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Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline

BACKGROUND: Occipital neuralgia (ON) is a disorder characterized by sharp, electrical, paroxysmal pain, originating from the occiput and extending along the posterior scalp, in the distribution of the greater, lesser, and/or third occipital nerve. Occipital nerve stimulation (ONS) constitutes a promising therapy for medically refractory ON because it is reversible with minimal side effects and has shown continued efficacy with long-term follow-up.

OBJECTIVE: To conduct a systematic literature review and provide treatment recommendations for the use of ONS for the treatment of patients with medically refractory ON.

METHODS: A systematic literature search was conducted using the PubMed database and the Cochrane Library to locate articles published between 1966 and April 2014 using MeSH headings and keywords relevant to ONS as a means to treat ON. A second literature search was conducted using the PubMed database and the Cochrane Library to locate articles published between 1966 and June 2014 using MeSH headings and keywords relevant to interventions that predict response to ONS in ON. The strength of evidence of each article that underwent full text review and the resulting strength of recommendation were graded according to the guidelines development methodology of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Guidelines Committee.

RESULTS: Nine studies met the criteria for inclusion in this guideline. All articles provided Class III Level evidence.

CONCLUSION: Based on the data derived from this systematic literature review, the following Level III recommendation can be made: the use of ONS is a treatment option for patients with medically refractory ON.

KEY WORDS: Occipital neuralgia, Guidelines, Clinical guidelines, Systematic evidence review

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ABBREVIATIONS: AANS, American Association of Neurological Surgeons; **CNS,** Congress of Neurological Surgeons; **JGC,** Joint Guidelines Committee; **ON,** occipital neuralgia; **ONS,** occipital nerve stimulation; **VAS,** visual analog scale

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Occipital neuralgia (ON) is a disorder characterized by sharp, electrical, paroxysmal pain, occasionally throbbing in quality, originating from the occiput and extending along the posterior scalp, in the distribution of the greater, lesser, and/or third occipital nerve.[1-3] Symptoms can be triggered or unprovoked and often have an associated dysesthesia in the same distribution. Although ON tends to be unilateral, bilateral pathology is not uncommon. Compression or trauma to one or more of the involved nerves may result in ON; however, a clear etiology is not always present.[3,4]

Medical management with neuropathic agents such as antiepileptic and/or antidepressant medications is the first line of treatment.[3] For cases that are refractory to medical management, more invasive interventions can be considered. Injections to the nerves with local anesthetic, steroids, or even botulin toxin can be effective in transiently relieving symptoms.[2,3] Surgical procedures such as dorsal root ganglionectomy and neurectomy have had mixed results.[3,5] Lesioning procedures, including dorsal root entry zone lesioning, posterior partial rhizotomy, and neurolysis, as well as decompressive techniques are other common modalities, with variable benefit, poor longevity, and frequent side effects.[1,3,6] Thus, the more recent application of occipital nerve stimulation (ONS) constitutes a promising therapy because it is reversible with minimal side effects and has shown continued efficacy with long-term follow-up. In the United States, ONS currently requires off-label use of neurostimulation devices approved by the US Food and Drug Administration for use in pain affecting the trunk and extremities. Although prospective, randomized, controlled studies demonstrating the effectiveness of ONS have been conducted, the patient populations evaluated in these studies were not specific to medically refractory ON patients.[7,8] For the purposes of this guideline, and as defined by Slaving et al,[3] medically refractory treatment refers to an initial medical therapy that was trialed and deemed unsuccessful due to lack of efficacy or severe side effects that outweigh the potential therapeutic benefit. Prospective comparative studies are needed to fully determine the long-term utility of ONS for the treatment of ON. The objective of this guideline is to systematically review the medical literature to provide recommendations for the use of ONS for the treatment of patients with ON.

Recommendation

The use of ONS is a treatment option for patients with medically refractory ON.

