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Original Article

Renal sympathetic denervation using an externally irrigated radiofrequency ablation catheter for treatment of resistant hypertension – Acute safety and short term efficacy

Sachin Yalagudri [a,*], Narayana Raju [b], Bharati Das [a], Ashwin Daware [c], Shreesha Maiya [d], Kannan Jothiraj [e], A.G. Ravikishore [f]

[a] Fellow in Cardiac Electrophysiology, Narayana Hrudayalaya, Bangalore, India
[b] Senior Resident, Dept of Cardiology, Narayana Hrudayalaya, Bangalore, India
[c] Consultant Cardiologist, Narayana Hrudayalaya, Bangalore, India
[d] Consultant Paediatric Cardiologist and Electrophysiologist, Narayana Hrudayalaya, Bangalore, India
[e] Senior Consultant Cardiologist and Electrophysiologist, Narayana Hrudayalaya, Bangalore, India
[f] Head of Electrophysiology and Arrhythmia Services, Narayana Hrudayalaya, Bangalore, India

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ABSTRACT

Objectives: This study was conducted to assess the acute safety and short term efficacy of renal sympathetic denervation (RSDN) using solid tip radiofrequency ablation (RFA) catheter and saline irrigation through the renal guiding catheter to achieve effective denervation.

Background: RSDN using a specialized solid-tip RFA catheter has recently been demonstrated to safely reduce systemic blood pressure in patients with refractory hypertension, the limitation being inadequate power delivery in renal arteries. So, we used solid-tip RFA catheter along with saline irrigation for RSDN.

Methods: Nine patients with resistant hypertension underwent CT and conventional renal angiography, followed by bilateral or unilateral RSDN using 5F RFA catheter with saline irrigation through renal guiding catheter. Repeat renal angiography was performed at the end of the procedure. In all patients, pre- and post-procedure serum creatinine was measured.

Results: Over 1-month period: 1) the systolic/diastolic blood pressure decreased by $-57 \pm 20/-25 \pm 7.5$ mm Hg; 2) all patients experienced a decrease in systolic blood pressure of at least −36 mm Hg (range 36–98 mm Hg); 3) there was no evidence of renal artery injury immediate post-procedure. There was no significant change in serum creatinine level.

Conclusions: This data shows the acute procedural safety and short term efficacy of RSDN using modified externally irrigated solid tip RFA catheter.

* *Corresponding author*. Sudhanva, No. 36/A, Second Floor, 12th A Cross, 6th A Main, J P Nagar 3rd Phase, Bangalore 560102, India. Tel.: +91 9902870869.
E-mail addresses: pedssachin@gmail.com, pedssachin@yahoo.co.in (S. Yalagudri).

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Hypertension is a significant growing global health issue. Current therapeutic strategies for this condition are mainly based on lifestyle interventions and pharmacological approaches. The rates of control of blood pressure and the therapeutic efforts to prevent their sequelae however remain unsatisfactory and additional options are required. Among patients with hypertension, there exists a subset who are unable to achieve adequate BP control despite the use of multiple medications and dietary and lifestyle modifications. These patients (termed —refractory or —resistant) are, by common definition, receiving >3 different classes of antihypertensive therapy, with one being a diuretic, and at maximal recommended or maximal tolerated doses.[1]

The estimates of resistant hypertension prevalence range from 13% to 30% among adults receiving drug treatment for hypertension.[2,3]These numbers reflect a serious global health challenge given the observation that with every 20/10-mm Hg increase in blood pressure, cardiovascular mortality doubles.[4] For such patients, treatment options are few. Device or procedure-based therapies have also been studied recently. One such approach involves a percutaneous, catheter-based renal sympathetic denervation procedure to disrupt renal afferent and efferent nerves using radiofrequency ablation.[4,5] There is evidence that resistant hypertension may, at least in part, be mediated by chronic activation of the sympathetic nervous system (SNS).[6]

