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Clinical Policy Bulletin:
Radiofrequency Ablation of the Renal Sympathetic N

Revised April 2014

Number: 0847

Policy

Aetna considers radiofrequency ablation of the renal sympathetic nerve experimental and investigational for the tre of the following indications (not an all-inclusive list) because of insufficient evidence in the peer-reviewed literature.

- Hypertension
- Obstructive sleep apnea
- Ventricular tachycardia

See also: CPB 0820 - Carotid Sinus Stimulation for Hypertension

Background

Hypertension is an independent risk factor for cardiovascular disease. Treatment frequently includes administratio or more drugs. Resistant hypertension is defined as blood pressure which remains above target levels despite use maximum tolerated dose of antihypertensive medications, consisting of at least three different classes of drugs, inc diuretic. Radiofrequency (RF) ablation of sympathetic nerve fibers around renal arteries has been proposed as a no pharmacologic treatment to reduce blood pressure in drug resistant hypertension (Simonyi et al, 2013).

Selective renal sympathetic denervation interrupts the influence of the sympathetic nervous system on the kidney systemic hemodynamics. The sympathetic innervation of the kidney is implicated in the pathogenesis of hypertens through effects on renin secretion, increased plasma renin activity that leads to sodium and water retention, and re renal blood flow. Renal sympathetic ablation is a minimally invasive procedure utilizing a RF catheter inserted through femoral artery and selectively engaging the renal artery (Papademitriou et al, 2011).

Krum et al (2009) performed a proof-of-principle trial of therapeutic renal sympathetic denervation in patients with r hypertension (i.e., systolic blood pressure greater than or equal to 160 mm Hg on 3 or more anti-hypertensive med including a diuretic) to assess safety and blood-pressure reduction effectiveness. The investigators enrolled 50 pa Australian and European centers; 5 patients were excluded for anatomical reasons (primarily due to dual renal arte systems). Patients received percutaneous RF catheter-based treatment between June 2007 and November 2008, subsequent follow-up to 1 year. The effectiveness of renal sympathetic denervation with renal noradrenaline spillo

http://qawww.aetna.com/cpb/medical/data/800_899/0847_draft.html

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assessed in a subgroup of patients. Primary endpoints were office blood pressure and safety data before the proc at 1, 3, 6, 9, and 12 months after the procedure. Renal angiography was done before, immediately after, and 14 to after procedure, and magnetic resonance angiogram was assessed 6 months after procedure. Blood-pressure low effectiveness was analyzed using repeated measures ANOVA. In treated patients, baseline mean office blood pre 177/101 mm Hg (SD 20/15), (mean of 4.7 anti-hypertensive medications); estimated glomerular filtration rate was ml/min/1.73m(2) (SD 23); and mean reduction in renal noradrenaline spillover was 47 % (95 % confidence interval % to 65 %). Office blood pressures after procedure were reduced by -14/-10, -21/-10, -22/-11, -24/-11, and -27/-17 1, 3, 6, 9, and 12 months, respectively. In the 5 non-treated patients, mean rise in office blood pressure was +3/-2 +14/+9, and +26/+17 mm Hg at 1, 3, 6, and 9 months, respectively. One intra-procedural renal artery dissection o before RF energy delivery, without further sequelae. There were no other renovascular complications. The author concluded that catheter-based renal denervation causes substantial and sustained blood-pressure reduction, with adverse events, in patients with resistant hypertension. They also stated that prospective randomized clinical trials needed to investigate the usefulness of this procedure in the management of this condition.

A prioritizing summary of the Australia and New Zealand Horizon Scanning Network on renal sympathetic denerva treatment of resistant hypertension concluded that based on the low level of available evidence, it would appear th denervation may be a viable option for the treatment of resistant hypertension (Mundy & Hiller, 2010). Blood pressu significantly lower after renal denervation than that measured at baseline; however, it is unclear whether this decre considered clinically significant. Final 12-month follow-up data were only reported for a small portion of the enrolled (22%) and in addition, six of the 45 patients were considered non-responders with non-significant reductions in blo pressure. The summary concluded that well conducted randomized controlled trial is needed to adequately investig whether renal denervation is capable of producing a sustained lowering of blood pressure in hypertensive patients medication (Mundy & Hiller, 2010).

