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The Untold Story of Occipital Nerve Stimulation in Patients With Cluster Headache: Surgical Technique in Relation to Clinical Efficacy

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ABSTRACT

Objectives: Approximately one in every 1000 adults experiences cluster headache (CH). Although occipital nerve stimulation (ONS) appears encouraging in treatment for most patients with refractory CH, some patients do not reach adequate pain relief with ONS. A reason for failure of ONS might be anatomical variations and different surgical approaches. Therefore, an extensive literature analysis was performed, and cadaveric experimentation was combined with our clinical experience to provide a standardized proposal for ONS and obtain optimal management of patients with refractory CH.

Materials and Methods: Data from 36 articles published between 1998 and 2023 were analyzed to retrieve information on the anatomical landmarks and surgical technique of ONS. For the cadaveric experimentation ($N = 1$), two electrodes were inserted from the region over the foramen magnum and projected toward the lower third of the mastoid process.

Results: The existence of multiple approaches of ONS has been confirmed by the present analysis. Discrepancies have been found in the anatomical locations and corresponding landmarks of the greater and lesser occipital nerve. The surgical approaches differed in patient positioning, electrode placement, and imaging techniques, with an overall efficacy range of 35.7% to 90%.

Conclusions: Reports on the surgical approach of ONS remain contradictory, hence emphasizing the need for standardization. Only if all implanting physicians perform the ONS surgery using a standardized protocol, can future data be combined and outcomes compared and analyzed.

Keywords: Cluster headache, landmarks, neuromodulation, occipital nerve, occipital nerve stimulation

INTRODUCTION

Cluster headache (CH) is a primary headache disorder, affecting people of all ages, races, income levels, and geographical areas.[1] Approximately one in every 1000 adults experiences CH.[2,3] CH is defined as an excruciating unilateral temporal or periorbital pain with attacks that last between 15 minutes and 180 minutes, sometimes accompanied by autonomic symptoms in the nose, eyes, and face.[4,5] Some have described CH to be one of the most painful conditions known to humans.[5] Because CH is reported to cause suicidal ideation, planning, and attempt, it also is referred to as "suicide headache."[6,7] Depending on the attack frequency, CH is classified into episodic CH or chronic CH.[3]

The pathophysiology of CH is not fully understood,[5] but disturbances in function of the trigeminal and occipital nerve are considered major causes of CH.[8] The occipital nerve branches are connected with the trigeminovascular complex; hence, disturbed nociceptive signaling within this complex is believed to be an important mechanism underlying CH.[2] The separate occipital nerve branches, including the greater occipital nerve (GON), lesser occipital nerve (LON), and third occipital nerve (TON), have been described in anatomical studies.[9] The GON originates from the medial branch of the dorsal ramus of the C2 spinal nerve and provides sensory innervation to a large portion of the posterior scalp up to the vertex.[10] The LON originates from the lateral branch of C2 and sometimes C3 in the cervical plexus and provides sensation to the inferior occiput, lateral scalp posterior, and superior to the ear.[10] Because the GON is the main sensory nerve to the occipital area, it has been most frequently targeted in treatment for CH.[11] Patients with CH can be refractory to the standard pharmacologic approaches for neuropathic pain and thereby face huge suffering if development and optimization of alternative treatments are constrained.[12,13]

Owing to the involvement of the occipital nerve in the pathophysiology of refractory CH, electric stimulation of its branches has

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been shown to be promising.[14] In neurostimulation, the physician aims to target all the occipital nerve branches simultaneously. From an anatomical point of view, knowing the location of these separate branches is important to achieve an optimal electrode placement. However, one should notice that terminologies regarding the separate occipital nerve branches are often used interchangeably by physicians. The precise mechanism of neurostimulation in patients with refractory CH remains not known; however, occipital nerve stimulation (ONS) is believed to produce diffuse noxious inhibitory control by reducing blood flow in the trigeminal caudal nucleus, thereby possibly decreasing central pain sensation.[15,16] Hence, ONS has become one of the options in the treatment spectrum of refractory CH.[12] Although the results of electrical stimulation are encouraging, several patients do not reach adequate pain relief, which, of course, could be multifactorial. In this review, we focus on the surgical approach that could give rise to failure of this treatment. In general, two surgical approaches have been described for permanent ONS implantation given the electrodes can be inserted in either the lateral-medial or medial-lateral direction.[17,18] Complications including lead migration and infection have been reported for ONS.[18,19] To reduce occurrences of adverse effects, precise patient positioning, electrode placement, and imaging techniques are essential. Nevertheless, information regarding the surgical approach of ONS remains contradictory and limited in the literature. Even though the location of the occipital nerve branches has been extensively described and visualized in standard textbooks, major disagreement remains on their exact projections.[9] For this reason, studies providing a clear overview of the anatomical distributions and surgical technique involved in ONS are necessary. This article therefore aims to review and visualize current information on the landmarks, surgical protocols, and clinical efficacy of ONS. In addition, cadaveric experimentation and our experiences gained in the last year will be combined to provide a universally acceptable approach for ONS. The findings of this study will improve our understanding of the anatomy of occipital nerve branches and technical aspects to the surgical approach of ONS.

MATERIALS AND METHODS

Study Design

In the present study, a systematic literature search was undertaken to provide a clear overview on landmarks, surgical technique, and clinical efficacy of ONS in patients with refractory CH. Reports obtained from the literature search also have been summarized using clear visualizations. In addition, cadaveric experimentation was performed, and a proposal for a standardized protocol was accomplished.

Literature Review

The literature search was performed with PubMed using the keywords "occipital nerve." All articles were originally published in English. A total of 546 articles from 1998 to 2023 were retrieved. Thereafter, these articles were categorized into 1) landmarks, 2) surgical technique, 3) clinical efficacy, and 4) correlation between clinical efficacy and electrode placement, using additional inclusion and exclusion criteria (Table 1). Articles that did not meet the inclusion criteria or narrative reports lacking study data were excluded from analysis (Table 1). Each study analyzed within this literature search was viewed by three independent persons (Erkan Kurt, Linda Kollenburg, Saman Vinke) to ensure consensus and the quality of the articles included. Goals of this study were to 1) provide an overview of the described anatomical location of the occipital nerve branches using surface landmarks, 2) provide details on surgical techniques for ONS with emphasis on electrode placement, imaging, and patient positioning, 3) summarize data on the clinical efficacy of ONS, and 4) describe a detailed and standardized surgical approach for ONS.

Cadaveric Study

To allow proper cadaveric experimentation, literature regarding the anatomy and surgical techniques of ONS was combined with our own experience. Cadaveric dissection was used to identify the anatomical location of the GON in relation to the electrode placement. In the cadaver ($N = 1$), a single vertical incision in the region over the foramen magnum to the superior part of the spinous process of C2 was performed, with the cadaver placed in a neutral prone position. Pisces Quad-Plus electrodes (388856, Medtronic Inc, Minneapolis, MN) were then directed toward the lower third of the mastoid process from medial to lateral direction. Thereafter, the GON was dissected, and x-ray imaging was performed from different angles. The surgical approach, as performed in the cadaver, has been implemented for the last year in Radboud University Medical Center for patients with refractory CH.

