Population-Based Health Utility Assessment of Migraine Headache Symptoms before and after Surgical Intervention

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Background: Approximately 30 million Americans suffer from migraine headaches. The primary goals of this study are to (1) use Migraine-Specific Symptoms and Disability criteria and Migraine Headache Index to describe the symptomatic improvement following decompressive surgery for refractory migraines, and (2) use the average Migraine Headache Index preoperatively and postoperatively for health utility assessment from a healthy patient's perspective.

Methods: The Migraine-Specific Symptoms and Disability criteria and the Migraine Headache Index were used to characterize migraine symptoms in the authors' patient population before and after decompressive surgery. Healthy individuals were randomized to a scenario in which they assumed either the preoperative or postoperative average patient symptom profile described by the authors' migraine patients. Health utility assessments were used to quantify the evaluation of health states the authors' patients experienced before and after surgical migraine therapy.

Results: Twenty-five patients underwent surgery for migraine headaches. The Migraine-Specific Symptoms and Disability questionnaire showed a significant decrease in both frequency of headaches per month ($p < 0.0001$) and overall pain score ($p = 0.007$). The Migraine Headache Index demonstrated a statistically significant improvement ($p = 0.03$). Healthy individuals in the preoperative group had significantly lower utility scores compared with the postoperative group in all of the health utility assessments completed for migraine symptoms.

Conclusion: This is the first study to use health utility assessments to attest the efficacy of decompressive therapy by demonstrating the population perspective, which perceived a significant improvement in quality of life following the surgical treatment of migraines in the authors' patients. (*Plast. Reconstr. Surg.* 145: 210, 2020.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

The National Institute of Neurological Disorders and Stroke estimates that approximately 30 million Americans suffer from migraine headaches, with women disproportionately affected by a 3:1 ratio.[1–5] Recently, a survey revealed that more than half of migraine patients suffer from severe impairment requiring bed rest. A staggering 91 percent indicated impairment to such a degree that they could not work during attacks, equating to roughly $13 billion lost annually. However, even in light of the disabling nature of migraine disease, it remains grossly undertreated.[6–9]

Approximately one-third of the migraine population believes standard pharmacologic therapies are ineffective at controlling symptoms.[10] Pharmacologic therapy focuses largely on the treatment of acute symptoms by means of continued dosing, which increases adverse effects and imposes a financial burden of $1.5 billion annually.[5,11,12] Consequently, surgical management

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targeting a combination of multiple trigger points has become increasingly popular for treating specific subgroups of people suffering chronic and intractable migraines.[13–17] Patients who fail traditional medical management have been shown to respond to botulinum toxin type A (Botox; Allergan, Inc., Dublin, Ireland) and surgical decompression of trigger points with significant reduction in migraines. Specifically, nerve decompression was found to be superior to nerve stimulation or radiofrequency with regard to success rate and complication rate.[18–20] The fundamental principle of surgical treatment is the decompression and/or removal of specific peripheral trigeminal or cervical nerve branches.[15] A review of more than 40 studies indicates favorable outcomes in 68 to 95 percent of patients undergoing surgical treatment, including the seminal work by Guyuron et al., which demonstrated 79.5 percent immediate improvement or elimination of symptoms.[13] In addition, the American Society of Plastic Surgeons released a policy statement on migraine headache surgery that evaluated the safety and efficacy of peripheral nerve/trigger-site surgery for refractory chronic migraine headache. They concluded that the surgery should be considered a standard treatment, in properly selected patients, given nearly 20 years of a high level of scientific evidence.[21] These results have held consistent with the published results of many subsequent institutions and programs.[13,14,16,17,22,23] Many of these studies compare preoperative and postoperative migraine indices using symptom frequency, intensity, and duration to calculate Migraine-Specific Symptoms and Disability criteria.

Health utility assessments have proven reliable in quantifying health states using subjective data provided by an affected patient population.[24–27] Designed for game theory, and used in economics, health utility assessments use mathematical models to determine the most rational course of action given a myriad of uncertain variables and potential outcomes.[28,29] Health utility assessments quantify the subjective preferences of individuals and groups for particular health states.[27] Therefore, preference-based health utility assessment data have impacted how physicians make clinical decisions because it serves as feedback for patient-perceived outcome satisfaction.