Voskuil et al (2011) described their first experience with a percutaneous treatment modality using renal artery RF a Selected patients were resistant to at least 3 types of anti-hypertensive medical therapy (office systolic blood press than or equal to 160 mm Hg; n = 9) or who did not tolerate medication (n = 2). Between July and November 2010, 11 patients received percutaneous RF treatment and were followed for 1 month after treatment. Urine and blood s were taken to evaluate the effects on renal function and neurohumeral factors. No peri-procedural complications o events during follow-up were noted. A reduction of mean office blood pressure was observed from 203/109 +/- 32 at baseline to 178/97 +/- 28/21 mm Hg at 1 month follow-up (mean difference 25 +/- 12 mm Hg, p < 0.01). The inv also noted a significant decrease in aldosterone level (391 +/- 210 pmol/L versus 250 +/- 142 pmol/L; p = 0.03), bu no decrease in plasma renin activity (190 +/- 134 fmol/L/s versus 195 +/- 163 fmol/L/s; p = 0.43). No change in ren was noted. The authors concluded that catheter-based renal denervation seems an attractive novel minimally inva treatment option in patients with resistant hypertension, with a low-risk of serious adverse events.

Mahfoud et al (2011) summarized the expert consensus and recommendations of the working group ‘Herz und Nie German Society of Cardiology (DGK), the German Society of Nephrology (DGN) and the German Hypertension Le (DHL) on renal denervation for anti-hypertensive treatment. Renal denervation was defined as a new, intervention approach to selectively denervate renal afferent and efferent sympathetic fibers. The authors noted that renal den has been demonstrated to reduce office systolic and diastolic blood pressure in patients with resistant hypertension as systolic office blood pressure greater than or equal to 160 mm Hg and greater than or equal to 150 mm Hg in p diabetes type 2, which should currently be used as blood pressure thresholds for undergoing the procedure. Exclu secondary hypertension causes and optimized anti-hypertensive drug treatment was described as mandatory in ev with resistant hypertension. They also specified that 24-hour blood pressure measurements should be performed in exclude pseudo-resistance. Preserved renal function was an inclusion criterion in the Symplicity studies. Therefor denervation should be only considered in patients with a glomerular filtration rate greater than 45 ml/min. Adequat qualification in both treatment of hypertension and interventional expertise are essential to ensure correct patient s and procedural safety. The authors stated that long-term follow-up after renal denervation and participation in the Renal Denervation (GREAT) Registry are recommended to assess safety and efficacy after renal denervation over
Lobodzinski (2011) reviewed renal denervation system technology for treatment of drug resistant hypertension. Th researchers described “an investigational device that is currently tested in an on-going clinical trial. The denerva uses the RF thermal ablation catheter attached to the RF generator. The RF catheter is inserted into the renal arte positioned in the vicinity of the efferent and afferent parasympathetic innervations. Renal denervation is a minimal localized procedure and the procedural and recovery times are very short. The entire procedure lasts about 40 mi early clinical trials, the systolic blood pressure in 87% of patients who underwent the denervation procedure result average blood pressure drop of greater than 10 mm Hg. The procedure has no systematic side effects, and appea beneficial in the management of hypertension in patients refractory to pharmacological therapy.”

Patel and White (2012) stated that renal artery intervention to treat hypertension is one of the frontiers of ongoing r combating this epidemic. The investigators discussed recent data regarding renal artery angioplasty with stenting and catheter-based renal sympathetic denervation. They noted that despite progress in this field, large, multi-cente randomized trials that compare these treatment modalities with medical therapy for hypertension are lacking.

