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GUIDELINES

Expert consensus: Renal denervation for the treatment of arterial hypertension

Consensus d'expert : dénervation rénale pour le traitement de l'hypertension arterielle

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Summary Catheter-based renal denervation is a new method for disrupting renal sympathetic nerves in the adventitia of renal arteries. A randomized clinical trial showed a decrease

Abbreviations: ABP, ambulatory blood pressure; ACC, American College of Cardiology; BP, blood pressure; DBP, diastolic blood pressure; GFR, glomerular filtration rate; HBP, home blood pressure; SBP, systolic blood pressure.

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KEYWORDS
Hypertension;
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in blood pressure (BP) in resistant hypertensive patients. To guide clinicians and interventional practitioners in the use of this new approach, the French Societies of Arterial Hypertension, Cardiology and Radiology decided to combine their expertise and propose a consensus document assessing the benefit/risk ratio of this technique in arterial hypertension. In 2012, this expert consensus proposed limiting renal denervation to patients with essential hypertension uncontrolled by four or more antihypertensive therapies and with: treatment that includes at least a diuretic; past or present exposure to spironolactone (at a dose $\geq$ 25 mg/d); and office BP greater or equal to 160 mmHg and/or 100 mmHg for systolic and diastolic BP, respectively, confirmed by daytime ambulatory or home BP measurement, with systolic BP greater than 135 mmHg and diastolic BP greater than 85 mmHg. Finally, renal artery anatomy and kidney function should allow proper intervention (i.e. two functional kidneys, absence of previous renal angioplasty). Renal denervation is a complex interventional procedure requiring appropriate training and associated with arterial complications. Antihypertensive treatment should not be interrupted immediately after renal denervation as the BP-lowering effect is delayed and reaches maximum effect after 3 months. Monitoring of BP, renal function and renal artery anatomy is required 12 months and 36 months after the procedure. The expert consensus requires the inclusion of patients experiencing this procedure in an observational study.

MOTS CLÉS
Hypertension ;
Hypertension résistante ;
Dénervation rénale ;
Cathétérisme avec radiofréquence

Résumé La dénervation rénale par voie endovasculaire est une méthode nouvelle qui permet la destruction de fibres nerveuses sympathiques qui cheminent dans l'adventice des artères rénales. Une étude clinique randomisée a montré une baisse de la pression artérielle chez des hypertendus résistants aux médicaments antihypertenseurs. Plusieurs sociétés savantes françaises regroupant des spécialistes de l'hypertension artérielle, de la cardiologie et de la radiologie interventionnelle ont souhaité fournir des repères et des règles de bon usage aux médecins cliniciens et interventionnels concernant cette méthode. En 2012, le consensus d'expert limite l'indication de la technique de dénervation rénale aux patients qui ont une HTA essentielle non contrôlée sous quadrithérapie ou plus, avec un traitement comportant au moins un diurétique, la spironolactone à la dose de 25 mg ayant été inefficace, avec au moins une PAS supérieure à 160 mmHg et/ou une PAD supérieure à 100 mmHg en consultation et la confirmation d'une PAS supérieure à 135 mmHg et d'une PAD supérieure à 85 mmHg en automesure ou par MAPA (période diurne), avec anatomie des artères rénales compatible avec l'intervention (deux reins fonctionnels, absence d'antécédents d'angioplastie). La dénervation rénale est une intervention complexe pouvant présenter des risques de complication artérielle et une formation est nécessaire pour l'utilisation du matériel spécifique. Le traitement antihypertenseur ne sera pas interrompu dans les suites immédiates du geste de dénervation rénale car l'effet sur la baisse de la pression artérielle est retardé et atteint son effet maximum après trois mois. La surveillance de la pression artérielle, de la fonction rénale et de l'anatomie des artères rénales est nécessaire après 12 mois et 36 mois. Le consensus d'expert impose l'inclusion dans un registre spécifique de tous les patients ayant bénéficié en France de la technique de dénervation rénale.

