Original Article

Comparison of the Effectiveness of Neurolysis and Neurectomy of the Greater Occipital Nerve in the Treatment of Chronic Refractory Migraine: A Randomized Clinical Trial

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ABSTRACT

Background: Migraine is a chronic and debilitating disease that, despite therapeutic advances, many patients do not respond to conventional treatments. Surgeries such as neurolysis and neurectomy of the greater occipital nerve (GON) have been proposed as surgical options for treating these patients. We aimed to compare the effectiveness of these two methods in reducing symptoms of chronic treatment-resistant migraine.

Methods: This study was conducted as a randomized, prospective clinical trial. Ten patients with chronic treatment-resistant migraine were divided into neurolysis and neurectomy groups. Primary and secondary outcomes including pain intensity using the Visual Analog Scale (VAS), migraine-related disability using the Migraine Disability Assessment (MIDAS) questionnaire, and headache impact on quality of life using the Headache Impact Test (HIT-6) questionnaire were evaluated at intervals of one month, three months, and six months after surgery.

Results: No significant difference was observed between the neurolysis and neurectomy groups in HIT-6, MIDAS scores, and pain intensity (VAS) at any of the measurement times (P-value>0.05). Also, using the Friedman test, no significant difference was observed between the three measurement stages in either group (P-value>0.05). For both pain intensity (VAS) and MIDAS variables, the changes observed over time were not significant, and there was no significant difference between the two groups at any time point.

Conclusion: Both neurolysis and neurectomy methods might be considered as effective treatment options for patients with chronic treatment-resistant migraine. Personalized treatment and team decision-making are helpful in selecting the appropriate surgical method for patients with chronic migraine.

KEYWORDS
Neurectomy; Neurolysis; Migraine; Surgery

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INTRODUCTION

Migraine, as one of the most common and debilitating neurological diseases, affects millions of people worldwide. This disease severely reduces patients' quality of life and imposes a significant economic and social burden on communities [1]. The global prevalence of migraine is around 14 to 15% [2], and this disease is recognized as the second leading cause of disability in the general population and the first disabling factor in women under 50 years of age [3]. In Iran, the prevalence of migraine in the general population is estimated to be about 15.1% [4]. Migraine attacks are accompanied by symptoms such as severe headache, nausea, vomiting, and sensitivity to light and sound, and can significantly affect patients' personal, social, and occupational functioning [5].

Despite significant advances in pharmacological treatments, many patients do not respond appropriately to conventional treatments or suffer from side effects of these medications [6]. This has led to alternative treatment methods, including surgical interventions, receiving attention [7]. In recent years, numerous studies have examined the effectiveness of various surgical procedures in treating chronic and treatment-resistant migraine. These studies have shown that migraine surgery, especially in patients who do not respond to pharmacological treatments, can be an effective and safe option. Migraine surgery can significantly reduce headaches' frequency, duration, and intensity and improve patients' quality of life [8]. However, there are significant differences in patient selection and a wide variety of surgical methods, indicating the need for more studies to determine the best treatment approach.

For example, some research has shown that surgical methods such as ganglionectomy can create a significant reduction in pain intensity[9]. In contrast, less invasive procedures such as radiofrequency erosion and cryoablation, although having fewer complications, may result in less pain reduction [10]. Overall, existing evidence suggests that migraine surgery can be considered as an effective treatment option for patients with chronic and drug-resistant migraine. Still, there is a need for more studies and more precise comparisons of different methods and determination of the best treatment approach for patients with treatment-resistant migraine.

Among surgical methods, neurectomy and neurolysis of the greater occipital nerve (GON) have been proposed as treatment options for patients with chronic and treatment-resistant migraine [11]. Neurectomy involves physically cutting the GON nerve, while neurolysis means releasing the nerve from pressure from adjacent structures such as muscles and vessels. Both methods aim to reduce pain signal transmission to the brain and improve migraine symptoms [12]. Despite previous studies, the superiority of these methods over each other has not yet been determined.

