

# New Procedure in a New Situation: Short-term Effect of Renal Denervation for Resistant Hypertension in Case of a Patient Living with Pacemaker

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## Abstract

**Aims:** Renal denervation using the point-by-point application of radiofrequency (RF) energy delivered by the first-generation Symplicity System is effective in lowering office blood pressure however it is time-consuming. The Vessix Renal Denervation System with eight balloon-mounted bipolar electrodes shortens and simplifies the procedure. This has been the first in-human case examining the efficiency of reducing blood pressure and also the effect of RF energy in case of renal denervation on the normal functioning of pacemaker and the tolerability of the procedure in case of a patient living with pacemaker.

**Materials and methods:** The diabetic patient with a coronary artery disease had a baseline office systolic blood pressure  $\geq 150$  mmHg and took four antihypertensive medications. She had a Biotronik Talos S pacemaker with a unipolar Biotronik PX 60 UP lead because of sick sinus syndrome however she was not dependent on pacemaker. We applied 30 sec. long RF treatments in the renal artery two times.

**Results:** The patients baseline systolic BP was 185 mmHg which reduced by 30 mmHg immediately after the denervation. The lowering of blood pressure was permanent during the 24-hour and four-months supervisions, despite the fact that we carried out the intervention only on one side. The radiofrequency energy did not have an impact on the normal functioning of the pacemaker during and after the intervention. It did cause less physical and psychological burden for the patient than a longer procedure.

**Keywords:** Refractory hypertension; Radiofrequency ablation; Renal denervation; Pacemaker; Hybrid therapy

## Introduction

Occasionally it occurs that in spite of treating the patients with multiply combined antihypertensive medications, the blood pressure does not decrease to the normal level steadily. These patients, after excluding the possibility of secondary hypertension, belong to the group of therapy-resistant hypertension. In practice the treatment of these cases was not possible so far, consequently, they were exposed to the danger of stroke, heart attack, or renal complications. For this group of patients renal denervation gives a chance to maintain normal blood pressure by further applying of drugs [1,2]. The joint application of the invasive therapy and the traditional drug therapy [3] can be considered as hybrid therapy [4,5]. In this article we present a case the novelty of which, beside the hybrid therapy, is the experience gained concerning the effect of RF denervation of renal artery on the pacemaker functions. Several articles have been published about the percutaneous RF ablation of a variety of tumors, for instance of a hepatic neoplasm [6], and different kinds of RF antiarrhythmic therapies in connection with pacemakers, to clarify the question whether RF catheter ablation may cause pacemaker dysfunction due to electromagnetic interferences [7-12]. However, no article has been published yet about the experience in connection with renal denervation with balloon catheter in case of a patient living with pacemaker.

## Materials and Methods

The 68-year-old woman's case history is the following: she has non-insulin dependent diabetes mellitus (NIDDM), coronary artery disease treated with a drug eluting stent (DES) implantation (2013) in her left anterior descendens (LAD) coronary. Her first VVI pacemaker was implanted in 2000 because of sick sinus syndrome (SSS). The generator was a Biotronik Kairos S and the lead was a Biotronik PX 60 UP. The

lead was placed in the right ventricle and positioned in the apex. The generator was changed in 2011 to Biotronik Talos S because of discharge.

She has treatment-resistant hypertension for a long time and takes the following medications regularly: perindopril 10 mg/day; nebivolol 7.5 mg/day; lercanidipine 20 mg/day; indapamid 2.5 mg/day and gliclazide 60 mg/day; acetylsalicyl acid 100 mg/day; clopidogrel 75mg/day; atorvastatin 60 mg/day; pantoprazole 40 mg/day and furosemide 40 mg/week; kalium chloride 1 gram/week.

We excluded the secondary hypertension - included renovascular disease, hyperaldosteronism, glucocorticoid excess, pheochromocytoma, hyperthyroidism, hyperparathyroidism, obstructive sleep apnea, aortic coarctation, renal parenchymal disease, other illicit or prescribed medications that could have raised the patient's blood pressure- prior to renal denervation.

