# Design of Multipoint Ablation Switch for Renal Artery Denervation

M. Venkateswara Rao*, Dr. M. Malini* Ammara Munazza*, B. Sailalitha**
*Department of Biomedical Engineering,
Osmania University, Hyderabad, India.

*Abstract*— **Hypertension (HTN) is a major cardiovascular risk factor throughout the world. Approximately 1 billion people worldwide have HTN, and it is projected that this will increase to 1.5 billion by 2025. The renal sympathetic nervous system plays a vital role in the onset and maintenance of HTN. In patients with resistant HTN where the medicines are ineffective, disruption of the renal sympathetic fibers using catheter-based radiofrequency (RF) ablation has proved to be safe and effective. The single electrode RF catheter system has been widely used for this technique. But it has the disadvantage of requiring the surgeon to manipulate the catheter within the renal artery lumen multiple times to achieve a series of lesions at required locations. A multi-electrode RF system, with electrodes geometrically arranged in prespecified positions, reduces the amount of catheter manipulation required within the renal artery and thus potentially reduces the risk of procedure-related renal artery injury apart from reducing the stress on surgeon. The aim of this paper is to design a multipoint ablation switch for RF ablation catheter to interrupt the renal sympathetic nerve fibers in patients with resistant HTN. The RF power is distributed equally among the selected electrodes. The number of electrodes that can be used for ablation is selected by the surgeon based on the requirement.**

***Keywords— Resistant hypertension, RF Ablation, Renal Artery Denervation, Multipoint Ablation.***

## I. INTRODUCTION

Hypertension is a condition in which the arteries have persistently elevated blood pressure. Hypertension (HTN) has a prevalence of 26.4% in the age group 30-60, rising to 65% in those over 60 years of age affecting nearly 1 billion worldwide [1]. It is a major risk factor for cardiovascular disease, stroke, heart failure, and premature renal failure, thus, it became the major cause of morbidity and mortality, responsible for 7 million deaths annually worldwide. Resistant hypertension is defined as "blood pressure that remains above goal in spite of concurrent use of three antihypertensive agents of different classes, one of which should be a diuretic"by American heart association in 2008. Approximately 25-35% of hypertensive patients can only achieve a blood pressure less than 140/90 mmHg, even with prolonged multi drug therapy [2]. Renal sympathetic denervation (RSDN), popularly known as renal denervation **(**RDN**)**, is a minimally invasive, endovascular catheter based procedure using radio frequency ablation technique for resistant hypertension. Results from international clinical trials is promising, demonstrating average blood pressure reduction of approximately 30mm Hg over three year follow up [3,1]. Since 2007, over 4000 patients have undergone catheter based renal denervation with the Medtronic Symplicity™ Renal Denervation System [4, 5].

Radio frequency ablation (RFA) is a medical procedure in which part of the electrical conduction system of the heart, tumor or other dysfunctional tissue is ablated using the heat generated from high frequency alternating current (in the range of 350 – 500 kHz).When RF energy is used, the applied voltage induces a current to flow between a small electrode inside or on the surface of the body to a large grounded dispersive electrode on the surface. For catheter ablation, RF energy is applied as a sinusoidal current through a small electrode to provide effective tissue heating [6].

By applying Radio-Frequency pulses to the walls of the renal artery, which in turn gets denervated. This causes reduction of renal sympathetic afferent and efferent activity and blood pressure can be decreased [7]. The goal of RF ablation is to induce thermal injury to the tissue through electromagnetic energy deposition. The term RF ablation applies to coagulation induced by all electromagnetic energy sources with frequencies less than 900 kHz, although most devices function in the range of 375 – 500 kHz [1, 8, 4, 9]. There are many commercially available RF generators and catheter probes for renal denervation some of them are: The Simplicity TM Renal Denervation System from MEDITRONIC, EnligHTN™ Multi-Electrode Renal Denervation System, Vessix Renal Denervation System, STOCKERT 70 RF Generators [10, 8, 11]. Currently available RF Generator at the Care Hospitals is STOCKERT 70 RF Generator is (fig.1) manufactured by Biosense Webster, a Johnson & Johnson company. It offers a revolutionary modular design for easy upgrades and supports both current and future catheter technologies with maximum control.