Due to the significance of this topic and the necessity for more evidence to establish the optimum treatment method, we aimed to compare the outcomes of neurectomy versus neurolysis of the greater occipital nerve for treating migraine patients. It is hoped that the findings of this research will aid in establishing more effective treatment methods and enhancing the quality of life for individuals suffering from migraines.

METHODS

Randomization and Blinding

This study was conducted as a prospective, double-blind, randomized clinical trial. Randomization was performed by a researcher not involved in patient care using a computer-generated random number table. Eligible patients were randomly assigned to the Neurolysis or Neurectomy groups. Both patients and outcome assessors remained blinded to group assignment throughout the study to minimize bias.

Study Population, Interventions, and Outcome Measures

Patients with chronic migraines that did not respond to medication and Botox injection, who had been referred to Sina and Imam Khomeini educational and medical centers' headache clinic, Tehran, Iran were enrolled. Sampling was carried out by census method due to the small size of patients fitting the inclusion of the study. The inclusion criteria were aged over 18 years, having a diagnosis of chronic migraine with onset from the occipital area, and willingness to join the study. The exclusion criteria were head and neck surgery, active malignancy, and chronic intake of anti-inflammatory medication.

The tools used to collect data were a demographic

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checklist, the Visual Analog Scale [13] (VAS) to determine the severity of pain, the Migraine Disability Assessment questionnaire [14] (MIDAS), and the Headache Impact Test questionnaire [15] (HIT-6). The VAS is a straightforward and commonly used method for measuring the severity of pain. It consists of the scale of 10 centimeters with "no pain" (0 score) written on one end and "worst possible pain" (10 score) written on the other. Patients identify the intensity of their pain on this line. Its acceptable reliability and validity in Iran have also been established with a Cronbach's alpha coefficient of 0.89 [16].

The MIDAS is a self-report questionnaire used to evaluate migraine-associated disability in three main areas: work, household chores, and social activities. The MIDAS includes five questions that estimate the number of days of migraine-related impairment in the three months prior.

The overall MIDAS score is graded into four grades of disability: low, mild, moderate, and severe. Nasirzadeh et al. conducted a validation study of the MIDAS questionnaire in Iran. The findings of this research were that the scale has a very high reliability as supported by the achievement of a Cronbach's alpha coefficient of 0.85. Content validity and construct validity of the questionnaire have also been determined [17]. HIT-6 questionnaire is a reliable and brief scale for assessing headache impact on quality of life among patients. This 6-question survey assesses the impact of headaches on various domains, including daily life, work ability, and emotional state of the patients. The overall HIT-6 score is categorized into four levels of impact: low, moderate, severe, and very severe. Mohammadi et al. validated the HIT-6 questionnaire in Iran. It was demonstrated that this questionnaire is valid, with a Cronbach's alpha coefficient of 0.87, as described above. In addition, this questionnaire's construct and content validity have been determined [18]. After identifying eligible patients, the diagnosis of chronic migraine was confirmed, by the headache specialist, in line with the International Classification of Headache Disorders criteria [19] (ICHD-3). To confirm that the headache emanated from the occipital area, patients were asked to mark the site of headache onset on a sheet provided. Provided that at least 80 percent of headache attacks during the last month had started in the occipital area, a GON block was performed using a mixture of lidocaine and 0.5% bupivacaine. Block success (more than 50% decrease in headache frequency and severity over two weeks after the block) was used as the ultimate study inclusion criterion.

In the Neurolysis Group, the greater occipital nerve was freed from all surrounding structures like muscles and blood vessels to prevent pressure on the nerve. By contrast, in the Neurectomy Group, a piece of the greater occipital nerve was severed surgically in an attempt to cut off nerve impulses carrying the pain to the brain. Each procedure was undertaken under general anesthetic. The greater occipital nerve was located in the suboccipital region, approximately 1.5 cm lateral to the midline and beneath the trapezius fascia, whereupon the respective intervention was done.