## Results

The results of her 24-hour ambulatory blood pressure monitoring

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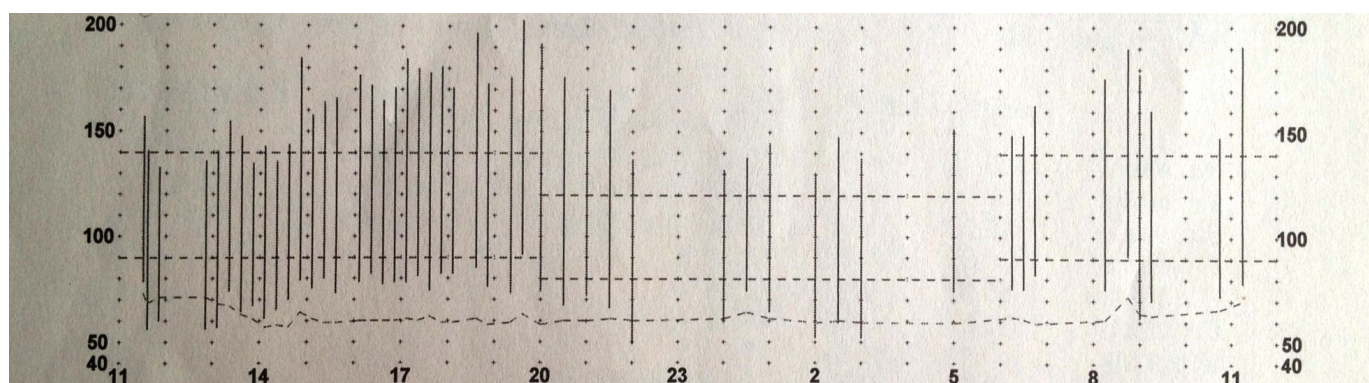
(ABPM) verified high values all day long (Figure 1) she had complained about having a headache very often.

The patient had a normal sinus rhythm, her heart rate was around 65/min. The pacemaker's basic rate was 60/min. and the hysteresis rate was 50/min. These parameters resulted in 18% ventricular pacing ratio. The technical parameters were the following: the pulse amplitude was 2.4 V with pulse width 0.4 ms, the pulse energy was 3.5  $\mu$ J, its elective replacement interval (ERI) was 7 year 7 months, the sensitivity was 2.5 mV, the refracter period was 300 ms and the pacing and sensing polarity was unipolar. All parameters were tested before the procedure. Minimal R wave amplitude was 10.7 mV, ventricular threshold was 0.5 V/0.4 ms, battery impedance was <0.3 Kohm, lead impedance was 498 Ohms.

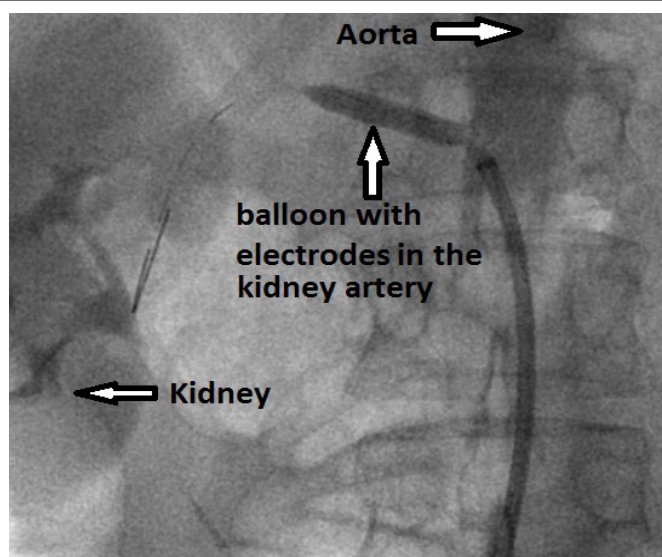
The following parameters were programmed for the procedure: 4.8 V pulse amplitude, 0.75 pulse width and 5.5 mV sensitivity. These values had led to 23.8  $\mu$ J pulse energy, and reduced the calculated ERI to 4 years 2 months. After the procedure the minimal R wave amplitude was 11.3 mV, ventricular threshold was 0.8 V/0.4 ms, the battery impedance was <0.3 Kohm, and the lead impedance was 510 Ohms. The original pacemaker parameters were reprogrammed. We used the Biotronik ICS 3000 programmer to change the parameters.