The severity of a disease state may be quantified using a health utility measure such as quality-adjusted life-years expressed as a continuous number between 0 (death) and 1 (perfect health).[30] Various instruments, such as visual analogue scales, standard gamble, and time tradeoff techniques, can be used to accomplish this quantification. Unfortunately, visual analogue scales suffer from end-of-scale and spacing-out bias, meaning participants avoid extremes of the scale or space scenarios out evenly regardless of the outcome.[31,32] Time tradeoff and standard gamble utilities incorporate an element of risk-to-benefit ratio and are more representative of patient preference.[33,34]

Despite their utility for determining group perspective, health utilities assessment and quality-adjusted life-year analyses have never been used to evaluate patients suffering from intractable migraines. The primary goals of this study are to use Migraine-Specific Symptoms and Disability criteria and Migraine Headache Index to describe the burden of intractable migraines in patients who qualify for decompressive surgery, before and after peripheral nerve decompression, over a mean follow-up of greater than 1 year. The preoperative and postoperative symptom profiles were used to create clinical vignettes, distributed by means of survey, to generate population-based health-related quality-of-life scores. These health-related quality-of-life scores represent the population perspective concerning postoperative improvement in symptom profile and the economic viability of surgical migraine therapy.

PATIENTS AND METHODS

Preoperative and Postoperative Symptoms of Patients Undergoing Surgery for Refractory Migraines

At our institution, 25 patients underwent surgery for migraine headaches between December 17, 2014, and January 14, 2016. Patients were offered elective decompressive surgery if they demonstrated symptoms refractory to medical management but alleviated by local nerve blocks with 1% lidocaine injection to their stated trigger areas. None of the patients had undergone prior surgical procedures to alleviate migraine headache symptoms. These patients were prospectively assessed preoperatively using Migraine-Specific Symptoms and Disability criteria to characterize their migraine symptom burden before and after surgical treatment. Postoperative symptoms were assessed at an average follow-up time of 13.1 months. Specifically, the symptoms recorded included frequency of migraine headaches per month, duration of migraine in hours per 24-hour period, and a subjective maximum pain assessment scale of 1 to 10 (where 1 was equivalent to minimal pain and 10 maximal). Patients were

asked to assess their overall migraine headache symptoms, and each entry in the questionnaire was not classified regarding each trigger site. All aspects of this study conform to the Declaration of Helsinki.

Health Utility Assessment of Preoperative and Postoperative Symptoms

Medical students at Louisiana State University Health Sciences Center, New Orleans, and Tulane University School of Medicine, were recruited to participate by means of e-mail. The participants were randomized to a scenario in which they assumed either the preoperative or postoperative symptom profile described by our migraine patients. The profiles were created from mean objective data gathered from our patients' Migraine-Specific Symptoms and Disability questionnaire results preoperatively and postoperatively. Next, we asked the participants to complete visual analogue scale, standard gamble, and time tradeoff health utilities assessments so we might quantify their evaluation of health states our patients experienced before and after surgical migraine therapy.

The visual analogue scale module prompted participants to assign a numeric value to the severity of the presented symptom profile based on a linear scale, which ranged from 1 (equivalent to death) to 100 (equivalent to perfect health). The score was divided by 100 to determine the visual analogue scale utility score. The standard gamble module presented participants with a choice to undergo surgical intervention and live in perfect health. However, the intervention carried a variable inherent risk of mortality. The mortality risk at which participants reached a point of indifference to perfect health was assessed and calculated as follows: (1.00 − risk of death at indifference)/100.[29,35] The time tradeoff module sought to determine the extent to which participants would trade life-years from the presented state of health to live the remainder of their lives in perfect health. Using a bisecting search protocol, we increased the number of years traded until the participant no longer wished to make the trade for perfect health. The time tradeoff utility score was then calculated as follows: (total life-years − years traded)/total life-years.[36]

To serve as a control, all participants completed the visual analogue scale, standard gamble, and time tradeoff health utilities assessments in presumed health states of monocular and binocular blindness. Exclusion criteria included participants who rated lower utility scores (worse quality of life) for monocular blindness compared to binocular blindness.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Version 20.0.0 (IBM Corp., Armonk, N.Y.). Independent samples t tests and Mann Whitney U tests were used to analyze statistically significant (1) changes in Migraine-Specific Symptoms and Disability criteria preoperatively and postoperatively and (2) utility score differences between group 1 compared to group 2. Statistical significance was denoted at $p < 0.05$.