Both primary and secondary endpoints were pain severity (on VAS), migraine-related disability (on MIDAS), headache impact on quality of life (on HIT-6), and postoperative complications. These endpoints were assessed preoperatively, as well as 1, 3, and 12 months after surgery. Statistical analysis was done by SPSS version 24 software (IBM Corp., Armonk, NY, USA). Quantitative data were presented as Mean ± SD and the first-third quartiles and qualitative data as frequency percentages. For comparing quantitative variables, the Kolmogorov-Smirnov test was initially applied for testing the normal distribution. As a result of the non-normal distribution found, the non-parametric Mann-Whitney test was utilized for comparing between the two treatment groups and, non-parametric Wilcoxon test was used to compare quantitative variables before and after 6 months, while the Friedman test was utilized for comparison across the different time points and Chi-square (Fisher's exact) test was used to compare gender in the two groups. All tests were conducted with a 5% level of significance.

The study was carried out in congruence with the ethical principles of the Helsinki Declaration. Ethics Approval and Trial Registration

This study was approved by the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.SINAHOSPITAL.REC.1403.036). All participants provided informed written consent, with the assurance of the right to withdraw from the study at any point. The trial was registered at the Iranian Registry of Clinical Trials (IRCT) under the ID IRCT20240614062133N1 (Trial ID: 77887).

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RESULTS

Ten migraine patients based on the inclusion criteria were treated with two therapeutic methods. The subjects were 4 men and 6 women. The mean age of the patients was 48.10 ± 9.69 years (31-62 years). One subject was single among the subjects. All the patients reported a family history of migraine (mother, sister, brother, etc.). One of the ten patients had a history of diabetes, and three had a history of hypertension. No cardiovascular disease, cancer, or renal disease were evident in the participants. The neurolysis and neurectomy groups each consisted of five patients. There was no statistically significant difference in the two groups in gender frequency distribution (*P*-value = 0.524). and mean age (*P*-value = 0.293).

Considering the sample size and the *P*-value of the Kolmogorov-Smirnov test (< 0.05), the Mann-Whitney test was used to compare data between groups. As shown in the Table 2 and Figure 1, there was no significant difference found in HIT, MIDAS and VAS scores between the neurolysis and neurectomy groups. There was statistically significant differences in the four measuring times of HIT and MIDAS in neurolysis group (*P*-value= 0.037) and in the subgroups, there was a statistically significant difference before and after one month

Table 1: Comparison of age and gender in the two study groups

Variables		Neurectomy	Neurolysis	*P*-value
Gender	Female	4 (80)	2 (40)	0.524
	Male	1 (20)	3 (60)	
Age (yr)		50.60 ± 7.50	45.60 ± 11.80	0.293

Data presented as frequency (%) and mean±std

Table 2: Comparison of Mean HIT, MIDAS, and VAS scores in the two study groups at different time points

Variables		Group		*P*-value (Mann-Whitney U Test)
		Neurolysis*	Neurectomy*	
HIT	Before	63.80±1.30 64 [62.5-65]	64.60±1.67 65 [63-66]	0.445
	One Month	46 48.40 ± 10.90 [39-59]	58.5 57.00 ± 8.76 [48.5-64]	0.172
	Three Months	44 49.40 ± 11.31 [40.5-61]	46 51.50 ± 15.26 [41.5-67]	0.916
	Six Months	46 47.40 ± 11.13 [38.5-57]	58.5 56.50 ± 12.23 [44-67]	0.219
	Difference six month and before	14.5 [3-24.5]	5.5 [(-5)-19]	0.221
	P-value Friedman Test	0.037*	0.347	---
MIDAS	Before	40.60±37.74 27 [14.5-73.5]	28.80±25.41 28 [8.5-49.5]	0.675
	One Month	3 8.20 ± 11.80 [0-19]	10 11 ± 10.70 [1.5-21]	0.595
	Three Months	1 23.10 ± 45.10 [0-57]	4 11 ± 12.88 [0.5-25]	0.671
	Six Months	0 17.71 ± 32.17 [0.5-42]	4 10 ± 12.17 [0-23]	0.738
	Difference six month and before	20.5 [7.25-29.25]	11.5 [1.5-36.5]	0.675
	P-value Friedman Test	0.019*	0.221	---
VAS	Before	9.40±0.55 9 [9-10]	8.40±1.82 9 [6.5-10]	0.504
	One Month	2.5 3.75 ± 4.50 [0.25-8]	3 2.80 ± 0.84 [2.5-3]	0.670
	Three Months	4.5 5.25 ± 3.40 [2.5-8.75]	3 2.80 ± 1.48 [1.5-4]	0.242
	Six Months	4 4.75 ± 3.86 [1.5-8.75]	2 2.40 ± 2.07 [1-4]	0.317
	Difference six month and before	5 [1-7.5]	4.5 [4-7.25]	0.532
	P-value Friedman Test	0.062	0.012*	---

