

SOUTH BAYLO UNIVERSITY

**Effect of Acupuncture Treatment on Migraine Headache - Modulating CGRP Signaling
in the Trigeminovascular System (TVS): Case Series**

by

Hyun Joo Kim

**A RESEARCH PROJECT SUBMITTED
IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE**

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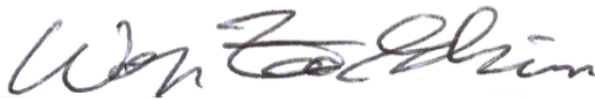
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ABSTRACT

Migraine is an episodic disorder, which is a severe headache generally associated with nausea and/or vomiting or light and sound sensitivity. The World Health Organization (WHO) states that migraine is one of the 10 most disabling medical illnesses on Earth. 148 million people suffer from chronic migraine in the world. According to the Center for Disease Control and Prevention (CDC), direct medical costs and earning losses each year of chronic migraine are more than \$20 million in the United States.^{1,5} The purpose of the study is to confirm the effectiveness of acupuncture treatment on migraine by modulating Calcitonin-Gene Related Peptide (CGRP) Signaling in the Trigeminovascular System (TVS). The participants received acupuncture treatments to modulate CGRP Signaling in the trigeminovascular system. The treatment was conducted from September 2024 to November 2024 in outpatient settings at Livingstone Clinic in California. Patients of 18 to 60 years old with migraine were selected based on the criteria of the International Headache Society. Author measured patient's pain by Visual Analogue Scale (VAS). Acupuncture treatments lasted for 4 weeks, and participants received 2 sessions per week, for a total of 8 treatments. The average of score of VAS (Visual

Analogue Scale) before the treatment was 5.7, and it decreased 1.7 after the 8th treatment. The average score of MSQ (Migraine-Specific Quality-of-Life Questionnaire) before the treatment was 63, and it increased 83 after the 8th treatment. The average grade of MIDAS (Migraine Disability Assessment Test) before the treatment was 2.3, and it decrease 1.3 after the 8th treatment. The results show that the acupuncture treatment is effective on migraine headache without aura.

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I. INTRODUCTION

According to the American Migraine Foundation, migraine is not only a severe headache, but also a disabling neurological disorder with different symptoms and treatment approaches compared to other headache disorders. According to the World Health Organization (WHO), migraine is one of the 10 most disabling medical diseases on the earth, with an estimated 148 million people in the world suffering from chronic migraine. Migraine is the third most common disease in the world affecting one in seven people worldwide. Migraines affect more than 37 million men, women, and children in the United States. Migraines interfere with educational, job, and/or social activities. It costs more than \$20 million annually in direct health care costs and lost productivity in the United States.^{1,5}

According to Cutrer, the cause of migraine is reported to be an overactive relationship with the trigeminovascular system. Migraine is a disorder of repetitive attacks. Migraine attacks develop through a series of phases that occur over a period of several hours to several days. The diagnosis of migraine is based on clinically compatible medical history, neurological and physical examination, and diagnostic criteria. There are no diagnostic tests specific to migraine.⁵ Migraine pharmacologic treatments typically include aspirin, other nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen. Triptans was developed for the treatment of acute migraine. Calcitonin- Gene Related Peptide (CGRP) antagonists was developed for the prevention of migraine. However, triptans cannot be used in patients over 50 years of age due to their vasoconstrictor effect. Other medicines may have side effects such as sleep disturbances and hives; therefore, it is believed that acupuncture or herbal treatment is necessary.¹⁹

In Eastern and Western countries, acupuncture is widely used in migraine management. Many studies have shown that acupuncture is a safe, effective, and readily available alternative therapy that may benefit certain migraine patients.²⁰ The effects of acupuncture are relieving severe migraine pain in acute, and preventing recurrent migraine attacks in the long term, i.e., reducing frequency and attack time.^{2,4} This study aims to confirm the effectiveness of acupuncture for migraine and the purpose of acupuncture is to reduce migraine attack frequency, severity, and duration.

Activation of the trigeminovascular system is the main mechanism of migraine. Migraine specific triggers cause primary brain dysfunction in the brainstem center. It causes dilation of cranial blood vessels innervated by cranial V nerve. This activates trigeminal sensory nerve fibers and entails release of vasoactive peptides such as substance P and CGRP from trigeminal fibers.^{7,12}

OBJECTIVES

The aim of this study is to evaluate the effectiveness and safety of acupuncture for the treatment of migraine over a four-week treatment period and a further 4-week follow-up period.

1. Pre-Treatment Migraine Headache Questionnaire the primary variable was used to measure the change in the frequency of migraine attacks and the number of days the migraine headache lasts in a month (Appendix-2).
2. Migraine-Specific Quality-of-Life Questionnaire (MSQ) (Appendix-3), and Migraine Disability Assessment Test (MIDAS) (Appendix-4) were used to measure changes in daily living impairment and quality of life.
3. Visual Analogue Scale (VAS) (Appendix-5) was used to measure the reduction in migraine intensity.

LITERATURE REVIEW

1.1 Western Medicine View of Migraine

1.1.1 Introduction

Migraine is an episodic disorder. Migraine is the most common form of headache that usually occurs on one side of the head. It is a type of headache that usually lasts from 4 to 72 hours. Migraine is often associated with nausea and/or vomiting, sensitivity to light and/or sound. The characteristic of pain is usually a throbbing pain. Internal or external factors can aggravate migraines. These are called "triggers". Each person's trigger is unique. The symptoms interfere with the patient's daily routine and affect the patient's ability to meet personal and social obligations. There are several types of Migraines: abdominal migraine in children, chronic migraine, hemiplegic migraine, menstrual migraine, migraine without headache (silent migraine), retinal migraine, and status migrainosus. Status migrainosus does not respond to usual treatment or lasts longer than 72 hours. The most common migraine categories are migraine with aura and migraine without aura. An aura is a phase of the migraine that are preceded by a warning symptom. Migraine often progresses in distinct phases over several hours to days. The process is prodrome, aura, headache, and postdrome.^{5,18}

1.1.2 Pathophysiology

Cortical spreading depression (CSD) is a slowly propagated wave of depolarization of neurons and glial cells that spreads across cerebral cortex. CSD has been implicated in migraine aura. The activation of trigeminal afferents by CSD, in turn, causes inflammatory changes in the meninges that generate migraine. This results in release of vasoactive neuropeptides, including substance P, CGRP, and neurokinin A.^{5,9}

The Calcitonin Gene-Related Peptide (CGRP) has a key role in migraine pathophysiology. CGRP is expressed in trigeminal ganglia nerves. CGRP is a potent vasodilator of cerebral and dural vessels. Stimulation of the trigeminal ganglion induces the release of CGRP. The CGRP infusion can trigger a migraine attack in patients with migraine. One study found elevation of CGRP levels in external jugular venous blood during migraine attacks.^{7,9}

1.1.3. The innervation of the cranial dura mater

- 1) The innervation of the cranial dura mater is primarily sourced from the trigeminal (CN V), vagus (CN X) nerves, and spinal nerves C2/C3. Three branches of the trigeminal nerve supply the dura mater.^{9,12}

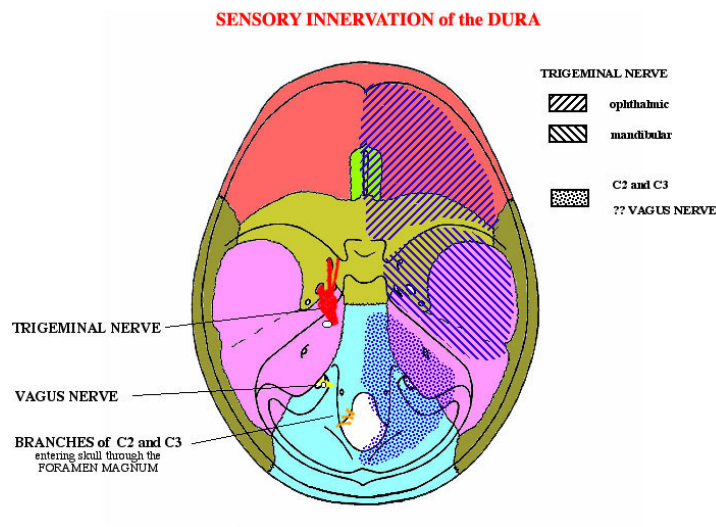


Figure 1a. The innervation of the cranial dura mater and trigeminal nerves^{8,12}

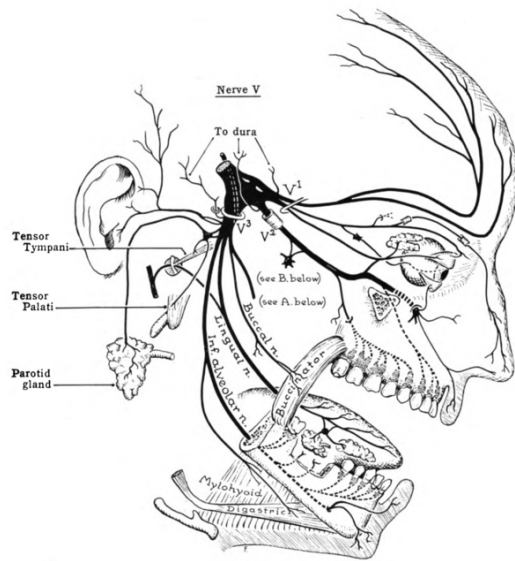


Figure 1b. The innervation of the cranial dura mater and trigeminal nerves^{8,12}

- 2) The trigeminal nucleus is an area of the lower brainstem that receives information from the area supplied by the trigeminal nerve. The trigeminal cervical nucleus receives information from the top three spinal nerves in the neck (C1, C2, and C3). This is the neuroanatomical basis on which upper cervical pain is felt as a headache or migraine.¹⁷

