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Occipital nerve stimulation for migraine prophylaxis: emerging evidence from randomized controlled trials

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Introduction

Migraine is a highly disabling neurological disorder characterized by recurrent episodes of moderate-to-severe headache and substantial impairment in quality of life and daily functioning. Patients are frequently exposed to excessive use of acute analgesic medications, which may further exacerbate headache burden. Moreover, therapeutic options remain limited for individuals who fail to respond adequately to conventional pharmacological treatments. In this context, occipital nerve stimulation (ONS), a neuromodulatory intervention delivered through subcutaneous or transcutaneous electrodes positioned over the cervico-occipital region, has emerged as a promising therapeutic strategy.

Objective

To evaluate the therapeutic efficacy of occipital nerve stimulation compared with sham or inactive stimulation in patients with migraine.

Methods

This systematic review was conducted according to PRISMA guidelines and the PICO framework. PubMed, Embase, Cochrane Library, and Web of Science were searched using terms related to migraine and occipital nerve stimulation (ONS). Randomized controlled trials involving patients diagnosed with migraine according to ICHD criteria and comparing ONS with sham or inactive stimulation were included. Study selection and data extraction were performed independently by two reviewers. Outcomes included headache frequency, pain intensity, quality of life, functional disability, medication use, and adverse events.

Results

Of 2,690 records identified, 1,348 remained after deduplication and six randomized controlled trials were included (N=398). ONS significantly increased the likelihood of achieving a ≥50% reduction in pain intensity compared with sham stimulation (RR=4.06; 95% CI: 1.61–10.25; p=0.003; I^2=40%). A significant reduction in pain intensity was also observed (SMD=−0.88; 95% CI: −1.29 to −0.47; p<0.0001; I^2=43%). No significant difference was found in monthly headache days (MD=−4.52; 95% CI: −10.14 to 1.10; p=0.12; I^2=74%). Improvements in functional disability and quality of life were consistently reported, including reductions in MIDAS scores and favorable changes in SF-36 and HIT-6 measures. Adverse events were generally mild and self-limiting with transcutaneous ONS, whereas subcutaneous ONS was associated with electrode migration, local pain, and infections. Statistical analyses were performed using R software, with pooled estimates calculated as Mean Differences (MDs) or Risk Ratios (RRs), both reported with 95% CI.

Conclusion

ONS appears to be an effective intervention for reducing pain intensity and improving functional outcomes and quality of life in patients with chronic migraine. These findings support ONS as a relevant therapeutic option, particularly for individuals with treatment-refractory disease. Nevertheless, further large-scale, standardized randomized controlled trials are warranted to strengthen the current evidence base and better define its long-term efficacy and safety profile.

Keywords:
Occipital nerve stimulation
Migraine
Prophylactic treatment
Meta-analysis

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