*Data presented as mean±std and median [q1-q3]

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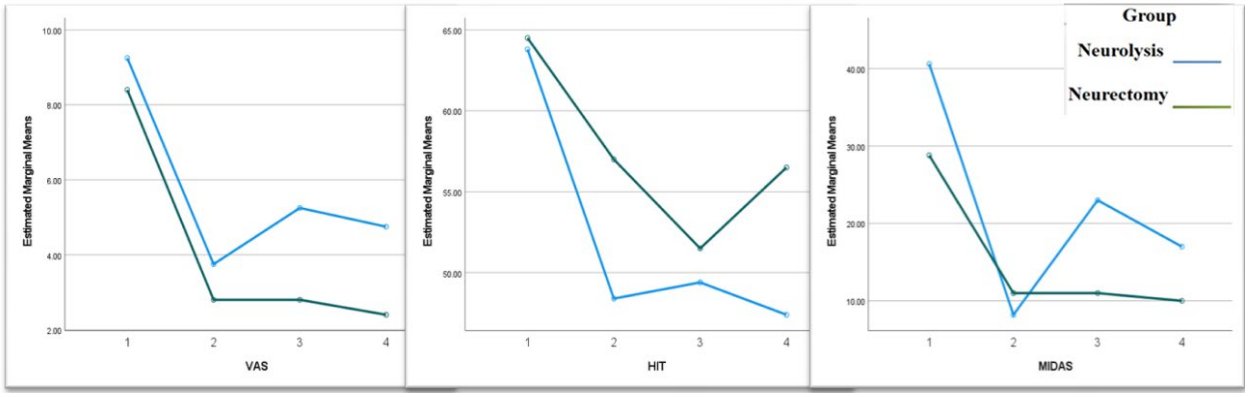


Figure 1: Mean Scores of HIT, MIDAS, and VAS over time in the intervention and control groups

in the MIDAS scores (*P*-value= 0.043), and before and after 6 months in the HIT (*P*-value= 0.042) and MIDAS(*P*-value= 0.043) scores. In addition, there was statistically significant difference in the measuring times of VAS score in neurectomy group (*P*-value= 0.012) and in the subgroups, there was a statistically significant difference before and after 6 months in this scores (*P*-value= 0.043), based on the Wilcoxon test. Between group comparisons of changes from baseline to six months showed no statistically significant differences for any outcomes.

DISCUSSION

Greater Occipital Nerve neurolysis and neurectomy are two surgeries employed in the management of refractory and chronic migraines that are unresponsive to the conventional forms of treatment. The findings of our recent study indicated in neurolysis group, statistically significant differences before and after one month in the MIDAS scores (P-value= 0.043), and before and after 6 months in the HIT and MIDAS scores. In addition, there was statistically significant difference in the measuring times of VAS score in neurectomy group and in the subgroups, there was a statistically significant difference before and after 6 months in this scores, but there was no statistical difference in the final outcomes of two surgeries group.

The efficacy of migraine surgery in the last two decades has been discussed in a review [20]. Migraine surgery has been reported to be an effective and safe procedure that has a positive impact on patients' quality of life and reduces long-term treatment costs[21]. Studies have demonstrated both greater occipital nerve neurectomy and neurolysis to be valuable in the management of intractable migraines [22], but in comparison the outcomes of these two methods the evidence is inconclusive, as in our study. McNutt et al. performed a systematic review of neurectomy versus neurolysis in the management of occipital neuralgia and concluded that there was no sufficient evidence to indicate that one form of treatment is superior to another [23]. Similarly, the review by Howard and colleagues focused on surgical techniques for migraine and concluded that because there is a wide range of surgical techniques to treat occipital neuralgia and no scientific evidence to favor one technique over another, team decision-making is needed for selecting a surgical technique for each patient [10].