Introduction

Catheter-based radiofrequency renal-nerve ablation via an endovascular approach is a new therapeutic option, which, according to a randomized clinical study, reduces blood pressure (BP) in patients with resistant hypertension. Since 2011, a specific system (the Symplicity® Catheter System™; Medtronic [Ardian] Inc., Minneapolis, MN, USA) has been commercially available in France. This system achieves renal denervation through the focal delivery of four to six low power radiofrequency energy ablations (5—8 W) along the length of both renal arteries. The thermal effect generated by heat dissipation disrupts the sympathetic nerves located in the adventitia of the renal artery.

To date, the indication for this system is not explicitly described in current recommendations and instructions for use. Therefore, the French Society of Arterial Hypertension, the French Society of Cardiology and the French Society of Radiology decided to provide guidelines for interventional and clinical physicians on indications for and procedural and follow-up aspects of renal denervation for the treatment of arterial hypertension.

The present document represents a consensus of leading experts in this field and will be amended to keep in line with improvements in devices and procedures, and the outcome of future clinical trials with this technique.

Resistant hypertension: diagnosis and current patient management

Arterial hypertension is the most frequent cardiovascular risk factor and chronic disease recorded in France, with more than 12 million patients (20%) being treated with antihypertensive drugs. Despite established treatment strategies to address this issue, control of treated hypertension—defined by an office systolic blood pressure (SBP) less than 140 mmHg and diastolic blood pressure (DBP) less than 90 mmHg—is still only achieved in 50% of patients under treatment [1].

Hypertensive patients who do not achieve target blood pressure values are described as patients with uncontrolled arterial hypertension. In such circumstances, appropriate management includes: the need to comply with lifestyle measures, such as reduction of salt or alcohol intake, weight loss, etc.; assessment of adequate patient adherence to prescribed treatments; and rationalized use of antihypertensive medications, with optimal selection of pharmacological classes with additive and/or synergistic effects. When single-medication treatment has been proven inefficient, combination therapy should be set up, including a renin-angiotensin system blocker (angiotensin II receptor blocker, angiotensin I converting enzyme inhibitor or direct renin inhibitor), a calcium channel blocker and a thiazide diuretic.

Patients in whom target office BP values are not reached despite prescription of triple therapy, including a thiazide diuretic at maximum tolerated dose, are defined as having resistant hypertension, according to the current guidelines of the European Society of Hypertension [2]. The diagnosis of resistant hypertension should be confirmed as follows: ambulatory BP (ABP) monitoring or self BP measurement at home (HBP) to confirm that BP is permanently uncontrolled, with values greater than 135 and/or 85 mmHg during the daytime; and a complete biological and imaging workup to exclude secondary hypertension [2], including chronic kidney disease of various origins, sleep obstructive apnoea, primary aldosteronism, pheochromocytoma or significant renal artery stenosis and drug-induced hypertension.

When confirmed, resistant hypertension requires specific patient management as indicated in the international guidelines and listed below [2]: antihypertensive treatment dosage increase or adaptation (use of maximum tolerated dose of antihypertensive agents, selection of another diuretic, such as a loop diuretic, in chronic kidney disease patients); addition of a mineralocorticoid receptor antagonist, such as a low dose of spironolactone (25—50 mg/d); addition of other pharmacological agents (alpha-blockers, beta-blockers, centrally acting antihypertensive agents, direct vasodilators); use of fixed combinations of antihypertensive agents; use of HBP to monitor treatment efficacy; and reinforcement of a salt-restricted diet.

The prevalence of resistant hypertension varies according to population characteristics. It was seen in about 9% of treated hypertensive patients among a general population of patients living in the USA between 2003 and 2008 in the NHANES study [3]. In the USA, a recent survey indicated that among 205,750 patients with incident hypertension, 1.9% developed resistant hypertension within a median 1.5 years of initial treatment (or 0.7 cases per 100 person-years of follow-up) [4].

Patients with resistant hypertension are exposed prematurely to target organ dysfunction and to early occurrence of cardiovascular, cerebrovascular and renal complications, leading to increased mortality. The cardiovascular prognosis in hypertensive patients is directly related to on-treatment BP levels, which warrants proactive management of BP treatment [5].

