



Faisal Sharif



Carl Byrne



Conor Judge

Flory Daniels  
Stella Kyvelou

## Improved Quality of Life in patients post renal denervation based on patient experience in Galway

### Introduction

Hypertension is increasing globally due to changing demographics and increasing obesity rates among adults. Worldwide, hypertension is one of the largest contributors to mortality and morbidity, and is responsible for over 9.4 million deaths a year.<sup>1,2</sup> By reducing systolic blood pressure by as little as 2 mmHg the risks of stroke and ischaemic heart disease are reduced by 10% and 7% respectively, emphasizing the importance of striving to decrease blood pressure in the general population.<sup>3</sup> Uncontrolled hypertension is defined as blood pressure above 140/90 mmHg, despite the use of three or more antihypertensive medications, including at least one diuretic prescribed at optimal doses.<sup>4</sup> The incidence of resistant hypertension is reported between 5–10%.<sup>5</sup>

Renal denervation (RDN) is a novel potential therapy for treatment of resistant hypertension. RDN is a minimally invasive procedure in which radio frequency (RF) energy is delivered to the renal arteries by a steerable catheter via the femoral artery. A series of 2-minute ablations are delivered along each renal artery, which acts to reduce sympathetic nervous stimulation, and subsequently reduce hypertension.

Earlier small single-arm studies and one randomized but un-blinded clinical trial in RDN have shown long-term reduction in office systolic blood pressure that has been maintained for at least 3 years.<sup>6,7</sup> However, the rapidly advancing clinical utilization of RDN has decreased after the results of SYMPPLICITY HTN-3 in March this year.<sup>8</sup> This large randomized, blinded and sham control trial did not show a significant reduction in office and ambulatory blood pressure reduction in comparison to sham group. It has been suggested recently that operator inexperience, resulting in ineffective or inconsistent RDN delivery, was possibly to blame for the failure of the trial. However, 12-month outcomes following un-blinding of subjects in the SYMPPLICITY HTN-3

trial at 6 months has shown that leaving 'trial conditions' led to a marked increase in BP in sham, but not in treatment group.<sup>9</sup> Moreover, a number of other studies reporting since HTN-3 have suggested that RDN is efficient<sup>10</sup> with well-established safety. These include data from real-world settings as demonstrated by the Global Simplicity Registry (GSR)<sup>11</sup> and ALSTER BP registry.<sup>12</sup> In this article, we discuss the effect on the Quality of Life (QoL) in patients (N=28) who have undergone renal artery denervation with Symplicity Flex™ at Galway University Hospital (GUH) between September 2011 and January 2013. We report the initial 1-year results from a non-validated survey on the QoL of the first 28 patients who underwent an RDN procedure for treatment resistant hypertension at GUH. The survey assessed patient health and lifestyle, as well as the patient's perception of the treatment both pre- and post-operatively. All patients previously suffered from resistant hypertension (as defined above). Of those surveyed, 75% were male with a mean age of  $56.3 \pm 10.1$  years.

Four key aspects were assessed in the survey: overall health and lifestyle; anxiety levels; negative effect of high blood pressure on health and lifestyle; and patient energy levels. Patients were asked to recall how they had felt pre-operatively compared with how they felt post-operatively.

### Results

At 1-year post-RDN, of the patients (N=28) participating in this study, 20 (71%) showed an improvement in their perception of overall health and lifestyle, 7 (25%) had no change and 1 (3%) showed a reduction. A Wilcoxon signed-rank test determined that there was a statistically significant median improvement (1/5 or 'fair' to 'good') in overall health and lifestyle rating post renal artery denervation,  $z=3.899$ ,  $P \leq 0.0005$  (figure 1). Patients were also asked to assess their anxiety levels on a scale of 1 (no anxiety) to 10 (very severe anxiety) both pre and post renal artery denervation.

