

Updated findings on the effects of stellate-ganglion block on hot flushes and night awakenings

Breast-cancer survivors frequently suffer from debilitating hot flushes. Treatments available up to now have not been uniformly successful in the alleviation or elimination of these hot flushes; therefore, we started using a simple and safe intervention aimed at blocking the underlying pathological processes—a unilateral stellate-ganglion block done as an outpatient procedure.¹ We postulated that the stellate-ganglion block provides relief of hot flushes by interrupting the CNS connections with the sympathetic nervous system, allowing the body's temperature-regulating mechanisms to reset.² The initial findings of our pilot study³ published in the June issue of *The Lancet Oncology*, which included 13 breast-cancer survivors treated with stellate-ganglion block, conclusively showed a decrease in the frequency of hot flushes and their severity. The incidence of night awakenings that frequently accompany hot flushes was also greatly decreased.³

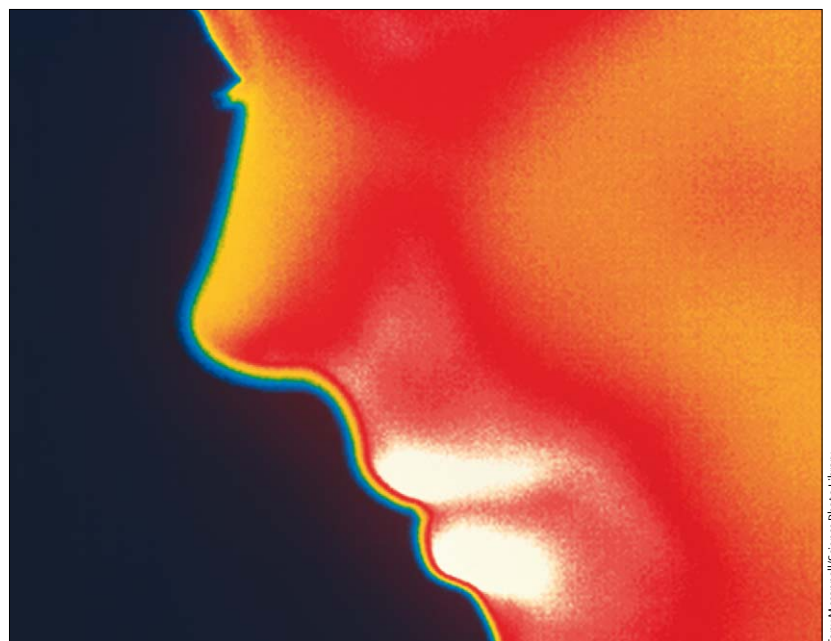
One of the concerns expressed in the Reflection and Reaction piece to our paper⁴ was the short duration of follow-up. With longer follow-up data now available for our study participants, we are able to provide an update in this letter. Follow-up data were obtained by use of the same methods as described in our pilot study:³ the Pittsburgh Sleep Quality Index and the Hot-Flash Score.

All 13 patients were prospectively followed. The mean duration of follow-up was 42.6 weeks (SD 6.33; range 37–52). The number of hot flushes and night awakenings gradually decreased (or became stabilised) throughout the follow-up period. The generalised-estimating-equations method was used to assess the effect of treatment on the number and intensity of hot flushes and night awakenings. The independent variables included a dummy variable for weeks 1–2 and a dummy variable for weeks 3 to the end of the follow-up period. Here, we report the treatment effect in the follow-up period from week 3 to the end of follow-up (the short-term effect in the first 2 weeks immediately after treatment has already been reported in the previous article).³ The total number of hot flushes decreased from a mean of 79.4 (SD 37.4) per week before the procedure to a mean of 6.9 (SD 5.0) per week between week 3 and the end of the follow-up period.