In patients with resistant hypertension, BP control may be improved via the implementation of device-based therapies that target the sympathetic or parasympathetic regulation of BP, including baroreflex activation therapy and catheter-based renal denervation [6,7].

The objective of the present expert consensus, based on a literature review and the experts' experience, is to propose a statement about the use of renal denervation in patients with resistant hypertension. This document should help clinicians to optimize indications, provides guidelines about appropriate technical implementation, and outlines patient follow-up requirements.

Pathophysiological mechanisms and prerequisites for catheter-based renal denervation in hypertension

Role of the autonomic nervous system in hypertension pathophysiology

The autonomic nervous system contributes to hypertension pathophysiology via the activation of the sympathetic system, which is regulated by excitatory and inhibitory reflexes (baro-, chemo- or mechanoreflexes) or various neurohormones [8]. The role of the renal sympathetic nervous system in BP regulation is complex due to the impact of the central efferent sympathetic tone on the kidneys and the role of afferent sympathetic signals from the kidneys towards the central autonomic centres. Thus, the renal sympathetic system, which contributes to BP regulation, is considered as one among multiple systems involved in the initiation, progression and persistence of hypertension.

Role of the renal sympathetic nervous system

Efferent renal sympathetic nerve activity and BP regulation

The efferent sympathetic innervation of the kidneys directly influences the regulation of the vascular system, the renal tubules and the juxtaglomerular apparatus. Stimulation of the sympathetic system contributes to vascular constriction via two mechanisms: stimulation of the beta-adrenergic receptors of the juxtaglomerular apparatus, resulting in the increase of renin release and thus increasing plasma and tissue concentrations of the vasoconstrictor peptide, angiotensin II; and stimulation of vascular alpha-adrenergic receptors, eliciting direct vascular constriction. Moreover, sympathetic nervous system activation also increases tubular sodium reabsorption either directly or indirectly, thus contributing to an increase in overall extracellular fluid

volume. Consequently, reduction of efferent renal sympathetic tone in an experimental model of renal denervation has been associated with a decrease in BP [9].

Afferent renal sympathetic nerve activity and BP regulation

Renal sympathetic afferent nerves contribute to the regulation of the central sympathetic nervous system. They are activated by various stimuli detected by mechano- or chemoreceptors located in the kidneys, which are sensitive to kidney stretch, various concentrations of metabolites or oxygen levels (i.e. hypoxia resulting from renal ischaemia [10]). The interruption of renal sympathetic signalling by surgical or chemical intervention decreases both total sympathetic activity and BP [11], and prevents the increase in BP induced by various experimental conditions, such as nephrectomy.

In the early 1950s, the use of surgical renal denervation in patients with arterial hypertension resulted in decreases in BP, morbidity and mortality, peripheral and central sympathetic activity and renin release without any modification of glomerular filtration rate (GFR). The availability of effective orally active antihypertensive treatments and the high incidence, severity and duration of surgery-related adverse events (including postoperative death, severe orthostatic hypotension, sphincter incontinence, sexual dysfunction and paradoxical excessive sweating) explains why surgical denervation techniques (splanchnectomy, sympathectomy) were abandoned in the 1960s [12—15].

Renal denervation by radiofrequency via the endovascular approach

Catheter-based renal sympathetic denervation by radiofrequency is a new method that can disrupt both the efferent and afferent sympathetic nervous fibres that follow the renal artery to the kidney within the adventitia. This, in turn, reduces renal sympathetic tone and subsequently BP.

Clinical trials of catheter-based renal denervation in the treatment of resistant hypertension

The SYMPLICITY HTN-1 and HTN-2 trials

Two clinical trials have assessed the effects of renal denervation using radiofrequency in patients with resistant hypertension [16,17]. SYMPLICITY HTN-1, conducted in 50 patients, was mainly a pilot feasibility and safety study and reported BP reductions with no major complications [16]. SYMPLICITY HTN-2 was an open-label randomized study of 106 among 190 preselected patients with resistant hypertension, with the aim of assessing the efficacy of renal denervation in reducing office BP values after 6 months compared with a control group of medically treated patients. In both groups, no change in antihypertensive medication was allowed during the first 6 months. Inclusion criteria were very similar in both trials.