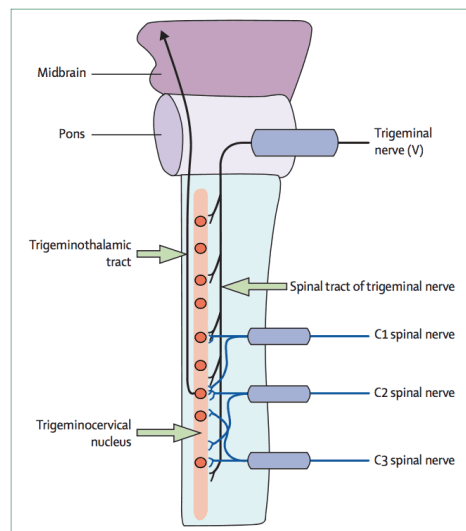


Figure 2. The trigeminocervical nucleus

- 3) Middle meningeal artery is the main supply of the dura mater.¹¹

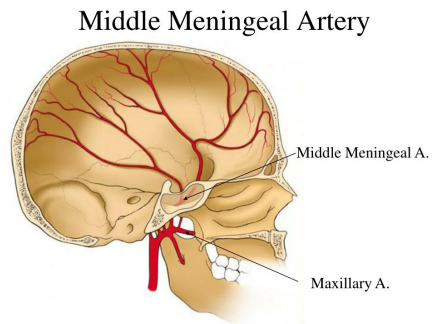


Figure 3. Middle meningeal artery supply of dura¹⁵

- 4) From the trigeminal ganglion, the three terminal divisions of the trigeminal nerve arise; the ophthalmic (V1), maxillary (V2) and mandibular (V3) nerves.¹⁷

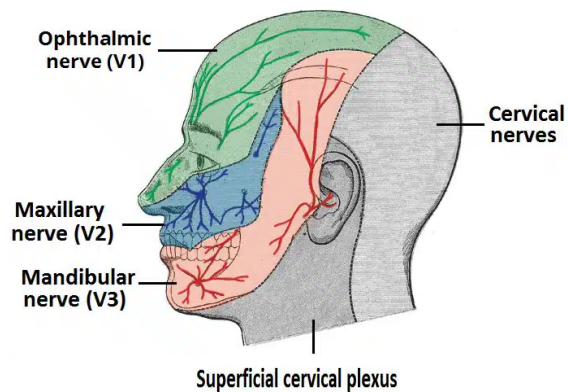
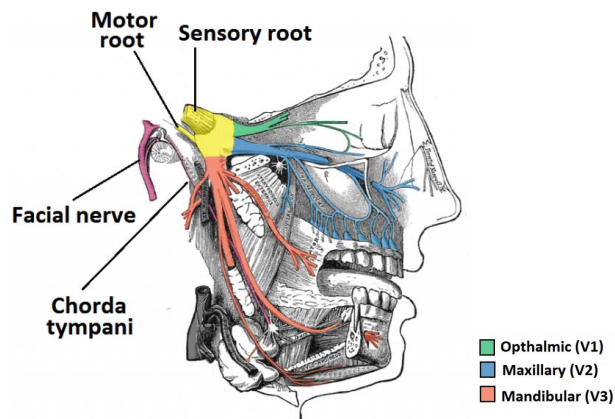


Figure 4. Overview of the distribution of the trigeminal nerve and its terminal branches

1.1.4. The International Classification of Headache Disorders, 3rd edition (ICHD-3)

The International Classification of Headache Disorders, 3rd edition (ICHD-3) specifies the diagnostic criteria for migraine, which are as follows:⁵

- 1) The ICHD-3 criteria for migraine without aura are the following:
 - a) At least five attacks fulfilling criteria B through D
 - b) Headache attacks lasting 4 to 72 hours (untreated or unsuccessfully treated)
 - c) Headache has at least two of the following characteristics:
 - Unilateral location
 - Pulsating quality
 - Moderate or severe pain intensity
 - Aggravation by or causing avoidance of routine physical activity (e.g., walking or climbing stairs)
 - d) During headache, at least one of the following:
 - Nausea, vomiting, or both Photophobia and phonophobia
 - Not better accounted for by another ICHD-3 diagnosis
- 2) The ICHD-3 criteria for migraine with aura are as follows:³
 - a) At least two attacks fulfilling criterion B and C
 - b) One or more of the following fully reversible aura symptoms:
 - Visual
 - Sensory
 - Speech and/or language
 - Motor

- Brainstem
 - Retinal
- c) At least three of the following six characteristics:
- At least one aura symptom spreads gradually over ≥ 5 minutes
 - Two or more symptoms occur in succession
 - Each individual aura symptom lasts 5 to 60 minutes
 - At least one aura symptom is unilateral
 - At least one aura symptom is positive
 - The aura is accompanied, or followed within 60 minutes, by headache
- d) Not better accounted for by another ICHD-3 diagnosis

1.1.5. Migraine phases⁵

Migraines often progress in distinct phases over a period of several hours to several days.

- 1) Prodrome - Cognitive symptoms such as sensitivity to light and/or sound, fatigue, neck pain or irritability or euphoria; It occurs up to 48 hours before the onset of a headache.
- 2) Aura – transient neurological symptoms; It takes a few minutes and lasts up to 1 hour.
- 3) Headache – Moderate to severe head pain; 4 to 72 hours duration.
- 4) Postdrome – Fatigue, residual head pain, that persists for hours up to one day due to movement.

1.1.6. Headache features

Common migraine features are unilateral pain, throbbing or pulsing quality, moderate to severe intensity, nausea and/or vomiting, photophobia, exacerbation with routine physical activity, cutaneous allodynia (sensitivity to touch), and/or particularly of the scalp.⁵

1.1.7. Management and treatment

Management of migraine in general are taking medications, avoiding migraine triggers, and using alternative migraine remedies. General principles of migraine management could be to treat early, maximize initial dose, tailor route (e.g., using nonoral agents for patients with significant nausea and vomiting). Moreover, migraine management could consider adjunctive preventive therapy when headaches are frequent and/or unresponsive to acute treatments. Also, Botulinum toxin (Botox) injection and nerve blocks can help prevent migraine attacks. Nerve blocks are typically used for more chronic migraines with headaches more than 15 days per month.

Calcitonin-Gen Related Peptide (CGRP) antagonists are used to manage migraines because CGRP antagonists block the effect of CGRP, which appears to mediate trigeminovascular pain transmission in migraine. CGRP antagonists are approved for migraine prevention.^{5,18} Acupuncture is nonpharmacologic intervention of migraine. Some studies suggests that classic acupuncture may have modest benefits for migraine headache prevention, but data from clinical trials and systematic reviews are mixed.^{15,21,22}

1.2. Traditional Chinese Medicine View of Migraine

1.2.1. Diagnosis according to channels

The Liver channel reaches the top of the head internally. A headache on top of the head is most often due to deficient Liver-Blood. A headache on top of the head may be due to Liver-Yang rising. Qi deficiency and/or Blood deficiency, or Heart-Blood deficiency can cause a headache on the top of head because of being unable to reach the top of the head. There is a headache that starts at the base of the occipital region and works its way up. This type of headache is due to the Bladder channel. Side(s) of the head corresponds to the Gall Bladder channel. A headache on the side of the head is most frequently due to Liver-Yang rising, Liver-Fire or Liver-Wind. The Temple area also corresponds to the Gall Bladder channel. A headache affects one side only. This headache is usually due to Liver-Fire, Liver-Yang, or Liver-Wind. A headache behind the eyes is a very frequent location for migraine. The headache is due to Liver-Blood deficiency. Headaches in forehead are usually related to the Stomach. If the pain is dull, they indicate Stomach deficiency; if it is sharp, Stomach-Heat. The causes of frontal headaches could be the retention in the head of either Dampness or Phlegm, or pathogenic factor, such as external Wind that has not been expelled after an invasion of exterior Wind-Cold or Wind-Heat. Chronic headaches in the occipital area are usually caused by kidney deficiency that appears in the bladder channels. An acute headache is caused by the invasion of an external wind (Wind-Cold). In some cases, occipital headaches may be related to bladder patterns, such as Damp Heat. Chronic headaches in whole head area are due to Kidney-Yin or Kidney-Essence deficiency. Acute headaches

affecting the whole head are due to invasion of external Wind (Wind-Cold or Wind-Heat).^{13,14}

1.2.2. Diagnosis according to type of pain

According to the Eight-Principal perspective, a dull pain indicates an Empty condition, while a sharp pain indicates a Full condition. A sudden onset tends to indicate an exterior invasion, while a gradual onset indicates an interior one. Empty conditions deficiency of Qi and/or Blood, Liver-Blood deficiency, and Kidney deficiency. Full conditions include Liver-Yang rising, Liver-Fire blazing, Liver-Wind, Phlegm, stasis of Blood, and Stomach-Heat.^{13,14}

- Dull: Deficiency.
- Feeling of heaviness: Dampness or Phlegm.
- Distending pain: Liver-Yang or Liver-Fire, also exterior Wind-Heat.
- Stiff: exterior Wind-Cold; if chronic, Liver-Yang rising.
- Pulling: internal Liver-Wind.
- Stabbing, boring: Blood stasis.
- Feeling of emptiness: deficiency of Kidneys (Yin or Yang).
- Wind-Cold: severe occipital with pronounced stiffness.
- Wind-Heat: severe, distending, in the whole head.
- Wind-Dampness: feeling of heaviness, as if the head were wrapped in a cloth.
- Liver-Yang, Liver-Fire: distending.
- Liver-Wind: pulling.
- Stasis of Blood: stabbing, splitting, boring.
- Phlegm: heavy sensation, as if the head were wrapped in a cloth; dizziness.

- Dampness: heavy sensation, as if the head were wrapped in a cloth.
- Qi and/or Blood deficiency: dull.
- Kidney deficiency: feeling of emptiness.

1.2.3. Patterns and principle of treatments of migraine

Migraine headaches can generally come from Liver- Yang Rising, Liver – Fire Blazing, Liver- Qi Stagnation, and Liver -Wind. Liver-Yang Rising is the most common type of headache.^{2,12} Clinical manifestations of Liver- Yang Rising include headache on the sides of the head, temple, or one the side of the head, dizziness, tinnitus, deafness, blurred vision, dry mouth and throat, insomnia, irritability, and nausea & vomiting. Principle of treatment is to subdue Liver-Yang, and to nourish Yin. Liver – Fire Blazing can cause very strong migraine attacks. Clinical manifestations of Liver- Fire Blazing include severe throbbing pain, temporal headache, dizziness, tinnitus, anxiety, and neck stiffness. Headaches can be accompanied by nausea, vomiting, constipation, anxiety, insomnia, and nightmares. Principle of treatment is to clear the Liver and to drain Fire. Liver-Qi Stagnation can cause headaches on the forehead or temporal. Unlike Liver-Yang rising, it is not throbbing pain and can move from one side to the other. Clinical manifestations include feeling of distension of hypochondrium, depression, moodiness, distension of breasts before the periods, premenstrual tension, and irritability. Liver-Qi Stagnation is related to anxiety, stress, or emotions. Principle of treatment is to smooth the Liver and to move Qi.^{13,14}

II. MATERIALS AND METHODS

2.1 Materials

2.1.1 Acupuncture needles

SEIRIN J-Type acupuncture needles with 0.20X30 mm (A), SEIRIN G-Type acupuncture needles with 0.25X40mm(B), SEIRIN J-15 acupuncture needles with 0.18X15mm(C) were used for body or scalp.

