Response to Quality of Life After Renal Denervation

We are grateful for the opportunity to respond to this unusually partisan and doctrinaire critique of our work. We particularly take umbrage at the inference that our market-driven speculations make us dupes of marketers (who) thrive on CE label certification in Europe and that we are not serving the best interests of patients.

Our study dealt with two issues: subjective health-related quality of life (QoL) in patients with resistant hypertension, and change in QoL in patients after renal denervation. For the former, a control cohort was drawn from the AusDiab database by investigators blinded to the health status of our resistant hypertensive cohort. With the latter, as noted in our article, the impetus for examining QoL after renal denervation stemmed from our clinical observation that a number of patients, or their partners, mentioned spontaneously at follow-up that they felt calmer and more at ease after renal denervation than before. We aimed to address this in a more objective way using established questionnaires. Indeed, it is important, and in the best interests of patients, to look beyond the substantial fall in blood pressure that was evident and assess this new therapy for any potential impact, positive or negative, on physical and mental aspects of QoL. All scales of the SF 36 are independently appropriate and validated measures of physical and mental aspects of QoL. We disagree with the unsubstantiated assertion that the physical scales are necessarily more objective than the mental health scales, and the authors’ conclusion that a change of QoL analysis on 40 participants only at 3 months invalidates any inference about QoL. There were no adverse events reported that could account for loss to follow-up; moreover, our results are in agreement with those of Fischer et al., who demonstrated improvement in QoL, anxiety, and depression in patients 3 and 6 months after renal denervation. In relation to the comment regarding our reference to data from animals for seeking a possible explanation of our findings—this is a time-honored strategy, drawing on experimental studies for insights when direct data are unavailable in humans.

Although the Symplicity HTN-3 trial (ClinicalTrials.gov Identifier: NCT01418261) should appease Persu et al., the value of clinical experience and well-conducted observational studies should not be underestimated. Conca et al. compared outcomes from randomized controlled trials and observational studies and found a concordance between the 2 approaches, noting that the popular belief that only randomized controlled trials produce trustworthy results and that all observational studies are misleading does a disservice to patient care, clinical investigation, and the education of health professionals. Astute clinical observations supported by thorough evaluation and investigation are fundamental in the process of discovery. Not sharing our experience because of the limitations clearly acknowledged in our article serves neither science nor patients.

Disclosures

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