RESULTS

The anatomical location of the occipital nerve branches forms a base for the development of surgical protocols for ONS. Variations on certain surgical aspects including patient positioning, electrode placement, and imaging affect the clinical efficacy of ONS. In this section, articles on anatomical and surgical aspects of ONS concerning clinical efficacy are summarized.

Anatomical Localization of Occipital Nerve Branches Regarding External Landmarks

Owing to the presence of anthropometric variations, limitations in manual dissection methods, and fine distributions of the occipital nerve branches, determination of its exact projections within the posterior scalp area has been shown to be rather complex.[20] Therefore, various studies have described the use of external landmarks to facilitate localization of the occipital nerve branches. Nevertheless, descriptions of the location of the occipital nerve branches appear to be variable in literature given the location of the GON and LON from the midline was found to be 15 to 55.3 mm and 14.9 to 61 mm, respectively (Fig. 1). Reports often tend to describe the localization of different occipital nerve branches separately. Some studies described the GON to be located at 1 to 2 cm from the midline and 3 cm inferior to the external occipital protuberance (EOP),[10] and 61 mm from the midline for the LON[21] (Fig. 1, Table 2). Other physicians prefer to describe a specific region of the occipital nerve branch as a general measure for its location. Khavanin et al mentioned that the piercement through the sternocleidomastoid (SSC) in relation to the mastoid was 65.5 ± 5.9 mm for the GON[23] and 45.2 mm for the LON[24] (Fig. 1, Table 2). In addition, the anatomical location of the occipital nerve branches in relation to the SSC,[23–25,26] aponeurosis of trapezius,[23,25,26] and superolateral area[9] has been reported.

Most studies reported the localization of the occipital nerve branches respecting bony landmarks including the EOP and mastoid. However, some reports used vertical and horizontal lines,

Table 1. Overview of Literature Searches Performed.

Topic literature search	Search terms	Inclusion criteria	Total studies generated	Studies obtained after exclusion
Anatomical landmarks and occipital nerve distributions	"occipital nerve landmarks," "anatomy of occipital nerve," "occipital nerve projections," and "occipital nerve distributions"	• $N > 2$ • Occipital nerve anatomy must be described • Anatomy of occipital nerve must be described using landmarks • Conducted between 1995 and 2023	10, 252, 22, and 51, respectively	9
Surgical technique (imaging, electrode placement, head positioning, and imaging)	"occipital nerve stimulation," "surgical technique of ONS," "electrical stimulation of occipital nerve," "peripheral nerve stimulation occipital nerve," and "occipital nerve stimulator implantation"	• Subjects were adults diagnosed with refractory CH/CCH • Published between 1995 and 2023 • Provides details on the surgical aspects of ONS • Neurostimulation must be applied to the occipital nerve	105, 29, 49, 45, and 22 respectively	38
Clinical efficacy ONS	"ONS efficacy," "efficacy occipital nerve stimulation," "peripheral nerve stimulation occipital nerve efficacy," and "efficacy of electrical stimulation of occipital nerve"	• Subjects were adults diagnosed with refractory CH. • Follow-up period >9 mo • $N > 15$ • Responders are described as having >50% reduction in attack frequency or VAS score	212, 147, 93, and 104, respectively	10
Correlation between electrode placement and clinical efficacy	"clinical efficacy electrodes in ONS," "surgical technique ONS clinical efficacy," "electrode placement and efficacy ONS," "sensitization and clinical efficacy ONS." and "occipital nerve stimulation and perceived sensory quality"	• Subjects were diagnosed with refractory headache disorders* • Describes several stimulatory regions on occipital/cervical area	30,79, 3,0, and 2, respectively	1

Overview of the search terms, inclusion criteria, and obtained study results for the literature search regarding the clinical efficacy, surgical ONS approach, and anatomical distribution of the occipital nerve. This literature search was performed in PubMed.

CCH, chronic CH; VAS, visual analog scale.

*This inclusion criterium was changed from "only subjects with refractory CH" to "subjects with any type of refractory headache disorder" because otherwise, no results were obtained.