2.2 Methods

2.2.1 Participants

- Registration procedure

The author recruited participants from July 2024 to September 2024. The participants were those who have experienced migraine without aura symptoms for more than 3 years.

- Staging criteria

To measure changes in the frequency of migraine attacks, changes in the number of days migraine headaches last, changes in quality of life, and reductions in migraine intensity, author used following methods to verify the case series results:

- Pre-Treatment Migraine Headache Questionnaire (Appendix-2, Table 1)
covers various aspects related to migraine headaches, including frequency, duration, pain intensity, location, triggers, and family history.

Table 1. Frequency of Attacks of Criteria for Migraine

Stage	Frequency of attacks per month
1	0-1 time
2	2-3 times
3	4-5 times
4	6-7 times
5	more than 8 times

- Migraine-Specific Quality-of-Life Questionnaire (MSQ) (Appendix-3, Table 2) measures headache impact health-related quality of life in migraine patients.¹⁸

Table 2. MSQ: Migraine Specific Quality of Life Questionnaire

Final Score	MSQ
85-100	Not/minimally impaired
75-84	Mildly impaired
55-74	Moderately impaired
40-54	Severely impaired
> 40	Extremely impaired

- The Migraine Disability Assessment Test (MIDAS) (Appendix-4, Table 3) assesses headache-related disability with the aim of improving migraine care.³

Table 3. MIDAS: Migraine Disability Assessment Test

MIDAS Grade	Definition	MIDAS Score
I	Little or No Disability	0-5
II	Mild Disability	6-10
III	Moderate Disability	11-20
IV	Severe Disability	21+

- Visual Analogue Scale (VAS) (Appendix-5, Table 4) measures pain.¹⁰

Table 4. Headache Intensity of Criteria for Migraine

Score	VAS
0	no headache
1-3	mild headache
4-6	moderate headache
7-10	severe headache.

Pre-Treatment Migraine Headache Questionnaire, Migraine-Specific Quality-of-Life Questionnaire (MSQ), and The Migraine Disability Assessment Test (MIDAS) were measured before starting the first treatment and after last treatment.

2.2.2. Inclusion criteria

- Meets diagnostic criteria for migraine without aura symptoms.
- 18 ~ 60 years old
- Patients who agree to refrain from Marijuana during the baseline period.
- Fill out and submit Informed Consent Form (ICF).

2.2.3. Exclusion criteria

- Migraine with aura symptoms, Tension type, Cluster
- New onset headaches after age 50
- Headache patients with new symptoms found in the nervous system
- Cardiovascular and cerebrovascular history (Cerebrovascular accident in the last 6 months), Myocardial infarction, Heart failure, Severe organic heart disease, Aneurysm of the main artery, Angina, Atrioventricular block, Sick sinus syndrome, Liver dysfunction, Renal dysfunction
- Abnormal Alanine aminotransferase (ALT), Aspartate transferase (AST), Blood

urea nitrogen (BUN) and Creatinine, or Hyperthyroidism

- Serious or potentially fatal diseases, such as Autoimmune disease, Cancer, Endocrine diseases
- Pregnancy, preparation for pregnancy or active lactation in women
- Patients with psychiatric illness or uncooperative patients
- Participation in another clinical trial within the past 2 weeks
- Refusal of consent for the case series

2.2.4. Rejection criteria

- Patients who refuse to fill out and to submit the informed outlet form (ICF)
- Patients who have been diagnosed migraine with aura symptoms
- Patients who have not agreed to refrain from Marijuana during the baseline period

2.2.5. Suspension criteria

- Patients who do not refrain from Marijuana during the baseline period.
- Patients who combine acupuncture with other treatments
- Patients who receive a prescription from a physician

2.2.6. Dropout criteria

- Patients who do not receive acupuncture treatment more than twice or do not follow the regular treatment time more than twice.
- Participant's Waiver

2.2.7. A case series design

Acupuncture is treated regularly twice a week for 4 weeks, followed up after 4 weeks.

2.2.8. Acupuncture intervention

Participants visited the Livingstone clinic twice a week. The participants were diagnosed by the same acupuncturist using TCM Diagnoses by observation, Interrogation, Hearing and Smelling, and Palpation. Visual Analogue Scale (VAS) and Range of Motion (ROM) were measured before and after the treatment sessions. MSQ and MIDAS were measured before starting the first treatment and after the last treatment for evaluating the effectiveness of acupuncture treatment on migraine headache by modulating CGRP Signaling in the Trigeminovascular System (TVS).

2.2.8.1. The selection of acupuncture points

The selection of acupuncture points for acupuncture treatment is shown in Table 5.⁶

Table 5. The Selection of Acupuncture Points^{6,13,14}

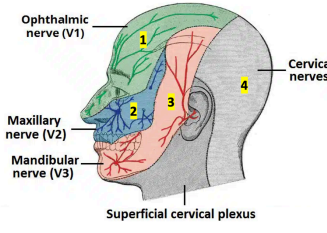
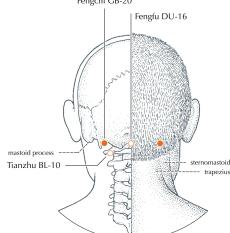
Acupoint	Actions	Needling
GB 20 Fengchi	<ul style="list-style-type: none"> Eliminates wind Benefits the head and eyes Clears the sense organs Activates the channel and alleviates pain 	Slightly oblique inferior insertion in the direction of the channel, 1 to 1.5 cun
<p style="text-align: center;">Location & CN V</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>		
DU 20 Baihui	<ul style="list-style-type: none"> Pacifies wind and subdues yang Raises yang and counters prolapse Benefits the head and sense organs Nourishes the sea of marrow Benefits the brain and calms the spirit 	Transverse insertion 0.5 to 1 cun

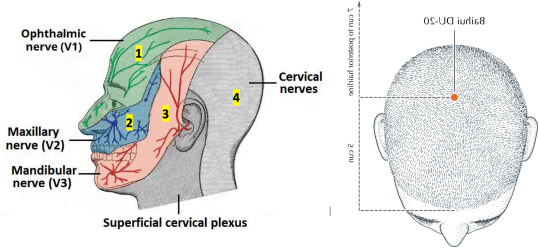
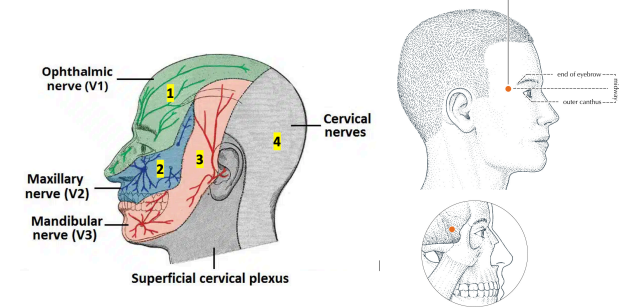
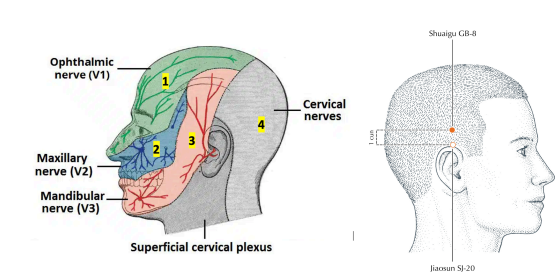
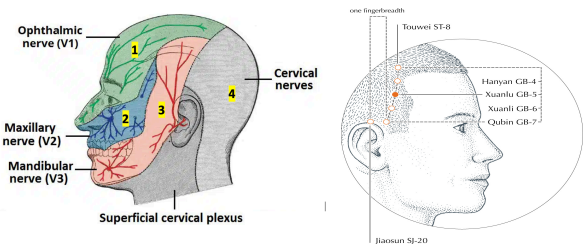
Table 5. Continued		
<p style="text-align: center;">Location & CN V</p> 		
EX-HN5 Taiyang	<ul style="list-style-type: none"> • Eliminates wind and clears heat • Reduces swelling and stops pain • Activates qi and blood and alleviates pain 	Perpendicular needling 0.5 to 0.8 cun
<p style="text-align: center;">Location & CN V</p> 		
GB 8 Shuaigu	<ul style="list-style-type: none"> • Eliminates wind, benefits the head and alleviates pain • Harmonizes the diaphragm and Stomach and alleviates vomiting • Treats alcohol intoxication 	Transverse insertion 0.5-1.5 cun
<p style="text-align: center;">Location & CN V</p> 		

Table 5. Continued		
GB 5 Xuanlu	<ul style="list-style-type: none"> Expels wind and clears heat Activates the channel and alleviates pain 	Transverse insertion 0.5-1.5 cun.
<p style="text-align: center;">Location & CN V</p> 		
LI 4 Hegu	<ul style="list-style-type: none"> Regulates the defensive qi and adjusts sweating Expels wind and releases the exterior Regulates the face, eyes, nose, mouth and ears Activates the channel and alleviates pain Induces labor Restores the yang 	Perpendicular insertion 0.5 to 1 cun
LIV 3 Taichong	<ul style="list-style-type: none"> Spreads Liver qi Subdues Liver yang and extinguishes wind Nourishes Liver blood and Liver yin Clears the head and eyes Regulates menstruation Regulates the lower jiao 	In the direction of Yongquan KID 1, 0.5 to 1.5 cun.
SP 6 Sanyinjiao	<ul style="list-style-type: none"> Tonifies the Spleen and Stomach Resolves dampness Harmonizes the Liver and tonifies the Kidneys Regulates menstruation and induces labor Harmonizes the lower jiao Regulates urination and benefits the genitals Calms the spirit Invigorates blood Activates the channel and alleviates pain 	Perpendicular or oblique proximal insertion, 1 to 1.5 cun.
ST 36 Zusanli	<ul style="list-style-type: none"> Harmonizes the Stomach Fortifies the Spleen and resolves dampness Supports the correct qi and fosters the original qi Tonifies qi and nourishes blood and yin Clears fire and calms the spirit Activates the channel and alleviates pain Revives the yang and restores consciousness 	Perpendicular insertion 1 to 1.5 cun.