METHODS

Guideline Task Force

A multidisciplinary task force of volunteer neurosurgeons and pain management physicians comprised the Guidelines Task Force and were responsible for the formation of these evidence-based guidelines.

Guideline Panel Consensus and Practice Guideline Approval Process

The literature searches were performed by a single member of the group and distributed to the entire group for literature review, article selection, and the formation of the evidentiary table. Task Force subgroups were then established by topic. Information was compiled by that subgroup and then distributed to the entire group for review until a final consensus by means of group discussion, voting, and approval was achieved.

The Task Force implemented a modified structured voting technique to finalize and approve the recommendations and strength of recommendations presented in this review.[9] If and when a disparity in opinions occurred, every effort was made to amend the guideline to adequately address each viewpoint until all members were in agreement. In the event that a unanimous decision could not be made, the question was posed to the Task Force as a whole, and the majority opinion was used. This method was agreed upon by all members of the Task Force.

The completed systematic review was then distributed to the Joint Guidelines Committee (JGC) of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) for consideration of endorsement by the CNS Executive Committee and the AANS Board of Directors. JGC reviewers were permitted to critique the content and methodology used to create this systematic review. Any concerns of the JGC were addressed by the Task Force, and the document was resubmitted to the JGC for endorsement. In addition, these guidelines were independently submitted to the American Society of Regional Anesthesia and Pain Medicine and the American Interventional Headache Society for review and were approved for endorsement by these organizations. As such, support of these guidelines was also multidisciplinary in nature. Once this process was completed, the document was submitted for publication. This was editorially independent of the funding agencies of the CNS Executive Committee and the AANS/CNS Joint Pain Section Executive Committee, whose involvement occurred after the approval of the guidelines by the JGC and was limited to acceptance vs rejection of endorsement of the work.

Grading Evidence and Levels of Recommendations

The strength of evidence of each article that underwent full text review was graded according to the criteria established by the AANS/CNS JGC. Each article was independently graded by multiple reviewers, and any conflicts between the reviewers' grading was resolved via discussion. The class of evidence (ie, Class I, II, or III) assigned to each article was determined after review of the sample size, study design, follow-up, and outcome measures (Table 1). The strength of clinical recommendations (ie, Level I, II, or III) was then linked to the level of evidence included to support the recommendation (Table 1).

Revision Plans

To meet the standards for developing clinical practice guidelines and to adhere to the criteria for such guidelines, the Guideline Task Force will continue to monitor for new publications relevant to the content of these

TABLE 1. AANS/CNS Classification of Evidence on Therapeutic Effectiveness and Levels of Recommendation[a]

Class I evidence: Level I recommendation	Evidence from ≥1 well-designed, randomized, controlled clinical trials, including overviews of such trials
Class II evidence: Level II recommendation	Evidence from ≥1 well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well designed randomized, controlled trials
Class III evidence: Level III recommendation	Evidence from case series, comparative studies with historical controls, case reports, and expert opinion, as well as significantly flawed randomized, controlled trials

[a]AANS/CNS, American Association of Neurological Surgeons/Congress of Neurological Surgeons.

guidelines. The entire document will be revisited at least every 5 years or sooner should any new published scientific evidence prove significant enough to warrant earlier revision.[10]

Literature Search

A systematic literature search was undertaken to address our primary question: Is ONS an effective treatment for ON? Using the PubMed database, a search of articles published between 1966 and April 2014 was conducted using the following text word combinations: "occipital nerve stimulation and occipital neuralgia" or "electrical stimulation and occipital neuralgia" or "neuromodulation and occipital neuralgia" or "peripheral neurostimulation and occipital neuralgia" or "occipital nerve stimulation and cervicogenic headache" or "neuromodulation and cervicogenic headache" or "occipital nerve stimulation and C2 headache." These searches generated lists of 50, 38, 21, 11, 11, 6, and 10 articles, respectively. Each article was reviewed by at least 2 independent reviewers to determine whether they met the qualifications for full text review. Cochrane Library was also searched with a combination of the keywords used to search PubMed (see **Cochrane Library search strategies**, **Supplemental Digital Content**, http://links.lww.com/NEU/A744); however, no unique results were located.