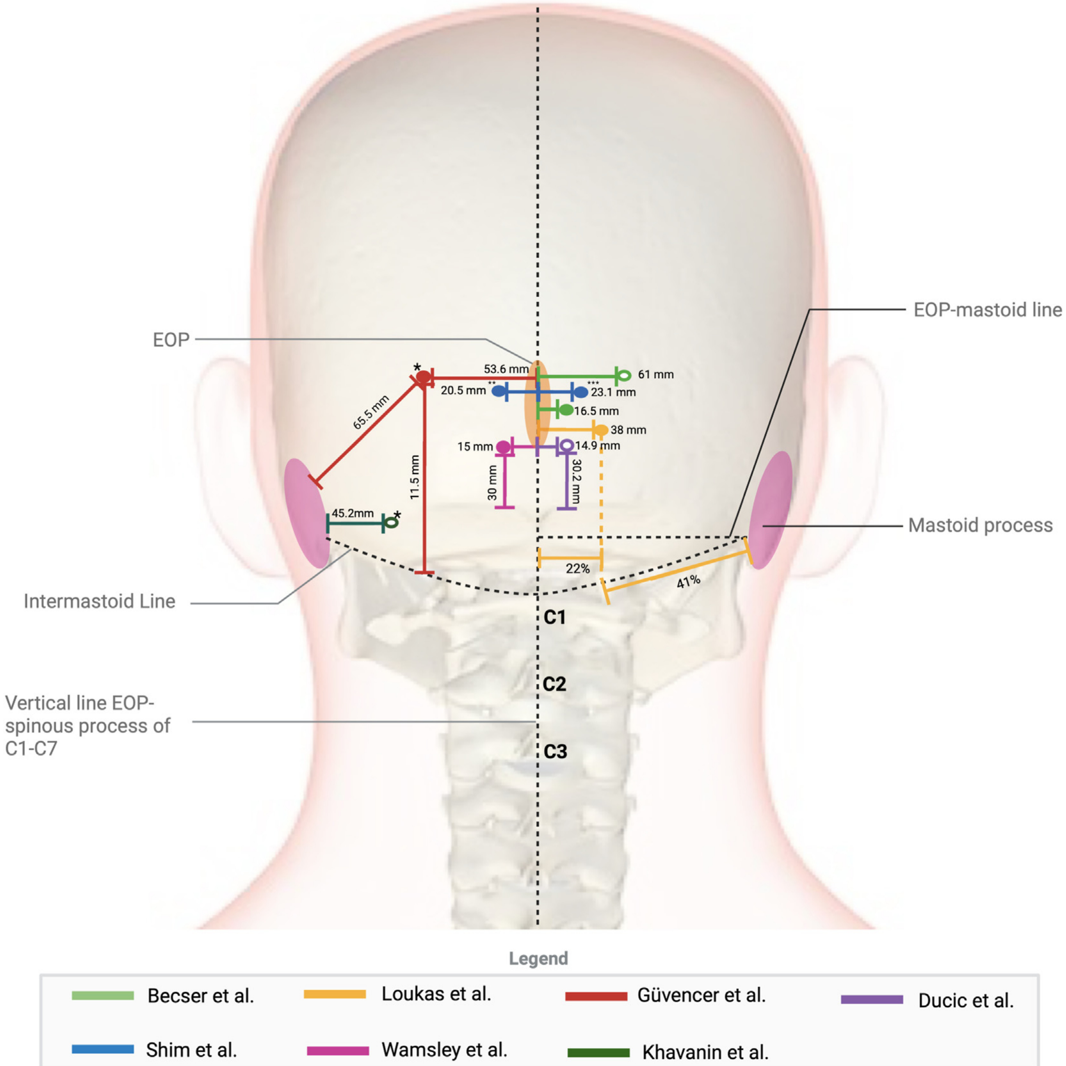


Figure 1. Overview of the currently described landmarks and localization of the GON and LON. The circles represent the described location of the occipital nerve according to its corresponding literature (open circle = LON, closed circle = GON). *Indicates the point at which the occipital nerve is described to pierce the sternocleidomastoid. If a range of values was mentioned in literature the average value was calculated and depicted in the scheme above. **,***Represent the anatomical location of the GON on the left side** and on the right side*** as defined by Shim et al. EOP, external occipital protuberance. Created with BioRender.com.

connecting these bony landmarks, to describe the location of the occipital nerve.[20,21] Results obtained in this alternative approach showed that the GON was located at a mean distance of 3.8 cm lateral to a vertical line through the EOP and the spinous process of the vertebrae C2 to C7, and at 22% of the distance between the EOP and the mastoid process. In addition, Becser et al[21] and Loukas et al[20] described the GON to be located at approximately 41% of the distance along and 5 to 28 mm from the midline at the level of the intermastoid line, respectively (Fig. 1, Table 2). Usage of percentages by Loukas et al to localize the occipital nerve might have eliminated confounding by topometric variations. Therefore, their results on GON localization might have improved validity.

Although many reports provided detailed descriptions of the anatomical location of the occipital nerve branches with respect to landmarks, differences between the right and left branch are often not described. Although a symmetrical division of the occipital nerve branches on both sides is assumed by many, Shim et al reported an asymmetrical division of the GON branches (23.1 ± 3.4 mm [right] and 20.5 ± 2.8 mm [left] from EOP)[22] (Fig. 1, Table 2). This might suggest that even if reports are consistent in the region on the occipital nerve and the branch that is measured, localization will remain variable because different measures might be obtained for the left and right occipital nerve branches.

Surgical Technique of ONS

The previously described landmarks provide guidelines for the development of the surgical technique underlying ONS. Several steps have been described in the protocol of ONS. Firstly, a Tuohy needle is inserted. Next, the electrodes are implanted, with the wires connected to the electrodes and tunneled together in caudal direction for connection to the implantable pulse generator.[27–30] The electrodes are inserted such that they cross the GON and LON branches. Despite the recognition of ONS in the management

Table 2. Summary of Outcomes Regarding Anatomical GON/LON Localization.

Study/study design	Occipital nerve branch described	No. of patients/ cadavers	Mean age, y	Distance from EOP (range)	Distance on/to EOP-mastoid line	Distance from mastoid	Distance on/to intermastoid line	Distance on external occipital protuber-ance-mastoid line	Distance to OA
Shim et al[22] /A	GON	*N* = 20 (pt)	22–37	23.1 ± 3.4 mm right and 20.5 ± 2.8 mm left	N/A	N/A	N/A	N/A	1.5 ± 0.6 mm (right) and 1.2 ± 0.6 mm (left)
Loukas et al[20] /A	GON	*N* = 80 (c)	86 (58–86)	3.8 (1.5–7.5) cm	22.0%	N/A	41.0%	22.0%	N/A
Wamsley et al[10] / LR	GON	N/A	N/A	3 cm inferiorly and 1–2 cm laterally	N/A	N/A	N/A	N/A	N/A
Guvencer et al[23] / A	GON*	*N* = 12	N/A	53.6 ± 5.0 mm	N/A	65.5 ± 5.9 mm	11.5 ± 3.9 mm	N/A	N/A
	GON†	*N* = 12	N/A	15.1 ± 7.0 mm	N/A	59.4 ± 2.3 mm	17.1 ± 2.8 mm	N/A	N/A
Khavanin et al[24] /A	LON	*N* = 7 (c)	N/A	45.2 mm (36–51 mm)	N/A	N/A	N/A	N/A	N/A
Becser et al[21] /A	GON	*N* = 10 (c)	N/A	16.5 mm (5–28 mm)	N/A	N/A	N/A	N/A	N/A
	LON	*N* = 10 (4 M, 6 F)	N/A	61 mm (32–90 mm)	N/A	N/A	N/A	N/A	N/A
Ducic et al[25] /A	GON*	*N* = 125 (112 pt, 13 c)	N/A	14.9 ± 4.5 mm laterally and 30.2 ± 5.1 mm inferiorly	N/A	N/A	N/A	N/A	N/A
	GON†	*N* = 125 (112 pt, 13 c)	N/A	37.8 ± 4.6 mm (24–49 mm)	N/A	N/A	N/A	N/A	N/A
	LON*	*N* = 125 (112 pt, 13 c)	N/A	3 cm inferiorly	N/A	N/A	N/A	N/A	N/A

Overview of the anatomical location of the GON and LON.
A, anatomical study; AT, aponeurosis of trapezius; c, cadavers; GON, greater occipital nerve; LON, lesser occipital nerve; LR, literature review; OA, occipital artery; pt, patients.
*Represents the point at which the GON/LON pierces the SSC and the EOP.
†Iindicates the point at which the GON/LON pierces the AT.

of refractory CH, physicians seem to disagree on the surgical technique.

Patient Positioning

Before surgery, the patient must be correctly positioned. Altering head and body positions of the patient during the ONS procedure can greatly enhance the accessibility of the occipital nerve. Used options for patient positioning include the supine,[31] concorde,[32] park-bench,[27] and prone manner.[28,32,33] Equipment including the Mayfield holder,[34] molded cushions,[32] and a radiolucent frame[33] is reported to be essential for optimal head fixation during ONS. Franzini et al[28] described head positioning in a slightly flexed manner, in line with the chest. Another study stated that the neck should be flattened during ONS using slightly inclined molded cushions.[32] However, Trentman et al[31] reported that the head should be turned maximally away from the infraclavicular region during ONS to obtain optimal positioning.

Electrode Placement

Electrodes are placed in a transverse manner to properly cross the nerve trunk of the LON and GON divisions. If electrodes are not correctly inserted within the appropriate connecting tissue level, adverse events (AEs) such as dermatomal paresthesia might occur.[35] In the ONS technique, it is favorable to cover all branches of the occipital nerve; however, it is clinically impossible to target all branches separately. Therefore, electrode placement on the major branches (LON and GON) and most proximally to the occipital nerve is considered sufficient for optimal electric field coverage. Stimulation of both occipital nerve branches can be reached through a lateral and medial approach. Some studies describe using the lateral approach for ONS in which the electrodes are inserted at the level of the mastoid process and advanced toward the midline at level of C1[17,36] (Fig. 2, Table 3). However, most studies have described the medial ONS approach, in which a midline incision is made at the level of C2 and electrodes are inserted in a medial-to lateral direction[14,17,18,21,31,38] (Fig. 2, Table 3).