The definition of resistant hypertension in these two trials was as follows: office SBP (average of three measurements) greater than 160 mmHg or 150 mmHg in diabetics; treatment with at least three antihypertensive medications, including a diuretic (only in SYMPLICITY HTN-1); persistence of uncontrolled hypertension after a run-in period of 15 days; appropriate adherence to treatment as assessed during screening; absence of severe renal insufficiency (estimated GFR > 45 mL/min/1.73 m^2).

Renal arterial anatomy was required to be suitable for the endovascular denervation technique, according to the following criteria: main renal artery on each side at least 20 mm in length and 4 mm in diameter; and an absence of renal artery stenosis or no history of renal revascularization procedure. In both SYMPLICITY trials, the renal denervation procedure was not feasible in 10—20% of preselected patients due to anatomical reasons.

Effects of renal denervation on BP

The primary efficacy endpoint was the change in office BP assessed 6 months after the renal denervation procedure in both the SYMPLICITY HTN-1 and HTN-2 trials [16—18]. In 86 patients issued from a group of 153 patients (i.e. the extended cohort of SYMPLICITY HTN-1), the mean decrease in office SBP/DBP was −25/−11 mmHg. In SYMPLICITY HTN-2, the mean change in office SBP/DBP was −32/−12 mmHg in 49 patients undergoing renal denervation and +1/0 mmHg in the 51 medically treated control group ($P < 0.0001$). At 12 months after randomization, the mean office SBP/DBP decrease was −28/−10 mmHg but the mean SBP/DBP increased by +4/+3 mmHg compared with the 6-month values (American College of Cardiology [ACC] 2012 meeting) (Table 1). In the 35 patients in the control group who crossed over 6 months after randomization and had renal denervation, the mean decrease in office SBP/DBP was −28/−8 mmHg, 6 months after the procedure (ACC 2012 meeting).

The percentage of patients with SBP less than 140 mmHg after renal denervation was 39%; this indicates that 61% of the patients remained with uncontrolled BP despite renal denervation. In the 35 patients who crossed over, the percentage of patients with SBP less than 140 mmHg after 6 months of renal denervation was much smaller (10—12%), despite the fact that physicians were allowed to make changes to medications once the 6-month primary endpoint was reached (ACC 2012 meeting).

The percentage of responders (defined as an arbitrary threshold of greater or equal to 10 mmHg decrease in SBP) was 85% in the group treated by renal denervation and 35% in the medically treated group ($P < 0.0001$). This information was not reported for the 35 patients who crossed over as per protocol.

ABP was assessed before and after 6-month follow-up in only 20 patients in the renal denervation group. The ambulatory SBP/DBP reduction was only −11/−7 mmHg ($P = 0.006/0.014$ vs baseline). The reduction was −3/−1 mmHg in the control arm (P = not significant vs baseline). No ABP data are available for the 35 patients who crossed over as per protocol.

Renal denervation yielded no BP benefit in the 10% of patients initially randomized to renal denervation. This information was not reported for the 35 patients who crossed over as per protocol.

Table 1 Effects of renal denervation on blood pressure in the SYMPLICITY HTN-1 and HTN-2 trials.

	Inclusion	Δ at 1 month	Δ at 3 months	Δ at 6 months	Δ at 9 months	Δ at 12 months	Δ at 24 months
Pilot study (SYMPLICITY HTN-1)							
Office BP (mmHg)	177/101 ($n=45$)	−14/−10 ($n=41$)	−21/−10 ($n=39$)	−22/−11 ($n=26$)	−24/-11 ($n=20$)	−27/−17 ($n=9$)	
ABP ($n=12$), mean 24 hours (mmHg)						−11 ± 7 ($n=9$)	
Randomized study (SYMPLICITY HTN-2)							
Office BP (mmHg)	178/97 ($n=52$)		−20/−6[a] ($n=49$)	−33/−11[a] ($n=49$)	−28/−10[b] ($n=47$)		
HBP (mmHg)				−22/−12[a] ($n=32$)			
ABP, mean 24 hours (mmHg)				−8/−6[a] ($n=20$)			

ABP: ambulatory blood pressure; BP: blood pressure; HBP: home blood pressure.
[a] Versus control.
[b] Versus baseline.