Tam et al (2013) stated that resistant hypertension, defined as the failure to achieve target blood pressure despite use of 3 anti-hypertensive agents of different classes, is estimated to affect 20 to 30% of hypertensive patients. T patients are vulnerable to cardiovascular, cerebrovascular and renal complications. There is ample evidence that sympathetic nervous system hyperactivity contributes to the initiation, maintenance, and progression of hypertensi renal sympathetic nervous system, in particular, has been identified as a major culprit for the development and pro hypertension, heart failure and chronic kidney disease in both preclinical and human studies. Traditional surgical sympathectomy proposed in the 1940s was halted due to unacceptable operative risk and the emergence of anti-h medications. The authors report that recently, catheter-based renal sympathetic denervation by RF ablation has sh encouraging intermediate-term results with minimal complications in patients with resistant hypertension.

A May, 2012 National Institute for Health and Clinical Excellence guideline stated that “current evidence on percut transluminal RF sympathetic denervation of the renal artery for resistant hypertension is from limited numbers of pa there is evidence of efficacy in the short and medium term. There is inadequate evidence on efficacy in the long te particularly important for a procedure aimed at treating resistant hypertension. The limited evidence suggests a low of serious periprocedural complications, but there is inadequate evidence on long-term safety. Therefore this proce should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2012

Esler et al (2012) noted that renal sympathetic nerve activation contributes to the pathogenesis of hypertension. S HTN-2, a multicenter, randomized trial, demonstrated that catheter-based renal denervation produced significant b pressure lowering in treatment-resistant patients 6 months after the procedure compared with controls, which were medication-only patients. The authors presented longer-term follow-up, including 6-month crossover results, is now presented. Eligible patients were on ≥3 antihypertensive drugs and had a baseline systolic blood pressure ≥160 mm Hg for type 2 diabetics). After the 6-month primary end point was met, renal denervation in control patients wa permitted. Patients randomized to immediate renal denervation (n=47) were evaluated one year post-procedure an crossover patients were evaluated 6 months post-procedure. At 12 months after the procedure, the mean fall in off blood pressure in the initial renal denervation group (-28.1 mm Hg; 95% confidence interval, -35.4 to -20.7; P<0.00 similar to the 6-month fall (-31.7 mm Hg; 95% confidence interval, -38.3 to -25.0; P=0.16 versus 6-month change). systolic blood pressure of the crossover group 6 months after the procedure was significantly lowered (from 190.0± 166.3±24.7 mm Hg; change, -23.7±27.5; P<0.001). In the crossover group, there was 1 renal artery dissection dur catheter insertion, before denervation, corrected by renal artery stenting, and 1 hypotensive episode, which resolve medication adjustment. Control patients who crossed over to renal denervation with the Symplicity system had a si drop in blood pressure similar to that observed in patients receiving immediate denervation. The authors conclude denervation provided safe and sustained reduction of blood pressure to 1 year.

Geisler et al (2012) conducted a study to assess cost-effectiveness and long-term clinical benefits of renal denerva resistant hypertensive patients. The authors noted that in the Symplicity HTN-2 randomized controlled trial, cathete renal denervation (RDN) lowered systolic blood pressure by 32 ± 23 mm Hg from 178 ± 18 mm Hg at baseline. A s
transition model was used to predict the effect of RDN and standard of care on 10-year and lifetime probabilities of myocardial infarction, all coronary heart disease, heart failure, end-stage renal disease, and median survival. The investigators adopted a societal perspective and estimated an incremental cost-effectiveness ratio in U.S. dollars per adjusted life-year, both discounted at 3% per year. Robustness and uncertainty were evaluated using deterministic and probabilistic sensitivity analyses. Renal denervation substantially reduced event probabilities (10-year/lifetime relat rate stroke 0.70/0.83; myocardial infarction 0.68/0.85; all coronary heart disease 0.78/0.90; heart failure 0.79/0.92; end disease 0.72/0.81). Median survival was 18.4 years for RDN versus 17.1 years for standard of care. The discounte incremental cost-effectiveness ratio was $3,071 per quality-adjusted life-year. The investigators acknowledged that were relatively insensitive to variations in input parameters except for systolic blood pressure reduction, baseline systolic blood pressure, and effect duration. The 95% credible interval for incremental cost-effectiveness ratio was cost-<s>$31,460 per quality-adjusted life-year. The model suggests that catheter-based renal denervation, over a wide range of assumptions, is a cost-effective strategy for resistant hypertension that might result in lower cardiovascular morbidity and mortality.