Initial proof-of-concept studies have demonstrated both reductions in BP and evidence of organ-specific sympathetic denervation. Furthermore, the procedure was found to be both simple to perform and safe.[7,8] Symplicity HTN-2 which is a randomized controlled clinical trial of renal denervation in patients with treatment-resistant hypertension, showed a 33/11 mm Hg reduction of 6-month office BP compared with controls.[8] Follow up of patients for 24 months in Symplicity HTN 1 had shown that blood pressure reduction with RSDN is durable.[9] Symplicity 3 did not show a significant reduction of systolic blood pressure in patients with resistant hypertension 6 months after renal-artery denervation as compared with a sham control.[10]

During RSDN, a Symplicity catheter connected to a radiofrequency (RF) generator is used to cause sympathetic denervation which is achieved percutaneously through the lumen of the main renal artery. As we do not have access to this catheter, we used conventional 5F solid tip ablation catheter for RSDN. We observed the inadequate power (sometimes as low as 0–1 W) delivery and rise in local temperature during RSDN. The initial clinical studies (Symplicity1 and 2) which demonstrated the proof of principle and safety of RSDN, have surprisingly not mentioned the amount of power delivered during renal denervation. During temperature-controlled RF ablation, the tip temperature, tissue temperature, and lesion size are affected by the electrode–tissue contact and cooling effects resulting from blood flow. With good contact between catheter tip and tissue and low cooling of the catheter tip, the target temperature can be reached with little power, resulting in small lesions even though a high tip temperature is being measured. In contrast, a low tip temperature can be caused by a high level of convective cooling, which results in higher power delivery to reach the target temperature, yielding a larger lesion. Power delivery determines the size and depth of the RF lesion created.[11] Velocity of blood flow in renal arteries is normally fast but once the arteries are engaged with renal guide, the flow reduces resulting in inadequate cooling of the catheter–endothelial surface interface. As a result adequate power is not delivered to create a lesion in the vessel wall at the level of adventitia where nerve endings are located. Theoretically rise in temperature at catheter–endothelial surface interface can cause endothelial injury, thrombus formation and charring. Rise in local temperature will not allow adequate power and in turn temperature to be delivered to the deeper tissues, thereby creating inadequate RF lesion at adventitial layer. It can be avoided by using irrigation tip catheter but the size of available catheters is larger than 7.5F. Manipulating larger catheter in renal arteries may not only be difficult, but harmful. So, we used external cooling by irrigating through the renal guiding catheter as described below. We report here our experience with external cooling by saline irrigation through the renal guiding catheter using conventional solid tip radiofrequency ablation catheters in nine patients with RH.

1. Methods

Procedure was performed after obtaining written informed consent in all patients according to the institutional guidelines at Narayana Hrudayalaya Hospital, Bengaluru, India.

1.1. *Patient characteristics*

All patients were suffering from chronic resistant hypertension (systolic BP ≥140 mm Hg for more than 6 months) refractory to ≥3antihypertensive medications (including at least one diuretic). Patients with secondary hypertension, renal dysfunction not on dialysis and unsuitable renal artery anatomy (haemodynamically significant stenosis, post renal angioplasty, short and smaller renal arteries) were excluded.

1.2. *Baseline measurements*

All patients were observed for six months on appropriate antihypertensives to ensure that there is compliance with medications. Serum creatinine was measured in all patients. CT renal angiogram was done in all patients to look for renal artery diameter, length and stenosis.

1.3. *Renal sympathetic denervation*

Procedure was performed under conscious sedation and analgesia. After standard right femoral arterial access, heparin was administered to maintain ACT >250. 7F renal double curve (RDC, Medtronic Vascular Santa Rosa, CA, USA) guiding catheter was advanced over the 0.32 inch Terumo wire into the abdominal aorta. Each renal artery was selectively engaged and angiogram was performed to study the anatomy. Digital subtraction angiography (DSA) was performed to get a shadow of renal arteries. Under fluoroscopic guidance 5F, 4 mm solid tip ablation catheter (St. Jude Medical, St. Paul, Minnesota, USA) was advanced into distal renal artery (Fig. 1). A Stockert RF generator was used to deliver RF energy in