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LETTERS TO THE EDITOR

Yoga versus educational film intervention in restless legs syndrome: extension of trial may be beneficial to patients

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The article by Innes et al,[1] "Effects of a 12-week yoga versus a 12-week educational film intervention on symptoms of restless legs syndrome and related outcomes: an exploratory randomized controlled trial," is interesting. As the authors point out, medications used in the management of restless leg syndrome (RLS) carry risk of serious side effects (affecting 6%–80% of patients), and most of these medications cannot be used in patients who are pregnant or in the 6 months postpartum period. However, the study excluded pregnant patients and patients within 6 months postpartum period.

Even though clinical drug trials do exclude pregnant and postpartum patients because of teratogenicity and other side effects, not including pregnant and postpartum women in nonpharmacological trials is not rational.

Women with RLS are more likely to have hypertensive disorder of pregnancy. Some non-first-line drugs such as clonazepam, clonidine, and opioids may be justified depending on severity. Neonatal withdrawal is a concern with these drugs, especially because RLS disease is more prevalent in late pregnancy.[2] Some drugs that may be teratogenic are not used in pregnancy. Considering these situations, it is even more important to include pregnant patients and patients within 6 months of the postpartum period.

Pregnant patients often ask physicians for permission to participate in yoga. The American Congress of Obstetricians and Gynecologists has no specific recommendations for yoga. A small study was conducted by Polis et al[3] in 25 women who completed 26 poses. There were no significant changes in vital signs during the poses. All participants had a reactive nonstress test before and after the session. All fetal heart tracings demonstrated accelerations and variability, and no decelerations of the fetal heart tracing were seen. No patients had regular contractions during the session.

Historically, there have been barriers to obtaining data from pregnant women in clinical trials to protect them and their fetuses. However, in certain situations, it may be helpful to collect data in pregnant women in a clinical trial.[4] The Food and Drug Administration considers it ethically justifiable to include pregnant women with a medical condition requiring treatment in clinical trials under the following circumstances: the clinical trial holds out the prospect of direct benefit to the pregnant woman and/or fetus that is not otherwise available outside the research setting or cannot be obtained by any other means. Extension of this clinical trial with a longer period may be of value for pregnant patients with RLS.

CITATION

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DISCLOSURE STATEMENT

The author has seen and approved the manuscript. The author reports no conflicts of interest.