2.2.8.2. Acupuncture approach

GB 20, DU 20, Taiyang, GB 8, and GB 5 were selected. The acupoints have been used for Migraine for more than 2000 years in Traditional Chinese Medicine (TCM).

Surprisingly, I found that these acupoints are related with trigeminovascular pathway. I assume that the acupoints can be effective in treating migraine headache by modulating CGRP Signaling in the Trigemino-vascular System (TVS).^{7,13,14}

Acupuncture treatments lasted for 4 weeks, and the participants received 2 sessions per week, for a total of 8 treatments. Author complied HIPPA Privacy Rule and Clean needle technique during the acupuncture treatments. SEIRIN J-Type acupuncture needles with 0.20X30 mm (A), SEIRIN G-Type acupuncture needles with 0.25X40mm(B), and SEIRIN J-15 Acupuncture Needles with 0.18X15mm(C) were inserted for body or scalp.

2.2.9. Adverse event and toxicity management

2.2.9.1. Reporting of adverse events

Participants should report any adverse events (AE) to the author immediately, The author would check that the study is proceeding as intended every 7 days when the participant visits the clinic. If a serious adverse event (SAE) occurs, the author should report immediately to the Principal Investigator (PI) and the Institutional Review Board (IRB) of the South Baylo University by completing a Serious Adverse Event (SAE) form. It should also be reported to the Food and Drug Administration (FDA) within 24 hours.

2.2.9.2. Documentation of adverse events

The AE form is in accordance with the incident report form of the South Baylo University. It should be written according to the actual situation, and some additional

information should be recorded, including the time, severity, duration, action items, and consequences of occurrence.

2.2.9.3. Relationship between adverse event and study treatments

The author would assess the relationship between AEs and the treatment under study based on the following criteria:

- Whether there are any suspected adverse reactions after treatment.
- Whether the suspected adverse event belongs to the known adverse reaction of the treatment.
- Whether the suspected adverse event disappeared or remission after treatment discontinuation.
- Whether the same reaction occurred again after resuming the treatment.
- Whether the event was preventable.
- Whether the participant's illness or suspected adverse events due to taking medications cannot be explained.

2.2.9.4. Relationship between adverse events and changes in symptoms

The acupuncture prescription would be adjusted to the participants according to the change in symptoms following the last acupuncture treatment, therefore, AEs could be useful for acupuncturists to adjust or improve clinical practice.

2.2.9.5. Criteria for the evaluation of safety

In this study, the safety of acupuncture would be assessed by liver and kidney function as follows:

- Safe without major changes in liver or kidney function
- Relatively safe with less than 20% change in liver and kidney function

- Discontinuation of intervention due to changes of more than 20% in liver and kidney function

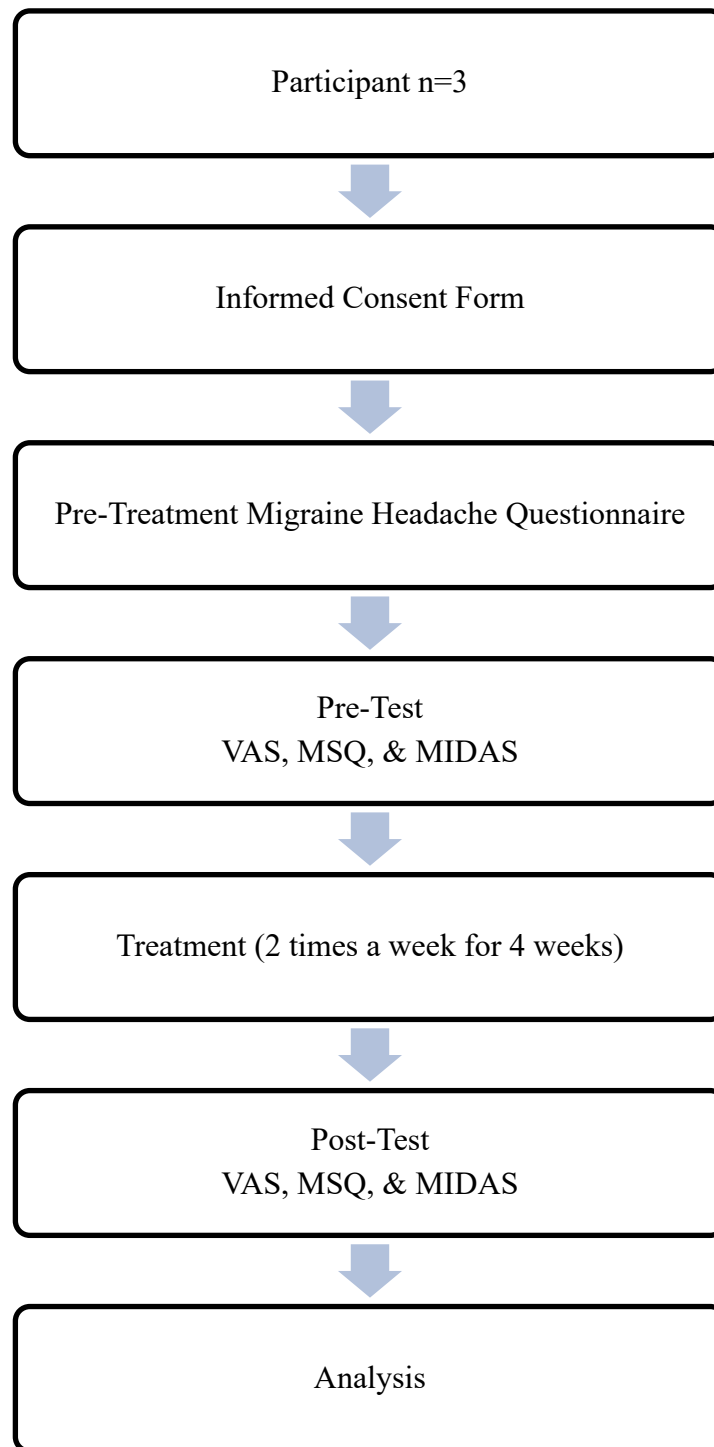


Figure 5. Schematic Diagram of Study Design

III. RESULTS

The purpose of this study is to evaluate the effectiveness of acupuncture treatment that modulates CGRP Signaling in the Trigeminovascular System (TVS). This study was conducted in patients with migraine without aura who have consented to the study. The improvement of migraine was examined by using MSQ and MIDAS before starting the first treatment and after last treatment. In a total of 8 treatments, VAS, frequency of migraine attack, and ROM were measured before and after the treatment, and the changes were reported.

3.1 General characteristics of the study subjects

A total of 3 study subjects who participated in this study were shown in Table 6 on age, gender, onset period, medication use, family history, and ethnicity. The age distribution of the three participants was between 31 and 62 years. The participants were 3 adult women who were all Koreans. The participants had been suffering from migraines for 20 or 30 years. Case 2 and Case 3 had not received professional migraine prevention treatment, such as pharmacological therapy (Table 6).

Table 6. Demographic Characteristics of the Subjects

Characteristic		
Mean Age (years)		46.7
Gender	Male	0
	Female	3
Mean of Onset in Migraine (Years)		18.3
Medication Use	No	0
	Yes	3
Family History in Migraine	No	1
	Yes	2
Ethnicity	Korean	3

3.1.1 Case 1

1) Gender and Age: female, 62 years old

2) Chief Complaint:

The patient experiences migraines 2-3 times per month. Her migraine usually last no more than 2 hours after she takes her migraine medicine. Her migraine usually last 3-4 hours or a few days if she does not take her migraine medicine. Her migraines are low or moderate intensity migraines. Patterns of throbbing/pounding pain are located in the left, right or both sides of the head. During the migraine attacks, the patient experiences usually indigestion, occasional nausea and vomiting. Her migraine occurs without any particular cause, but stress (worry, anger) could be a trigger factor. Rest and/or drinking coffee makes her migraine better.

3) Past Illness, Family History:

The patient did not have a head injury or a neck injury requiring medical treatment. The patient reported no previous major illnesses or surgeries, no family history of illness, and no use of medications, and use of nutritional supplements. Any family member does not have a migraine.

4) Present Illness:

The patient has been suffering from migraines since her 20s and she has been having them almost constantly for over 40 years. Her neurologist ran a few tests and found nothing wrong with her. Magnetic Resonance Imaging (MRI) of the brain was performed in 2021, but no tumor and other cerebral diseases have been found. The patient is currently taking Nurtec ODT (CGRP receptor blocker).

During the migraine attack, the patient experienced a feeling of fullness of the epigastrium in the evening, indigestion, a feeling of heaviness in the left shoulder and arm, hypochondrial pain, constipation, and bitter taste.

5) Social History:

- a. Tobacco use: Non-Smoker
- b. Alcohol/drug use: None
- c. Occupation: None
- d. Marital Status: Married

6) Medication:

Taking the medication only when moderate or severe migraine occurred. Nurtec ODT (CGRP receptor blocker).

7) Allergies: N.K.D.A.

8) Inspection: Slightly yellow, bright skin color, clear and shining eyes, thin hair, 5.3ft in height, 110 lbs. in weight

9) Listening Examination: Thoughts and words come out simultaneously.

10) Questioning Examination: Likes hot coffee, sensitive personality, stable mental states, usually not being thirsty.

11) Tongue and Pulse Examination: Pale-pink tongue, thin coating, rolling /wiry pulse

12) Questions:

- a. Digestion and Appetite: Normal appetite with satisfactory digestion
- b. Stool: 1 time/day
- c. Urine: 5~6 times/day

- d. Sleep: 5~6 hours/day, taking about 10 minute to fall in sleep, sometimes feeling fatigue in the morning.
- e. Perspiration: No
- f. Menstruation: Menopause
- g. Stress level: 5-6/10
- h. Emerge level: 4-5/10

13) TCM Diagnosis: Liver Qi stagnation

14) Treatment Principle: Smooth the Liver Qi and blood, Regulate Liver-Qi, and Eliminate Stagnation (open four gates)

15) Western Medicine Diagnosis: Categorized as migraine without aura in accordance with the International Classification of Headache Disorders, 3rd edition (ICHD-3) enacted at International Headache Society (HIS).

