Peripheral Nerve Stimulation of the Occipital Nerves for the Management of Headache Pain and Disability Associated with Chronic Migraine: Technical Considerations from a Prospective, Multicenter, Double-blinded, Controlled Study

Ashwini Sharan, MD[1], Samer Narouze, MD[2], Terrence Trentman MD[3], Ken Reed, MD[4], Alon Mogilner, MD, Ph.D.[5], Jerome Goldstein, MD[6], Julien Vaisman, MD[7], Joe Ordia, MD[8], Tim Deer, MD[9], Robert M Levy, MD[10] and Konstantin Slavin, MD[11]

[1]Thomas Jefferson University Hospital, Philadelphia, PA, [2]Summa Western Reserve Hospital, Cuyahoga Falls, OH, [3]Mayo Clinic, Phoenix, AZ, [4]Ascendant Neuro, Dallas, TX, [5]Northshore-LIJ Health System, Dept of Neurological Surgery, Great Neck, NY, [6]San Francisco Headache Clinic, San Francisco, CA, [7]Pain and Wellness Center, Peabody, MA, [8]Pain and Wellness Center, Peabody, MA, [9]The Center for Pain Relief, Charleston, WV, [10]Northwestern University, Chicago, IL, [11]Department of Neurosurgery, University of Illinois/Chicago, Chicago, IL

Introduction

Chronic migraine is a common and disabling complication that afflicts approximately 2% of the population (Manack et al., 2011). Peripheral nerve stimulation (PNS) of the occipital nerves is emerging as a potentially promising therapy for intractable chronic migraine patients. Identification of the risks and an understanding of the implant procedure are crucial given the novelty of this therapy. Implant and revision information from a prospective, multicenter, double-blinded, controlled study is presented.

Study Design

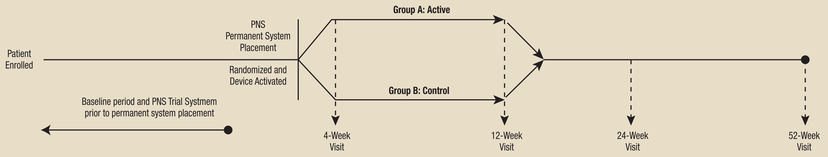


Figure 1. In this IRB-approved prospective, multicenter, double-blinded, controlled study, patients were trialed with a neurostimulation system (St. Jude Medical Neuromodulation Division, Plano, TX). Patients who had a successful trial (defined as at least 50% reduction in pain or adequate paresthesia coverage in the painful areas) were implanted with a permanent system. Patients were then randomized to an Active or Control group for 12 weeks. Patients continued in an open-label phase with 24, 48, and 52 week evaluations.

Additional Surgery Descriptions

Additional surgeries for peripheral (occipital) nerve stimulation systems are divided into several categories depending on the underlying problem and goals that the patient and physician are trying to achieve. A 'revision' procedure is a surgery that utilizes the existing implanted devices and moves them to a new location (i.e. moving IPG from one side of the body to another or moving a lead that has migrated). A 'removal' procedure is a surgery that existing implanted device(s) are removed from the patient. A 'replacement' procedure is a surgery where the existing implanted device(s) are removed from the patient and new devices are implanted.

Revision/Replacement/Explant of the Lead or Extension Only

This surgery is performed when there is documented migration of the lead, lead fracture, disconnection, superficial erosion without infection, or loss of stimulation (undesirable changes in stimulation) requiring lead repositioning. Similarly, lead revision is needed when a lead is positioned too superficially producing cosmetic disturbance or too deep resulting in muscle spasms during stimulation. The entire procedure usually takes between 30 and 60 minutes.

Revision/Replacement/ Explant of the IPG Only

This surgery is performed when there is a discomfort at the IPG site or if the device is positioned in such a way that its programming and/or charging become challenging or difficult. The entire procedure usually takes between 20 and 40 minutes. IPG replacement is similar to IPG revision. The duration of an IPG replacement procedure is between 15 and 35 minutes.

Revision/Replacement /Explant of the IPG and Lead

The entire PNS system may need to be revised when there is a combination of loss of efficacy or malfunction of the lead with either discomfort at the IPG site or challenge in telemetry or recharging of the IPG device.

Removal of the entire PNS system is needed in cases of device infection, in patients whose stimulation benefits are completely lost and could not be recovered with reprogramming or lead revision, and in those patients who improved and did not require PNS for 6 months or longer. The entire procedure usually takes between 20 and 50 minutes.

Implant Procedure

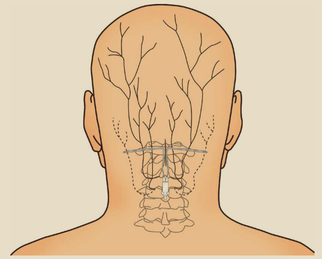


Figure 2. The implanting physicians had a choice of using one or two leads containing four electrodes spaced by 4 mm or 6 mm, or containing eight electrodes spaced by 4 mm or 6 mm. The leads were supplied in three different lengths (30, 60, and 110 cm). At the initial surgery, 150 patients (95.5%) were implanted with two leads and 7 patients (4.5%) were implanted with one lead. This figure illustrates a bilateral implant.

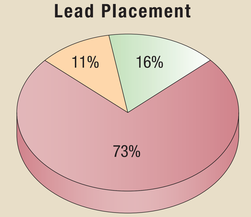


Figure 3. At the initial surgery, 150 patients (95.5%) were implanted with two leads and 7 patients (4.5%) were implanted with one lead. One hundred fifteen patients (73.2%) were implanted with the lead placed perpendicular to the nerve (from midline), 17 (10.8%) were implanted with the lead parallel to the nerve, and 25 (15.9%) were implanted with other lead placement configurations.