RESULTS

Demographics of Migraine Patients

A total of 25 patients underwent surgery for migraine headaches (Table 1). This included 22 women (88 percent) and three men (12 percent), with an average age at surgery of 45.9 ± 15.7 years and average age at migraine headache symptom onset of 21.2 ± 13.1 years. This population consisted of individuals who were Caucasian (88 percent),

Table 1. Study Participant Demographics

Characteristic	Value (%)
Mean age ± SD, yr*	45.9 ± 15.7
Mean age at onset ± SD, yr*	21.2 ± 13.1
No. of patients	
Total	25
Female	22 (88)
Male	3 (12)
Race	
White/Caucasian	22 (88)
Hispanic/Latino	2 (8)
Other	1 (4)
Highest degree earned	
No degree	2 (8)
High school or GED	11 (44)
College	7 (28)
Advanced degree	5 (20)
Marital status	
Married	15 (60)
Divorced	5 (20)
Widowed	2 (8)
Never married	3 (12)
No. of children	
None	4 (16)
1	7 (28)
>1	14 (56)
Working status	
Full-time	13 (52)
Part-time	2 (8)
Unemployed	3 (12)
Homemaker	1 (4)
Retired	4 (16)
Preferred not to answer	2 (8)

GED, General Educational Development.
*Values presented as number of patients (%) unless otherwise specified.

married (60 percent), with multiple children (56 percent), with a minimum of a high school degree or equivalent (92 percent), and with full-time employment (52 percent). An average of 2.1 sites were treated per patient, including 84 percent frontal, 68 percent temporal, and 52 percent occipital trigger sites. Three patients developed migraine headaches in a new area following the release of another trigger site. These patients underwent surgery for the unmasked trigger site and symptoms were included in analysis, following all treatment.

Patients Demonstrated Significantly Decreased Migraine Symptoms following Surgery

The Migraine-Specific Symptoms and Disability questionnaire demonstrated that, preoperatively, patients suffered, on average, 16.3 ± 9.7 headaches per month, lasting 9.5 ± 9.3 hours, with a pain score of 7.5 ± 1.6 of 10. Postoperatively, Migraine-Specific Symptoms and Disability respondents reported, on average, 5.8 ± 4.1 migraines per month, lasting 5.6 ± 6.6 hours, with a pain score of 5.4 ± 3.6 of 10. This represented a significant decrease in both frequency of headaches per month ($p < 0.0001$) and overall pain score ($p = 0.007$) (Table 2). Calculating Migraine Headache Index (frequency of headaches × duration per headache/24 hours × severity) demonstrated a statistically significant improvement (48.4 preoperatively versus 7.3 postoperatively; $p = 0.03$). Based on large standard deviations, a nonparametric Mann-Whitney *U* test was performed (Table 3). The results show statistical significance in number of headaches per month ($p < 0.001$), pain score ($p = 0.024$), and Migraine Headache Index ($p < 0.001$). However, there failed to be statistical significance for length of headache ($p = 0.057$).

Participants of Health Utility Assessments Demonstrated a Lower Utility Score for Preoperative Symptoms Compared with Postoperative Symptoms

A total of 103 medical students completed health utility assessment controls for monocular blindness and binocular blindness, and were randomized to assume migraine symptoms similar to our surgical cohort preoperatively (16 headaches per month, lasting 9 hours, with a pain score of 7.5, $n = 51$), or postoperatively (six headaches per month, lasting 6 hours, with a pain score of 5.4, $n = 52$). Participant inclusion criteria to assess comprehension required having a lower utility score for binocular blindness compared with monocular blindness (Fig. 1). Three participants randomized to the preoperative cohort and six participants randomized to the postoperative cohort were excluded using this criterion.