We performed a secondary literature search to see whether there were interventions that predict response to ONS in ON. Using the PubMed database up to June 2014, the following text words were combined for the search: "occipital nerve block and occipital nerve stimulation" or "occipital nerve block and occipital nerve stimulation and occipital neuralgia" or "occipital nerve blocks predictive of occipital nerve stimulation" or "response to occipital nerve stimulation and occipital neuralgia" or "occipital nerve block and stimulation response" or "occipital nerve block predictive of peripheral nerve stimulation" or "predictors of occipital peripheral nerve stimulation" or "predictors of peripheral nerve stimulation and occipital neuralgia" or "occipital nerve injections and occipital neuralgia" or "occipital nerve injection and occipital nerve stimulation." A total of 89 unique articles were found. Only 8 articles looked at an intervention in patients with ON and none of these articles included patients with ONS. Cochrane Library was also searched with a combination of the keywords used to search PubMed (see **Supplemental Digital Content**, http://links.lww.com/NEU/A744); however, no unique results were located.

Article Inclusion Criteria

Inclusion criteria were as follows: (1) clinical series must have a minimum of 3 patients undergoing ONS for treatment of medically refractory ON, (2) clinical series must have a minimum of 2 months postoperative follow-up from ONS implantation, and (3) series that enrolled mixed patient populations were included only if they reported separate results for the target ON population. The results of the target population were the only results considered as evidence to support our recommendations. A total of 81 unique articles were found. Clinical series containing 3 or more patients with a minimum follow-up of 2 months were pooled for analysis.

Of the 81 articles, 72 studies were excluded for the following reasons: 1 was an abstract only, 2 were animal studies, 4 were not in English, 11 were case reports with a single patient, 6 were meta-analyses, 17 were review articles, 30 addressed either an alternative disease process (eg, trigeminal neuralgia or chronic migraines) or a treatment option other than ONS (eg, occipital nerve blocks), and 1 was a mixed population of patients that did not separate the results for each population group. Ultimately, 9 original articles were selected and retrieved for analysis. These articles are listed in the Evidentiary Table (Table 2).

It is important to note that we restricted our analysis to the use of ONS for the treatment of ON. This technique has also been used for the treatment of other disorders, most prominently migraine headaches. Given the heterogeneity of that diagnosis, we did not include it in this set of guidelines.

A secondary analysis of the 9 selected articles was also performed in an effort to address any significant anatomic or technical considerations for ONS implantation. All of the 9 articles made at least 1 reference to an anatomic and/or technical aspect of ONS, which are also shown in Table 2.

RESULTS

Primary Question: Is ONS an Effective Treatment Option for Medically Refractory ON?

Nine primary articles addressed the efficacy of ONS for the specific treatment of ON (Table 2). All articles provided Class III Level evidence. Three articles were prospective case series without a control group and as such were graded as Class III.[1,2,11] One article was a cohort study in which each patient served as his or her own control.[12] However, the data were collected and reviewed retrospectively, making this Class III evidence as well. Four articles were retrospective case series, thus accounting for their classification.[3,13-15] Finally, 1 article did not specify whether it was prospective or retrospective, but, given it was a small case series, it was also graded as Class III.[4] Complications from the 9 primary articles are summarized and shown in Table 3.

The largest prospective series was published by Melvin et al[11] in 2007, reporting on 11 patients with medically refractory ON.