For the penetration of the balloon catheter through the right femoral artery we used a 8 Fr size Flexor Check-Flo Introducer catheter with High-Flex Dilator and Hydrophilic Coating (Cook Medical), a 0.018" size guidewire and for the radiofrequency ablation the Vessix renal denervation system. It includes a low pressure (3 atm.) inflatable non-compliant over the wire balloon placed on the surface offset solid gold electrode pairs in helical pattern and all electrodes deliver energy simultaneously. The second part of the system is a bipolar RF generator with one button operation. The temperature was sensed and controlled at 68°C optimal for the delivery of thermal energy to adventitia to 3-4 mm deep for 30 seconds. The Graphical User Interface confirmed the size of electrode, the position of balloon catheter and displayed the key parameters of treatment time and the temperature. Bipolar technology obviates the need for the grounding pad.

We positioned a 5 mm diameter and 25 mm long balloon to the right renal artery as in the case of a standard percutan intervention (Figure 2). The technology requires only basic interventional skills. We applied 30 sec. long RF treatments in the renal artery two times (one distal and one proximal part) without overlapping the surfaces. The patient was given 5 mg midazolam and 0.1 mg phentanyl intravenously only one time and also 10.000 U Na-heparin bolus before the operation.

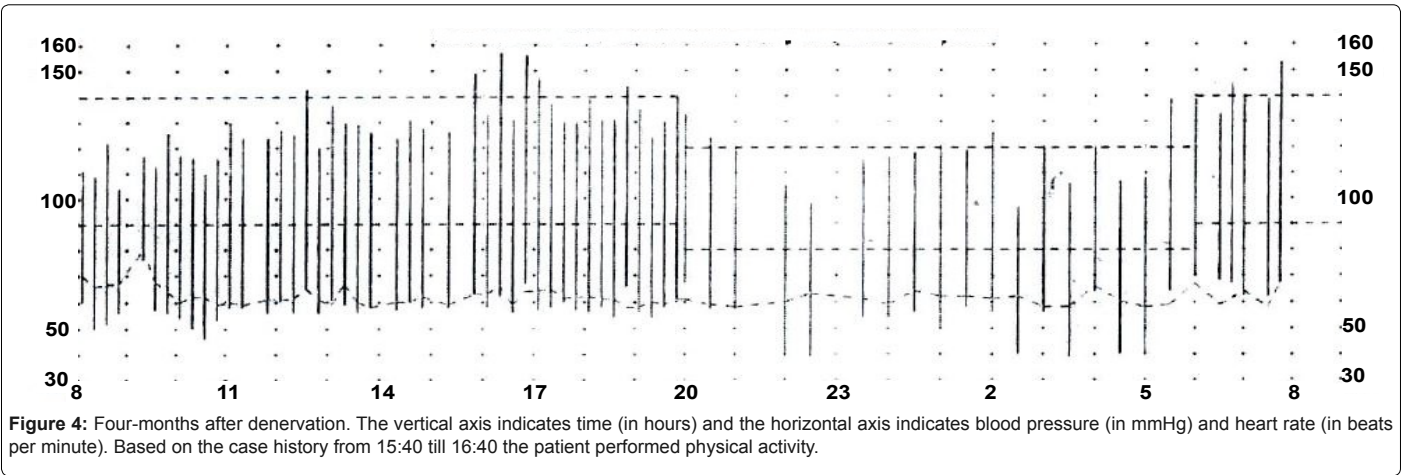
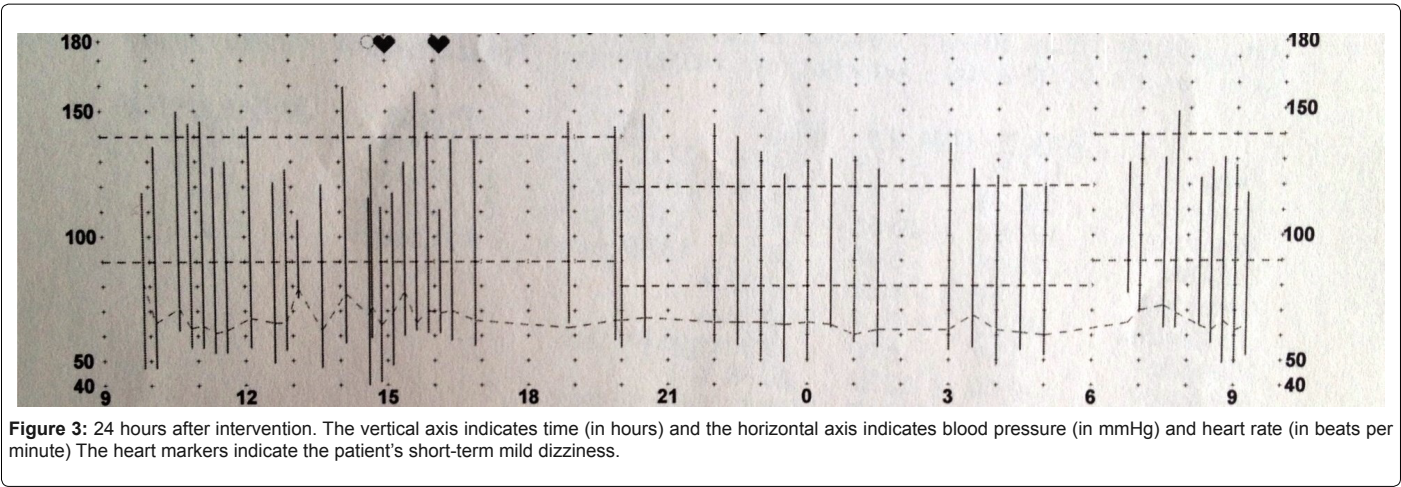