There were no significant differences in monocular and binocular blindness utility scores between the preoperative and postoperative groups for visual analogue scale, standard gamble, or time tradeoff health utility assessments (Tables 4 and 5). Participants in the preoperative group had significantly lower utility scores compared with the postoperative group for the visual analogue scale (0.45 versus 0.69; $p < 0.0001$), standard gamble (0.70 versus 0.84; $p = 0.005$), and time tradeoff (0.65 versus 0.83; $p < 0.0001$) health utility assessments completed for migraine symptoms (Table 6).

Table 2. Preoperative and Postoperative Symptoms of Patients Undergoing Surgery for Migraine Headaches*

	Preoperative	Postoperative	*p*
Headaches per month	16.3 (9.7)	5.8 (4.1)	<0.0001†
Duration of headaches	9.5 (9.3)	5.6 (6.6)	0.21
Pain score	7.5 (1.6)	5.4 (3.6)	0.007†
MHI	48.4 (72.1)	7.3 (27.4)	0.03†

MHI, Migraine Headache Index.
*Values expressed as mean ± SD.
†Statistically significant.

DISCUSSION

Migraine headache pathophysiology is poorly understood; however, a large quantity of published data have suggested a link between migraine headaches and trigeminal nerve hypersensitivity.[37,38] Some theories propose that migraines are mediated by vasodilation of meningeal vasculature, which triggers somatic branches I, II, or III of the trigeminal nerve.[39] Other data suggest that medullary dorsal horn trigeminal nerve hypersensitivity

Table 3. Independent Samples by Means of Mann-Whitney *U* Test

Null Hypothesis	*p*	Decision
The distribution of headaches per month is the same across categories of preoperatively or postoperatively	<0.001*	Reject the null hypothesis
The distribution of length of headaches is the same across categories of preoperatively or postoperatively	0.057	Retain the null hypothesis
The distribution of pain score is the same across categories of preoperatively or postoperatively	0.024	Reject the null hypothesis
The distribution of MHI is the same across categories of preoperatively or postoperatively	<0.001*	Reject the null hypothesis

MHI, Migraine Headache Index.
*Statistically significant.

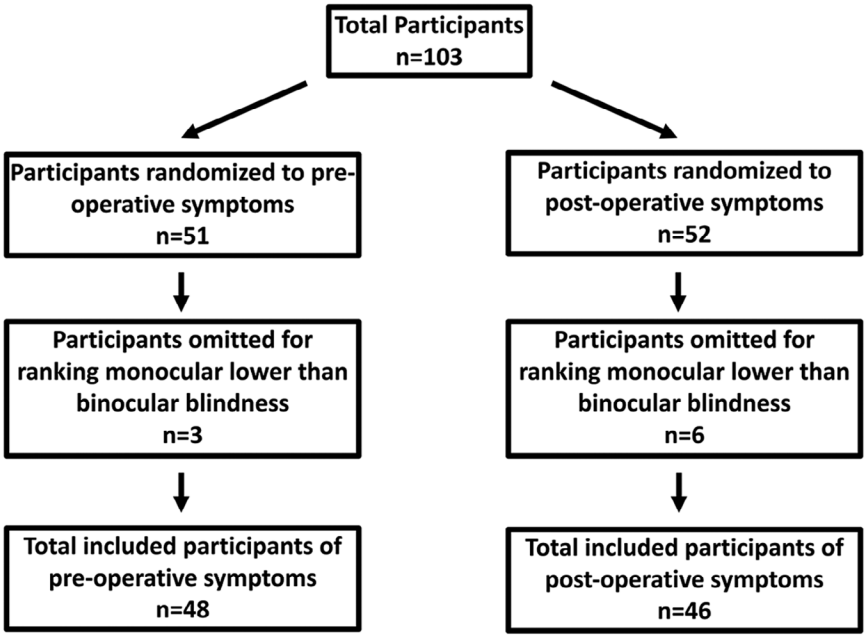

Fig. 1. Randomization of study participants and exclusion criteria. Participants were excluded if they assigned a lower quality of life for monocular blindness in comparison to binocular blindness.

Table 4. Utility Scores for Monocular Blindness*

	Preoperative	Postoperative	*p*
VAS	0.52 ± 0.20	0.51 ± 0.17	0.756
SG	0.83 ± 0.18	0.80 ± 0.23	0.497
TTO	0.77 ± 0.21	0.79 ± 0.23	0.748

VAS, visual analogue scale; SG, standard gamble; TTO, time tradeoff.
*Values presented as mean ± SD.