TABLE 2. Evidentiary Table[a]

Ref./Year	Description of Study	Evidence Class	Conclusions/Rationale for Grading Assignment
Abhinav et al, 2013[13]	Study type: retrospective case series	Level III: this study is a retrospective review of a small series of patients in a mixed population of patients with no comparison group	Study conclusions: significant improvement in symptoms in all 4 ON patients with at least 6 mo of follow-up
	Data type: retrospective, case series		Justification of inclusion in guidelines: although this is a mixed population of patients, the results are separated based on the different patient populations; long duration of follow-up
	Patient population: 4 patients with ON included		Limitations of inclusion: very small number of patients with ON, no comparison group
	Follow-up: 6-18 mo		
	Trial: trial of peripheral neurostimulation before ONS trial		
	Surgical technique: midline approach with 1 paddle via an epiducer at level of C1 with IPG infraclavicular, performed under general anesthesia		
	Results: median VAS score pre- and postoperatively was 9 and 0, respectively (ONS patients). (The patient with chronic migraine had 80% reduction in frequency of attacks from 5 to 1 per month.)		
Palmisani et al, 2013[14]	Study type: therapeutic intervention	Level III: this study is a retrospective review of a small series of patients in a mixed population of patients with no comparison group	Study conclusions: this series of 3 ON patients reported ≥50% decrease in pain at >1 year follow-up
	Data type: retrospective, case series		Justification of inclusion in guidelines: although this is a mixed population of patients, the results are separated based on the different patient populations; long duration of follow-up
	Patient population: 3 patients with ON included		Limitations of inclusion: very small number of patients with ON, no comparison group
	Follow up: 28-31 mo		
	Trial: trial, followed by implantation if successful[b]		
	Surgical technique: 12 percutaneous quadrapolar leads implanted, performed under general anesthesia		
	Results: all 3 ON patients reported ≥50% reduction in pain intensity and/or frequency at 28-31 mo		
Magown et al, 2009[2]	Study type: therapeutic intervention	Level III: this study is a prospective case series of a small series of patients, without a comparison group	Study conclusions: this series of 7 ON patients reported a decrease in pain with at least 2 mo of follow-up
	Data type: prospective, case series		Justification of inclusion in guidelines: larger series of patients, homogeneous patient population, third-party rater (nonblinded)
	Patient population: 7 patients with ON included		Limitations of inclusion: short follow-up, ranging from 2 to 30 mo, no comparison group

(Continues)

TABLE 2. ***Continued***

Ref./Year	Description of Study	Evidence Class	Conclusions/Rationale for Grading Assignment
	Follow up: 2-30 mo		
	Trial: intermittent bupivacaine and methylprednisolone injections every 2-4 mo; no trial was performed but patient had to have a positive response to blocks[b]		
	Surgical technique: paramedian approach with 1 paddle lead; Dopplered occipital artery		
	Results: mean reduction of pain of 96% on the VAS at mean of 17 mo (range, 2-30)		
Melvin et al, 2007[11]	Study type: therapeutic intervention	Level III: this study is a prospective case series of a small number of patients, without a comparison group	Study conclusions: ONS reduces ON symptoms (and medication use)
	Data type: prospective, case series		Justification of inclusion in guidelines: prospective study, organized data collection
	Patient population: 11 patients with ON included		Limitations of inclusion: no comparison group
	Follow-up: 3 mo		
	Trial: analgesic blocks and steroid blocks and a trial performed[b]		
	Surgical technique: lateral or medial approach with 1-2 percutaneous leads, quadrapolar (n = 4) or 1 octapolar (n = 7) leads; IPG site in the infrascapular or abdominal region		
	Results: mean of 64% improvement in SF-MPQ score compared with baseline and 67% decrease in VAS score at 12 wk		
Johnstone and Sundaraj, 2006[4]	Study type: therapeutic intervention	Level III: case series without a comparison group	Study conclusions: 5 of the 7 ON patients had a decreased VAS score at ≥6 mo of follow-up
	Data type: not specified whether prospective or retrospective, case series		Justification of inclusion in guidelines: larger series of patients, homogeneous patient population
	Patient population: 8 patients with ON included		Limitations of inclusion: no comparison group
	Follow-up: 6-47 mo		
	Trial: in all patients with a positive block, a trial was performed[b]		
	Surgical technique: midline approach with 1 paddle lead for unilateral (n = 5) and 2 leads for bilateral (n = 2) at the level of the occipital protuberance, with an IPG in the infraclavicular or lower abdominal region, performed under general anesthesia		
	Results: there was a reduction in the VAS score after implantation in 5 of the 7 patients at a mean follow-up of 25 mo (range, 6-47 mo); 2 acquired full-time employment		
Slavin et al, 2006[3]	Study type: therapeutic intervention	Level III: retrospective chart review, no comparison group	Study conclusions: ONS effective and durable for ON with successful trial and proper patient selection
	Data type: retrospective, case series		Justification of inclusion in guidelines: 14 ON patients, follow-up period of ≥2 mo
	Patient population: 14 patients with ON included		Limitations of inclusion: retrospective no comparison group
	Follow up: 5-32 mo		

