Original Article

# A comparison of outcome of medical and surgical treatment of migraine headache: In 1 year follow-up

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## Abstract

**Background:** This study was designed to compare the efficacy of the medical treatment versus the surgical treatment approach to decompression of trigger point nerves in patients with migraine headaches.

**Materials and Methods:** Fifty volunteers were randomly assigned to the medical treatment group ($n = 25$) or the surgical treatment group ($n = 25$) after examination by the team neurologist to ensure a diagnosis of migraine headache. All patients received botulinum toxin type A to confirm the trigger sites. The surgical treatment group underwent surgical deactivation of the trigger site(s). The medical treatment group underwent prophylactic pharmacologic interventions by the neurologist. Pretreatment and 12-month posttreatment migraine headache frequency, duration, and intensity were analyzed and compared to determine the success of the treatments.

**Results:** Nineteen of the 25 patients (76%) in the surgical treatment group and 10 of the 25 patients (40%) in the medical treatment group experienced a successful outcome (at least a 50% decrease in migraine frequency, duration, or intensity) after 1 year from surgery. Surgical treatment had a significantly higher success rate than medical treatment ($P < 0.001$). Nine patients (36%) in the surgical treatment group and one patient (4%) in the medical treatment group experienced cessation of migraine headaches. The elimination rate was significantly higher in the surgical treatment group than in the medical treatment group ($P < 0.001$).

**Conclusions:** Based on the 1-year follow-up data, there is strong evidence that surgical manipulation of one or more migraine trigger sites can successfully eliminate or reduce the frequency, duration, and intensity of migraine headaches in a lasting manner.

**Key Words:** Medical treatment, migraine headache, migraine headache index, surgical treatment

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## INTRODUCTION

Migraine headaches are a common and debilitating disorder.[1-7] Current studies have estimated that migraine headaches affect about 12% of the entire population, indicating a prevalence of 18% of women and 6% of men.[7-13] On average, one of every four households has someone who suffers from migraine headaches.[7-9] The prevalence of migraine headache is highest in patients aged 25-55 years, corresponding to the peak years of work productivity and childbearing.[2,7,9,14,15]

The symptoms can last from 4 h to several days and can include recurrent unilateral or bilateral throbbing pain, nausea, vomiting, photophobia, and phonophobia.[9,13] Most migraine sufferers manage migraine headaches with pharmacologic interventions.[8-10] There is no

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widely accepted permanent cure at this time, and many patients continue to experience symptoms even under pharmacologic treatment.[16,17] Furthermore, approximately one-third of migraine sufferers are not helped by standard therapies.[18-20] The preventive and abortive pharmaceutical agents have associated adverse effects and are often very costly.[20,21] The most common treatments available for migraine headaches today include a combination of avoidance of common migraine triggers, prophylactic pharmacologic interventions, acute abortive therapy, and acute analgesic therapy.[8-12] Pharmacologic substances commonly used to treat migraine headache include beta blockers, antidepressants, anticonvulsants, calcium channel blockers, and serotonin antagonist.[22] Alternative treatment options, such as injections of botulinum toxin type A at migraine headache trigger sites, are used to prevent and alleviate migraine headaches.[22-29]

Although the pathophysiology of migraine headaches remains controversial, studies have shown that irritation of the trigeminal nerve causes the release of calcitonin gene-related peptide and neurokinin A into the cell bodies of the trigeminal nerve.[13,30] These substances induce inflammation and pain in the areas around the trigeminal nerve.[13,17,30,31] Bahman Guyuron's theory is that the musculature, vessels, bony foramen, and possibly fascia bands around the trigeminal nerve branches in the head and neck irritate the nerves, leading to inflammation.[9,17,31] Anatomical studies have supported the potential for such irritation.[23-27,32-34] Based on this theory, surgical treatment of migraine headaches has evolved to include the removal of various surrounding superficial muscles, fascia, or vessels to reduce irritation to the nerve, resulting in the reduction of migraine headaches.[9,17,31,35,36] Migraine surgery can be performed at four common trigger sites: Frontal, temporal, septonasal, and occipital.[9,17,21,25,31,34-39]

The purpose of this study was to evaluate and compare the effectiveness and success rates of surgical treatment of nerve decompression and medical treatment in the reduction of migraine headaches.