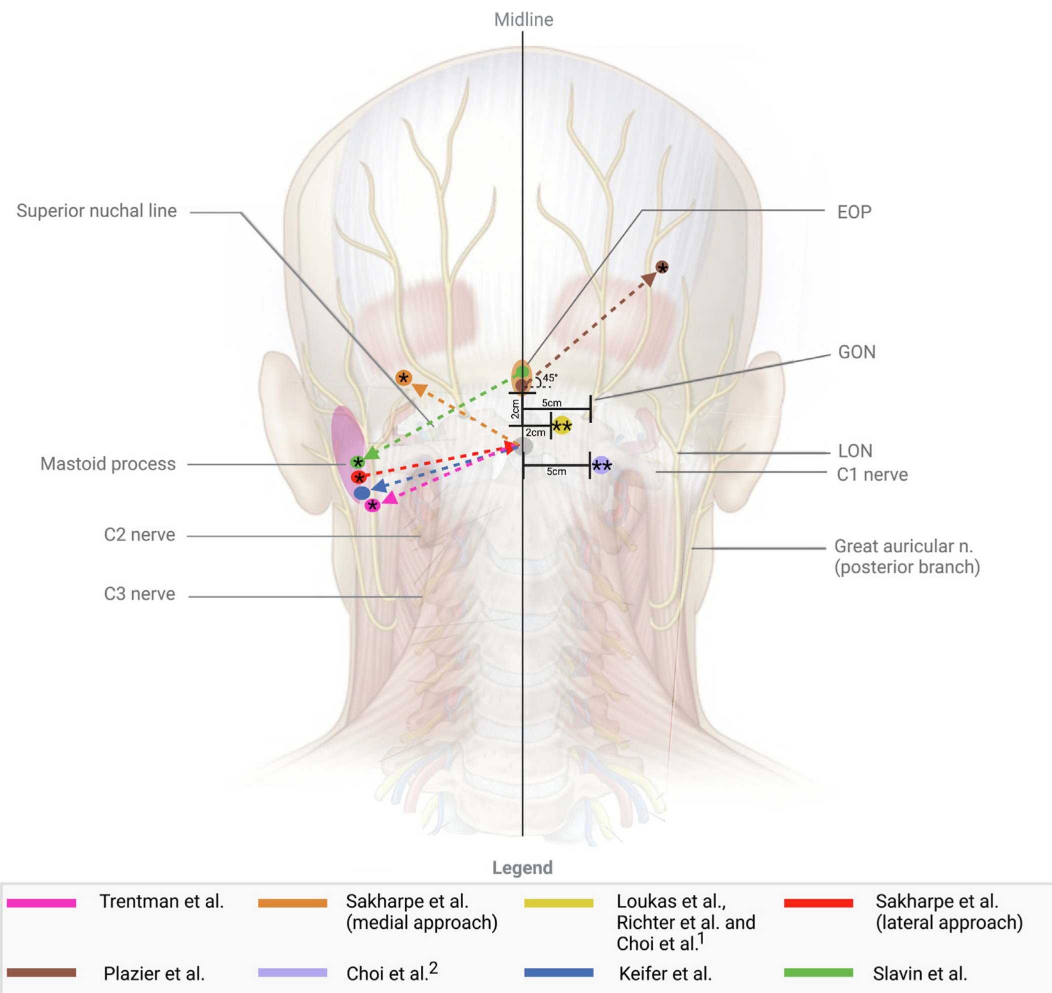


Figure 2. Overview of the currently described insertion methods for the electrodes in ONS. The arrows indicate the direction and origin of the needle insertion. The circles indicate the anatomical structures involved in the insertion point described by the corresponding literature. *Indicates that the precise projection point of the needle has not been accurately identified within the anatomical structure but rather described to be somewhere in that region. **Indicates that in the corresponding literature, only the insertion point was described, and therefore, the projection of the needle could not be indicated with an arrow. Choi[1,2] described the electrode placement for the GON[1] and LON[2] separately. Slavin et al described both the medial and lateral approach to ONS; however, only the medial approach has been depicted in this figure. Studies that did not accurately describe placement on midline were not included in this figure. EOP, external occipital protuberance; GON, greater occipital nerve; LON, lesser occipital nerve. Created with BioRender.com.

Table 3. Summary of Outcomes Regarding Electrode Placement in ONS.

Study/study design	Region of electrode placement	No. of patients randomized/completed study	Age, y	Place of Insertion	Direction of projection after insertion
Plazier et al[37]	OP	Trial implantation: $N = 51$ (6 M, 45 F)	47 y (mean: 46.62 ± 9.82 y)	1 cm underneath EOP	Tunneled at a 45° angle
		Permanent implantation: $N = 41$ (5 M, 36 F)	49 y (mean: 49.02 ± 9.53 y)	1 cm underneath EOP	Tunneled at a 45° angle
Keifer et al[38]	UC	$N = 1$	47 y	Posterior arch of C1 vertebra	Toward mastoid process
Sakharpe et al[17]	OP	N/A	N/A	Mastoid process	Midline at level of C1
	UC	N/A	N/A	Midline at C1 level	Laterally from the midpoint
Loukas et al[20]	OP	$N = 80$ (35 M, 65 F)	86 (58–86)	2 cm laterally and 2 cm inferiorly to EOP	N/A
Richter et al[39]	OP	N/A	N/A	2 cm laterally and 2 cm inferiorly to EOP	N/A
Choi et al[40]	OP*	$N = 10$ (3 M, 7 F)	52 (34–70)	2 cm infrolateral of EOP	N/A
	OP†	$N = 10$ (3 M, 7 F)	52 (34–70)	2 cm inferiorly and 5.0 cm laterally of EOP	N/A
Trentman et al[31]	UC	N/A	N/A	Midline incision (2.5 cm retromastoid and <1 cm at C1 level)	Toward retromastoid region (midline to lateral)
Slavin et al[36]	OP‡	$N = 30$ (8 M, 22 F)	47.3 (22–97)	Midline just below occipital protuberance	Toward contralateral mastoid process
	OP§	$N = 30$ (8 M, 22 F)	47.3 (22–97)	Lateral within occipital area	Medial within occipital area
Johnstone et al[18]	UC	Trial implantation: $N = 8$ Permanent implantation: $N = 7$	46 y (30–65)	Medial at C1 level	To lateral along lateral nuchal line
Nguyen et al[41]	OP	$N = 33$ (14 M, 9 F)	49.8 ± 12.3 (28–87)	Superior part of occipital region	N/A

Overview of electrode placements in ONS. UC stands for the older approach in which electrode insertion is within upper cervical region. OP stands for the newer approach in which electrode insertion is within upper occipital region. Choi et al described the electrode placement for the GON[1] and LON[2] separately.
GON, greater occipital nerve; LON, lesser occipital nerve.
*Choi et al described the electrode placement for the GON separately.
†Choi et al described the electrode placement for the LON separately.
‡Slavin et al described the medial approach to ONS separately.
§Slavin et al described the lateral approach to ONS separately.