The STOCKERT 70RF Generator is compatible with CARTO XP Navigation and Ablation system, and is designed to interface with the COOLFLOW Irrigation Pump. The STOCKERT 70 RF Generator system consists of a radiofrequency (RF) generator and accessories and two reusable interface cables. The device is intended to generate RF energy that is delivered to the tissue by a percutaneously placed catheter for the treatment of dysfunctional tissue. The thermal energy at the site of application produces a lesion that interrupts a defective electrical conduction pathway in the cardiac wall. The STOCKERT 70 RF Generator is used in unipolar mode only, and includes functions for controlling temperature at the catheter tip and for monitoring impedance and ECG signals. Ablation parameters, such as power, impedance, voltage, current, and temperature, can be recorded. The same RF generator can be used for renal artery denervation with the help of multipoint ablation switch designed by us.

Fig. 1 STOCKERT 70 RF Generator

## II. METHODOLOGY

The challenges faced and design details of multipoint ablation switch are presented in this section

### *A. Design of multipoint ablation switch for renal artery denervation*

After a series of visits for RF RDN procedure at care hospitals we observed that they were using STOCKERT 70 RF generator with Navistar DS Diagnostic/ Ablation catheter which is a multi-electrode catheter. All the electrodes can be used for recording, pacing, ablating but only the tip electrode is used to deliver RF energy from the generator. For ablating renal artery the required power is 8W-10W. Electrophysiology's has to adjust the power to the required level during the procedure as only one electrode is being used for ablation, the maximum time required for ablating at multiple points (approx. 5-6) for achieving the required results is nearly 20-30 min. so we are motivated to design a switch box for this procedure where the total power from the RF generator is equally divided by an intermediate box to deliver the desired energy. To reduce the ablation time, a catheter with multiple ablation electrodes can be used by distributing the RF power equally among these electrodes. The switch designed distributes the RF power generated by the RF generator equally among multiple ablation electrodes of the catheter. The required number of electrodes can be selected as desired. Overcoming the challenges faced we acquired positive results.

### *B. Challenges in designing the switch*

The RF switch to be designed has to meet the following challenges:

1. It should reflect the body impedance which is around 125Ω to 250Ω to the RF generator
2. The RF generator checks the temperature at the electrode site and if it is in the tolerable limits of the body temperature i.e. around 37.1 $^0$ C, only then the RF power is delivered to the electrode.
   In order to test the switch externally, this condition has to be created externally, so that the developed switch can be checked without introducing the catheter system into the body.
3. In order to have effective renal artery denervation, it is usually required to have six electrodes, which need to be strategically located, on the catheter tip (the catheter needs to be designed to meet this requirement). As per the medical experts from Care hospitals, the RF power needs to be shared by the electrodes equally.
   To meet this requirement, the RF switch front panel requires a provision, through which the surgeon can select the required number of electrodes, in the operation theatre.
   Based on the selection switch setting, the designed circuit has to distribute the RF power equally among the selected electrodes. The total RF power to be delivered can also be selected.
4. The RF has to with stand the voltage and current ratings of the RF generator selected.

Considering the above challenges and after careful scrutiny of the required features, it was identified that an RF switch which can withstand the voltage and current ratings of the RF generator when delivering maximum energy has to be designed. Firstly, the maximum output voltage of the RF generator has to be measured. Being proprietary equipment, the RF generator output voltage and frequency were not mentioned either on the name plate or in the technical manual of STOCKERT 70 RF Generator [3]. Therefore, the following method is adopted to measure the required parameters.

The RF generator output is connected to a series combination of 100 Ω, 5W and 10 Ω, 1W resistors. By this, the impedance observed by the RF generator while delivering power is 110 Ω, which mimics the normal tissue impedance. The voltage across 10 Ω resistor is applied to storage CRO for measurement purpose.

For the RF power to be delivered, the other condition is to maintain the catheter tip at body temperature. A water bath at 40$^0$C was used for this purpose.
Then the frequency and voltages are measured manually at different RF power levels. The procedure is repeated several times, to ensure that there were no errors. From the recordings it was found that the peak-to-peak voltage is 300V maximum at 100W power delivery, and the frequency is 500 KHz and is constant.