The reduction in BP did not occur immediately after the procedure; the maximum effect was observed after about 2—3 months of follow-up.

Antihypertensive treatment (medications and doses) was not reduced in the majority of study patients (20% in the denervation group and 6% in the control arm, $P=0.04$), and complete treatment discontinuation was not achieved in any patient. In the 35 patients who crossed over, the antihypertensive treatment was decreased in six patients and increased in five patients.

Impact of renal denervation on sympathetic nerve activity

The decrease in overall and renal sympathetic nerve activity was assessed in 10 patients in the SYMPLICITY HTN-1 study: there was a decrease in muscle sympathetic nerve activity and a 47% reduction in renal noradrenaline spillover, 30 days after renal denervation.

Complications of catheter-based renal denervation

Patients experience intense visceral and diffuse pain during the 2-minute ablation sequences. It is thus mandatory to provide the patients with appropriate analgesia, which may be administered by an anaesthesiologist.

In the SYMPLICITY HTN-2 trial, atropine was required in 7/52 patients who experienced bradycardia during the procedure.

Among 50 patients in the SYMPLICITY HTN-1 trial, only one case of renal artery dissection and one case of femoral pseudoaneurysm were reported.

In the SYMPLICITY HTN-2 trial, among the 52 patients who underwent the initial procedure, the following complications were reported: one case of femoral pseudoaneurysm; one case of arterial hypotension requiring a reduction in the number of hypertensive medications; one case of urinary infection; one case of postprocedural paraesthesia; and one case of lumbar pain resolving after 1 month. Among the 35 patients who crossed over, one case of renal artery dissection following guide catheter insertion during angiography occurred; the lesion was stented without further complication. Additionally, one hospitalization due to hypotension necessitating intravenous fluids occurred following the renal denervation procedure; the antihypertensive medications were decreased and the patient was discharged without further incident. Three hypertensive events requiring hospitalization occurred in two patients.

Long-term follow-up (24 months) of the extended open-label study cohort of SYMPLICITY HTN-1 [18], involving 153 patients, showed one case of renal artery dissection and three cases of femoral pseudoaneurysm.

Six-month anatomical follow-up of the renal arteries of 43 patients enrolled in the SYMPLICITY HTN-2 trial and 81 patients included in an open-label substudy did not reveal any vascular lesions of the renal arteries. One case of worsening renal arterial stenosis requiring angioplasty was reported at 6-month follow-up.

In the SYMPLICITY HTN-2 trial, the GFR of 49 patients with a baseline value greater than 45 mL/min/1.73 m^2 remained stable 6 months after the denervation procedure. The absence of GFR variation was confirmed at 12 months (ACC 2012 meeting). No long-term data beyond this time period are available to date.

There was no death during follow-up in the SYMPLICITY HTN-2 trial. Two deaths were reported in the study cohort who reached 24-month follow-up (one myocardial infarction and one sudden death); these deaths were not attributed to the denervation procedure.

Overall, early adverse events were reported in approximately 3—4% of patients enrolled in these studies. The

low number of highly selected patients included in these studies, who were under very close medical supervision, precludes any elimination of a potential severe adverse event risk with a less than 5% frequency at short-, mid- and long-term follow-up. This warrants long-term clinical and imaging follow-up in patients undergoing renal denervation.