## MATERIALS AND METHODS

This study is a clinical trial. Approval for this study was obtained from the Isfahan University of Medical Sciences Institutional Review Board. The recruited volunteers with moderate to severe headaches were examined by a team of neurologists to ensure the diagnosis of migraine headache in accordance with the guidelines established by the International Headache Society. A total of 50 volunteers met the initial criteria. A random allocation method was used to randomize the study and patients underwent detailed evaluation to identify their trigger sites. It was a single-blind study, as there was no information about the method of treatment among the patients, the decision being made by the treatment team. The patients were then asked about the most common focal site of onset of their migraine headache (migraine trigger sites). These trigger sites were palpated to detect any tenderness. For the nasal trigger site, examination of the internal nose was undertaken to observe the septum and the inferior turbinates; if applicable, the presence of enlarged turbinates and the type of septal deviation were documented. The observed intranasal pathology was confirmed with a computerized tomography (CT) scan. All patients received injections of botulinum toxin type A (Botox; Allergan, Irvine, CA, USA.) into three of the four trigger sites (frontal, temporal, and occipital) in a logical, stepwise manner; the most prominent site was injected first to provide confirmation.

The patients were included if the migraine was approved for the study by a neurologist or if their disease was not controlled by previous treatment. The other inclusion criteria included the patients' satisfaction to participate in the study; no associated diseases such as diabetes, hypertension, etc., no pregnancy, and no history of sensitivity to Botox (if used before). If the patients did not want to continue the study or showed side effects from the medications used in the drug treatment group they were excluded.

All patients enrolled in the study were asked to complete the Migraine Headache Assessment Questionnaire before treatment and at 12 months posttreatment follow-up visits. These self-reported questionnaires assess the frequency (migraines per month), duration (in days), and intensity (based on a Visual Analog Scale (VAS) from 1 to 10, with 10 being the most severe) of migraine headaches experienced by each patient before and after treatment. The recorded information for each visit also included the calculation of a migraine index using the following formula: (frequency × duration × intensity).

Medical therapy with prophylactic drugs was performed by a team of neurologists on the medical treatment group. The neurologists prescribed Inderal (80 mg once daily) and amitriptyline (100 mg per day) to treat the patients.

Surgery in the surgical treatment group was performed on one or any combination of trigger sites in the same setting. For patients with frontal headaches (trigger site I), the glabellar muscles, including the corrugator supercilii, depressor supercilii, and the

lateral portion of the procerus, which surround both the supraorbital and the supratrochlear nerves, were removed using either a transpalpebral or an endoscopic forehead approach. For patients with temporal headaches (trigger site II), approximately 2.5 cm of the zygomaticotemporal branch of the trigeminal nerve was removed using an endoscopic approach. For patients with migraines originating from the septum (trigger site III), septoplasty and/or turbinectomy was performed based on anatomic abnormalities seen on CT imaging. For patients with occipital headaches (trigger site IV), a portion of the semispinalis capitis muscle was removed to release the greater occipital nerve bilaterally and shielding of the nerves with a subcutaneous flap to fully decompress the greater occipital nerve was done, with removal of the occipital artery when it was entangled with the nerve.

Data collected included demographic information (age, sex, alcohol use, and smoking history) and migraine-specific information from both pretreatment and posttreatment questionnaires (frequency, duration, intensity, location, aura, trigger points, onset of migraine headache). A migraine headache index score was calculated by multiplying frequency, duration, and intensity of migraine headaches. Headache severity was evaluated by VAS with five degrees (score of 0 denoting "no pain," 1-3 "mild pain," 3-7 "moderate pain," 7-9 "severe pain," and a score of 10 the "worst pain possible"). A successful treatment was defined as a decrease by 50% or more in the migraine headache index after 12 months. Elimination was defined as a migraine headache index of 0 after 12 months.

The success and elimination rates in the medical and surgical treatment groups were compared using Chi-square tests. Trigger points were compared using Fisher's exact test in both groups. In addition, *t*-tests were performed to compare mean reductions in frequency, duration, intensity, and migraine index within and between the medical and surgical treatment groups. A *P* value less than 0.05 was considered significant. Statistical analyses were performed using SPSS version 22.

## RESULTS

There were a total of 50 patients included in this study. The follow-up ranged between11 months and 15 months, with a mean follow-up of 12 months. Of these 50 patients who underwent treatment for migraine headaches, 25 received medical treatment and 25 underwent surgical treatment. Demographic data related to each group are listed to the Table 1.