(Continues)

TABLE 2. ***Continued***

Ref./Year	Description of Study	Evidence Class	Conclusions/Rationale for Grading Assignment
	Trial: in all patients with a positive block, a trial was performed[b]		
	Surgical technique: midline approach for bilateral leads and lateral approach for unilateral lead, percutaneous leads with an IPG in the infraclavicular region		
	Results: 10/14 trials proceeded to implantation. Three had systems removed (1 for infection, 1 for hardware issues, 1 due to resolution of pain syndrome). Remaining 7 patients rated relief between 60% and 90% reduction at a mean of 22 mo (range, 5-32 mo)		
Kapural et al, 2005[1]	Study type: therapeutic intervention	Level III: Class III due to small number of patients and short follow-up	Study conclusions: successful pilot study showing short-term improvement in pain and functional capacity from ONS using paddle electrodes
	Data type: prospective, case series		Justification of inclusion in guidelines: prospective series, all ON patients, validated outcome measures
	Patient population: 6 patients with ON included		Limitations of inclusion: small series, short follow-up
	Follow up: 3 mo		
	Trial: N/A		
	Surgical technique: midline approach, 2 paddle leads at the level of C1, with an IPG in the buttocks, performed asleep		
	Results: significant decrease in the mean VAS score at 3 mo from 8.66 to 2.5 ($P < .0001$). Pain Disability Index score decreased significantly from 49.8 to 14.0 ($P < .0005$)		
Oh et al, 2004[12]	Study type: therapeutic intervention	Level III: observational, each patient was his/her own control on medications prior to surgery	Study conclusions: ONS is safe and effective for the treatment of ON
	Data type: retrospective, cohort		Justification of inclusion in guidelines: although this is a mixed population of patients, the results are separated based on the different patient populations
	Patient population: 10 patients with ON included		Limitations of inclusion: retrospective series; no validated outcome measure
	Follow-up: 6 mo		
	Trial: In all patients with >70% pain relief with an occipital block, a trial was performed[b]		
	Surgical technique: lateral approach, 1 paddle lead, quadrapolar, at the level of C1, with an IPG in the posterior hip region, performed with conscious sedation for the lead placement and under general anesthesia for the IPG placement		
	Results: 9 of 10 patients with >75% relief at 6 mo		
Weiner and Reed, 1999[15]	Study type: therapeutic intervention	Level III: retrospective, observational study	Study conclusions: ONS appears to be a reasonable alternative to more invasive procedures for the treatment of ONS

(Continues)

TABLE 2. *Continued*

Ref./Year	Description of Study	Evidence Class	Conclusions/Rationale for Grading Assignment
	Data type: retrospective, case series		Justification of inclusion in guidelines: index study of ONS, relatively large series for this type of study
	Patient population: 13 patients with ON included		Limitations of inclusion: retrospective series; no validated outcome measure
	Follow-up: 1.5-5.5 y		
	Trial: in all patients with a positive block, a trial was performed[b]		
	Surgical technique: lateral approach, 1 percutaneous lead, at the level of C1, with an IPG infraclavicular or abdominal region, performed with conscious sedation for the lead placement		
	Results: all patients with ≥50% pain relief at the last follow-up (mean, 2 y; range, 1.5-5.5 y). Complications included lead migration in 1 patient and the need for revision related to a severed electrode in another		