Table 5. Utility Scores for Binocular Blindness*

	Preoperatively	Postoperatively	*p*
VAS	0.26 ± 0.15	0.29 ± 0.13	0.400
SG	0.60 ± 0.30	0.59 ± 0.30	0.843
TTO	0.52 ± 0.27	0.56 ± 0.27	0.407

VAS, visual analogue scale; SG, standard gamble; TTO, time tradeoff.
*Values presented as mean ± SD.

translates to intracranial (i.e., dural) and extracranial (i.e., cutaneous) somatic hypersensitivity, which may trigger a migraine headache in response to mechanical stimulation.[37,40]

In 2000, Guyuron et al. incidentally discovered that patients undergoing brow lifts for cosmetic purposes experienced a decrease in migraine symptoms.[13,14] Subsequent studies investigating botulinum toxin manipulation and corrugator supercilii muscle resection have provided strong evidence that peripheral nerve compression (i.e., trigger points) may play a role in the development of migraine headaches.[13,14,16,17,19,38,41] One of the resultant studies used a double-blinded, sham-surgery investigative protocol and determined that operative trigger-point decompression may be used to treat refractory migraines with very favorable results.[16] Poggi et al. subsequently conducted a retrospective, descriptive analysis of patients who received a combination of surgical decompression of the supraorbital, supratrochlear, and greater occipital nerves to confirm prior published results.[22] A growing cache of evidence-based research supports the hypothesis that peripheral nerve compression may trigger migraines and can be treated effectively with surgery.[13,14,16,17,22,41,42]

In this study, our 25 carefully selected patients were administered a preoperative nerve block to confirm location(s) of possible peripheral nerve compression. After identification, the affected trigger points were appropriately decompressed by standard surgical method. Preoperative and postoperative assessment was conducted using the Migraine-Specific Symptoms and Disability questionnaire. Preoperatively, our patients suffered an average of 16 migraines per month that lasted an average of 9 hours per incident, reported as a 7.5 of 10 scaled pain score. Postoperatively, our patients suffered an average of six migraines per month that lasted an average of 5 hours per incident, reported as a 5.4 of 10 scaled pain score. This correlated with a significant improvement in Migraine Headache Index from 48.4 preoperatively to 7.3 postoperatively.

Table 6. Utility Scores for Migraine Headache Symptoms*

	Preoperatively	Postoperatively	*p*
VAS	0.45 ± 0.21	0.69 ± 0.18	<0.0001†
SG	0.70 ± 0.26	0.84 ± 0.22	0.005†
TTO	0.65 ± 0.27	0.83 ± 0.16	<0.0001†

VAS, visual analogue scale; SG, standard gamble; TTO, time tradeoff.
*Values presented as mean ± SD.
†Statistically significant.

The popular methodology of assessing potential peripheral nerve compression involves temporary, pharmaceutical decompression with subsequent patient feedback at a follow-up visit.[43] Janis et al. implemented an initial injection of botulinum toxin type A and instructed patients to record headache patterns and return for a follow-up appointment 30 days later. If they had a 50 percent or greater reduction in migraine symptoms, the site was identified as a trigger point. Our study implemented trial decompression using peripheral nerve blocks with 1% lidocaine in lieu of botulinum toxin. Previously published literature identifying sites of peripheral nerve compression suggests that the frontal trigger point (83.3 percent) is the most frequently encountered, followed by temporal (79.2 percent) and occipital (66.7 percent) trigger points.[17] Supraorbital rim syndrome refers to the frontal peripheral nerve entrapment responsible for frontal headache pain.[44]

Approximately 4 percent of the global population suffers from chronic migraines that are refractory to the most common abortive or prophylactic medications such as serotonin receptor agonists, ergot alkaloids, nonsteroidal antiinflammatory drugs, and opioid-derived medications.[42,45] Attempting to control migraine symptoms by serially increasing the dose of these drugs can result in a myriad of unpalatable adverse effects, including sedation, paresthesia, weight gain, cognitive impairment, cardiac arrhythmia, and sexual dysfunction.[16,38,42] D'Amico et al. classified a chronic migraine as refractory when adequate trials of preventative therapies at adequate doses have failed to reduce headache frequency and improve quality of life.[46] We believe that certain patients who complain of frequent, refractory migraines, and who are responsive to trial pharmaceutical decompression, are good candidates for surgical treatment.

