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The importance of surgical maneuvers during treatment of frontal migraines (site I): A prospective, randomized cohort study evaluating foraminotomy/fasciotomy, myectomy, and arterectomy



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KEYWORDS

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Summary Background: The current prospective, blinded, randomized cohort study aims to delineate the relative contribution of different surgical treatments for frontal migraines.

Methods: Patients undergoing migraine surgery in the frontal region (site I) were prospectively enrolled and blindly randomized into one of the following four groups: (1) myectomy alone, (2) myectomy and foraminotomy/fasciotomy, (3) myectomy and arterectomy, and (4) foraminotomy/fasciotomy alone. Pre- and post-surgical migraine headache severity, duration, Migraine Headache Index (MHI) score, and migraine-free days (MFDs) were obtained.

Results: Thirteen patients agreed to participate in the study. For all patients, the mean pre- and post-operative MHI scores demonstrated a significant improvement from 52.6 (3.8–85) to 4.7 (0–21.3) ($p = 0.0001$). Thirty-one percent of patients required a site I revision that included an arterectomy. Patients who had an arterectomy at their initial surgery demonstrated statistically significant improvement in both frequency (12 vs. 6.11; $p = 0.02$) and MHI scores (51.71 vs. 5.55; $p < 0.01$). Arterectomy patients also demonstrated a significant improvement in the number of MFDs following surgery, from 18 to 24 MFDs ($p = 0.021$). Those patients not undergoing arterectomy demonstrated statistically significant improvements in the number of MFDs after their initial surgery (13.25 MFDs, $p = 0.01$), but the improvement was significantly less when compared to the arterectomy group (13.25 vs. 24 MFDs; $p = 0.026$). Following revision arterectomy, both groups had statistically equivalent improvement in MFDs (20.75 vs. 24 MFDs; $p = 0.178$).

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Conclusions: These findings suggest that arterectomy is necessary for successful treatment of frontal migraines (site I).

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Background

Migraine is a common and debilitating primary headache disorder affecting approximately 12% of American adults, with 22% of those suffering moderate or severe disability and resulting in a total of 112 million bedridden days and close to \$14 billion in direct and indirect costs in the United States annually.¹⁻³ The “gold standards” of migraine treatment continue to be pharmaceutical and behavioral. However, 5.1% of patients in a headache clinic population have symptoms that meet criteria for “refractory migraines,” which are unresponsive to optimal medical management.⁴ Additionally, there are patients who are unable to tolerate medical treatment and may even prefer surgery over the negative side effects associated with pharmacologic therapies.

There is a mounting body of evidence demonstrating superior outcomes following migraine surgery when compared to traditional management. Our research has shown that 80–90% of appropriately selected patients, despite previously failed non-surgical treatment, will achieve at least a 50% improvement in frequency, severity, duration, and migraine-free days (MFDs). Despite these promising results, there is a significant portion of the scientific community that is critical of the surgical treatment of migraine headaches, and they dismiss it as either controversial or experimental.⁵⁻⁹ These claims are largely unfounded and are inconsistent with published studies to the contrary, which include retrospective,⁵ prospective,⁸ comprehensive prospective randomized,⁶ prospective randomized with sham surgery,¹⁰ and 5-year follow-up⁷ studies. These studies have been unfairly criticized for flaws in design and arguments that patients were not appropriately selected. These unjustified claims are made in direct contradiction to peer-reviewed, published studies that were designed and analyzed by reputable biostatisticians. In addition, patients were selected by respected, board-certified, fellowship-trained neurologists. Previous study results were collected and analyzed independently by a nurse coordinator and dedicated biostatistician, respectively. Another common and unsubstantiated claim is that these results represent a placebo effect, which has been extensively addressed on a study-by-study basis by the senior author.⁹ Therefore, the claim that an over 50% improvement in 80–90% of the patients sustained over 5 years can be attributed solely to a placebo effect is scientifically unfounded.

Modern migraine surgery is the product of an observation by patients who underwent forehead rejuvenation and noticed improvement and sometimes complete elimination of their migraine headaches. Similarly, patients have observed these same effects following injection of botulinum toxin-A in the forehead; however, it was not clear which component of surgery had the most important role in the elimination of headaches. Frontal migraine headaches, believed to originate from compression or irritation of the

supraorbital and supratrochlear nerves in the brow area (migraine site I),⁸ represent the most commonly reported trigger site in the senior author’s surgical patient population.⁷ This area can be treated in several different ways: (1) resection of the glabellar muscle group, consisting of corrugator supercilii, depressor supercilii, and lateral procerus (myectomy), (2) removal of any arteries in close proximity to the nerves (arterectomy), and/or (3) decompression of the nerves at their exit from the skull through bony foramina or notches (foraminotomy/fasciotomy). Each of these decompression techniques can be performed alone or in combination. The current prospective, randomized cohort study aims to delineate the relative efficacies of each of these previously described surgical techniques at the frontal headache trigger site.

Methods

After obtaining Institutional Review Board approval, patients undergoing migraine site I surgery at the senior author’s practice, following informed, written consent, were prospectively enrolled to undergo randomization into one of the following four groups: (1) myectomy alone, (2) myectomy and foraminotomy/fasciotomy with or without arterectomy, (3) myectomy and arterectomy, and (4) foraminotomy/fasciotomy alone. Surgeries were performed as previously described.^{11,12}

To randomize patients, a biostatistician prepared serially numbered, opaque, sealed envelopes containing randomly ordered instruction cards, which were drawn by the senior author in the operating room immediately preceding surgery. Patient enrollment and data collection were performed by a clinic nurse who was blinded to the patients’ study conditions. Furthermore, patients themselves remained blinded to their own study conditions until the follow-up period was completed. All patients were evaluated for migraine headache frequency (number of headaches per month), severity (on a scale from 0 to 10), duration of headaches (hours per day), and Migraine Headache Index (MHI) score (calculated by multiplying frequency, duration, and severity) pre-operatively and at post-operative follow-up. Self-reported MFDs were also recorded according to the normal post-operative follow-up of the senior author’s practice. Patients who did not achieve a clinically significant reduction in their MHI scores were offered a revision surgery to address any remaining sites of potential nerve compression. Post-revision frequency, severity, duration, and MHI scores were also collected for patients requiring revision.

Statistical analysis was performed using SPSS (SPSS Inc.; Chicago, IL, USA) using paired Student’s t-test and Fischer’s exact for parametric and non-parametric continuous variables.

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