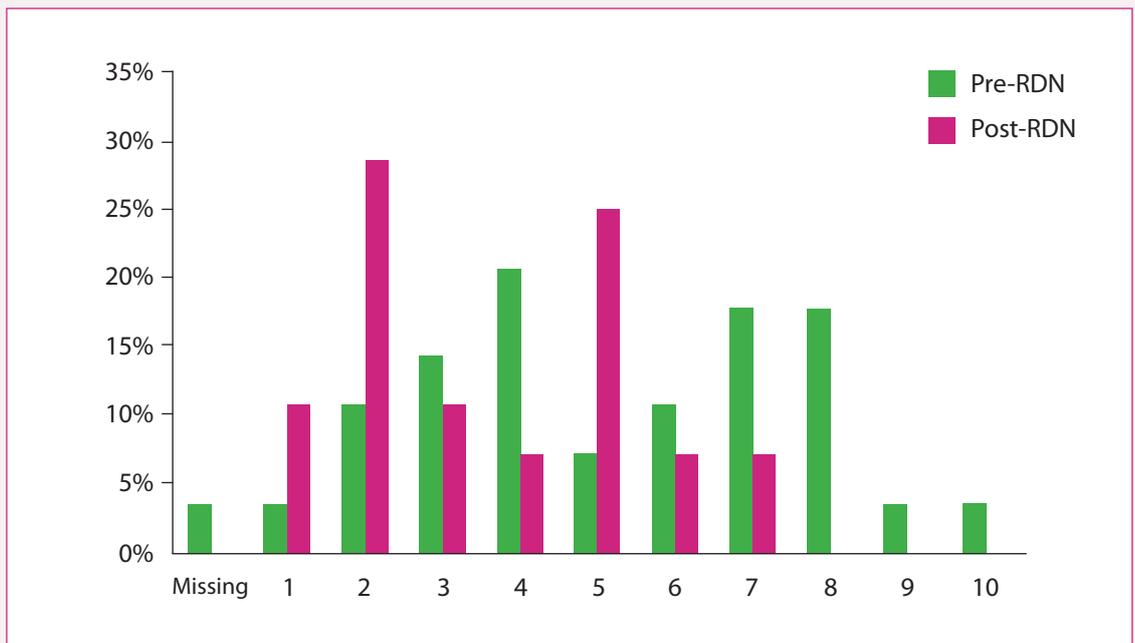
fig. 1

Overall health and lifestyle, pre and post renal denervation



fig. 2

Anxiety levels, pre and post renal denervation



18 patients (64%) showed a reduction, 9 (32%) showed no change and 1 failed to answer. A further Wilcoxon signed-rank test determined that there was a statistically significant median score reduction of 3 (6 to 3) in overall anxiety post renal artery denervation,  $z=3.749$ ,  $P\leq 0.0005$  (figure 2). This reduction in anxiety level post renal denervation was also found by Lenski et al., when assessing anxiety, depression and QoL in renal denervation patients.<sup>13</sup>

Patients were then asked to rate the negative impact of high blood pressure on their overall health and lifestyle both pre and post renal artery denervation. 21 patients (75%) showed an improvement, 5 (18%) showed no change and 2 (7%) showed a deterioration. A further Wilcoxon signed-rank test determined that there was a statistically significant median score reduction of 1 ('very much' to 'moderately') in the negative effect of high blood pressure on their health and lifestyle post renal artery denervation,  $z=3.39$ ,  $P=0.001$  (figure 3).

fig. 3

Negative impact of high blood pressure on health and lifestyle, pre and post renal denervation