Variations in the medial ONS approach can be found in the level of electrode placement along the midline. Some articles describe electrode insertion on the midline at the level of the EOP within the occipital area[20,40,41] whereas other studies report insertion on the midline at the level of the upper cervical region.[42] Even though several points along the midline have been described, the exact distances of these points using the landmarks are either not reported at all or remain contradictory (Fig. 2, Table 3). Another aspect of electrode insertion that seems variable in the literature is the projection of the electrode after insertion. A wide range of electrode projections has been described, including the mastoid process,[11,38] along the nuchal line (at C1 level),[18] into the retro mastoid incision,[21,31] and at 45° from the EOP (Fig. 2, Table 3).[37] Even though some studies reported the electrode direction after insertion, other studies often tend to completely neglect the description of electrode projection.[20,40]

Imaging Techniques

As previously described, the anatomical location of the occipital nerve is quite variable among individual patients.[35] Hence, several imaging techniques that facilitate localization of neurovascular structures have been reported and used in clinics. Nevertheless, there is currently no universal proposal for imaging in the surgical protocol of ONS. Several articles described fluoroscopy to be a clear and accurate verification method to determine electrode positioning.[11,30,43–46] Fluoroscopy was reported to be performed in an anteroposterior or lateral direction.[43] Another report recommended using a surgical technique of fluoroscopy and intraoperative tactile orientation because it reduces radiation exposure and provides reproducible results during ONS.[43] However, other studies reported a preference for ultrasound imaging during ONS because fluoroscopic radiation is prevented and tissue planes and neurovascular structures can be visualized, thereby allowing accurate, real-time electrode placement.[22,35,47,48] Shim et al even concluded that ultrasonography offers an attractive alternative for the use of landmarks to guide electrode placement.[22]

Clinical Efficacy of ONS

Many studies determined the efficacy of ONS; however, wide ranges of success are reported. After an average follow-up period of 22.25 ± 16.2 months, an overall response ratio (ORR) of 35.7% to 90% was calculated (range was calculated with "descriptive statistics" in IBM SPSS statistics 27, using the data of Table 4). After six years, the ORR was found to be 61.1% to 66.7%[55,51] (Table 4). Efficacy is partially dependent on the occurrences of AEs. The presence of AEs in ONS has been widely confirmed within this literature search. Lead migration[49,50,56–59] and infection[33,49,50,54,56] are the most reported AEs of ONS (Table 4). Fewer studies have mentioned excessive scar tissue formation[32] or side shift with contralateral attacks[50] due to ONS.

Cadaveric Study

The literature on landmarks, efficacy, and surgical technique of ONS has been combined with our own clinical experience to allow proper cadaveric experimentation with visualization of the GON and electrodes. We performed a cadaveric study in which we simulated different approaches from the midline toward the mastoid process, in relation to anatomy, combined with fluoroscopy. A single vertical incision in the region over the foramen magnum was performed, with the cadaver placed in a neutral prone position (Fig. 3). Pisces Quad-Plus electrodes were then directed toward the lower third of the mastoid process (Fig. 3). Thereafter, the GON was dissected, and x-ray imaging was performed at −20°, −10°, 0°, +10°, +20° angles. This allowed determination of the electrode placement in relation to the GON. Results showed that the x-ray tube should be placed at an angle of 10° because the best representation of the actual electrode placement in relation to the GON and mastoid process was obtained using these settings.

DISCUSSION

The technique of ONS has been described in this comprehensive overview. The present analysis confirms the existence of a wide variety in the use of anatomical landmarks, patient positioning, imaging, electrode placement, and clinical efficacy. As a result, the surgical technique of ONS is often chosen on the basis of the surgeon's preference.[36] Furthermore, this analysis indicated the existence of a wide clinical efficacy range for ONS. Although the range of efficacy was narrowed as much as possible within this analysis by defining responders clearly and including only patients with refractory CH, success ranges remained quite wide. A possible explanation for this is the variety of surgical approaches (eg, electrode insertion, patient positioning, and surgical devices/implants) of ONS, which has shown to be evident in the present analysis. The lack of qualitative studies within the field of clinical efficacy of ONS and usage of various descriptions to define responders also might be responsible for this wide range of success. Although some authors use reduction in number of headaches per month, others mention alteration in average overall pain intensity as a measure to determine the efficacy. Given anatomical landmarks are considered an important base for the surgical technique of ONS, variations in the anatomical location of the occipital nerve branches are likely to have caused discrepancies in the surgical ONS technique. Consistencies in the anatomical approach and surgical technique are required so that data between physicians who perform ONS can be combined and compared. All considered, implementation of a universal approach for ONS can improve management for all patients with refractory CH.

Despite limited research being performed on the optimal surgical technique for ONS, Göbel et al[60] found a correlation between electrode placement and perceived sensory location to clinical efficacy in 32 patients with refractory chronic migraine who underwent ONS. A computer-based method was used to determine the peripheral nerve stimulation-induced perceived sensory location and a verbal rating scale to determine the clinical efficacy. Results indicated that sensations spatially perceived above the meati-occipital protuberance (MOP) line (the line connecting the external acoustic meati and EOP) caused greater clinical efficacy than do sensations perceived below the MOP line[60] (Fig. 4). In addition, given most of the occipital nerve-end branches are located higher upon the occipital area, increased electric field coverage of the occipital nerve branches is expected when stimulation is applied higher upon the occipital area. These findings support the idea that electrode stimulation higher upon the occipital area will provide higher efficacy.

A similar surgical approach, with stimulation higher upon the occipital area, has been implemented in the last year in our medical center. In our proposal, the electrodes should be inserted in the region over the foramen magnum and directed toward the lower third of the mastoid process (Fig. 5). The head must be

Table 4. Summary of ONS Efficacy Outcomes for Patients With Refractory CCH.