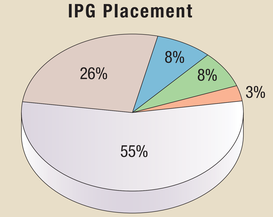
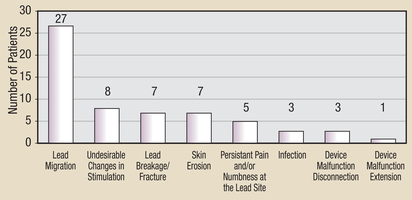


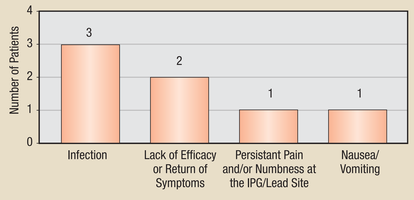
Figure 4. Implantation of the system was performed according to standard surgical procedures and according to the directions for use. The IPG was implanted at a pocket incision location at the discretion of the investigator.

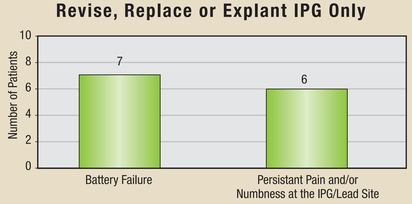
Adverse Events

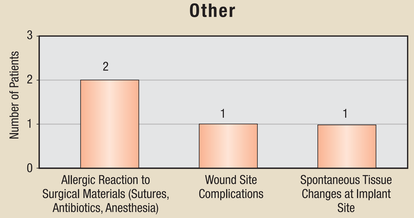
Category	Adverse Event	Controlled Phase (0–12 weeks)		Open-Label Phase (12–52 Weeks)
		Active Group (n=105)	Control Group (n=52)	All Patients (N=153)
Hardware-Related	Lead migration	15 (14.3%)	5 (9.6%)	9 (5.9%)
	Normal battery depletion	0 (0%)	0 (0%)	12 (7.8%)
	Battery failure	0 (0%)	0 (0%)	8 (5.2%)
	Lead breakage/fracture	2 (1.9%)	0 (0%)	5 (3.3%)
	Battery passivation	0 (0%)	0 (0%)	3 (2.0%)
	Device malfunction–Disconnection	2 (1.9%)	1 (1.9%)	0 (0%)
	Device malfunction–Programmer	0 (0%)	0 (0%)	3 (2.0%)
	Device malfunction–Extension	1 (1.0%)	0 (0%)	0 (0%)
	Device malfunction–IPG	0 (0%)	0 (0%)	1 (0.7%)
	IPG migration	0 (0%)	0 (0%)	1 (0.7%)
Biological	Persistent pain and/or numbness at IPG/lead site	14 (13.3%)	9 (17.3%)	15 (9.8%)
	Infection	4 (3.8%)	3 (5.8%)	4 (2.6%)
	Expected post-op pain/numbness at IPG/lead site	6 (5.7%)	3 (5.8%)	2 (1.3%)
	Skin erosion	4 (3.8%)	2 (3.8%)	2 (1.3%)
	Allergic reaction to surgical materials (sutures, antibiotic, anesthesia)	3 (2.9%)	1 (1.9%)	1 (0.7%)
	Wound site complications	3 (2.9%)	1 (1.9%)	1 (0.7%)
	Hematoma	0 (0%)	0 (0%)	1 (0.7%)
	Pain or swelling at IPG site–Trauma-related	0 (0%)	0 (0%)	1 (0.7%)
	Seroma	0 (0%)	0 (0%)	1 (0.7%)
	Subcutaneous tissue changes at implant site	0 (0%)	1 (1.9%)	0 (0%)
Stimulation-Related	Lack of efficacy/Return of symptoms	2 (1.9%)	4 (7.7%)	15 (9.8%)
	Unintended stimulation effects	6 (5.7%)	1 (1.9%)	10 (6.5%)
	Nausea/Vomiting	0 (0%)	1 (1.9%)	3 (2.0%)
	Diminished or loss of motor or musculoskeletal control	1 (1.0%)	0 (0%)	0 (0%)
	Unintended changes in headache (severity, type, or frequency)	1 (1.0%)	0 (0%)	0 (0%)
	Unintended stimulation effects–Muscle spasms/cramping	1 (1.0%)	0 (0%)	0 (0%)
Non-Device-Related	Other	8 (7.6%)	2 (3.8%)	16 (10.5%)
TOTAL		**73**	**34**	**114**

Replacements, Revisions and Explants









Eighty-five (40.7%) adverse events resulted in an additional surgery. To provide further explanation of these events, we have grouped them according to the type of additional surgery required to resolve the event. Figures 5 – 8 to the left display this information. Procedures that did not involve revision, replacement, or explant of the IPG and/or lead (other) accounted for 4.7% of all additional surgeries.

Summary and Conclusions

- A total of 157 systems were implanted
- Nine total systems were replaced, 4 were revised, and 29 were explanted
- Of the 157 IPGs, 15 were replaced and 1 was explanted
- Lead revision or replacement occurred in 33 patients
- Leads were explanted in 3 patients
- Patients underwent additional surgery to revise, explant, or replace device components in 96 cases
- The results from the study provide preliminary information on implantation technique and revision rates for PNS of the occipital nerves for the management of headache pain and disability associated with intractable chronic migraine.

References

Manack, A.N., Buse, D.C., and Lipton, R.B. (2011) Chronic Migraine: Epidemiology and Disease Burden. *Current Pain and Headache Reports*, 15, 70-78

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