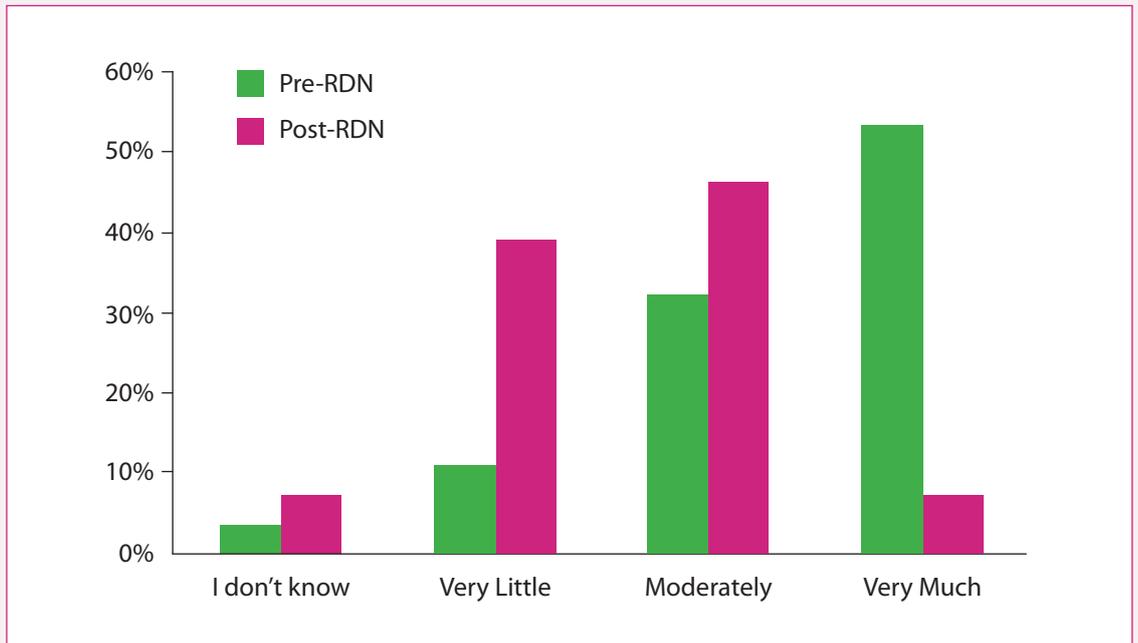
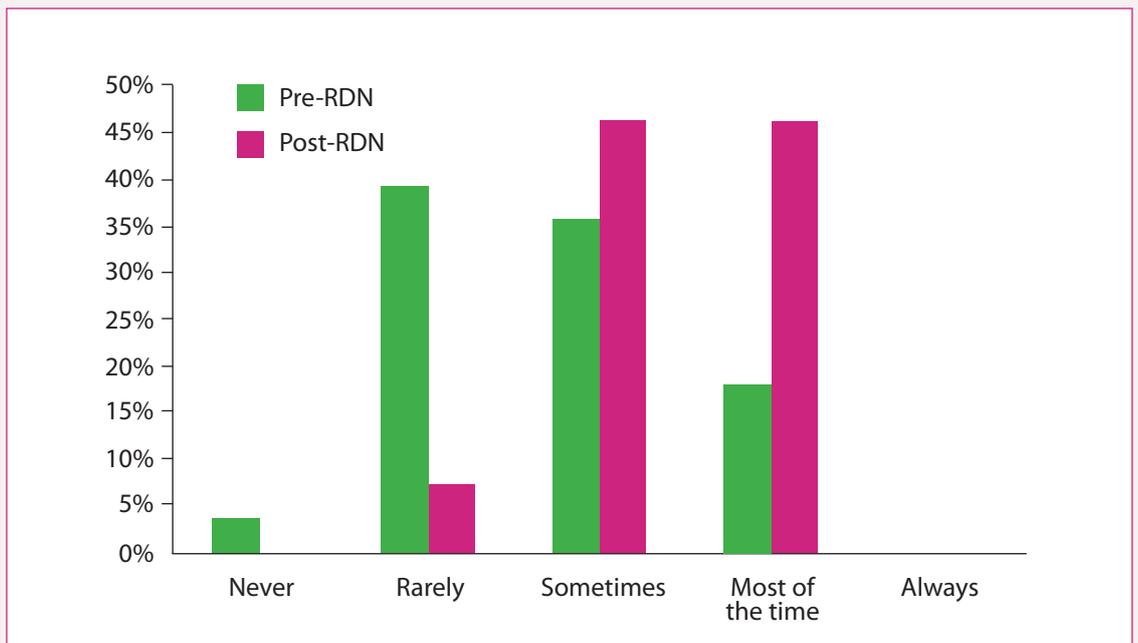