The mean decrease from baseline to the mean score between week 3 and the end of follow-up was 72.5 (SD 33; $p < 0.0001$). The mean decreases in the individual categories of hot flushes were: mild (mean 5.9 [SD 10.9]; $p < 0.0001$); moderate (21.1 [13.1], $p < 0.0001$); severe (24.5 [17.6]; $p < 0.0001$); and very severe (21.0 [40.6]; $p < 0.0001$). The mean number of night awakenings decreased from 19.5 (14.8) before the procedure to 1.3 (1.2) per week during the follow-up period (week 3 to the end of follow-up). The mean decrease from baseline to the mean score between week 3 and the end of follow-up was 18.2 (14.0; $p < 0.0001$). Ten patients needed additional stellate-ganglion blocks at a median time of 11 weeks after the original intervention.

Once again, there were no serious adverse events in the entire series, confirming our original conclusion that stellate-ganglion blocks in survivors of breast cancer and the effects of this treatment are both safe and efficacious.

Other concerns expressed by the commentators,⁴ such as the need for a multicentre prospective randomised controlled trial, the current absence of information regarding the financial implications



Long-term relief of hot flushes is now possible

Tony McCormell/Science Photo Library

related to the cost of this procedure, and its acceptance by patients and insurance companies, are currently being addressed.

*Eugene G Lipov**, Jaydeep R Joshi, Hui Xie, Konstantin V Slavin

Advanced Pain Centers, Hoffman Estates, IL, USA (EGL, JR); Department of Epidemiology and Biostatistics and Quantitative Biomedical Sciences Program, University of Illinois Medical Center at Chicago, Chicago, IL, USA (HX); Department of Neurosurgery, University of Illinois Medical Center at Chicago, Chicago, IL, USA (KVS)

elipovmd@aol.com

The authors declared no conflicts of interest.

- 1 Lipov E, Lipov S, Stark JT. Stellate ganglion blockade provides relief from menopausal hot flashes: a case report series. *J Womens Health* 2005; **14**: 737–41.
- 2 Lipov EG, Lipov S, Joshi JR, Santucci VD, Slavin KV, Beck Vigue SG. Stellate ganglion block may relieve hot flashes by interrupting the sympathetic nervous system. *Med Hypotheses* 2007; **69**: 758–63.
- 3 Lipov EG, Joshi JR, Sanders S, et al. Effects of stellate-ganglion block on hot flushes and night awakenings in survivors of breast cancer: a pilot study. *Lancet Oncol* 2008; **9**: 523–32.
- 4 Loprinzi CL, Barton DL, Carns PE. Stellate-ganglion block: a new treatment for hot flushes? *Lancet Oncol* 2008; **9**: 506–07.

Quality of life as an endpoint of treatment efficacy in malignant lung tumours

We read with interest the findings of the RAPTURE study by Lencioni and colleagues,¹ published in the July issue of *The Lancet Oncology*, in which the researchers assessed the efficacy of radiofrequency ablation of malignant lung tumours in patients who were not candidates for surgical resection and showed it to be

an acceptable alternative. There are certain issues related to this study, however, which need further clarification.

First, quality of life (QOL), as determined by the Short Form (SF)-12 (physical and mental summary) scores and the Functional Assessment of Cancer Therapy-Lung (FACT-L) (lung-cancer scale and trial outcome index) scores, was not significantly affected by radiofrequency ablation. Non-surgical therapeutic modalities used for the treatment of lung cancer, including chemotherapy and targeted therapy, have, in general, been shown to have a positive effect on QOL.^{2,3} Conversely, surgical resection has been shown to have a detrimental effect on QOL in the immediate postoperative period. QOL scores usually improve in the long term, but there are data to suggest that they might never return to baseline values.^{4,5}

It is therefore logical to assume that there would have been factors other than the procedure that would have contributed to the absence of benefit in QOL in this study, despite excellent rates of complete response of target tumours assessed and 1-year and 2-year survival. These concerns have not been addressed by the researchers, but a plausible reason would be that the presence of substantial comorbidities or severely impaired pulmonary function, especially if these were not managed optimally, not only contributed to the patient being excluded from surgery (and other definitive forms of treatment), but also adversely affected the QOL of the study population and, thus,



Paul Rapson/Science Photo Library

Spirometric testing can be used to measure quality of life