels.

RFA would appear to be more cost-effective than laparoscopic adrenalectomy in the short-term due to the shorter time to resumption of normal activities and shorter hospital stay.[9] However, the long-term cost-effectiveness of RFA compared with adrenalectomy is uncertain.

Limitations

There are several limitations to this study. PA was impressed in few patients due to a high clinical suspicion (resistant hypertension, unprovoked hypokalemia) and high serum aldosterone level. We did not perform adrenal venous sampling to differentiate unilateral adenoma from bilateral hyperplasia due to its invasiveness. However, further CT findings with a unilateral adrenal adenoma and a normal contralateral adrenal gland confirmed the diagnosis of APA. Other limitations include the small sample size, retrospective nature of the study and incomplete biochemical data during short-term and long-term follow-up. This may have influenced the clinical and laboratory data including aldosterone level and ARR. Nevertheless, our findings demonstrated significantly improved BP control with fewer antihypertensive agents and normalized serum potassium level regardless of the plasma aldosterone level and ARR. Due to the lack of previous long-term outcome studies, our results may support the safety, effectiveness and long-term treatment success of RFA for APA. Further large-scale prospective randomized controlled studies are needed to confirm the efficacy and benefits of RFA over adrenalectomy or medical therapy.

CONCLUSIONS

CT-guided percutaneous RFA appears to be an effective and safe treatment for patients with APA, with clinical improvements in BP, reduced number of antihypertensive agents and normalization of serum potassium level. The long-term follow-up results were also favorable.

ACKNOWLEDGMENT

None.

CONFLICT OF INTEREST

All authors declare no conflicts of interest.

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