Quality of Life After Renal Denervation

To the Editor:

Lambert et al recently reported that the quality of life of 62 treatment-resistant hypertensive patients, as assessed by the Medical Outcomes Study 36-Item Short-Form Health Survey and Beck Depression Inventory-II, improved 3 months after renal sympathetic denervation. All patients had been enrolled in the authors’ ongoing research into the effectiveness of renal denervation, without any reason given why they were selected to assess quality of life. These patients must have received more than usual attention. Lambert et al admit that in a purely observational study they could not exclude a placebo effect on the subjective self-assessment of health-related quality of life. This major limitation did not restrain the authors to extrapolate animal experiments to humans and to speculate how disruption of afferent sympathetic nervous traffic might have affected the subjective perception of quality of life. The improvement in the 36-Item Short-Form Health Survey was largely driven by improvement in vitality, social function, role emotion, and mental health, domains which are vulnerable to placebo effects, whereas no significant change was observed in the more objective Physical Component Summary Score. Furthermore, antihypertensive drug treatment remained unchanged at 3 months. Thus, the observed improvement in quality of life cannot be attributed to a decrease in the pill load or to switching patients to drugs with fewer side effects. Finally, follow-up was limited to 3 months and incomplete (40/62 patients; 64.5%). This makes it impossible to extend the proposed conclusion to 6 months, when most of the blood pressure benefit of renal denervation is believed to be present. In fact, failure to assess the complication rate in 22 patients (35.5%) invalidates any inference about quality of life.

The publication of numerous small nonrandomized studies looking for additional benefits of renal denervation often labeled as hypothesis-generating, in high-ranking journals, is a matter of grave concern and is not serving the best interest of patients. At this point in the development of renal denervation, marketers thrive on CE label certification in Europe and exploit the absence of firm regulations for the clinical use of devices. We believe that all energy should be channeled to truly evidence-generating randomized controlled clinical trials instead of hypothesis-generating market-driven speculations. A much more rigorous approach is state of the art for the pharmaceutical industry, but until now has not systematically been imposed on producers of devices, including those of renal denervation systems. Loose publication standards and deficient regulations only serve the financial interests of manufacturers.

Disclosures

None.

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