There was no significant difference in gender (medical treatment group, 80% female; surgical treatment group, 88% female; $P > 0.05$), average age (medical treatment group, 44.00 ± 7.6; surgical treatment group, 42.2 ± 6.9; $P > 0.70$), alcohol use and smoking status (medical treatment group, 16%; surgical treatment group, 12%; $P > 0.99$), and mean duration of onset of migraine headaches (medical treatment group, 20.3 ± 7.5 years; surgical treatment group, 18.5 ± 10.2 years; $P > 0.36$) between the two groups [Table 1]. Also there was no significant difference in percentage of migraine headache with aura (medical treatment group, 28%; surgical treatment group, 32%; $P > 0.99$), between the two groups [Table 1].

According to Fisher's exact test, the frequency distribution of trigger points was not significant between the two groups, ($P = 0.99$) [Table 2].

Pretreatment and posttreatment migraine headache parameters were analyzed for all patients in both groups. In pretreatment, there was no significant difference in frequency (medical treatment group, 15.21 ± 3.11 per month; surgical treatment group, 15.91 ± 3.31 per month; $P = 0.49$), duration (medical treatment group, 1.02 ± 0.42 day; surgical treatment group, 1.05 ± 0.46 day; $P = 0.75$), intensity (medical treatment group, 8.42 ± 0.30; surgical treatment group, 8.31 ± 0.28 on VAS; $P = 0.78$), or migraine headache index score (medical treatment group, 131.50 ± 54.10; surgical treatment group, 134.00 ± 41.70; $P = 0.86$) between the two groups [Table 3].

At 1-year follow-up, a significant reduction for all parameters analyzed was seen in an all

**Table 1: Patient characteristics**

| Characteristics of patients and migraine headache | Medical treatment group (%) | Surgical treatment group (%) | *P* value |
|---|---|---|---|
| No. of patients | 25 | 25 | |
| Mean of age, years | 44±7.6 | 42.2±6.9 | 0.38 |
| Percentage of female patients | 80 (20) | 88 (22) | 0.7 |
| Alcohol or tobacco use | 16 (4) | 12 (3) | 0.99 |
| Migraine headache with aura | 28 (7) | 32 (8) | 0.99 |
| Onset of migraine headache, years | 20.3±7.5 | 18.5±10.2 | 0.36 |

**Table 2: Percent of trigger points of migraine headache in treatment groups**

| Type of trigger point | Medical treatment group (%) | Surgical treatment group (%) | *P* value |
|---|---|---|---|
| Trigger point I | 60 | 64 | 0.99 |
| Trigger point II | 20 | 20 | 0.99 |
| Trigger point III | 8 | 4 | 0.99 |
| Trigger point IV | 12 | 12 | 0.99 |

patients in the two groups, when compared with pretreatment values [Table 4]. However, a direct comparison of outcomes between the two groups demonstrated a significant improvement in the surgical treatment group over the medical treatment group with regard to the following: Headache frequency, 6.41 per month (-59.69%) versus 10.51 per month (-30.91%), ($P < 0.001$); duration, 0.47 day (-55.24%) versus 0.83 day (-18.65%), ($P < 0.001$); intensity, 4.06 (-51.15%) versus 6.01 (-29.01%), ($P = 0.001$); and migraine headache index scores, 11.81 (-91%) versus 52.40 (-60%), ($P < 0.001$), [Table 4].

Of the 25 medical treatment patients, 10 (40%) experienced a reduction by 50% or greater in the migraine headache index score, with one (4%) experiencing the cessation of migraine headaches. Of the 25 surgical treatment patients, 19 (76%) experienced a migraine headache index score reduction by 50% or more, with nine (36%) experiencing elimination. The success rate (percentage of patients who experienced ≥50% reduction in migraine headaches) of surgical treatment (76%) was significantly higher than that of medical treatment (40%; $P < 0.001$). The elimination rate after surgical treatment (36%) was also significantly higher than that after medical treatment (4%; $P < 0.001$), [Table 5].

There were no complications in either the surgery or the drug treatment group. Also, there was no case of a patient experiencing more severe posttreatment headache in either group.

