What is the clinical and cost effectiveness of treatment with renal denervation for patients with resistant hypertension?

Healthcare Improvement Scotland

Record Status
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Citation

Authors' objectives
This evidence note will consider the following questions: 1. What is the clinical and cost effectiveness of treatment with RDN for patients with RH? 2. What model of treatment centres should be adopted?

Authors' conclusions
RH is a significant problem for many patients and has considerable impact on mortality and morbidity. Evidence published before 2014 suggests that RDN reduces BP in patients with RH, and may be a valuable and safe treatment option for this population of patients. These studies were mostly observational and included no control group, and thus are prone to bias. Results from the first sham-controlled trial in this area found that there was no statistically or clinically significant difference in the change in office and ambulatory BP, between RDN and a sham procedure, at 6 months. The RDN procedure was however found to be safe, at 6 months. The results highlight the importance of well designed and rigorously conducted studies that assess new medical devices before adopting them in clinical practice, as large treatment effects observed in uncontrolled clinical studies or trials without a sham group are often not reliable. Furthermore, as there were no added benefits with RDN, the findings also highlight that many patients with RH can achieve reductions in BP, if they are closely monitored and optimally treated with antihypertensive medications. Long-term data to determine the true effect, therapeutic durability and safety of the procedure on BP reduction and other cardiovascular outcomes are still lacking. This has been highlighted by all the studies included in this report. No specific evidence concerning the model of treatment centres was identified. However, NICE IPG suggests that patients should be carefully selected by a multidisciplinary team and the procedure should be performed by specialists experienced in endovascular interventions. The uncertainties in the evidence base to support the relative efficacy of RDN—following the publication of first sham-controlled trial in this area—undermine the economic studies which concluded that RDN was a costeffective treatment option. In addition, there is uncertainty surrounding the assumed long-term efficacy of RDN within the economic studies, with the studies also limited in their generalisability to Scotland. Further evidence to establish the role of RDN is required. This will only be achieved by appropriately designed trials with patients with true RH.

Final publication URL

Additional data URL

Indexing Status
Subject indexing assigned by CRD

MeSH
Humans; Scotland; Hypertension; Catheter Ablation; Sympathectomy
Language Published
English

Country of organisation
Scotland

English summary
An English language summary is available.

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AccessionNumber
32013000493

Date abstract record published
25/06/2013