3.1.1.2. Evaluation of the changes and results

After the first week of acupuncture, the patient reported improvement in migraine after first treatment, but her migraine increased to the same level as the first visit on the second visit (Table 7). The VAS score was a 3 on a patient self-report numeric pain scale from 1 to 10 (10 being the most severe pain). The patient experienced a mild migraine one right side of her head, but her migraines were milder and of shorter duration. At week 2, the patient reported improvement in migraine. After the fourth treatment, she reported having feeling better. At week 3, the patient reported no migraine. At week 4, the patient felt overall improvement and no migraine on the seventh treatment, However, she had a family event after the seventh treatment. She immediately had a moderate migraine on the right side of her head, and experienced nausea & vomiting, and a feeling of fullness

of the epigastrium. The VAS score was 5/10 on 8th visit. After 4 weeks of treatments, the patient returned for follow-up. The patient reported no migraine after the eighth treatment. She stated that she would keep avoiding stress that triggered her migraine. She reported that acupuncture helped to relieve her migraines (Table 7).

Table 7. Intensity of headache, frequency of migraine attack, and ROM in Case 1

	Date of Visit								
	1st Visit	2nd Visit	3rd Visit	4th Visit	5th Visit	6th Visit	7th Visit	8th Visit	Follow-Up
	Base Line	After 3 days	After 7 days	After 10 days	After 14 days	After 17 days	After 21 days	After 23 days	After 53 days
VAS of Migraine	3	3	1	1	0	0	0	5	0
Frequency of Migraine	1	1	0	0	0	0	0	1	0
Range of Motion (ROM)	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal

3.1.2. Case 2

- 1) Gender and Age: female, 47 years old
- 2) Chief Complaint:

The patient experiences migraine 1 time per month on average and experiences regular headache 1-2 times per month on average. Her migraine usually last no more than 2 hours after she takes her migraine medicine. Her migraines usually last 3-4 hours if she does not take her migraine medicine. Her migraines are moderate intensity migraines. Patterns of pains are throbbing/pounding, pressure, or dull in the both sides of the head. During the migraine attacks, the patient usually experiences nausea, bothered by light/noise, and difficulty concentrating. Stress (worry, anger), fatigue, or certain smell or perfume makes her migraine worse. Rest, or hot/cold compress makes her migraine headache better.

3) Past Illness, Family History:

A head injury or a neck injury: the patient fell from a swing at age 7 and hit her head. She was hospitalized overnight for observation. Her brother has migraine.

4) Present Illness:

The patient has been suffering from migraine headaches since her 20s and she has been having them almost constantly for over 20 years. She has been diagnosed with asthma and psoriasis. Her migraines have not been evaluated by a neurologist. She is taking over-the-counter drugs, such as Tylenol, or Excedrin to treat her migraine. The patient feels general malaise in both physical and emotional, minor stomach upset, and bitter taste.

5) Social History:

- a. Tobacco use: Non-Smoker
- b. Alcohol/drug use: None
- c. Occupation: Manager
- d. Marital Status: Married

6) Medication: Asthma spray inhaler, Tylenol, or Excedrin to treat her migraine.

7) Allergies: N.K.D.A.

8) Inspection: Slightly yellow, bright skin color, clear and shining eyes, thin hair, 5.6ft in height, 143 lbs. in weight

9) Listening Examination: Thoughts and words come out simultaneously.

10) Questioning Examination: Likes hot tea, fried foods, flashed face, dry mouth, sensitive personality, stable mental states.

11) Tongue and Pulse Examination: Pink, redder side, dry tongue, thin coating, wiry, rapid pulse

12) Questions:

- a. Digestion and Appetite: Normal appetite with satisfactory digestion
- b. Stool: 1 time/day
- c. Urine: 5~6 times/day
- d. Sleep: 7 hours/day, sometimes feeling fatigue in the morning
- e. Perspiration: no
- f. Menstruation: irregular
- g. Stress level: 6-7/10
- h. Emerge level: 5/10

13) TCM Diagnosis: Liver Yang Rising

14) Treatment Principle: Nourish Yin, Pacify the Liver, Subdue Yang

15) Western Medicine Diagnosis: Categorized as migraine without aura in accordance with the International Classification of Headache Disorders, 3rd edition (ICHD-3) enacted at International Headache Society (HIS).

3.1.2.1. Evaluation of the changes and results

After the first week of acupuncture, the patient reported improvement in migraine headache after first treatment. The migraine headache decreased on the second visit (Table 8). The VAS score was 4/10 on a patient self-report. At week 2, the patient reported improvement in migraine. After the fourth treatment, she reported having feeling better. The patient experienced a mild migraine, but her migraine was milder and shorter. At week 3, the patient reported improvement in her migraine headache. She

experienced a mild migraine that VAS core was 1/10. At week 4, the patient felt overall improvement and no migraine headache on seventh visit and eighth visit. After 4 weeks of treatments, the patient returned for follow-up. The patient reported a mild migraine headache that lasted 1 hour after the eighth treatment. She reported that acupuncture helped to relieve her migraines (Table 8).

Table 8. Intensity of headache, frequency of migraine attack, and ROM in Case 2

	Date of Visit								
	1st Visit	2nd Visit	3rd Visit	4th Visit	5th Visit	6th Visit	7th Visit	8th Visit	Follow-Up
	Base Line	After 5 days	After 8 days	After 12 days	After 15 days	After 19 days	After 21 days	After 26 days	After 57 days
VAS of Migraine	6	4	3	3	1	1	0	0	0
Frequency of Migraine	2	2	1	1	0	0	0	0	0
Range of Motion (ROM)	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal

3.1.3. Case 3

1) Gender and Age: female, 31 years old

2) Chief Complaint:

The patient experiences migraines 3 times per month on average. Her migraines usually last no more than 2 hours after she takes her migraine medicine. Her migraines usually last several days if she does not take her migraine medicine. Her migraines are severe intensity migraines. Patterns of pains are throbbing/pounding in the right side of the head and behind the right eye. During the migraine attacks, the patient usually experiences nausea, vomiting, bothered by light/noise, feeling lightheaded, blurred/double vision, difficulty concentrating or weakness of arm/leg. Stress (worry, anger), fatigue, missed meals, bright

sunshine, dehydration, or menstrual cycle makes her migraine headaches worse.

Rest, pressure over migraine headache area, quiet/darkness, drinking plenty of water, or taking Excedrin migraine makes her migraine headache better. The patient stated that a menstrual period or birth-control pill could change her migraine headaches.

3) Past Illness, Family History:

A head injury or a neck injury: the patient slammed forehead into a brick wall in 3rd grade and had bleeding cuts and bruises. Her mother has migraine headaches.

4) Present Illness:

The patient has been suffering from migraine headaches for 15 years old. She has been having them almost constantly for over 15 years. She has never been diagnosed to have any health disorder. Her migraines have not been evaluated by a neurologist. She is taking over-the-counter drugs, such as Excedrin to treat her migraine. The patient feels general malaise in both physical and emotional.

5) Social History:

- a. Tobacco use: Non-Smoker
- b. Alcohol/drug use: None
- c. Occupation: Office staff
- d. Marital Status: Single

6) Medication: Excedrin to treat her migraine.

7) Allergies: N.K.D.A.

8) Inspection: Slightly yellow, bright skin color, clear and shining eyes, thin hair, 5.3ft, in height, 100 lbs. in weight

- 9) Listening Examination: Thoughts and words come out simultaneously.
- 10) Questioning Examination: Likes ice tea, cold water, spicy fried foods, flushed face, dry mouth, a tendency to become angry or irritable easily, sensitive personality, stable mental states.
- 11) Tongue and Pulse Examination: Pink/red, dry tongue, thin coating, wiry, rapid pulse.

12) Questions:

- a. Digestion and Appetite: Normal appetite with satisfactory digestion
- b. Stool: 1 time/day
- c. Urine: 5~6 times/day
- d. Sleep: 7-8 hours/day, feeling fatigue in the morning
- e. Perspiration: no
- f. Menstruation: irregular
- g. Stress level: 5-6/10
- h. Emerge level: 6/10

13) TCM Diagnosis Liver Yang Rising

14) Treatment Principle: Nourish Yin, Pacify the Liver, Subdue Yang

15) Western Medicine Diagnosis: Categorized as migraine without aura in accordance with the International Classification of Headache Disorders, 3rd edition (ICHD-3) enacted at International Headache Society (IHS).

3.1.3.1. Evaluation of the changes and results

At 1st visit, she described her migraine as the worst feeling, with a pain scale rating of 8 out of 10 (10 being the highest level of pain). She did suffer from a severe

migraine headache that lasted 2 days, and she vomited twice. After the first week of acupuncture, the patient reported improvement in migraine after first treatment. The migraine decreased on the 2nd visit (Table 9). The VAS score was 5/10 on the 2nd visit. At week 2, the patient reported a little improvement in migraine. After the fourth treatment, she reported having feeling better. The patient experienced a mild migraine and her migraine headaches were milder and shorter. At week 3, the patient reported improvement in her migraine headache. She experienced a mild migraine headache that VAS score was 1/10. At week 4, the patient felt overall improvement and a mild migraine headache on 7th visit and no migraine on seventh visit and eighth visit. After 4 weeks of treatments, the patient returned for follow-up. The patient reported a mild migraine that lasted 1-2 hours after the eighth treatment. She reported that acupuncture helped to relieve her migraines (Table 9).

Table 9. Intensity of headache, frequency of migraine attack, and ROM in Case 3

	Date of Visit								
	1st Visit	2nd Visit	3rd Visit	4th Visit	5th Visit	6th Visit	7th Visit	8th Visit	Follow-Up
	Base Line	After 5 days	After 8 days	After 12 days	After 15 days	After 19 days	After 21 days	After 26 days	After 57 days
VAS of Migraine	8	5	5	4	2	2	1	0	0
Frequency of Migraine	3	3	1	1	1	1	0	0	0
Range of Motion (ROM)	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal

IV. DISCUSSION

This study focused on patients diagnosed with migraine headaches without aura. Mild or moderate intensity of throbbing/pounding attacks usually occur on one side of the head, while severe intensity attacks could occur all over the head. The duration of migraine was proportional to the intensity of migraine headache and the clinical characteristics were reported to vary by individual.

4.1. Case 1

4.1.1. Clinical progress

- 1) Progress on 1st visit ~3rd visit: There was minimal alleviation of pain after the 1st treatment, but the pain increased to the same level as the first visit on the second visit (Table 7). The pain decreased to level 1 on the 3rd visit.
- 2) Progress on 4th ~5th visit: There were no severe or moderate intensity attacks between the 3rd and 5th visit while a little intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 0 time/week on the 5th visit (Table 7). The VAS score decreased from level 1 on the 4th visit to Level 0 on the 5th visit.
- 3) Progress on 6th Visit ~7th visit: The frequency of moderate or mild intensity attacks decreased on each visit and from the 5th visit. Mild intensity attack did not appear anymore (Table 7).
- 4) Progress on 8th Visit: There were no severe intensity attacks, but the patient had a family event and it caused more stress than usual after the 7th treatment. The VAS score was 5/10 on 8th visit.

