SA Heart

SASCI
South African Society of Cardiovascular Intervention

22 November 2013

SASCI STATEMENT ON RENAL DENERVATION (Re 2nd market entrant)

An Advisory Board was set up more than a year ago to establish South African guidelines for the use of renal denervation in the treatment of uncontrolled essential hypertension. The Advisory Board was a good mix of academic and private practitioners and the details of the recommendations are available on the website.

To date we only have the Simplicity Study related to the Medtronic Ardian Device which shows a very high degree of safety and efficacy in patients treated out to three years. Over a 1,000 patients have been evaluated in the Simplicity Studies and the American Study will be commencing later this year. The purpose of these Studies is to document the long term safety and efficacy of renal denervation in the real world patient population with hypertension and/or other diseases characterised by elevated sympathetic drive. A recent presentation at TCT showed a renal artery dissection rate of 0.09% (one patient), a vascular pseudo aneurysm in four patients and a hematoma in one. This would indicate the extreme safety of the procedure. There was no late renal artery stenosis.

The initial Simplicity 1 and 2 Studies showed a consistent fall of office systolic blood pressure of 25% - 28% with the diastolic drop of about 15% and similar drop in ambulatory blood pressure. There were patients who did not respond but the percentage of non-respondents is low. Recently the 3 year data was presented at TCT showing a persistent benefit in maintaining the greater than 20% reduction indicating ongoing efficiency and no complications. The patients reported were the average severe hypertensive patients including 86% of patients with a systolic blood pressure of greater than 140mmHg and 13% of patients with blood pressures as high as 180/ 110. In all these groups the fall in systolic blood pressure was approximately 20mmHg at three years' post denervation.

Renal denervation for the treatment of uncontrolled essential hypertension has been shown to be an effective, safe and sustainable therapy in a wide cohort of patients.

All the data to date has related to the Medtronic Ardian Device but at the recent TCT congress the Vessix device marketed by Boston Scientific was presented. It is amazing that the 6 and 12 month fall in blood pressure is identical with the two devices and the degree of safety is the same.

Although there is no comparative data between the different devices available on the market it is reasonable to assume that if the efficacy is equal at one year it will remain equal out to three years and beyond. Similarly if the safety profile is the same at one year this too can be assumed to be seen out to 3 or 5 years.

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It is SASCI's contention that if newer devices have the same safety and efficacy out to one year as the original device it is reasonable to assume that those results will remain at 3 years and beyond.

It is not the role of SASCI to dictate to Funders which products or procedures they should or should not fund but it is our duty to make available to the Funders the efficacy and safety data of all devices on the market.

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