Critical assessment of data issued from trials assessing the benefit/risk ratio of renal denervation for the treatment of resistant hypertension

The limitations characterizing the results of published studies are as follows: the number of patients enrolled in these studies is small and the population is highly selected (202 patients with published outcome to date); the shortness of the follow-up duration precludes risk assessment for infrequent or long-term adverse events; not all patients included in these studies were on optimal hypertensive treatment—indeed, 5—10% of patients were not taking any diuretics and less than 20% were prescribed a mineralocorticoid receptor antagonist; the majority of patients did not have ABP or HBM measurements, which allow detection of uncontrolled hypertension in patients prone to the white-coat effect; the long-term BP outcome beyond 36 months is unknown (it was reported for a very limited number of patients at 24 months [$n = 59$] and at 36 months [$n = 24$] for the extended cohort study [ACC 2012 meeting]); there are no criteria allowing accurate prediction of the degree of BP reduction resulting from catheter-based renal denervation; currently in daily practice, there are no available markers of the impact of renal denervation on the renal sympathetic system during and following the procedure; and analysis of the effect of renal denervation on sympathetic system activation by complex experimental technical strategies is not feasible in clinical practice.

Therefore, further studies are warranted in order to address unresolved issues with respect to the implementation of renal denervation for treatment of resistant hypertension, which include: quantification of BP decreases using ABP and/or HBP monitoring; predictive factors of the efficacy of catheter-based renal denervation on BP; immediate procedural efficacy endpoints of renal denervation; long-term assessment of BP efficacy and anatomical evolution of the renal arteries; and cost-effectiveness assessment of catheter-based renal denervation as part of the management strategy for resistant hypertension.

Indications for catheter-based renal denervation in the treatment of resistant hypertension in 2012

According to the 2012 expert consensus, indications for catheter-based renal denervation should be restricted to patients with resistant arterial hypertension despite the use of four or more antihypertensive drugs and with: treatment that includes at least a diuretic (thiazide or loop diuretic if needed); past or present exposure to spironolactone (at a dose ≥ 25 mg/d); office SBP greater than 160 mmHg and/or DBP greater than 100 mmHg, confirmed by daytime ABP or HBP, with SBP greater than 135 mmHg and DBP greater than 85 mmHg; an estimated GFR greater than 45 mL/min/1.73 m^2; suitable renal arterial anatomy for renal denervation (see below); the presence of two functional kidneys greater or equal to 90 mm; a preprocedural examination of the renal arteries by computed tomography angiography, magnetic resonance angiography or conventional angiography; no history of angioplasty/stenting of the target renal arteries; a peripheral vascular access compatible with catheterization; and the decision to carry out the denervation procedure taken by a multidisciplinary 'renal' team, including a physician specialized in the management of patients with resistant hypertension.

The renal denervation technique should not be performed in hypertensive patients with the following characteristics: renal artery stenosis greater than 30%; renal artery fibromuscular dysplasia; age less than 18 years; pregnant.

Recommended procedural technique for performance of catheter-based renal denervation

The procedural technique for and organization of endovascular renal denervation recommended in the 2012 expert consensus guidelines are outlined below.

Technical requirements

The technical facilities should include an angiography/catheter laboratory providing: appropriate visualization of the two nephrograms by bilateral angiography; high-quality X-ray equipment (the use of an operating room C-arm is not adapted to this intervention); and optimal protection against X-ray exposure.

Images (cine views) must include images of the kidneys (left and right renal arteries) before and after renal denervation confirming the absence of dissection or renal embolic complications. The angiographic views at the beginning and the end of the procedure, as well as the position of the catheter at all ablation sites, should be recorded and stored in a computerized system.

The angiography/catheter laboratory should be located in a facility where analgesia/sedation can be safely administered by anaesthesiologists.

Operator training

Renal denervation is a complex procedure that may generate increased risks of renal and vascular complications as well as procedural failure due to inappropriate procedure. Prior training is deemed necessary before the first procedures can be safely performed, especially during the learning phase for specific equipment use.

Interventional radiologists and cardiologists should have previous experience of: at least 15 renal artery angioplasties with or without stent placement; or at least 10 renal artery angioplasties and 50 peripheral artery angioplasties over the preceding 2 years; or regular performance of renal angioplasty in the previous 5 years and regular performance of

renal artery catheterization for all-indication embolization (10 per year in the two previous years).