5) MSQ and MIDAS grades after 8th visit: The quality of life of patients with migraine was evaluated by MSQ and MIDAS before starting acupuncture treatment and at the end stage of the treatment. The score of MSQ increased from 67 to 84, and the grade of MIDAS decreased from grade 2 to 1. The results show the improved function in daily life (Table 10).

Table 10. Change of MSQ and MIDAS Questionnaire Scores/Grades in Case 1

Change of MSQ and MIDAS Questionnaire Scores/Grades		
	Pre-treatment	Post-treatment
MSQ	67	84
MIDAS	2	1

4.1.2. Acupuncture treatment

On the first visit, the patient was examined and found to have sensitive personality, Pale-pink tongue, thin coating, rolling /wiry pulse. During the migraine attack, the patient experienced a feeling of fullness of the epigastrium in the evening, indigestion, a feeling of heaviness in the left shoulder and arm, hypochondrial pain, constipation, and bitter taste. Therefore, the patient was diagnosed with Liver Qi Stagnation. Acupuncture treatment was planned for twice a week and the progress was observed.

GB 20 (Fengchi), DU 20 (Baihui), EX-HN5 (Taiyang), GB 8 (Shuaigu), and GB 5 (Xuanlu) were used for migraine. These acupuncture points are not only traditional acupuncture points, but also, they are located in the trigeminovascular system. Therefore, the acupuncture points could modulate CGRP Signaling in the Trigemino-vascular System

(TVS). LI 4 (Hegu), LIV 3 (Taichong), SP 6 (Sanyinjiao), and ST 36 (Zusanli) were used as supplementary points. LI 4 (Hegu) and LIV 3 (Taichong) were used for eliminating stagnation. SP 6 (Sanyinjiao) was used for regulating the circulation of Qi in the Liver, and ST 36 (Zusanli) was used for treating functional dyspepsia symptoms (Table 11).

Table 11. Acupuncture Point Selection and Indication of Case 1^{6,13,14}

GB 20 (Fengchi)	Meeting point of the Gall Bladder and Sanjiao channels with the Yang Motility. Yang Linking vessels. promote the circulation, relieve headache, one-sided and generalized headache, dizziness
DU 20 (Baihui)	Meeting point of the Governing vessel with the Bladder, Gall Bladder, Sanjiao and Liver channels, meeting of all the yang qi of the body, treat one-sided headache
EX-HN5 (Taiyang)	Treat headache at the side of head
GB 8 (Shuaigu)	Treat headache at the side of head, eliminate dampness, resolve phlegm, and relieve dizziness; treating parietal or temporal headache and heaviness
GB 5 (Xuanlu)	Treat one side headache extending to the outer canthus
LI 4 (Hegu) & LIV 3 (Taichong)	Open the four gates, enhance the circulation of Qi and blood throughout the body, be associated with Liver Qi Stagnation
SP 6 (Sanyinjiao)	The crossing point of the three yin channels of the foot; clears liver fire and regulates the circulation of qi in the liver
ST 36 (Zusanli)	He-sea and earth point of the stomach channel, stimulate the action of stomach and spleen in generating qi and blood, treat epigastric pain, nausea and vomiting

4.1.3. Evaluation of the changes and results

There was minimal alleviation of pain after the first treatment, but the pain increased to the same level as the 1st visit on the 2nd visit. The pain decreased to level 1 on the 3rd visit. There were no severe or moderate intensity attacks between the 3rd and

5th visit while a little intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 0 time/week on the 5th visit. The VAS score decreased from level 1 on the 4th visit to Level 0 on the 5th visit. The frequency of moderate or mild intensity attacks decreased on each visit from the 5th visit. Mild intensity attack did not appear anymore on the 6th and 7th visit. However, the patient had a family event and it caused more stress than usual after the 7th treatment. The VAS score was 5/10 on 8th visit. Acupuncture therapy was applied without any herbal medicine or manual therapy (Figure 6).

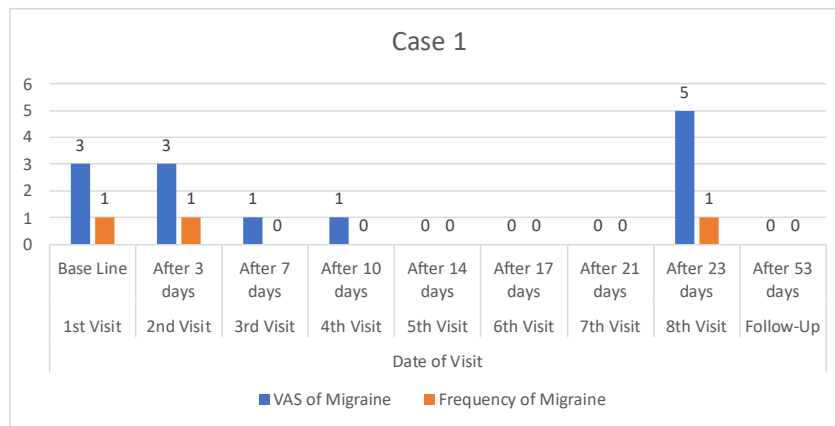


Figure 6. Change of intensity of headache and frequency of migraine attack in Case 1

4.2. Case 2

4.2.1. Clinical progress

- 1) Progress on 1st visit~3rd visit: There was alleviation of pain after the 1st treatment, and the pain decreased to level 4 on the second visit (Table 8). The pain decreased to level 3 on the third visit.
- 2) Progress on 4th ~5th visit: There was alleviation of pain after the 3rd treatment, but the pain increased to the same level as the third visit on the 4th visit. There

- were no severe or moderate intensity attacks between 3rd and 5th visit while a mild intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 0 time/week on the 5th visit (Table 8). The VAS score decreased from level 3 on the 4th visit to level 1 on the 5th visit.
- 3) Progress on 6th Visit ~8th visit: The frequency of mild intensity attacks decreased on each visit from the 5th visit. Mild intensity attack did not appear anymore (Table 8). The VAS score decreased from level 1 on the 6th visit to level 0 on the 7th and 8th visit.
- 4) MSQ and MIDAS grades after 8th visit: The quality of life of patients with migraine was evaluated by MSQ and MIDAS before starting acupuncture treatment and at the end stage of the treatment. The score of MSQ increased from 63 to 80, and the grade of MIDAS decreased from grade 2 to 1. The results show the improved function in daily life (Table 12).

Table 12. Change of MSQ and MIDAS Questionnaire Scores/Grades in Case 2

Change of MSQ, MIDAS Questionnaire Scores/Grades		
	Pre-treatment	Post-treatment
MSQ	63	80
MIDAS	2	1

4.2.2. Acupuncture treatment

On the first visit, the patient was examined and found to have sensitive personality, pink, redder side, dry tongue, thin coating, wiry, rapid pulse. During the migraine attack, the patient experienced experiences nausea, bothered by light/noise, and

difficulty concentrating. Therefore, the patient was diagnosed with Liver Yang Rising. Acupuncture treatment was planned for twice a week and the progress was observed. The following 5 traditional acupuncture points were treated for migraine headaches: GB 20 (Fengchi), DU 20 (Baihui), EX-HN5 (Taiyang), GB 8 (Shuaigu), and GB 5 (Xuanlu). These acupuncture points are located in the trigeminovascular system as well, so that these points could modulate CGRP Signaling in the Trigemino-vascular System (TVS) (Table 13).

LI 4 (Hegu), LIV 3 (Taichong), GB 43 (Xiaxi), LIV 2 (Xingjian), and KID 3 (Taixi) were used as supplementary acupuncture points. LI 4 (Hegu) and LIV 3 (Taichong) were used for eliminating stagnation, GB 43 and LIV 2 were used for subduing Yang, clearing Liver fire, or pacifying Liver wind. KID 3 was used for nourishing yin and cooling fire (Table 13).

Table 13. Acupuncture Point Selection and Indication of Case 2^{6,13,14}

GB 20 (Fengchi)	Meeting point of the Gall Bladder and Sanjiao channels with the Yang Motility. Yang Linking vessels. promote the circulation, relieve headache, one-sided and generalized headache, dizziness
DU 20 (Baihui)	Meeting point of the Governing vessel with the Bladder, Gall Bladder, Sanjiao and Liver channels, meeting of all the yang qi of the body, treat one-sided headache
EX-HN5 (Taiyang)	Treat headache at the side of head
GB 8 (Shuaigu)	Treat headache at the side of head, eliminate dampness, resolve phlegm, and relieve dizziness, treating parietal or temporal headache and heaviness
GB 5 (Xuanlu)	Treat one side headache extending to the outer canthus
LI 4 (Hegu) & LIV 3 Taichong	Open the four gates, enhance the circulation of Qi and blood throughout the body, be associate with Liver Qi Stagnation

GB 43 (Xiaxi)	The Ying-spring point of the Gall Bladder channel, Treat one side headache extending to the outer canthus, clear heat, subdue Yang
LIV 2 (Xingjian)	The Ying-spring point of the Liver channel, clear Liver fire, pacifies Liver wind
KID 3 (Taixi)	Nourishing yin and cooling fire.

4.2.3. Evaluation of the changes and results

There was alleviation of pain after the first treatment, and the pain decreased to level 4 on the 2nd visit. The pain decreased to level 3 on the 3rd visit. There was alleviation of pain after the third treatment, but the pain increased to the same level as the 3rd visit on the 4th visit. There were no severe or moderate intensity attacks between 3rd and 5th visit while a mild intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 0 time/week on the 5th visit. The VAS score decreased from level 3 on the 4th visit to level 1 on the 5th visit. The frequency of mild intensity attacks decreased on each visit from the 5th visit. Mild intensity attack did not appear anymore (Table 13). The VAS score decreased from level 1 on the 6th visit to level 0 on the 7th and 8th visit (Figure 7).

