Occipital nerve stimulation for chronic migraine: Already advised?

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Chronic migraine is a relatively new concept in the headache world. Until recently, the biased view in many headache specialist centres was that chronic migraine was usually due to medication overuse and improved once patients were detoxified (1). Large population-based studies, however, identified patients with chronic migraine without medication overuse (2–5). With such a recent addition to the nomenclature of headaches (6), it is easily understood that only a handful of intervention studies have addressed drug therapy for the treatment of chronic migraine. Examples are the studies with topiramate (7,8) and onabotulinumtoxinA (9–11). These studies showed that active treatment was superior to placebo, that the treatment difference to placebo was small and that the placebo effect was very high.

Neuro-modulation has experienced a renaissance in recent years for the treatment of pain conditions including chronic headache (12). Most of the studies have been conducted among patients with treatment refractory cluster headache (13–15). Failure to treatment was defined as a patient who did not respond to treatment of cluster attacks (by oxygen or triptans) and failing preventive drug therapy with verapamil, lithium, methysergide and topiramate.

The study by Silberstein and colleagues published in this issue of *Cephalalgia* investigated occipital nerve stimulation (ONS) in patients with chronic migraine refractory to treatment of acute migraine attacks and having failed at least two different classes of prophylactic medication. One-hundred and fifty-seven patients received ONS device implants of whom 105 were randomised to active and 52 to sham stimulation. The study failed to show a significant benefit for the primary endpoint, defined as a 50% reduction in mean daily visual analogue scale score after 12 weeks. The study was positive for a number of secondary endpoints, including 30% reduction in mean daily visual analogue scale scores, number of headache days, and migraine-related disability. Seventy-three patients in the active group (69%) and 34 in the sham group (65%) had adverse events. Common adverse events were lead migration (13% of all patients) and consistent implant site pain or numbness (15% of all patients).

Should ONS be recommended for the treatment of patients with chronic migraine? I think at present there is not enough evidence to promote this procedure for patients with chronic treatment refractory migraine for the following reasons:

1. In analogy to the approval of new drugs, at least two well-conducted randomised trials meeting the primary endpoint or two studies in which one is positive for the primary endpoint and a pooled analysis is positive are required to introduce an invasive procedure into clinical practice.
2. A major shortcoming of randomised trials with nerve stimulation is blinding. It is almost impossible to blind patients because active stimulation leads to paraesthesias.
3. The treatment effect in the present study was small, with a responder rate of 17.1% in the active group and 13.5% in the sham group.
4. A rate of lead migration of 14.0% in the active group and 4.7% in the control group is not acceptable and suggests that implanters were still early in their learning curve of implanting the device. Obviously the surgical procedure and the design of the leads needs refinement.

Another consideration is the difference in health care systems in the USA and in Europe. In Europe, many patients with chronic migraine have access to integrated headache care with education and counselling, optimal treatment of acute migraine attacks, preventive drug therapy, behavioural therapy and treatment of...
co-morbidities (16,17). Therefore, few patients with chronic migraine remain treatment refractory. In contrast, there are very few headache centres in the USA considering the population of 314 million inhabitants. In addition, there is no financial incentive for invasive procedures in Europe. Most hospitals offering these procedures make a large deficit.

What is the future of ONS for the treatment of chronic headache? The most promising indication is refractory cluster headache. The placebo effect in this patient group is small and the high costs of the treatment of cluster attacks over time (18) make ONS stimulation cost effective in the long run. We, however, need randomised trials for this indication. I am sceptical concerning the benefit of ONS for patients with chronic migraine. The highest priority for this patient group is to offer adequate interdisciplinary integrated care.

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Conflicts of interest

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