[a]ON, occipital neuralgia; ONS, occipital nerve stimulation; IPG, implantable pulse generator; VAS, visual analog scale; SF-MPQ, Short Form McGill Pain Questionnaire; N/A, not available.
[b]Occipital nerve blocks were considered positive if >50% pain reduction was achieved (unless otherwise specified); ONS trials were considered successful if >50% pain reduction occurred.

Patients were evaluated preoperatively with the Short-Form McGill Pain Questionnaire, the visual analog scale (VAS), the Present Pain Index, a headache questionnaire, and headache diaries on 2 separate occasions. The highest scores on each scale from the 2 baseline evaluations were used and compared with the scores for the same measures taken at 4 and 12 weeks postoperatively. Sixteen patients were screened for the trial; 11 patients completed the study (1 patient chose not to participate, 1 patient demonstrated drug-seeking behavior, and in 3 patients the stimulation trial failed, without a VAS decrease of at least 50%). Eleven patients underwent a trial of an externalized percutaneous ONS electrode for 4 to 10 days, with a VAS score decrease of at least 50% required for a patient to proceed to permanent ONS system implantation. There was a statistically

TABLE 3. Complications From Articles of Evidence Table

Author/Year	Complication	Complication Rate % (No. of Patients/Total No. of Patients)
Weiner and Reed, 1999[15]	Breakage of lead with infection	8% (1/13)
	Lead migration	8% (1/13)
Oh et al, 2004[12]	Worsening cervical pain (despite improved occipital pain)	10% (1/10)
Kapural et al, 2005[1]	Allergic reaction of skin overlying pulse generator	10% (1/10)
	No complications	0% (0/6)
Slavin et al, 2006[3]	Infection	10% (1/10)
Johnstone and Sundaraj, 2006[4]	Lead migration, followed by loss of efficacy after repositioning	10% (1/10)
	Infection	29% (2/7)
Melvin et al, 2007[11]	Loose connection requiring additional extension cable	9% (1/11)
	Lead migration	9% (1/11)
Magown et al, 2009[2]	Wound dehiscence followed by infection	14% (1/7)
Abhinav et al, 2013[13]	No complications	0% (0/4)
Palmisani et al, 2013[14]	Repositioning of generator	33% (1/3)

significant decrease in the Short-Form McGill Pain Questionnaire score (64% change, $P = .001$), VAS (67% change, $P < .001$), and Present Pain Index (67% change, $P = .001$) at 12 weeks after permanent system implantation. Ten patients (91%) decreased their use of analgesic medication, and 7 patients (64%) had a decrease in the number of headaches after ONS system implantation.[11]

Magown et al,[2] in 2009, reported on 7 patients with medically intractable ON. These patients did not have a trial of stimulation before permanent system implantation, but had experienced significant pain relief from a double-blinded C2 root block. Patients were assessed by a third-party using VAS scores. In 6 of the 7 patients (86%), the VAS score decreased to 0 postoperatively, resulting in a 100% improvement in pain. The remaining patient (14%) experienced a 75% reduction in the VAS score. In the third study, Kapural et al[1] (2005) evaluated 6 patients with medically refractory ON. All patients underwent a preoperative pain psychology evaluation and an ONS trial with good results. Patients completed a Pain Disability Index questionnaire comprising 8 subscales, including the VAS, before ONS implantation and again at 3 months post-implantation. All 6 patients had significant reductions in VAS scores ($P < .001$) and significant improvement in the Pain Disability Index score ($P < .001$) at 3 months.[1]

In 2004, Oh et al[12] retrospectively evaluated 20 patients treated with ONS, 10 of whom had intractable ON. Patients underwent a staged trial/implantation with a 4-contact paddle electrode. All 10 patients with ON who underwent a trial received permanent implants. Eight patients (80%) had more than 90% pain relief at 1-month follow-up, with the remainder reporting more than 75% pain relief. At 6-month follow-up, 7 patients (70%) had more than 90% pain relief, 1 patient (10%) had more than 50% pain relief, and 1 patient (10%) had less than 50% pain relief. One patient was lost to follow-up by 6 months, but was reported to have more than 75% pain relief at 3 months.