The Systolic HTN-3 Trial is currently in progress. Early clinical evaluation with catheter-based, selective renal sympathetic denervation in patients with resistant hypertension has mechanistically correlated sympathetic efferent denervation decreased renal norepinephrine spillover and renin activity, increased renal plasma flow, and has demonstrated clinically significant, sustained reductions in blood pressure. The SYMPLICITY HTN-3 Trial is a pivotal study designed as a prospective, randomized, masked procedure, single-blind trial evaluating the safety and effectiveness of bilateral renal denervation for the treatment of uncontrolled hypertension despite compliance with at least 3 antihypertensive medications of different classes (at least one of which is a diuretic) at maximal tolerable doses. The primary effective endpoint is defined as the change in office-based systolic blood pressure from baseline to 6 months (Kandzari et a

In a pilot study, Ott et al (2013) examined the effect of RDN in patients with treatment-resistant hypertension (TRH to the established definition (Joint National Committee VII and European Society of Hypertension/European Society of Cardiology guidelines), i.e., office blood pressure (BP) greater than or equal to 140/90 mm Hg (with at least 3 antihypertensive drugs, including a diuretic, in adequate doses) and confirmed by 24-hour ambulatory BP monitoring (this study, there were 54 patients with moderate TRH (office BP greater than or equal to 140/90 mm Hg and less than 160/100 mm Hg and diagnosis confirmed by 24-hour ABPM of greater than or equal to 130/80 mm Hg) who underwent catheter-based RDN using the Symplicity catheter (Medtronic Inc., Mountain View, CA). Patients were treated with anti-hypertensive drugs on average. Office BP was significantly reduced by 13/7 mm Hg 6 months after RDN (systolic 6 mm Hg versus 138 ± 21 mm Hg, p < 0.001; diastolic: 83 ± 11 mm Hg versus 75 ± 11 mm Hg, p < 0.001). In patients who underwent ABPM 6 months after treatment, there was a reduction in average 24-hour ABPM by 14/7 mm (systolic: 150 ± 16 mm Hg versus 136 ± 16 mm Hg, p < 0.001; diastolic: 83 ± 10 mm Hg versus 76 ± 10 mm Hg, p < 0.001). In 51% of patients, office BP was controlled below 140/90 mm Hg after RDN. In addition, heart rate decreased from 63 ± 10 beats/min (p = 0.006). The authors concluded that these findings indicated that RDN may reduce office hour ambulatory BP substantially in patients with moderate TRH. The main drawbacks of this study were the lack of a control group and the relatively small sample size. These researchers stated that there is a need for a large-scale, prospec randomized, multi-center, controlled trial in this group of TRH patients to precisely define the therapeutic role of RDN in moderate TRH.

Fadi Elmula et al (2014) examined the BP-lowering effect of RDN versus clinically adjusted drug treatment in true excluding patients with confounding poor drug adherence. Patients with apparent TRH (n = 65) were referred for RDN those with secondary and spurious hypertension (n = 26) were excluded. Treatment-resistant hypertension was defined as office systolic BP (SBP) greater than 140 mm Hg, despite maximally tolerated doses of greater than or equal to 3 antihypertensive drugs including a diuretic. In addition, ambulatory daytime SBP greater than 135 mm Hg after evidence of anti-hypertensive drugs was required, after which 20 patients had normalized BP and were excluded. Patients with TRH were randomized and underwent RDN (n = 9) performed with Symplicity Catheter System versus clinically adjusted treatment (n = 10). The study was stopped early for ethical reasons because RDN had uncertain BP-lowering effects. SBP and diastolic BP in the drug-adjusted group changed from 160 ± 14/88 ± 13 mm Hg (± SD) at baseline to 132 mm Hg at 6 months (p < 0.0005 and p = 0.02, SBP and diastolic BP, respectively) and in the RDN group from 156
15 to 148 ± 7/89 ± 8 mm Hg (p = 0.42 and p = 0.48, SBP and diastolic BP, respectively). Systolic BP and diastolic significantly lower in the drug-adjusted group at 6 months (p = 0.002 and p = 0.004, respectively), and absolute cha SBP were larger in the drug-adjusted group (p = 0.008). Ambulatory BPs changed in parallel to office BPs. The au concluded that these findings suggested that adjusted drug treatment has superior BP-lowering effects compared w patients with true TRH.