**Table 3: Comparison of pretreatment migraine headache characteristics by groups**

| Characteristics of migraine headache | Medical treatment group | Surgical treatment group | *P* value |
|---|---|---|---|
| Frequency (migraine headaches/month) | 15.21±3.11 | 15.91±3.31 | 0.49 |
| Duration (days) | 1.02±0.42 | 1.05±0.46 | 0.75 |
| Intensity (visual analog scale 0-10) | 8.42±0.30 | 8.31±0.28 | 0.78 |
| Migraine headache index score | 131.50±54.10 | 134.00±41.70 | 0.86 |

**Table 4: Comparison of posttreatment migraine headache characteristics by groups at 1-year follow-up**

| Characteristics of migraine headache | Medical treatment group | Surgical treatment group | *P* value |
|---|---|---|---|
| Frequency (migraine headaches/month) | 10.51±2.20 | 6.41±2.33 | <0.001 |
| Duration (days) | 0.83±0.31 | 0.47±0.25 | <0.001 |
| Intensity (Visual analog scale 0-10) | 6.01±0.24 | 4.06±0.18 | =0.001 |
| Migraine headache index score | 52.40±23.98 | 11.81±9.03 | <0.001 |

**Table 5: Comparison of success and elimination rates of surgical versus medical treatment of migraine headaches at 1-year follow-up**

| Results of treatment | Medical treatment group (%) | Surgical treatment group (%) | *P* value |
|---|---|---|---|
| Success rate | 10 (40) | 19 (76) | <0.001 |
| Elimination rate | 1 (4) | 9 (36) | <0.001 |

## DISCUSSION

This study was designed to assess and compare the success of the surgical deactivation of migraine headache trigger points versus medical treatment of migraine headaches. The 1-year follow-up data reported here provide strong evidence that surgical deactivation of one or more trigger sites can successfully eliminate or reduce the frequency, duration, and intensity of migraine headache, and that the results are enduring. Although medical therapy affords patients and physicians some control over their migraine headaches, complete elimination of migraine headaches for prolonged periods of time is often not possible.[9-14] In addition, pharmacologic interventions have numerous side effects and comorbidities, such as fatigue, dizziness, cardiovascular arrhythmias, and hepatotoxicity.[22]

The use of alternative treatments by patients with migraine headaches to complement traditional medical therapies may include Botox injections, massage therapy, acupuncture, biofeedback, and chiropractic services.[8,10,16]

In a study by Bahman Guyuron *et al.*, it was demonstrated that the surgical deactivation of migraine trigger sites is a cost-effective approach to the treatment of migraine headache.[9,16] After deactivation, patients can expect to spend less on drug therapy and alternative treatment modalities and may require fewer doctor and emergency room visits.[9,16] The researchers also demonstrated that patients showed an increase in the number of days spent at work and within the household and had improvements in their overall productivity.[9,16]

Decompression of the four main peripheral trigger sites (i.e., frontal, temporal, septal/turbinates, and occipital) in the treatment of migraine headaches has a reported success rate of between 75% and 92% of patients.[17,18,31,35-43] Migraine surgery is a novel approach for the patients suffering incapacitating episodes of migraine headache.[17,31,35-43] Importantly, surgery for migraine headache is not first-line therapy but is reserved only for those patients who are inadequately treated with conventional regimens

that include multiple attempts with pharmacologic and behavioral interventions.[9,17] In addition, because migraine attacks have been associated with a variety of causes, patients qualify for migraine surgery only if discrete peripheral nerve trigger points are identified by injection of botulinum toxin and careful physical examination.[37,38,41,42] Migraine surgery is not indicated for treatment of acute migraine headache and should instead be viewed as a prophylactic measure.[9]

There is interest in migraine surgery among a subset of plastic surgeons who affirm an understanding of the available evidence supporting its practice.[9] A significant barrier to performing migraine surgery appears to be referral pattern.[9] Increased referral of suitable patients by neurologists and improved familiarity with the concept and techniques of migraine surgery may motivate more plastic surgeons to perform migraine surgery.[9]

The limitations of the study were the lack of complete awareness among the neurologists about the surgical techniques of migraine treatment and the fact that patients were not referred for surgery, which resulted in a small sample size. With more improvement in intergroup relations and growing familiarity with this kind of treatment among the neurologists and plastic surgeons and further studies with more samples, more desirable results can be achieved in future.

## CONCLUSIONS

Surgical deactivation of migraine headache trigger sites is an effective treatment modality for improving symptoms of migraine headache.[9,12,37-43] Patients who fail optimal medical management and experience amelioration of headache pain after injection of botulinum toxin at specific anatomical location of trigger points can be considered for subsequent surgery to decompress the entrapped peripheral nerves.[9,18] Migraine surgery is an exciting prospect for appropriately selected patients suffering from migraine headache and will continue to be a burgeoning field that is replete with investigative opportunities.[9,18]

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