

## **ELECTRICAL STIMULATION IS AN IMPORTANT ADVANCE IN THE TREATMENT OF HEADACHE DISORDERS: NO**

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Neurostimulation is a rapidly growing field in the headache disorders and provides an alternative therapeutic option particularly for intractable and chronic primary headaches such as chronic migraine, chronic cluster headache, SUNCT, or hemicrania continua. By employing invasive or non-invasive methods, central or peripheral neural structures can be targeted for stimulation in headache syndromes. For example, hypothalamic deep brain stimulation, transcranial direct current stimulation, repetitive transcranial magnetic stimulation, cervical spinal cord stimulation, occipital nerve stimulation, stimulation of sphenopalatine ganglion, vagus nerve stimulation, and transcutaneous electrical nerve stimulation were all studied in various headaches. Though the exact mechanism of action is unknown it is obviously different for each application as well as the headache disorder itself. Review of the literature reveals that major problems associated with those studies are the lack of randomized clinical trials, limited number of patients, low efficacy, low safety and device-related serious complications (sometimes fatal) particularly with invasive procedures.

For neuromodulation studies for headaches, European Headache Federation draws attention to the fact that 'A CE-mark is not equivalent to a randomized study following IHS requirements, as no clinical data supporting the benefit of a medical device are needed to acquire the CE mark'. European Headache Federation (EHF) further suggests that 'Any devices that have not been investigated in such controlled studies and have shown to be effective with an acceptable side effect profile should not be used at all' (Martelletti et al, 2013). In accordance with the statement above by EHF, the neuromodulation for headache disorders merits further controlled and randomized studies with the use of a proper sham stimulation. However currently the clinical use of neurostimulation devices can not be recommended for headache disorders due to 1) lack of proper randomized clinical studies 2) their invasive approach, 4) low efficacy, and 5) potential serious side-effects, 6) inadequate follow-up data for long-term use.