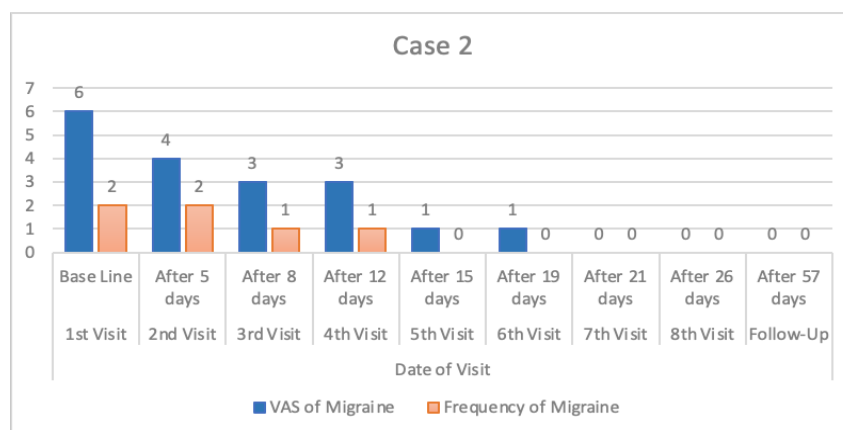


Figure 7. Change of intensity of headache and frequency of migraine attack in Case 2

4.3. Case 3

4.3.1. Clinical progress

- 1) Progress on 1st visit ~3rd visit: There was minimal alleviation of pain after the 1st treatment. The pain decreased to level 5 on the 2nd visit and the 3rd visit, but moderate intensity attacks occurred 3 times/week on the 2nd visit.
- 2) Progress on 4th ~5th visit: There was alleviation of pain after the third treatment, and the pain decreased to level 4 on the 4th visit. There were no severe intensity attacks between 3rd and 5th visit while a moderate intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 1 time/week on the 5th visit (Table 9). The VAS score decreased from level 4 on the 4th visit to level 2 on the 5th visit.
- 3) Progress on 6th Visit ~8th visit: The frequency of mild intensity attacks decreased on each visit from the 5th visit. A mild intensity attack occurred 1 time/week on the 6th visit, but a mild intensity attack did not appear anymore (Table 9). The VAS score decreased from level 1 on the 6th visit to level 0 on the 7th and 8th visit.
- 4) MSQ and MIDAS grades after 8th visit: The quality of life of patients with migraine was evaluated by MSQ and MIDAS before starting acupuncture treatment and at the end stage of the treatment. The score of MSQ increased from 59 to 77, and the grade of MIDAS decreased from grade 3 to 1. The results show the improved function in daily life (Table 14).

Table 14. Change of MSQ and MIDAS Questionnaire Scores/Grades in Case 3

Change of MSQ, MIDAS Questionnaire Scores/Grades		
	Pre-treatment	Post-treatment
MSQ	59	77
MIDAS	3	1

4.3.2. Acupuncture treatment

The patient was examined and observed on the first visit. The patient likes cold water, spicy fried foods, and has a flushed face, dry mouth, a tendency to become angry or irritable easily, sensitive personality, stable mental states. Patterns of pains are throbbing/pounding in the right side of the head and behind the right eye. During the attacks, the patient usually experiences nausea, vomiting, bothered by light/noise, feeling lightheaded, blurred/double vision, difficulty concentrating or weakness of arm/leg. Therefore, the patient was diagnosed with Liver Yang Rising. Acupuncture treatment was planned for twice a week and the progress was observed.

The following 5 traditional acupuncture points were treated for migraine headaches: GB 20 (Fengchi), DU 20 (Baihui), EX-HN5 (Taiyang), GB 8 (Shuaigu), and GB 5 (Xuanlu). These acupuncture points are located in the trigeminovascular system as well, so that these points could modulate CGRP Signaling in the Trigemino-vascular System (TVS) (Table 15).

LI 4 (Hegu), LIV 3 (Taichong), GB 43 (Xiashi), LIV 2 (Xingjian), and KID 3 (Taixi) were used or supplementary acupuncture points. LI 4 (Hegu) and LIV 3 (Taichong) were used for eliminating stagnation, GB 43 and LIV 2 were used for

subduing Yang, clearing Liver fire, or pacifying Liver wind. KID 3 was used for nourishing yin and cooling fire. Moreover, PC 6 (Neiguan) was used for harmonizing stomach and alleviating nausea and vomiting (Table 15).

Table 15. Acupuncture Point Selection and Indication of Case 3^{6,13,14}

GB 20 (Fengchi)	Meeting point of the Gall Bladder and Sanjiao channels with the Yang Motility. Yang Linking vessels. promote the circulation, relieve headache, one-sided and generalized headache, dizziness
DU 20 (Baihui)	Meeting point of the Governing vessel with the Bladder, Gall Bladder, Sanjiao and Liver channels, meeting of all the yang qi of the body, treat one-sided headache
EX-HN5 (Taiyang)	Treat headache at the side of head
GB 8 (Shuaigu)	Treat headache at the side of head, eliminate dampness, resolve phlegm, and relieve dizziness, treating parietal or temporal headache and heaviness
GB 5 (Xuanlu)	Treat one side headache extending to the outer canthus
LI 4 (Hegu) & LIV 3 (Taichong)	Open the four gates, enhance the circulation of Qi and blood throughout the body, be associate with Liver Qi Stagnation
GB 43 (Xiashi)	The Ying-spring point of the Gall Bladder channel, Treat one side headache extending to the outer canthus, clear heat, subdue Yang
LIV 2 (Xingjian)	The Ying-spring point of the Liver channel, clear Liver fire, pacifies Liver wind
KID 3 (Taixi)	Nourishing yin and cooling fire.
PC 6 (Neiguan)	Luo-Connecting point of the Pericardium channel Confluent point of the Yin Linking vessel, harmonizes the Stomach and alleviates nausea and vomiting

4.3.3. Evaluation of the changes and results

There was minimal alleviation of pain after the 1st treatment. The pain decreased to level 5 on the second visit and the third visit, but moderate intensity attacks occurred 3 times/week on the 2nd visit.

There was alleviation of pain after the third treatment, and the pain decreased to level 4 on the 4th visit. There were no severe intensity attacks between 3rd and 5th visit while a moderate intensity attack occurred 1 time/week on the 4th visit. The frequency decreased to 1 time/week on the 5th visit (Table 9). The VAS score decreased from level 4 on the 4th visit to level 2 on the 5th visit.

The frequency of mild intensity attacks decreased on each visit from the 5th visit. A mild intensity attack occurred 1 time/week on the 6th visit, but a mild intensity attack did not appear anymore. The VAS score decreased from level 1 on the 6th visit to level 0 on the 7th and 8th visit (Figure 8).

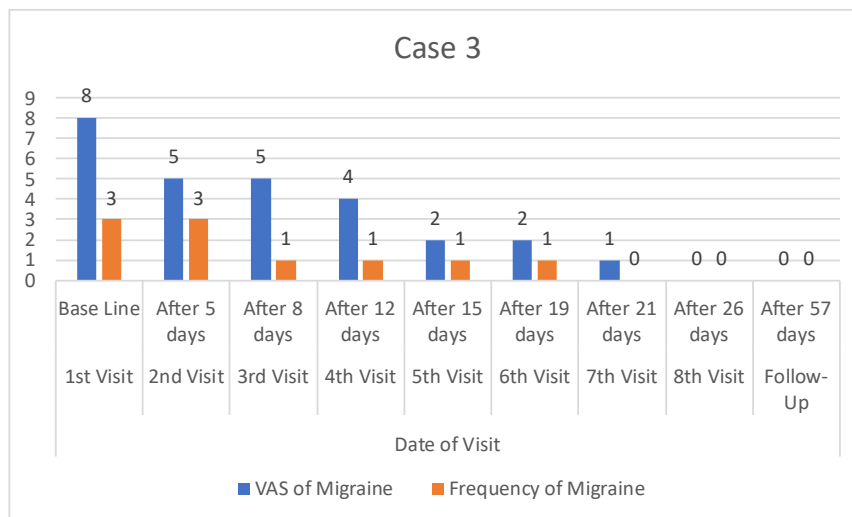


Figure 8. Change of intensity of headache and frequency of migraine attack in Case 3

4.4. The efficacy of acupuncture treatment

As a result, this study showed a significant decrease in the frequency of migraine attacks, migraine days, and VAS scores from pre-treatment to week 8 in all of the three cases. Moreover, this case study showed that the number of days per month with migraine, absence from work, and the need for medication significantly decreased from pre-treatment to post-treatment as well. Therefore, the acupuncture treatment could modulate CGRP Signaling in the Trigeminovascular System (TVS), and could prevent frequent migraines, and could have fewer migraine days and less severe migraine.

V. CONCLUSION

Migraine headache is a very common condition, but it has a significant adverse impact on quality of life. For this reason, migraine prevention treatment is recommended for migraine patients who frequently experience migraine headaches or whose headache symptoms are severe. The goal of migraine prevention treatment is to reduce the frequency, intensity, duration, and number of headaches taken, and to reduce the number of medications taken.

The CGRP antagonist is one of the most effective medications for preventing migraine headaches. The CGRP antagonist can provide relief in 2 hours while acupuncture treatment is effective after 6-8 sessions, however, acupuncture might be safer than the medication in treating migraines without aura. The CGRP antagonist may cause serious side effects including allergic reactions, such as swelling of the face, mouth, tongue or throat, and trouble breathing. Like the CGRP antagonist, the acupuncture treatment is expected to reduce migraine pain and prevent migraine attacks, so that GB 20 (Fengchi), DU 20 (Baihui), EX-HN5 (Taiyang), GB 8 (Shuaigu), and GB 5 (Xuanlu) were selected. In this study, these acupuncture points are located similar to the treatment site of modulating CGRP Signaling in the Trigeminovascular System (TVS) for the prevention of acute or chronic migraine.

While there is no specific treatment for migraines, the main goal of migraines is to reduce the frequency and severity of migraines. Lifestyle modification is very important for migraine patients, such as sleep, diet, exercise etc. Migraine patients need to be educated how to recognize and avoid their specific migraine triggers. Also, migraine patients need to be educated on their benefit in acupuncture migraine treatment.

In this clinical study, the clinical trial was conducted on three patients twice a week for a total of 8 sessions, for 4 consecutive weeks to investigate the effect of improvement of migraine headache without aura. Author compared and analyzed the VAS, MSQ, and MIDAS before and after treatment.

1. The average score of VAS was 5.7 before the first treatment, and the average score of VAS after the 8th treatment was 1.7, indicating a gradual decrease.
2. The average score of MSQ was 63 before the first treatment, and the average score of MSQ after the 8th treatment was 83, indicating improvement of Quality-of-Life.
3. The average grade of MIDAS was 2.3 before the first treatment, and the average grade of MIDAS after the 8th treatment was 1.3, indicating improvement of Migraine Disability.