In a review of surgeries for occipital-origin migraines, it was reported that while surgery for chronic occipital migraines could be an effective method, additional evidence was needed to firmly establish it as a standard procedure [24].

These and our own experience have not resulted in a decision regarding the comparative value of surgical technique. The inability to discover a conclusion serves to emphasize the requirement for additional, more comparative studies contrasting the outcomes of the two treatments.

However, both of these procedures have important differences that the surgeon needs to consider while making his decision. Neurectomy is a more invasive operation and one with higher side effects, albeit potentially marginally more effective in helping to relieve migraine headache pain. It is usually an open procedure requiring an incision and direct entry into the nerve, where the physician removes and cuts out a portion of the greater occipital nerve. This is carried out in order to establish a permanent

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block in pain transmission by this nerve. Being a surgical procedure, neurectomy has more side effects compared to neurolysis, some of which are infection, bleeding, injury to nearby tissues, and permanent numbness of the targeted area [25]

Neurolysis is a less traumatic procedure with fewer side effects. In neurolysis, the objective is to relieve the nervous from compression caused by the surrounding muscles and arteries rather than removing the nerve itself. However, its effect may be short-term or less effective [26].

Although initial studies of neurectomy have demonstrated that it might cause dramatic reductions in the frequency, severity, and duration of migraine attacks [27] later studies with other groups of patients have had inconsistent results [28]. The response rate to neurectomy is highly variable among patients. Although some patients experience dramatic improvement, others experience minimal change [29]. Just like neurolysis, in initial studies, has been shown to decrease migraine pain, decrease attack frequency, and improve quality of life in patients, subsequent studies have shown a variable range of results on pain relief and duration of effect [11].

The better one compared to the other depends on several factors such as: Type and severity of migraine: Neurectomy might be more suitable for severe and refractory migraines, whereas neurolysis can be a better choice for mild migraines or for those patients who want less aggressive procedures; Duration of action: Analgesic effects of neurectomy can last long, although in some instances, pain can return over time. Whereas recurrence of pain is more frequent in neurolysis; Patient condition: The general health status of the patient, medical history, and patient's personal wish also influence the choice of treatment. Neurolysis is generally employed as a first, less invasive step in pain management, and neurectomy is reserved where neurolysis has failed, where there is intractable pain, or where there are patients who will accept more side effects for more pronounced reduction of pain. Aside from this, neurolysis may be an optimal option for those patients who want a less invasive with fewer side effects procedure, even though multiple procedures have to be performed; Surgeon experience: Surgeon skills and experience in performing each one of these procedures also influence the outcome [27]. Since both operations have unique benefits and drawbacks, the choice between them should be based on the particular circumstances of each case and the patient's reaction to the therapy. In addition, both long-term results and side effects should be monitored.

Limitations

The study was subject to several limitations. Firstly, the small sample size may have decreased the power to detect significant difference between groups and interaction effects. Secondly, the six-month follow-up period may be too short for a complete evaluation of the effectiveness of the surgical interventions employed. Finally, the lack of control group, i.e., patients who underwent sham surgery, may make the interpretation of results difficult.

CONCLUSION

Both of the surgical interventions—neurolysis and neurectomy of the GON can be defined as effective therapeutic interventions for the management of patients with chronic treatment-resistant migraine. Since both of the treatments possess some advantages and disadvantages, this research stresses the importance of personalized treatment and collaborative decision-making among the healthcare professionals in order to select the most suitable surgical intervention for the patients with chronic migraine. Longer follow-up and larger numbers are needed in future studies in order to ascertain the optimal regimen of treatment. Studies that look into the effect of confounding factors, e.g., lifestyle and stress, can also provide valuable information on the efficacy of these treatments.

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Conflict of Interest

None.

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