Among the remaining retrospective case series, the first one was a retrospective review of 13 patients with medically refractory ON, all of whom received temporary benefit from an occipital nerve block and many of whom had undergone a previous ONS trial with benefit as well.[15] All 13 patients received a permanent ONS, and all reported greater than 50% pain relief with little or no pain medications with a mean follow-up of 2.4 years (range, 1.5-5.5 years). Two thirds of these patients also reported more than 75% pain relief.[15]

Slavin et al,[3] in 2006, reported retrospective data on 14 patients with intractable ON who underwent a 2-stage procedure, whereby the stage 1 trial was considered successful if patients reported at least a 50% reduction in pain. Ten of 14 patients were permanently implanted with a pulse generator. Of the 10 implanted patients, 3 (30%) had their stimulator removed, 2 due to complications and 1 due to resolution of pain. Of the remaining 7 patients, all reported 60% to 90% improvement of pain at their last follow-up (ranging from 5 to 30 months; mean, 20 months). Similarly, Johnstone et al,[4] in 2006, evaluated 8 intractable ON patients who went on to ONS after pain psychology clearance and a successful trial. Of the 7 patients who underwent implantation, 5 (71%) had decreased VAS scores at last follow-up of 6 to 47 months (mean, 25 months; range, 6-47 months), and 2 patients (29%) acquired full-time employment. All patients required fewer interventional treatments and reduced opiates after implantation compared with pre-implantation.

More recently, Abhinav et al,[13] in 2013, retrospectively evaluated 5 patients (4 of whom had medically refractory ON) treated with ONS after a successful trial was performed. The median preoperative VAS score was 9, and the median postoperative score was 0 at last follow-up, which ranged from 6 to 18 months. Palmisani et al,[14] in 2013, also assessed 25 patients who underwent ONS implantation, but only 3 patients had medically refractory ON. In all 3 patients, the procedure was staged, and a stage 2 implantation occurred if there was a 50% or greater reduction in pain intensity and/or frequency. All 3 patients proceeded to implantation and reported continued reduction of pain intensity and/or frequency of greater than 50% at 28 to 31 months.

All 9 primary articles provide Class III Level evidence because they consist of either a retrospective chart review or a small prospective case series without control or comparison groups. Other limitations of these studies are the small number of patients assessed and the frequently short duration of follow-up. However, the clinical outcomes in these case series have been excellent. Given this, we believe that the use of ONS is an option for the treatment of patients with medically refractory ON with a Level 3 recommendation (Table 4), based on the published scientific evidence (Table 2).

Secondary Considerations

Anatomy

Understanding the anatomy of the greater and lesser occipital nerves, as well as their possible variations, can help to determine

TABLE 4. Recommendation

Question	Recommendation Strength	Recommendation
Is an occipital nerve stimulator a treatment option for occipital neuralgia?	Level III	The use of occipital nerve stimulators is a treatment option for patients with medically refractory occipital neuralgia.

both the level and depth of ONS lead implantation.[16] Additionally, the lead may be passed medially from a lateral incision that is made inferomedially to the mastoid process[3] or, conversely, the lead may be placed laterally from a midline incision,[3,17] which is particularly useful when placing bilateral leads. Although fluoroscopy can be helpful in identifying bony landmarks for lead placement,[3,7] it does not aid in determining the depth of lead insertion, although the use of ultrasound has been reported for this indication.[2,18] However, our literature search for the use of ONS for the treatment of ON did not provide sufficient evidence to make recommendations with regard to these variations.