**Figure 1:** Before intervention. The vertical axis indicates time (in hours) and the horizontal axis indicates blood pressure (in mmHg) and heart rate (in beats per minute).



**Figure 2:** Renal denervation with the Vessix balloon catheter. The renal artery absolutely closed by the balloon and the electrodes are in contact with the vessel wall perfectly.





Blood pressure		Systolic	Diastolic
Mean (mmHg)	BD:	158	70
After denervation	24 hours	133.5	56.5
	4 Months	123.8	55.7
Maximum (mmHg)	BD:	203	91
After denervation	24 hours	160	77
	4 Months	157	76
Minimum (mmHg)	BD:	130	49
After denervation	24 hours	107	40
	4 Months	97	39
SDS (mmHg)	BD:	19.95	10.11
After denervation	24 hours	12.19	7.46
	4 Months	13.57	7.56
Diurnal index	BD:	9.32	15.7
After denervation	24 hours	1.57	4.58
	4 Months	11.79	14.38
PTE (%)	BD:	91.46	3.42
After denervation	24 hours	58.2	0
	4 Months	16.2	0
HBI (mmHg*h/24h)	BD:	622.9	0.82
After denervation	24 hours	160.58	0
	4 Months	37.35	0

**Table 1:** The values of blood pressure, BD: before denervation; AD: after denervation; SDS: standard deviation score; PTE: percentage time of excess; HBI: hyperbaric impact.

After the procedure we closed the femoral arterial penetration area with a 8 Fr size AngioSeal™ device and monitored the patient's blood pressure and circulation parameters for a few hours in our department before mobilization.

### Discussion

The sudden falling of blood pressure can partly be explained by the effects of painkillers used during the intervention. However our periprocedural results were different from the ones experiences in the Symplicity studies. The blood pressure decreased significantly much sooner and it proved to be steady during the control ABPM examinations.

During renal denervation pacemaker sensing and pacing function was stable and reliable. No pacemaker dysfunction was detected. The patient complained only about a short mild abdominal pain. We could not place the balloon into the left renal artery because of an angulation traced at the beginning of the artery. Therefore the procedure carried out was a unilateral RF denervation. During both occasions of the delivery of radiofrequency energy the patient had only complained about a few seconds long, tolerable pain.

24 hours and 4 months after the procedure we put on her a 24-hour ABPM again which verified normal parameters almost during the whole day (Figure 3). The patient's heart rate had not changed, but her maximum blood pressure - both of systolic and diastolic - decreased

(Table 1) and her headache complaints ceased totally however she had complained two times about a short-term mild dizziness in the first 24 hours with being on the same medication as before. According to the four-month ABPM control the blood pressure of the patient did not rise above normal level (Figure 4). The blood test showed normal renal functions and the parameters of the pacemaker remained unchanged. The patient has no complaints.

## Conclusion

This first in-human case of the Vessix renal denervation balloon system with a patient living with pacemaker, by successfully delivering RF energy to the renal arteries, has been proved to be a short and secure procedure. The RF energy in this case did not have an impact on the functioning of the pacemaker. This method of renal denervation used with balloon catheter results in immediate and effective decrease of blood pressure also in case of unilateral intervention. As a consequence of the renal denervation, while continuing the traditional drug therapy, permanent and efficient reduction of blood pressure can be achieved. The intervention cannot replace the drug therapy [12], however by excluding certain pathological nervous reflexes, helps keep the blood pressure in the normal range, thus preventing several cerebrovascular and cardiovascular complications.

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