

## Letter to the Editor: *Panax Ginseng* for Cancer-Related Fatigue

Re: Sriram Yennurajalingam, Nizar M. Tannir, Janet L. Williams, et al. A Double-Blind, Randomized, Placebo-Controlled Trial of *Panax Ginseng* for Cancer-Related Fatigue in Patients With Advanced Cancer. *J Natl Compr Canc Netw* 2017;15(9):1111–1120.

We read with interest the recent paper by Yennurajalingam et al<sup>1</sup> on a phase III trial of *Panax ginseng* (PG) for cancer-related fatigue (CRF). In confirmation of the results of this study, we would like to report our unpublished observation on the same subject. Following a previous positive report,<sup>2</sup> in September 2010 we started a multicenter, randomized, double-blind, placebo-controlled study to evaluate the effect of PG on CRF. (The study was partially funded by the “II Programma Sperimentale Medicina non Convenzionale della Regione Emilia-Romagna.”) The primary objective was improvement of CRF, assessed as score reduction in the Brief Fatigue Inventory (BFI).<sup>3</sup> To be eligible, patients with no evidence of disease after adjuvant chemotherapy for solid tumors or with metastatic disease in progression after first-line treatment had to complain of fatigue with a score of  $\geq 4$  on the BFI. Patients with anemia, clinical hypothyroidism, diabetes, or persistent insomnia, or who had undergone treatment with warfarin or anxiolytic therapy with a dose not yet stabilized were excluded. Patients were randomized to receive PG at 250 or 500 mg/d or placebo for 8 weeks. Doses were given in 2 oral administrations of similar-looking capsules containing 250 mg of PG dried extract or placebo. Patients were asked to complete a diary containing self-assessment scales weekly and were seen in the outpatient clinic every 2 weeks.

An enrollment of 207 patients in 24 months was planned, and improvement of BFI score in 40% of patients treated with PG and 15% of those treated with placebo was hypothesized, with an 80% power and an alpha error of 5%. The study was approved by the Ethics Committees of the participating centers. Because enrollment

was lower than expected, with only 64 patients randomized in 33 months, the study was discontinued. Although the small sample size prevented a formal statistical analysis, the available data seemed to show (1) a gradual reduction of the median BFI score after the first 4 weeks (from 7 to 5), followed by stabilization up to week 8; (2) perception of high to moderate treatment benefit in 43.7% of patients; and (3) correct perception of the blinded treatment only in 26.6% of patients. Remarkably, these results appeared independent of the treatment received. Although unpowered, our study showed data in a similar direction as those of The University of Texas MD Anderson Cancer Center, supporting the conclusion that there is no benefit of PG in the treatment of CRF.

Andrea Angelo Martoni, MD  
S. Orsola-Malpighi University Hospital  
Bologna, Italy  
Email: andrea.martoni@fastwebnet.it

Luigi Cavanna, MD  
Piacenza Hospital  
Piacenza, Italy

Gianpiero Porzio, MD  
San Salvatore Hospital  
University of L'Aquila  
L'Aquila, Italy

doi: 10.6004/jnccn.2018.7006

### References

1. Yennurajalingam S, Tannir NM, Williams JL, et al. A double-blind, randomized, placebo-controlled trial of *Panax ginseng* for cancer-related fatigue in patients with advanced cancer. *J Natl Compr Canc Netw* 2017;15:1111–1120.
2. Barton DL, Soori GS, Bauer BA, et al. Pilot study of *Panax quinquefolius* (American ginseng) to improve cancer-related fatigue: a randomized, double-blind, dose-finding evaluation: NCCTG trial N03CA. *Support Care Cancer* 2009;18:179–187.
3. Mendoza TR, Wang XS, Cleeland CS, et al. The rapid assessment of fatigue severity in cancer patients: use of the Brief Fatigue Inventory. *Cancer* 1999;85:1186–1196.

### Call for Correspondence

JNCCN is committed to providing a forum to enhance collaboration between academic medicine and the community physician. We welcome comments about the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines), articles published in the journal, or any other topic relating to cancer prevention, detection, treatment, supportive care, or survivorship. Please send correspondence to JNCCN.edmgr.com or to JNCCN@nccn.org.

Letters should be no more than 400 words, with no more than 5 references if included. Please include the full names, degrees, and affiliations of all letter authors and a phone number or e-mail address for contact.

Letters are considered for publication as space allows. NCCN reserves the right not to publish correspondence for any reason it deems appropriate. All letters are subject to editing and/or abridgment.