INAHTA Brief Issue 2012/013

Title **Renal sympathetic denervation using endovascular radiofrequency ablation for the management of resistant hypertension**

Agency Avalia-t. Galician Health Technology Assessment Agency.
Edificio Administrativo San Lázaro · 15781 Santiago de Compostela
Telf.: 881 541 831 · Fax: 881 542 854 · e-mail: avalia-t@sergas.es ·
http://avalia-t.sergas.es

Reference http://www.sergas.es/Docs/Avalia-t/avalia-t201208DenervacionRenal.pdf

Aim
To assess the renal sympathetic denervation using Symplicity® catheter-based endovascular radiofrequency renal-nerve ablation, in terms of its safety, efficacy and/or effectiveness for treatment of resistant arterial hypertension. Assessment focused mainly on the changes short and long-term changes in systolic and diastolic blood pressure and their effects on cardiovascular morbidity and mortality.

Conclusions and results
The bibliographic search yielded 289 papers. Of these 10 met the inclusion criteria, with the scientific evidence being drawn from 3 studies in the Symplicity Clinical Trial Program and another 7 studies, some of which were an extension of the former. The studies had different experimental designs (with five being case series) and displayed important methodological limitations.

The renal denervation technique reduces blood pressure, which is maintained up to 2 years after the procedure, though ambulatory monitoring at 6 months shows a blood pressure pattern that is similar albeit less pronounced. Other beneficial effects included an improvement in glucose metabolism, diastolic function and severity of obstructive sleep apnoea. The technique showed itself to be safe, with a low incidence of immediate and short- and long-term complications. Current evidence is nevertheless based on a small number of studies, with limitations that include: small sample size; overlapping of patients; presence of conflicts of interest; short follow-up; possible biases in the evaluation of variables; and a high degree of heterogeneity in the response to renal sympathetic nerve ablation.

Recommendations
In view of the uncertainty surrounding the efficacy, safety and therapeutic utility of radiofrequency sympathetic renal-nerve ablation for the treatment of resistant arterial hypertension, its incorporation into the health service portfolio is not recommended at the present time. There is a need for randomised clinical trials, aimed both at assessing the technique in the long term and its impact on the reduction of cardiovascular morbidity and mortality, and comparing the different existing renal denervation methods; and, for cost-effectiveness studies.

Methods
A search of the scientific literature was undertaken to July 2012, covering the following databases: Medline; Embase; Health Technology Assessment (HTA); Database of Abstracts of Reviews of Effectiveness (DARE); NHS Economic Evaluation Database (NHSEED); Cochrane Library Plus; ISI Web of Science; Índice Médico Español (IME); Clinical Trials Registry; and Cochrane Central Database. From among the papers yielded by the bibliographic search, only those that met the selection criteria were selected; data were then extracted and the evidence summarised.

Written by
Gerardo Atienza, Galician Health Technology Assessment Agency (avalia-t), Spain.