Bhatt et al (2014) stated that prior unblinded studies have suggested that catheter-based RDN reduces blood pres patients with resistant hypertension. These investigators designed a prospective, single-blind, randomized, sham-c trial. Patients with severe resistant hypertension were randomly assigned in a 2:1 ratio to undergo RDN or a sham Before randomization, patients were receiving a stable anti-hypertensive regimen involving maximally tolerated do least 3 drugs, including a diuretic. The primary efficacy end-point was the change in office SBP at 6 months; a sec efficacy end-point was the change in mean 24-hour ambulatory SBP. The primary safety end-point was a compo end-stage renal disease, embolic events resulting in end-organ damage, renovascular complications, or hypertens 1 month or new renal-artery stenosis of more than 70 % at 6 months. A total of 535 patients underwent randomiza mean (± SD) change in SBP at 6 months was -14.13 ± 23.93 mm Hg in the denervation group as compared with -1 25.94 mm Hg in the sham-procedure group (p < 0.001 for both comparisons of the change from baseline), for a diff 2.39 mm Hg (95 % CI: -6.89 to 2.12; p = 0.26 for superiority with a margin of 5 mm Hg). The change in 24-hour am SBP was -6.75 ± 15.11 mm Hg in the denervation group and -4.79 ± 17.25 mm Hg in the sham-procedure group, fo difference of -1.96 mm Hg (95 % CI: -4.97 to 1.06; p = 0.98 for superiority with a margin of 2 mm Hg). There were significant differences in safety between the 2 groups. The authors concluded that this blinded trial did not show a reduction of SBP in patients with resistant hypertension 6 months after RDN as compared with a sham control.

Bakris et al (2014) noted that prior studies of catheter-based RDN have not systematically performed ambulatory b pressure monitoring (ABPM) to assess the efficacy of the procedure. SYMPLICITY HTN-3 (Renal Denervation in P With Uncontrolled Hypertension) was a prospective, blinded, randomized, sham-controlled trial. The current analy the effect of RDN or a sham procedure on ABPM measurements 6 months post-randomization. Patients with resis hypertension were randomized 2:1 to renal denervation or sham control. Patients were on a stable anti-hypertensi including maximally tolerated doses of at least 3 drugs including a diuretic before randomization. The powered sec efficacy end-point was a change in mean 24-h ambulatory SBP. Non-dipper to dipper (nighttime BP 10 % to 20 % diurnal BP) conversion was calculated at 6 months. The 24-hour ambulatory SBP changed -6.8 ± 15.1 mm Hg in group and -4.8 ± 17.3 mm Hg in the sham group; difference of -2.0 mm Hg (95 % CI: -5.0 to 1.1; p = 0.98 with a 2 m superiority margin). The daytime ambulatory SBP change difference between groups was -1.1 (95 % CI: -4.3 to 2. 0.52). The nocturnal ambulatory SBP change difference between groups was -3.3 (95 CI: -6.7 to 0.1; p = 0.06). T of non-dippers converted to dippers was 21.2 % in the RDN group and 15.0 % in the sham group (95 % CI: -3.8 % p = 0.30). Change in 24-hour heart rate was -1.4 ± 7.4 in the RDN group and -1.3 ± 7.3 in the sham group; (95 % C 1.4; p = 0.94). The authors concluded that this trial did not demonstrate a benefit of RDN on reduction in ambulato either the 24-hour or day and night periods compared with sham.