### *C. The proposed block diagram of the multipoint ablation system*

The block diagram (shown in fig.2) basically consists of seven RF switches, out of which six are normally opened and the other switch is closed. Apart from these RF switches, the circuit consists of microcontroller based control circuit, to provide necessary controls to the RF switches based on the selector switch setting.

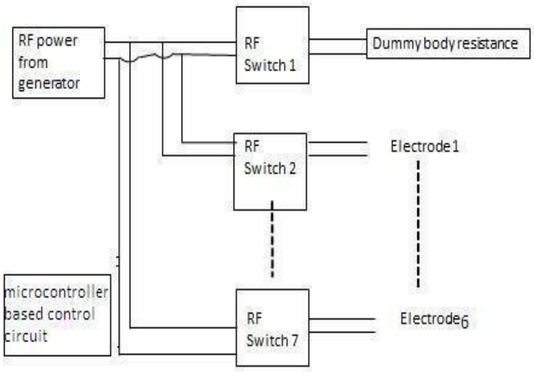

Fig. 2 Block diagram of the system

When the power delivery to the electrode is not required, the electrodes are not connected to the RF generator, but the RF power generator need to be kept on. To meet this condition, the first RF switch is provided, which is normally ON and this RF switch is terminated with 150Ω, 50W resistor to mimic the body resistance. But once the RF generator starts to deliver power to the selected electrodes, switch 1 will get turned OFF. This is done to avoid power delivery to the dummy resistance.

Now manually, if only one electrode is selected, RF switch 2 is turned ON, and remains ON until the main RF generator is turned OFF. Thus the entire power is delivered to the selected electrode only, with only a small RF power loss across the Switch. When main RF power is switched off by the surgeon, immediately the control circuit will revert back to the initial condition i.e. switching ON the RF Switch1 and switching OFF of RF Switch 2.

If two electrodes are selected by the surgeon manually, the RF power must be shared by the two electrodes equally. In order to meet this situation, the circuit works as follows. Initially RF Switch 1 is kept ON, so that the dummy resistance is connected to the RF power generator. When it starts delivering the power, the control circuit turns OFF RF switch 1. Generally, RF power splitters can be used to achieve this but it is not that easy in this situation.

So, best option as per our research is Pulse Width Modulation (PWM) technique. This is very useful in many of industrial and power electronics applications. The same technique has been adopted in the present application. As per the PWM technique, both the switches need to be turned ON and OFF with 50% duty cycle. Keeping the cycle time very small compared to the time constant of the loads at electrodes 1 and 2, the power will be delivered equally. The cycle time in our present work is considered as 0.01 m Sec, i.e. ON periods of both the electrodes are 0.005 msec.

If three electrodes are selected, the RF power is shared by the three electrodes in a similar fashion. In this case, the ON period of each switch is again 0.005 m Sec, so the duty cycle of each RF switch is 1/3. The different switch selection conditions along with respective timings of ON and OFF are shown in table 1. To change the timing intervals only the microcontroller program needs to be changed and the rest of the circuits remain the same.

Table 1 The RF switch ON times in mSec for various manual switch selections

| | Sw-1 | Sw-2 | Sw-3 | Sw-4 | Sw-5 | Sw-6 | Sw-7 |
|---|---|---|---|---|---|---|---|
| No RF Power Delivery | On | Off | Off | Off | Off | Off | Off |
| One Electrode | Off | On | Off | Off | Off | Off | Off |
| Two Electrodes | Off | 0.005 | 0.005 | Off | Off | Off | Off |
| Three electrodes | Off | 0.005 | 0.005 | 0..005 | Off | Off | Off |
| Four electrodes | Off | 0.0025 | 0.0025 | 0.0025 | 0.0025 | Off | Off |
| Five electrodes | Off | 0.0025 | 0.0025 | 0.0025 | 0.0025 | 0.0025 | Off |
| Six electrodes | Off | 0.0025 | 0.0025 | 0.0025 | 0.0025 | 0.0025 | 0.0025 |

### *D. Design Methodology of RF Switch*

In the market, there are several RF switches available in monolithic form, which have their applications in RF transceivers. But these switches have a very low voltage withstanding capabilities and for this reason, they cannot be used for the present application, and also they do not have any means to connect them in series. So we started designing the RF Switch using discrete components (as shown in fig.3).