Study/ study design	Headache category	No. of patients randomized/ completed study	Mean age, y	Mean follow-up (range)	Definition of responder	Percentage of responders	AEs
Mueller et al[32] / P, CS	CCH	*N* = 10 (2 M, 8 F)	30	12 mo (3–18)	≥50% reduction in number of headaches/mo or greater reduction in average overall pain intensity than at baseline	90%	Infection (10%), severe scar tissue formation (10%)
Leplus et al[49] / P, CO	CCH	*N* = 105 (73 M, 32 F)	45 (25–72)	12 mo 43.8 mo	>50% reduction in attack frequency	68.6%	Infection (6%), lead migration (12%), lead fracture (4.5%, hardware dysfunction (8.2%), local pain (20%
Magis et al[50] / P, CS	CCH	Randomization *N* = 15 (14 M, 1 F) Completed = 14	47.6 ± 11.5	36.82 mo[11–64]	>50% reduction in attack frequency	90%	Battery depletion (64%), immediate or delayed material infection (20%), electrode migration (1/15), side shift with contralateral attacks (36%)
Díaz-de-Terán et al[51] / R, CO	CCH	Definitive ONS = 18 Completed = 17	41.2 ± 8.7	72 mo (54–108)	>50% reduction in attack frequency	61.1%*	Mild adverse side effects 41.2%
Burns et al[52] / R, CS	CCH	*N* = 14	44 (31–58)	17.5 mo (4–35 mo)	>50% reduction in attack frequency	42.9%	Battery depletion (43%), lead/ electrodes complications (29%)
Cadalso et al[53] / MA	CCH	*N* = 96 (76% M, 23% F)	44	18.5 mo (12–36 mo)	>50% reduction in attack frequency	20–92%	50%–90% AEsn
Raoul et al[54] / R, LR	Several forms of refractory occipital headaches (including CCH)	*N* = 60 (38 F, 22 M)	58 (22–82)	13–27 mo	>50% reduction in VAS score	76%	Electrode displacement or fracture (10%) and infection (10%)
Leone et al[55] / OL	CCH	*N* = 35 (30 M, 5 F)	42	73.2 (19–128) mo	≥50% reduction in headache number/d	66.7%	Battery depletions (65.6%), electrode displacement of fracture (34.4%)
Aibar-Durán et al[33] / P, CS	CCH	*N* = 17 (13 M, 4 F)	44 (31–61)	48 mo	>50% reduction in attack frequency	41.18%	Infection (6%), implant displacement (6%)
Wilbrink et al[14] / R, OL							
100% stimulation	CCH	*N* = 44 (37 M, 28 F)	44 (± 13)	24 wk	>50% reduction in attack frequency	50%	Lead migration (5%), replacement IPG (3%), replacement lead or cable (5%), local pain (3%), impaired wound healing (3%)
30% stimulation	CCH	*N* = 44 (46 M, 19 F)	44 (± 13)	24 wk	>50% reduction in attack frequency	50%	Lead migration (5%), replacement lead or cable (2%), impaired wound healing (3%)

Overview of the ONS efficacy outcomes for refractory chronic cluster headache. Adverse events were reported if the occurrence was >1 and surgical revision was required.
CO, cohort study; CCH, chronic CH; CS, case study; F, female; LR, literature review; OL, open label study; M, male; MA, meta-analysis; P, prospective; R, retrospective; VAS, visual analog scale.
*For this study, the ORR of 30% to 100% was reported instead of >50%.

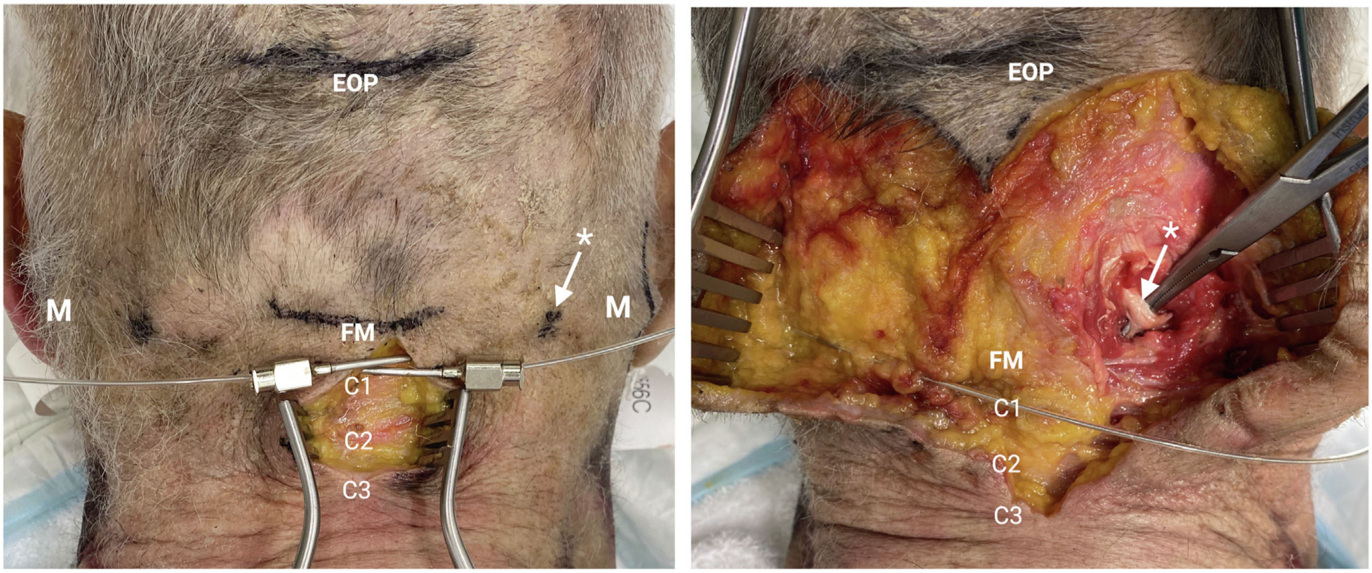
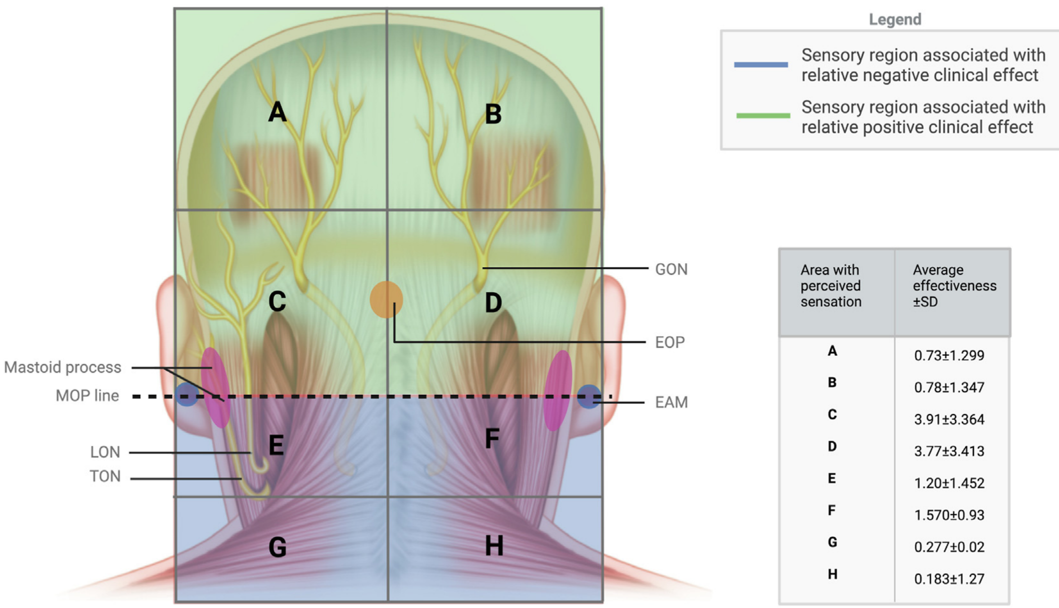


Figure 3. Cadaveric experimentation with electrode insertion from the foramen magnum toward the lower third of the mastoid process. *Indicates localization of the greater occipital nerve. FM, foramen magnum; M, mastoid process.

placed in line with the thorax to prevent curvature of the occipital region. Preferably, this line should be 180°. For a straight head-thorax alignment, a tool (eg, an infusion bag) is necessary in most patients and must be placed under the head and/or thorax to achieve sufficient flexion of the head (Fig. 6). After insertion of the electrodes, extension cables should be connected to the electrodes and tunneled in caudal direction for connection to the implantable pulse generator. In addition, in our proposal, the x-ray tube should be placed at an angle of 10°, given cadaveric experimentation showed the best representation of the actual electrode placement in relation to the GON and the mastoid for this angle (Fig. 6).