On January 9, 2014, Medtronic, Inc. announced that its U.S. pivotal trial in RDN for TRH, SYMPLICITY HTN-3, fail its primary efficacy end-point. Medtronic intends to formulate a panel of independent advisors made up of physicia researchers who will be asked to make recommendations about the future of the global hypertension clinical trial p well as provide advice on continued physician and patient access to the Symplicity technology in countries with reg approvals. Pending this panel review, the company intends to: (http://newsroom.medtronic.com/phoenix.html? c=251324&p=irol-newsArticle&ID=1889335&highlight)

Suspend enrollment in the 3 countries where renal denervation hypertension trials are being conducted for approvals (SYMPLICITY HTN-4 in the U.S., HTN-Japan and HTN-India).
Begin informing clinical trial sites and investigators, global regulatory bodies, and customers of these finding decisions.
Continue to ensure patient access to the Symplicity technology at the discretion of their physicians in marke is approved.
Continue the Global SYMPLICITY post-market surveillance registry and renal denervation studies evaluating hypertension indications.

Ukena et al (2012) stated that sympathetic activity plays an important role in the pathogenesis of ventricular tachyarrhythmias. Radiofrequency Ablation of the Renal Sympathetic Nerve

of patients with resistant hypertension, proved to reduce local an body sympathetic activity. Two patients with chronic heart failure (CHF) (non-obstructive hypertrophic and dilated cardiomyopathy, New York Heart Association [NYHA] III) suffering from therapy-resistant electrical storm underw therapeutic RDN. In both patients, RDN was conducted with agreement of the local ethics committee and after obt informed consent. The patient with hypertrophic cardiomyopathy had recurrent monomorphic ventricular tachycardia despite extensive anti-arrhythmic therapy, following repeated endocardial and epicardial electrophysiological ablation attempts to destroy an arrhythmogenic intra-mural focus in the left ventricle. The second patient, with dilated non-ischemic cardiomyopathy, suffered from recurrent episodes of polymorphic VT and ventricular fibrillation. The patient declined ablation of these tachycardias. In both patients, RDN was performed without procedure-related complications. For RDN, ventricular tachyarrhythmias were significantly reduced in both patients. Blood pressure and clinical status were stable during the procedure and follow-up in these patients with CHF. The authors concluded that these findings suggest that RDN is feasible even in cardiac unstable patients. Moreover, they stated that randomized controlled trials (RCT) urgently needed to study the effects of RD in patients with electrical storm and CHF.

Tsioufis (2013) reported that a small study presented at ACC 2013 has shown that RDN, besides reducing resists hypertensive, produces a favorable effect on atrial and ventricular arrhythmias. In the study, the researchers treated patients with resistant hypertension who underwent ABPM and Holter monitoring at baseline and 1 month after RD procedure, the investigators used the EnlitHTN ablation catheter (St Jude Medical). Patients with grade II and abo Lown-Wolf classification were considered to have complex ventricular arrhythmias while the presence of greater than to 3 consecutive premature supraventricular contractions was defined as paroxysmal atrial fibrillation. These rese results found that after 1 month, office and 24-hour BP was significantly reduced by 38/14.1 mmHg, p < 0.001/0.003 and 1 mmHg, p < 0.001/0.001, respectively. Office heart rate was reduced by 7 beats per minute (bpm), (p = 0.046), am heart rate by 5.5 bpm, and average 24-hour heart rate by 6.7 bpm (p = 0.022). The researchers also found that complex ventricular arrhythmias were present in 5 out of the 14 patients (1 with non-sustained VT and 4 with ventricular cou basal) but persisted only in 2 of them 1 month after RDN (2 patients with ventricular couplets). The number of pr ventricular contractions was significantly decreased after RDN (from 2.23/hour to 0.39/hour, p = 0.019). Episodes of paroxysmal atrial fibrillation were detected in 5 of 14 subjects at baseline and in 2 of those patients 1 month after RDN total number of premature supraventricular contractions was also significantly decreased after RDN from 1.62/hour 0.72/hour (p = 0.039), the authors found. There was no relationship between the observed difference in premature supraventricular and ventricular contractions after RDN and the drop in office and 24-hour BP.