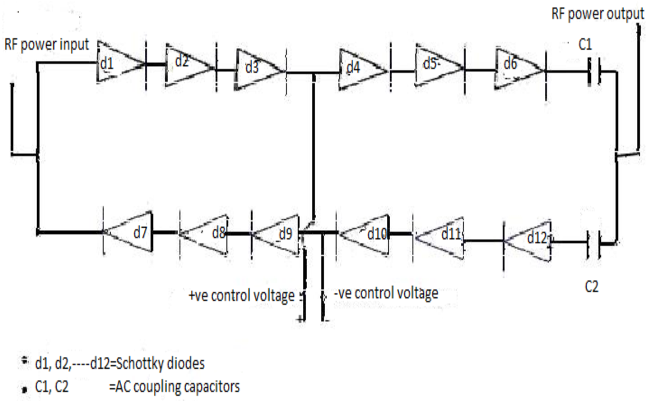

Fig. 3 Circuit diagram of the Switch

For RF power control applications schottky diodes are used. But the main problem with these diodes is their low PIV ratings. Typically the PIV rating of these diodes is around 10V to 200V. In the present application the reverse voltage that will appear across the diode string (from end to center) is the peak voltage of the applied RF power at the inputs. Thus with 300V peak to peak voltage, the number of diodes required from end to center in any direction is three (each of 120V). A capacitor C (0.1µF) is attached in series with both positive and negative string diodes, so that the DC voltage does not appear at the output. Without applying positive or negative control voltages, and keeping the control terminals open makes the entire circuit as a conductor for high frequencies, with some conduction losses, because of diodes.

But when positive and negative control voltages, that too more than peak amplitude of the input RF voltage is applied then during the positive half cycle, the top left half section is reverse biased. Similarly during the negative half cycle, the bottom left half section is reverse biased. This reverse biasing makes the diodes not to conduct RF power and does not appear at the output. Thus, by application of positive and negative control voltages makes the switch not to conduct RF energy, and by the removal of the control voltage, makes the switch to conduct RF energy.

### *E. Control Voltage applying Circuit*

The control voltage applying circuit is designed using power MOSFET and the circuits are shown in figure 4 explains the application of the supply voltage and getting the control voltage. The power MOSFET has a built-in freewheeling diode, to nullify the effect of it; another series diode is externally connected. The power MOSFET acts as a switch and it is controlled by the gate signal. The MOSFET is switched ON by applying +12V to its gate, with respect to the source. It can be turned OFF by applying either 0 V or - 12V to its gate. The application of -12V is preferred because of a fast and guaranteed turn OFF. The control signal is generated by the microcontroller circuit. The microcontroller circuit provides only logic signals, and it cannot be used to control the MOSFET and is also not isolated. For these reasons an opto-coupler is used. The opto-coupler input pins of both positive and negative controls are shorted and are provided with the control signal from the microcontroller. When a logic 1 is provided to the opto-coupler input pins, the positive and negative control voltages are applied to the RF switch. If a microcontroller provides logic 0 at the opto-coupler input the control voltage terminals are opened. The opto-coupler requires a +12V,-12V at the photo transistor side. The circuit also requires +300V and -300V at the terminals as shown. In the present application this is drawn from an external power source, but it can also be implemented in the same circuit.