Interspecialty response has been favorable, with providers embracing the surgical approach as a valid treatment of refractory migraines that does not subject the patient to expensive and potentially harmful pharmacotherapy.[13,38] On reviewing the initial report by Guyuron et al., one of the surgeon authors, after years of recurrent, languishing migraines, immediately decided to undergo corrugator supercilii muscle resection himself. He experienced an astounding 80 percent reduction in migraine symptom frequency and severity.[23] Most published data are in accordance with his findings and report that 68 to 95 percent of patients who undergo surgical decompression experience a decrease in symptom severity, whereas up to 66 percent experience complete elimination of migraine symptoms at long-term follow-up (≥1 year).[13,14,16,17,19–21,41,44]

With nearly 30 million Americans suffering from migraine headaches, and the substantial financial burden that migraines impose on society, the efficacy of migraine treatment may be ascertained through population-based, health-related quality-of-life preferences.[16,47] Population-based utility scores represent how unaffected persons interpret the improvement in health-related quality of life sustained by patients who underwent surgical treatment for refractory migraines. The control group was divided into two groups: one receiving a health utilities assessment representing the symptomatology of our patients preoperatively ($n = 51$) and the other representing the symptomatology of our patients postoperatively ($n = 52$). Each health utility assessment was composed of three evaluation tools—visual analogue scale, standard gamble, and time tradeoff—to represent patient quality of life either before or after surgical therapy. The preoperative group demonstrated significantly decreased visual analogue scale, standard gamble, and time tradeoff utilities scores compared with the postoperative group. The health utility assessment described above, using symptomatic improvements observed in our migraine patient population, offers validation, by means of the population perspective, that quality of life for patients suffering from refractory migraine headaches is significantly improved by surgical therapy. The focus of this study was not econometric, but other studies have shown the economic burden associated with migraines. Although surgical management of chronic migraines has higher initial costs, overall it is more cost-effective in terms of long-term direct or indirect costs compared with other treatment modalities.[48] Although no specific correlation has been studied between health-related quality-of-life points and economic burden, chronic migraines were significantly associated with higher disability, lower related quality of life, and greater health care resource use and productivity loss compared with episodic migraines.[49]

This study supports previously published literature touting the efficacy of decompressive surgical therapy for treating refractory migraines in appropriately selected patients. A substantial portion of our patients (73 percent) reported greater than 75 percent symptomatic improvement, with 32 percent of our patients achieving complete resolution of symptoms, similar to published data.[19] Despite the mounting evidence of the efficacy of surgical decompression, a weakness of this study is that we have not been able to address the characteristics of nonresponders preoperatively, despite symptomatic resolution using local nerve blocks. This may be because of possible multifactorial causes of migraines in certain patients that include central and peripheral nervous system processes. Medication-overuse headache is a commonly described phenomenon in patients with migraines that leads to a decline in quality of life with great comorbidity of depression and anxiety.[50,51] Patients undergoing surgery for migraine headaches tend to be on multimodal medical therapeutics at the time of surgery. This may explain the subset of patients that do not respond to surgery because of medication overuse, and this would have to be addressed in future studies. Initiating educational and behavioral therapies previously described to improve medication-overuse headaches in the patients undergoing surgical decompression may further improve symptomatology postoperatively, which will have to be addressed in future studies. Medication overuse has poor response to nerve blocks. Prednisone and celecoxib, being no different in efficacy, are more appropriate for management of medication overuse.[52,53]

CONCLUSIONS

This is the first study to use visual analogue scale, time tradeoff, and standard gamble to attest the efficacy of decompressive therapy by demonstrating the population perspective, which perceived a significant improvement in quality of life following the surgical treatment of migraines in our patients. Therefore, we feel that surgical therapy is a useful tool for treating refractory migraines in the majority of patients with symptoms refractory to medical management but who respond to local nerve blocks.

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