Using this proposal, we observed thus far similar and, in some patients, even superior pain reduction with a lower voltage than in the old approach in which the electrodes were inserted at the level of C1. X-ray imaging in one of our patients who underwent revision surgery illustrates the difference between the "new" and "old" approach for ONS (Fig. 7). Implementation of this proposal in the cadaver also indicated proper GON coverage by the electrodes. The surgical proposal of the present study also is believed to hold great



Area with perceived sensation	Average effectiveness ±SD
A	0.73±1.299
B	0.78±1.347
C	3.91±3.364
D	3.77±3.413
E	1.20±1.452
F	1.570±0.93
G	0.277±0.02
H	0.183±1.27

Figure 4. Association between the perceived sensory location and clinical efficacy in patients with refractory chronic migraine as studied by Göbel et al. EAM, external acoustic meatus; EOP, external occipital protuberance; GON, greater occipital nerve; LON, lesser occipital nerve; MOP, meati-occipital protuberance line; TON, third occipital nerve. Created with BioRender.com.

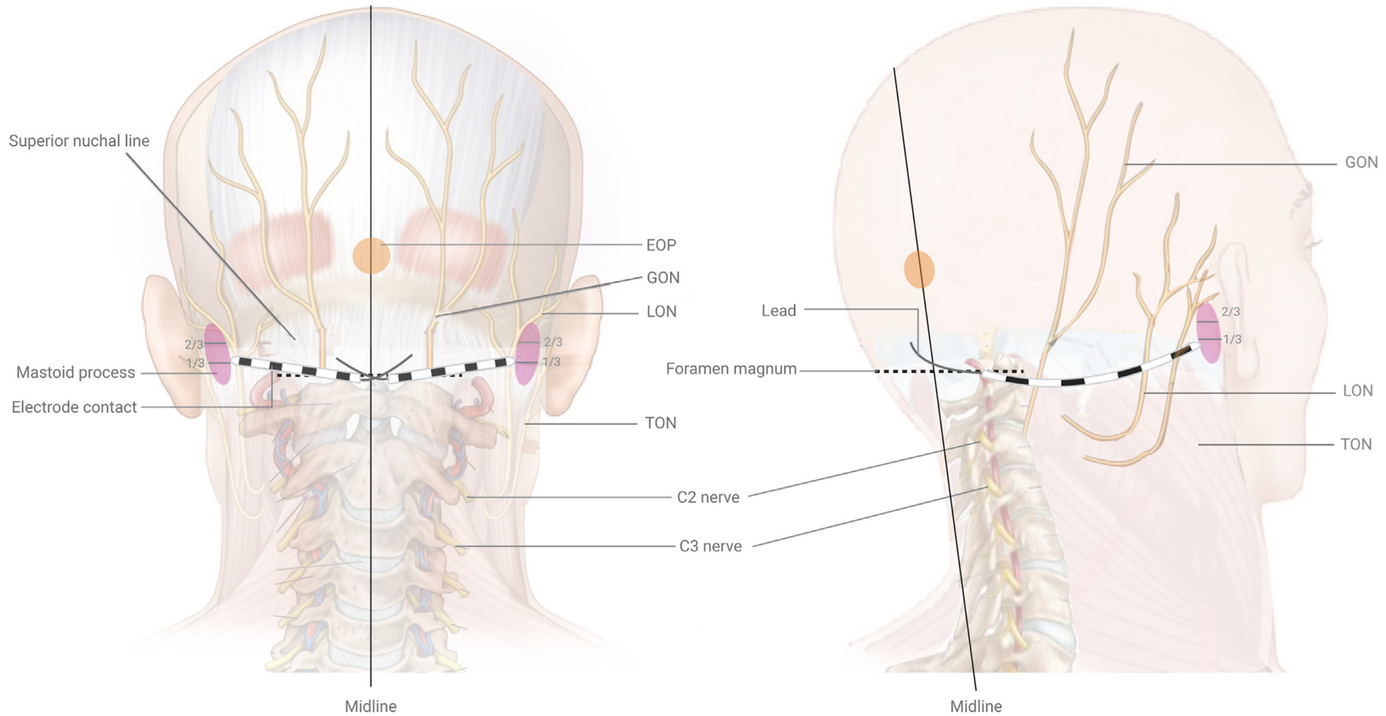


Figure 5. Electrode insertion in the standardized surgical proposal to ONS in patients with refractory CH, as implemented in the last year at our medical center. EOP, external occipital protuberance; GON, greater occipital nerve; LON, lesser occipital nerve; TON, third occipital nerve. Created with BioRender.com.

potential for reducing ONS-related local pain that some patients experience as AE because the subcutaneous space is often much smaller around the EOP than around the foramen magnum. Hence, the insertion of electrodes in the region over the foramen magnum, as proposed, is expected to reduce local pain as compared with insertion from the EOP itself or higher than the EOP line.

Although the results regarding this standardized surgical proposal are encouraging, future research is required given limitations were present in this study. Although the cadaveric dissection and the ONS implantation in patients were extensively conducted with regard to the anatomy and x-ray imaging performance, we realize that anatomical variations still might prevent some patients

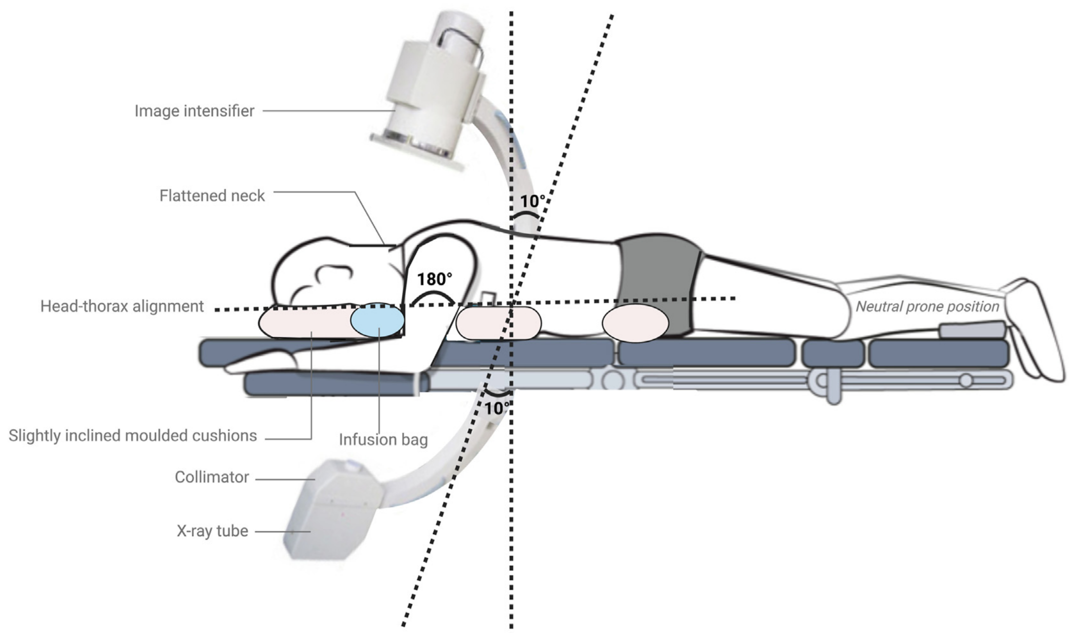


Figure 6. Position of head and thorax, and the x-ray during the ONS procedure as proposed in our protocol. Created with BioRender.com.