Technique

The 9 articles describe the procedure being performed with local anesthetic and conscious sedation, monitored anesthesia care, or general anesthesia (especially in the prone position for better airway control). In addition, quadrapolar and octapolar percutaneous leads as well as paddle leads were used. Again, the literature does not provide sufficient evidence of a recommendation. The major technical problem is lead migration, ranging in several prospective studies on ONS for the treatment of migraines from 13.9% to 24%.[7,8,19]

With respect to determining the predictive value of an occipital nerve block, prior to ONS, only the studies by Oh et al[12] and Slavin et al[3] evaluated this. However, in these studies, despite a favorable response to an occipital nerve block, not all patients had successful percutaneous ONS trials, and thus not all patients underwent permanent ONS implantations. No prospective studies exist specifically examining the relationship between the response to an occipital nerve block and the response to ONS therapy, for the treatment of ON. Thus, there is insufficient evidence to either support or refute performing an occipital nerve block prior to trialing ONS.

DISCUSSION

Limitations

The primary limitation of this guideline is the current level of evidence available for the use of ONS specifically for the treatment of medically refractory ON. Although prospective, randomized, controlled trials and other well-designed studies demonstrating the effectiveness of ONS have been conducted, the patient populations evaluated in these studies were not specific to medically refractory ON patients.[7,8,20-23] Prospective comparative studies are needed to fully determine the long-term utility of ONS for the treatment of ON. It will be difficult to conduct blinded trials of ONS because the therapy depends on the production of paresthesia detected by the patient in the painful region. The closest alternative is the use of subthreshold stimulation, but there are some who believe that even subthreshold stimulation can result in a therapeutic effect. Research also needs to be conducted into the optimal region for lead placement and the optimal lead type.

CONCLUSION

Summary of Recommendations

The data from a recent systematic review of the literature supports the use of ONS as a treatment option for patients with medically refractory ON (Level III recommendation). A summary of the recommendation for the use of ONS for the treatment of ON can be found in Table 4.

Disclosures

Dr Machado has ownership interest and consulting agreements with Enspire, ATI, and Cardionomics. Dr Sharan has consulting relationships with Medtronic, has received grants and honoraria from St. Jude Medical, is a Director and has ownership interest in ICP and in ICVRX. Dr Petersen is a consultant for St. Jude Medical and Medtronic. Dr Hayek is a consultant for Boston Scientific, Flowonix, and Mallinckrodt. Dr Arle is a consultant for St. Jude Medical. Dr Rosenow is a consultant for Boston Scientific and the GLG Group. Dr Schwalb has received honoraria from Medtronic. Dr Pilitsis is a consultant for and has received grants from Medtronic, St. Jude Medical, and Boston Scientific, and is a recipient of an NIH grant. Dr Falowski has research grants from and is a consultant for Medtronic and St. Jude Medical. All other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article and related to occipital nerve stimulators.

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Disclaimer: The literature review and presented evidence-based guidelines were developed by a multidisciplinary group of physician volunteers. The purpose of these guidelines is to serve as an educational resource assessing the currently available scientific evidence pertaining to the use of occipital nerve stimulation for the treatment of medically refractory occipital neuralgia. The guidelines in this article are based on up-to-date information at the time of completion of this document. These guidelines are not intended to be a rigid protocol, and clinical interventions may vary according to a patient's needs. Clinical judgment should always take precedence in the treatment of patients. These guidelines are presented with the understanding that they are not meant to replace the individualized care and treatment of a specific patient by his or her physician(s). These guidelines may not be suitable in all situations or applicable to all patients with occipital neuralgia. Implementation of these guidelines should be done by a patient's managing physician(s) in accordance with each patient's individual circumstances and clinical needs.

No part of this article has been published or submitted for publication elsewhere.

Commentaries provided by Alexander Feoktistov on page 342; Konstantin V. Slavin on page 344; and Oscar A. de Leon-Casaola on page 345.