Hoffman et al (2013) presented a case of ventricular storm (VS) in a patient with acute ST-elevation myocardial infarction (STEMI). After initial successful thrombus extraction and percutaneous coronary intervention (PCI) of the proximal anterior descending (LAD) coronary artery, a 63-year old male patient showed recurrent monomorphic VT and ventricular fibrillation (VF) episodes refractory to anti-arrhythmic drug therapy. After initial successful VT ablation, fast VT and episodes remained an evident problem despite maximum anti-arrhythmic drug therapy. Due to an increasing instability was performed. Implantable cardioverter defibrillator interrogation and 24-hour Holter monitoring excluded recurrence of VT or VF at a 6-month follow-up after discharge. The authors concluded that this case highlighted that RDN was safely performed in a hemodynamically unstable patient with VS after STEMI and adjunct catheter ablation. Therefore, RDN may open a new avenue for an adjunctive interventional bailout treatment of such highly challenging patients.

Remo et al (2014) reported the largest case series to-date using RDN as adjunctive therapy for refractory VT in pa tients with underlying cardiomyopathy. A total of 4 patients with cardiomyopathy (2 non-ischemic, 2 ischemic) with recurrent ventricular tachycardia and prior endocardial (n = 2) or endocardial/epicardial (n = 2) ablation underwent repeat VT ablation. Renal denervation was performed spirally along each main renal artery with either a non-irrigated 50°C for 60 seconds) or an open irrigated ablation catheter (10 to 12 W for 30 to 60 seconds). Renal arteriography performed before and after RDN. Renal denervation was well-tolerated acutely and demonstrated no clinically signifi
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complications during follow-up of 8.8 ± 2.6 months (range of 5.0 to 11.0 months). No hemodynamic deterioration or worsening of renal function was observed. The number of VT episodes was decreased from 11.0 ± 4.2 (5.0 to 14.0 the month before ablation to 0.3 ± 0.1 (0.2 to 0.4) per month after ablation. All VT episodes occurred in the first 4 months after ablation (2.6 ± 1.5 months). The responses to RDN were similar for ischemic and non-ischemic patients. The conclusion that this case series provided promising preliminary data on the safety and effectiveness of RDN as an add-on therapy in the treatment of patients with cardiomyopathy and VT resistant to standard interventions.

There is an ongoing clinical trial, "RESCUE-VT" (REnal SympathetIC Denervation to sUpprEss Ventricular Tachya but this study has suspended participant recruitment (Last verified August 2014). http://clinicaltrials.gov/show/NCT

Shantha and Pancholy (2014) noted that recent evidence associates sympathetic tone with severity of obstructive sleep apnea (OSA). Renal sympathetic denervation, by decreasing sympathetic tone, has the potential to decrease OSA. Small observational studies that assessed this hypothesis lacked precision. In a meta-analysis, these investigator attempted to pool available data from studies that have assessed the effect of RDN on OSA severity in patients with Medline, Embase, Cochrane central, Ovid, Cinahl, web of science, and conference abstracts were searched for eligible citations by 2 independent reviewers using key words "renal denervation", "hypertension", and "obstructive sleep apnea". From a total of 2,863 identified citations, using meta-analysis of observational studies in epidemiology method, 5 studies were assessed eligible and included in the meta-analysis. All 5 studies followed an observational study design, involved patients with OSA and hypertension, and reported an apnea-hypopnea index (AHI) 6 months post-RDN; 4 were "be after" studies and 1 compared continuous positive airway pressure with RDN. In the pooled analysis, involving 49 subjects who underwent RDN, there was a significant reduction in mean AHI [weighted mean difference -9.61 (95% CI: -15.43 to 0.001)] 6 months post-RDN. One study also reported improvement in oxygen desaturation index and Epworth sleep scale score 6 months post-RDN. The authors concluded that RDN is associated with significant improvement in OSA severity. Moreover, they stated that these findings need validation in RCTs that evaluate the effect of RDN in patients with OSA, which can potentially broaden the clinical applicability of RDN.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

Radiofrequency ablation of the renal sympathetic nerve:

No specific code

0338T - 0339T

ICD-9 codes not covered for indications listed in the CPB (not all inclusive):

401.0 - 401.9 Essential hypertension

The above policy is based on the following references:


http://www.aetna.com/cpb/medical/data/800_899/0847_draft.html

12/08/2014