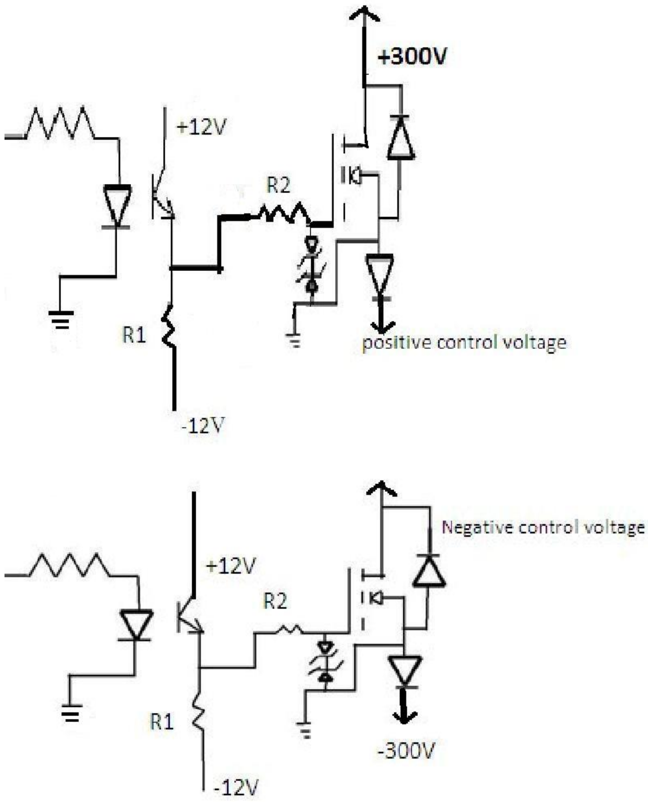

Fig. 4 Positive and Negative control voltage applying circuit

## III. RESULTS AND DISCUSSION

Initially, the microcontroller circuit is assembled and the precondition of the RF source is met as explained. This part of the circuit is checked for its satisfactory operation.

After ensuring the satisfactory working of the program, the rest of the circuit is assembled and interfaced to the microcontroller.

The switches are connected to a multi-electrode catheter and the entire circuit is tested with different manual switch selections. Each time the catheter is inserted into a fresh flush drawn from chick and observed that uniform ablation took place as per the selection. The surgeons were satisfied with the ablations produced and we are planning for further animal testing.

## IV. REFERENCES

1. Arun Chockalingam, MS PhD FACC, “Impact of World Hypertension Day”, Can J Cardiol. 2007 May 15; 23(7): 517–519.
2. Hazem Khamis a,*, Ahmed Abdelaziz b, Ahmed Ramzy c “Catheter-based radiofrequency renal sympathetic denervation for resistant hypertension; initial Egyptian experience” http://dx.doi.org/10.1016/j.ehj.2013.08.006
3. Murray D. Esler, MBBS, PhD, FRACP; Henry Krum, MBBS, PhD; Markus Schlaich, MD; Roland E. Schmieder, MD; Michael Bo¨hm, MD; Paul A. Sobotka, MD Renal Sympathetic Denervation for Treatment of Drug-Resistant Hypertension One-Year Results From the Symplicity HTN2Randomized,ControlledTrial”DOI:10.1161/CIRCULATION AHA.112.130880.
4. Arun K. Thukkani, MD, PhD; Deepak L. Bhatt, MD, MPH, FAHA “Renal Denervation Therapy for Hypertension” DOI:10.1161/CIRCULATIONAHA.113.004660.

5. Hitesh C Patel*, Carl Hayward, Carlo Di Mario “SYMPLICITY HTN 3: The death knell for renal denervation in hypertension?” http://dx.doi.org/10.5339/gcsp.2014.15
6. Luke J. Higgins1 Kelvin Hong “Renal Ablation Techniques: State of the Art” DOI:10.2214/AJR.15.14752
7..http://www.humanitas.it/internationalpatients/treat-profile/25.html
8. Andréa Araujo Brandão, Erika Maria Gonçalves Campana, Maria Eliane Campos Magalhães, Esmeralci Ferreira “Renal Sympathetic Denervation for Resistant Hypertension Treatment - Current Perspectives”DOI: 10.5935/abc.20130187.
9. Qiming Dai*, Jing Lu*, Benwen Wang, Genshan Ma “Effect of percutaneous renal sympathetic nerve radiofrequency ablation in patients with severe heart failure” Int J Clin Exp Med 2015;8(6):9779-9785.
10. Aditya Bhat, YeMin Kuang, Gary C. H. Gan, David Burgess, and Alan Robert Denniss “An Update on Renal Artery Denervation and Its Clinical Impact on Hypertensive Disease” http://dx.doi.org/10.1155/2015/607079
11. Csaba A Dézsi1*, Szabolcs Czuczor1, Béla Gartner2, Péter Bartek3, László Tamás4, Zsolt FI1 and Veronika Szentes1 New Procedure in a New Situation: Short-term Effect of Renal Denervation for Resistant Hypertension in Case of a Patient Living with Pacemaker” http://dx.doi.org/10.4172/2167-1095.100014.