



COMMENT ON FEDORKO ET AL.

Hyperbaric Oxygen Therapy Does Not Reduce Indications for Amputation in Patients With Diabetes With Nonhealing Ulcers of the Lower Limb: A Prospective, Double-Blind, Randomized Controlled Clinical Trial. *Diabetes Care* 2016;39:392–399

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I read with interest the trial by Fedorko et al. (1) and have concerns about whether this trial has produced evidence of relevance to patients. The U.S. Patient Protection and Affordable Care Act of 2010 created the Patient-Centered Outcomes Research Institute (PCORI) to fund and promote research that evaluates questions that matter to patients. Patient-centered outcomes research evaluates questions and outcomes that are meaningful and important to patients and their caregivers (2). Evidence from this research should help patients and their health care providers communicate and make informed health care decisions about their daily dilemmas (2). The engagement of patients, clinicians, and other stakeholders in designing research is important to achieve this goal (3).

Unfortunately, this trial (1) was not patient-centered, which led to results that did not add any new information to our knowledge about the effect of hyperbaric oxygen therapy on diabetic foot ulcers. Patients with diabetic foot

ulcers do not care about research that evaluates a condition in which the intervention is contraindicated (45% of patients enrolled in the trial had Wagner grade 2 ulcers, which guidelines tell us we should not treat with hyperbaric oxygen therapy [3]). Patients with diabetic foot ulcers also do not care about research that evaluates an outcome that is seen in a picture (the trial unfortunately determined the outcome of amputation by having a surgeon look at a picture and determine if amputation is needed, which is different from prior literature in this field). This trial and the resources spent on it would have benefited patients much more if it exclusively enrolled individuals with Wagner grade 3 or higher ulcers (who are actually eligible for the intervention) and did not use the outcome of “should be amputated as seen in a picture.” Prior trials have reported actual amputation rates as an outcome (4).

In a time of scarce resources and limited research funding, stakeholders demand research that matters. The trial by

Fedorko et al. (1) does not advance science and will leave patients, clinicians, and payors more confused than before.

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