fig. 4

Energetic frequency, pre and post renal denervation



The final aspect of patient QoL assessed was patient energy levels. Patients were asked to assess how often they felt energetic before and after the renal denervation therapy. 17 patients (61%) showed an improvement, 11 (39%) showed no change and no patient showed a deterioration. An additional Wilcoxon signed-rank test determined that there was a statistically significant median score increase of 1 ('sometimes' to 'most of the time') in the energetic frequency post renal artery denervation,  $z=3.824$ ,  $p\leq 0.0005$  (figure 4).

Overall, there was a significant improvement across all QoL questions post renal artery denervation. This correlates well with anecdotal reports when talking with patients about their QoL improvements after the procedure, and with published literature on QoL in renal denervation patients.<sup>13,14</sup>

Patients were asked to assess whether the procedure met their pre-operative expectations of the intervention. 53.6% of patients felt the

Address for correspondence  
Dr Faisal Sharif  
Comerford Education Centre  
Clinical Science Building  
National University of Ireland  
Galway, Newcastle Road  
Galway, County Galway  
Ireland  
faisal.sharif@nuigalway.ie

procedure met their pre-operative expectations, 28.6% responded "maybe", while 14.3% of patients felt the procedure did not meet their pre-operative expectations. Patients reported a high satisfaction rate with both hospital staff professionalism (90.7%±16.5) and responsiveness to their needs (88.6%±20.1).

Although not the focus of this case report, pre- and post-RDN office blood pressure decreases were assessed; 64.2% and 46.4% of patients had a decrease in systolic blood pressure and diastolic blood pressure of more than 10 mmHg, respectively. These results show impressive overall decreases in post-operative blood pressure levels.

### Conclusions

There is a relative paucity of research into the effects on QoL in patients following RDN. Our findings, suggest that RDN therapy improves

the QoL in patients suffering with resistant hypertension. Overall, there was an improvement in the QoL among the patients surveyed. Notably, there were significant improvements in both anxiety levels and energy levels. These results correlate with research previously carried out on patient QoL post-RDN by Lenski et al., and Dorr et al.<sup>13, 14</sup>

The lack of a sham comparison group, to elucidate whether the improvements in QoL are due to RDN or placebo, is the major limitation of this study; however, this was beyond the scope of this case report and further controlled clinical trials are required to validate the results of this study. Moreover, research into this key aspect of patient wellbeing is invaluable to broaden our understanding of the beneficial effects of RDN, in all aspects of the biopsychosocial model.

#### REFERENCES:

1. Organisation WH. A global brief of hypertension: World Health Organisation; 2013.
2. Ezzati M, et al. *Lancet* 2002;360(9343):1347-60.
3. Lewington S, et al. *Lancet* 2002;360(9349):1903-13.
4. Callhoun DA, et al. *Hypertension* 2008;51(6):1403-19.
5. Acelajado MC, et al. *J Clin Hypertens* 2012;14(1):7-12.
6. Krum H, et al. *Lancet* 2014;383(9917):622-9.
7. Esler MD, et al. *Lancet* 2010;376(9756):1903-9.
8. Bhatt DL, et al. *N Engl J Med* 2014;370(15):1393-401.
9. Bakris GL. SYMPLICITY HTN-3 trial:12-month outcomes following un-blinding of subjects at 6 months. Presentation at ESC, Barcelona 2014.
10. Esler MD, et al. *Eur Heart J* 2014;35(26):1752-9.
11. Mahfoud F. Presentation at EuroPCR Scientific Meeting 2013 2013.
12. Kaiser L, et al. *EuroIntervention* 2014;10(1):157-65.
13. Lenski D, et al. *EuroIntervention* 2013;9(6):700-8.
14. Dorr O, et al. *J Interv Cardiol* 2013;26(5):536-41.

DISCLOSURES: CB, CJ, FD AND SK have no conflicts of interest. FS has received a research grant from Medtronic, Inc.