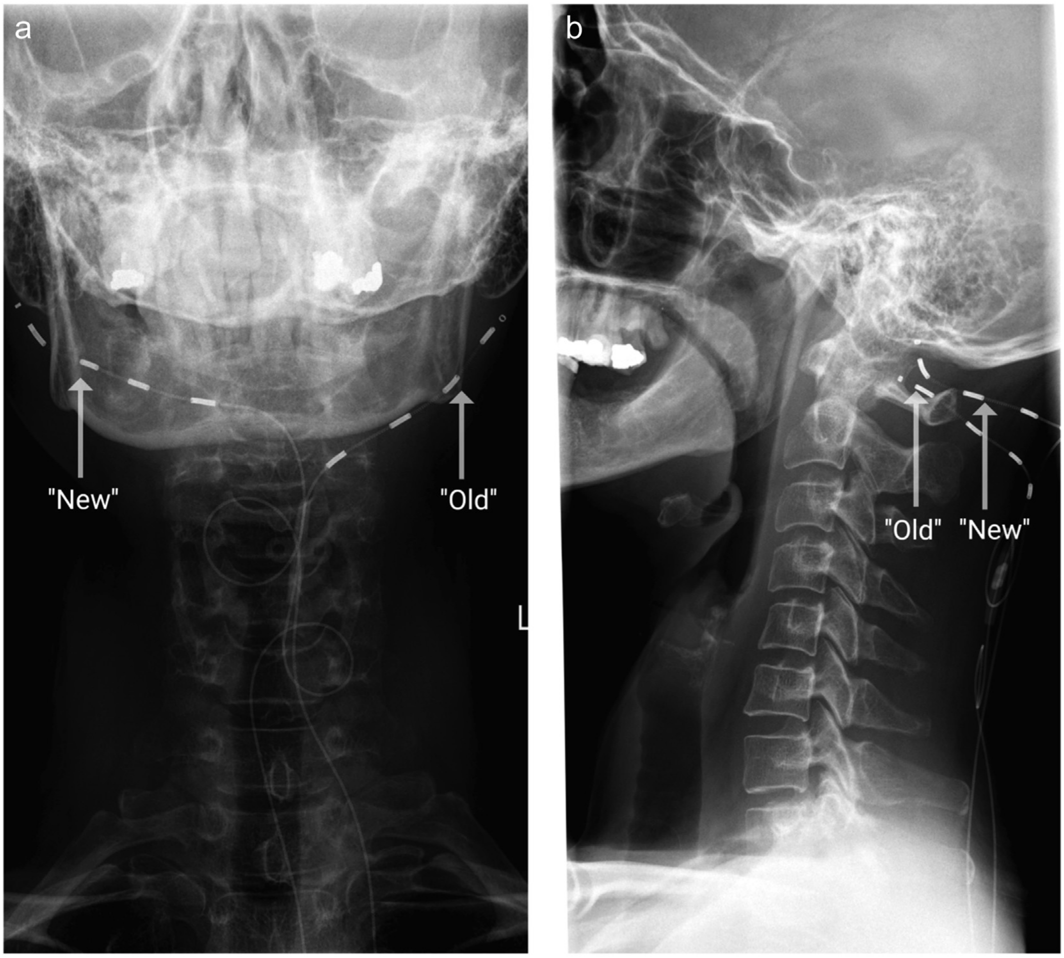


Figure 7. X-ray image of a patient who underwent revision surgery after lead breakage. Notice the difference in position of the leads. "Old" indicates electrode insertion at level of C1. "New" indicates electrode insertion from the region over the foramen magnum directed toward the lower third of the mastoid process, as implemented in the last years in our medical center. a, dorsal view; b, lateral/sagittal view. Lead is positioned more cranially than on the left side.

with refractory CH from obtaining similar results. In addition, owing to the absence of a follow-up in the patients who underwent our ONS approach, the efficacy of this proposal is yet to be determined.

CONCLUSIONS

The present analysis shows that ONS is accepted as an established treatment for refractory CH. Results also have emphasized the importance of precision within each surgical aspect of the ONS procedure to allow optimal efficacy. Essential technical aspects of ONS include anatomical localization, electrode placement, imaging, and positioning. Although literature on landmarks, surgical techniques, and clinical efficacies has been reported for ONS, results remain contradictory. Only if all implanting physicians perform the ONS surgery in the same setting, using a standardized protocol, can future data be combined, and outcomes compared and analyzed. This is essential to improve the efficacy of ONS and to optimize management for all patients with refractory CH. All considered, there is a need for standardization. For that matter, a standardized proposal has been presented for ONS in patients with refractory CH. This proposal is expected to hold great potential to optimize clinical benefit of ONS owing to increased electric field coverage. Even though the present observations are promising, follow-up studies are required to confirm the efficacy of the present proposal.

Clinical Implications

1. There is a wide variety in the use of anatomical landmarks, patient positioning, imaging, and electrode placement in the technique of occipital neurostimulation.
2. There is a need for a standardized surgical protocol in ONS.
3. Such a protocol enables comparison of data between physicians who treat patients experiencing intractable CH with ONS.

Authorship Statements

Erkan Kurt and Linda Kollenburg undertook the review and analysis of the eligible publications, data, and results of the analysis. Erkan Kurt and Linda Kollenburg prepared the manuscript with indispensable intellectual input from all other coauthors. The cadaveric dissection was performed by Erkan Kurt and Wim Mulleners. All authors approved the final version of the manuscript.

Conflict of interest

The authors reported no conflict of interest.

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COMMENTS

The authors of this study did a remarkable job analyzing multi-institutional experience with peripheral nerve stimulation (PNS) over a ten-year period. The conclusions are very interesting and create many new questions, most of which are highlighted in the section on study limitations. Unfortunately, by grouping all PNS patients together, the study ended up being much less convincing because the PNS population is quite diverse in terms of pain locations, etiologies, and chosen hardware options. Each of these categories would probably have very different expectation of the presurgical nerve block, and therefore, the value of nerve block for both diagnostic confirmation and prognostication would be very different too. Nevertheless, the study creates a foundation for many other groups—and for the authors themselves—to analyze narrower cohorts of patients, not only to quantify the significance of diagnostic nerve blocks but also to create a universally accepted treatment algorithm or a protocol that could be both practical and scientifically supported. There also may be room to consider changing the technique of the blocks used in the authors' practice because, anecdotally, I continue to use diagnostic blocks in my PNS practice and use their results in the therapeutic decision-making process.

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Kurt et al should be commended for their comprehensive and clinically relevant review of occipital nerve anatomy and their proposal for a standardized surgical technique for occipital nerve stimulation.

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