SOUTH AFRICAN HEART ASSOCIATION AND HYPERTENSION SOCIETY CONSENSUS STATEMENT ON RENAL DENERVATION THERAPY

Resistant or uncontrolled hypertension occurs in about 12.8% of treated hypertensive persons, and is associated with increased morbidity and mortality. Although there are no outcome data related to the treatment of resistant hypertension it is estimated that for very 12/6 drop in systolic and diastolic pressure, major adverse cardiovascular outcomes can be expected to be reduced by between 25-50% and every attempt should be to get patients to blood pressure targets in keeping with current SA Society of Hypertension guidelines.

Renal denervation offers a novel approach to BP reduction by targeting the renal sympathetic over activity. To date unequivocal evidence of efficacy is not yet available and despite promise from preclinical studies, the results from recent studies have been discrepant. The recently published randomized sham controlled SIMPLICITY 3 study showed no significant blood pressure reduction of denervation compared to the control arm. This was is stark contrast to initial evidence from smaller non sham controlled trials and the cumulative data from the Global SIMPLICITY registry which would suggest reductions in blood pressure of approximately 30/10 mmHg, sustained over > 36 months. There are a number of possible explanations for the observed discrepancies that will be explored in ongoing and planned studies.

This document summarizes the view of the SA Hypertension Society, SA Heart and South African Society of Cardiovascular Interventionalists, to provide guidance regarding appropriate patient selection for referring physicians, interventionists, healthcare providers and funders. Renal denervation should only be considered in highly selected patients if the following criteria are met:

Prerequisites for denervation:

1. Adherent patients with uncontrolled hypertension defined by an office BP > 160/90 mmHg taking >3 antihypertensive drugs, one of which must be a diuretic (hydrochlorothiazide 25 mg or indapamide 2.5 mg), in the optimal doses

2. An abnormal ambulatory BP is defined according to the SA Hypertension Guidelines 2011 as any of the following: Day time mean BP > 135/85 or night time mean > 120/70 mmHg
3. The patient is assessed by a specialist physician or sub-specialist (e.g., cardiologist, nephrologist or endocrinologist) for exclusion of secondary causes of hypertension. Furthermore, it is recommended that following determination of an aldosterone/renin ratio in all patients, if the aldosterone is >500 pmol/L and or the ratio > 70 the patient should receive a trial spironolactone or be worked up for primary aldosteronism prior to renal denervation.
4. A trial of low dose spironolactone (up to 25mg b.d.) should be considered in patients with no clinical contraindications or relative contraindications (serum K^+ > 4.5 mmol/L or eGFR < 60mls/min).
5. eGFR > 45mls/min
6. No clinically significant renal artery stenosis on a pre-procedure CT renal angiogram or direct angiography at the time of the denervation. (The latter approach may reduce costs and exposure to contrast).
7. Given the current state of clinical equipoise, RDN in South Africa should only be performed at centers participating in global or local prospective studies or registries.

Contra-indications to denervation

1. Complex renal vascular anatomy making denervation technically difficult
2. eGFR < 45mls/min
3. Pregnancy
4. Significant aortic stenosis

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