Radiofrequency renal denervation procedure

In compliance with the principles of arterial catheterization, this procedure requires the insertion of a single-use specific catheter for renal denervation. The denervation catheter, homologated for its use in the renal arteries, is connected to a low energy radiofrequency generator. The afferent and efferent nervous fibres that run along the adventitia of the renal arteries are disrupted by the thermal effect produced by heat dissipation of radiofrequency energy.

The method should be implemented using a standardized technique, with correct positioning of the catheter tip confirmed by visual check under fluoroscopy and by impedance measurement. Regarding delivery of radiofrequency energy, the requirements are: 2-minute radiofrequency pulse delivery sequences (the energy delivered via the catheter and the temperature should be recorded in real time); delivery of radiofrequency energy repeated four to six times in each renal artery; circumferential denervation following a helicoidally pattern by removal of the catheter using 60° to 90° rotation of each 5-mm segment, starting from the distal ablation area close to the bifurcation of the main renal artery up to its ostium; and cooling of the tip of the catheter by blood flow.

Renal denervation is feasible in instances where the following criteria are met: renal artery diameter greater than 4 mm on both sides; trunk of the main renal artery greater or equal to 20 mm in length in order to allow at least four to six radiofrequency ablation sequences; and treatment of only one artery in each kidney.

The following measures are required during the procedure: monitoring of vital variables (heart rate and BP); anticoagulation with adjusted-dose heparin according to the notice for use; preprocedural injection of nitrates in each renal artery; postprocedural check of pacemaker or defibrillator programming in patients with such devices undergoing renal denervation; and administration of appropriate analgesic drugs for pain management.

Vascular complications during the procedure should be managed as follows: the catheterization laboratory should be equipped with the appropriate devices, allowing urgent implantation of a stent in the renal artery in cases of dissection; the radiofrequency procedure should be completely discontinued in the event of a vascular complication occurring in one of the renal arteries; complications should be reported to the centre's equipment safety monitoring committee.

Recommendations for monitoring and follow-up of patients undergoing endovascular denervation for treatment of resistant hypertension

Short-term monitoring should follow the rules of management of patients after renal/peripheral angioplasty. Patient monitoring for 1 hour postprocedure in the recovery unit and a 24-hour hospital stay are recommended. Office BP should be checked at 1, 3, 6, 12, 24 and 36 months postprocedure. ABP and/or HBP monitoring should be checked at least at 6, 12, 24 and 36 months after the renal denervation procedure.

Renal artery imaging by computed tomography scan should be performed at 12 and 36 months following the renal denervation procedure. In the absence of an acute complication, monitoring of plasma creatinine and albuminuria (in patients with baseline albuminuria) should be done at 6, 12, 24 and 36 months following the renal denervation procedure.

Antihypertensive treatment should not be discontinued immediately after the renal denervation procedure because the expected decrease in BP is delayed and reaches its peak after about 2—3 months, according to the findings of the SYMPLICITY trial. Any change in hypertensive treatment should be prescribed by the specialized physician specifically managing the hypertension.

The expert consensus requires the inclusion of patients experiencing this procedure in an observational study (registry).

Conclusions

Catheter-based renal artery denervation is still a technique in its very early development. Despite promising preliminary results, several uncertainties remain regarding its benefit/risk ratio. The French consensus group recommends that renal denervation should be restricted to patients with essential resistant hypertension until further information is available. These recommendations will be regularly updated according to technical and clinical progress in the field of renal denervation. The expert consensus requires that all patients undergoing renal denervation should be included in a prospective registry conducted by the French Societies of Arterial Hypertension, Cardiology and Radiology, in order to provide real-life assessment of the benefit/risk ratio of this new technique.

Disclosure of interest

Michel Azizi is an investigator in the SYMPLICITY HTN-2 trial (Ardian Inc.) and a consultant for Vessix Vascular. Thierry Lefèvre is a consultant for Medtronic Inc. Marc Sapoval is an investigator in the SYMPLICITY HTN-2 trial (Ardian Inc.), an investigator in the Reduce HTN trial (Vessix Vascular) and a consultant for ReCor Medical.

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