In conclusion, this study shows that the acupuncture treatment was effective on migraine headache. However, this study only deals with three cases, so that it is difficult to generalize. Therefore, further studies with such cases are required even though acupuncture treatment could be effective and showed significant improvement in migraine patients without aura in this study.

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APPENDICES

Appendix-1

Informed Consent Form

You are invited to participate in a research study about “A Case Series of The Effect of Acupuncture Treatment on Migraine Headache: Modulating CGRP Signaling in the Trigeminovascular System (TVS)”.

Total goal of this research study is to investigate the effectiveness of acupuncture on migraine headache without aura.

The study design is that the patients with migraine headaches without aura will receive acupuncture treatment. Acupuncture will be applied to outpatients twice a week, a total of 8 times for 4 weeks from September 2024. VAS, frequency of migraine attack, and ROM will be measured before and after the acupuncture treatment for evaluating changes and results.

This study is being conducted by Hyun Joo Kim, L.Ac.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic. You may change your mind later and stop participating even if you agreed earlier.

Participating in this study may not benefit you directly, but it will help to enrich the knowledge on Acupuncture and Asian Medicine.

By Participating in this research, it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your condition will not get better and

that the new medicine or treatment doesn't work even as well as the old one. If, however, the medicine or treatment is not working, we will give the medication or treatment routinely offered to make you more comfortable. While the possibility of this happening is very low, you should still be aware of the possibility.

The information you will share with us if you participate in this study will be kept completely confidential to the full extent of the law. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Hyun Joo Kim, L.Ac.

If you have any questions about this study, please contact Hyun Joo Kim, L.Ac. at 1-714-248-9500 and kimhy101@southbaylo.edu. If you have any questions or concerns regarding your rights as a subject in this study, you may contact Chair of the South Baylo University. Institutional Review Board (IRB) at 213-738-0712.

YOU WILL BE GIVEN A COPY OF THIS FORM WHETHER OR NOT YOU AGREE TO PARTICIPATE.

Appendix-2

Pre Treatment Migraine Headache Questionnaire

Name _____ Date _____

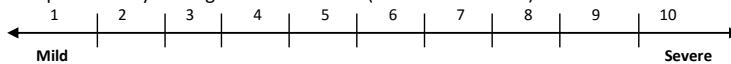
1. How many migraine headaches do you experience per month? _____ on average.

2. How many regular headaches do you have per month? _____ on average.

3. How long do your migraine headaches usually last after you take your migraine medicine?
☐ No more than 2 hours ☐ 3-4 hours ☐ 5-12 hours ☐ 12-24 hours ☐ Several days ☐ 1 week or longer

4. How long do your migraine headaches usually last if you do not take your migraine medicine?
☐ No more than 2 hours ☐ 3-4 hours ☐ 5-12 hours ☐ 12-24 hours ☐ Several days ☐ 1 week or longer

5. How painful are your migraine headaches? (Circle one number)



6. Where is your migraine headaches **usually** located? (Circle all that apply and indicate which area hurts the most.)

☐ Above/Behind the Eye Right Left Both ☐ Other areas: _____
☐ Temporal Area Right Left Both
☐ Occipital/Back of Head Right Left Both ☐ Area that hurts the most: _____

7. How old were you when your migraine headaches started? _____

8. How would you describe your migraine headaches? (Check all that apply)

☐ Throbbing/pounding ☐ Ache/pressure ☐ Like a tight band ☐ Dull ☐ Other

9. Do your migraine headaches awaken you at night?

☐ Never ☐ Occasionally ☐ Often

10. Do any of the following occur before or during your migraine headaches? (Check all that apply)

<input type="checkbox"/> Nausea	<input type="checkbox"/> Vomiting	<input type="checkbox"/> Diarrhea
<input type="checkbox"/> Bothered by light/noise	<input type="checkbox"/> Blurred/double vision	<input type="checkbox"/> Sparkling, flashing, or colored lights
<input type="checkbox"/> Eyelid puffy	<input type="checkbox"/> Eyelid droops	<input type="checkbox"/> Loss of vision
<input type="checkbox"/> Feeling lightheaded	<input type="checkbox"/> Numbness / tingling	<input type="checkbox"/> Weakness of arm or leg
<input type="checkbox"/> Difficulty concentrating	<input type="checkbox"/> Speech difficulty	<input type="checkbox"/> Loss of consciousness
<input type="checkbox"/> Runny nose	<input type="checkbox"/> Other _____	

11. Do any of the following bring on your migraine headaches or make them worse? (Check all that apply)

<input type="checkbox"/> Stress (worry, anger)	<input type="checkbox"/> Bright Sunshine	<input type="checkbox"/> Weather change
<input type="checkbox"/> Letdown" after stress	<input type="checkbox"/> Loud noise	<input type="checkbox"/> Heavy lifting
<input type="checkbox"/> Air travel	<input type="checkbox"/> Fatigue	<input type="checkbox"/> Certain smells or perfume
<input type="checkbox"/> Missed meals	<input type="checkbox"/> Sexual activity	<input type="checkbox"/> Coughing, straining, bending over
<input type="checkbox"/> Certain foods (chocolate, cheese, beer, MSG)	<input type="checkbox"/> Other _____	

12. Do any of the following make your migraine headaches better?

<input type="checkbox"/> Rest	<input type="checkbox"/> Exercise	<input type="checkbox"/> Quiet and darkness
<input type="checkbox"/> Hot or cold compress	<input type="checkbox"/> Massage	<input type="checkbox"/> Warm shower
<input type="checkbox"/> Pressure over migraine headache area	<input type="checkbox"/> Other _____	

12. If you are female, do your migraine headaches change with the following? (Check all that apply)

☐ Menstrual periods ☐ Birth control pills ☐ Pregnancy ☐ Other hormonal drugs

13. Do any of your family members have migraine headaches?

☐ No ☐ Yes - If "yes", explain (who): _____

14. Have you ever had a head or a neck injury requiring medical treatment?

☐ No ☐ Yes - If "yes", describe: _____

15. Have you ever been diagnosed to have any health disorder (e.g. high blood pressure, asthma, heart disease, gastric ulcers)?
☐ No ☐ Yes - If "yes," please list: _____

16. Have you had your migraine headaches evaluated by a neurologist? ☐ No ☐ Yes - If "yes", when, where, and by whom?
 What was the diagnosis? (Check all that apply):
☐ Migraine ☐ Tension-type ☐ Cluster ☐ Other, specify _____

17. List all past tests you had for your migraine headaches: ☐ MRI Brain/Neck/Both (circle: **Brain / Neck / Both**)
☐ MRI w/contrast ☐ MRI w/o contrast ☐ CT Scan ☐ EEG ☐ Sleep Study ☐ Other: _____ When/How long ago: _____

18. List all past treatment(s) for your migraine headaches: ☐ Botox ☐ Nerve Block ☐ IV Meds ☐ Medication
 Other Preventatives: _____

19. Have you had Botox to treat your migraines in the past? ☐ No ☐ Yes - If so, how many treatments did you receive and what was the dosage? _____ What kind of relief did you get? ☐ Complete ☐ Partial ☐ None
 How long did the relief last? _____

20. Which Medications are or have you taken?

Abortive	Past	Current	Preventative	Past	Current	Other - List	Past	Current
Triptan			Topomax					
Maxalt			Valproic Acid					
Relpax			Amitriptyline					
Amerge			Topiramate					
Zomig			Beta Blockers					
Imitrex			Inderal					
Frova			Lopressor					
Axert			Propanolol					
Treximet			Anti-Depressants					
Fiorinal/Florocet			Other Blood Pressure					
Ergots			Other Anti-Depressants					

21. Are you taking any *over-the-counter* drugs to treat your migraine headaches? ☐ No ☐ Yes - If "yes", list the medications under the "Other List" column above and how many times in the last month have you used the *over-the-counter* medications?

22. Have you been treated for a psychiatric condition, if so what condition and when was the last treatment?

23. Have you had hormone or vitamin levels checked? ☐ No ☐ Yes - If "yes", list when and the results.

24. Have you been treated for sinus or other related issues such as deviated septum? ☐ No ☐ Yes - If "yes", list the treatment provided.

25. Do you have numbness or tingling in the hands and/or neck? ☐ No ☐ Yes

26. How would you rate your general health in the last month? (Check one) ☐ Excellent ☐ Good ☐ Fair ☐ Poor

27. To what extent do your migraine headaches affect your quality of life? (Check one)
☐ Extremely ☐ Moderately ☐ Very little ☐ Not at all

28. Have you suffered from a head trauma or injury? ☐ No ☐ Yes - If "yes", state the nature of the injury, when the injury occurred and treatment provided.

29. Have you been diagnosed with or had the following treatments within the past year? If so when/how often?

☐ Eye exam _____ ☐ TMJ _____ ☐ Snore _____ ☐ Wear mouth guard _____ ☐ Wake up w/migraine _____
☐ Wear CPAP _____ ☐ Have seizures _____ ☐ Other _____

30. List any other medical condition, injury or concern not previously asked above that you feel we should know about.

Appendix-3

MSQ: MIGRAINE SPECIFIC QUALITY OF LIFE QUESTIONNAIRE

Please answer the following questions if you had a migraine attack in the previous 4 weeks. To complete, please circle the answer for each question.

1. Interfered with how well you get along with family, friends and others who are close to you?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
2. Interrupted with your leisure time activities such as reading or exercising?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
3. Difficulty in performing work or other daily activities?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
4. Kept you from getting as much accomplished as you normally do at work or at home?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
5. Limited your ability to work or do other activities as carefully as you usually do them?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
6. Had to cancel or delay work or social activities because you were exhausted?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
7. Left you with limited energy levels?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
8. Had to stop work or other activities?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
9. Needed the help of other people in handling routine tasks such as everyday household chores, doing necessary business, shopping, or caring for others when you had a migraine attack?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
10. Avoided social or family activities to treat your migraine attacks?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
11. Difficult for you to go to social events such as parties?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
12. Felt fed up or frustrated?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
13. Felt like you were a burden on others?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always
14. Been afraid of letting others down?
① Never ② Rarely ③ Sometimes ④ Pretty ⑤ Almost ⑥ Always

Total Score

--

Patient Name

Date of Birth

Date

Appendix-4

The Migraine Disability Assessment Test

The **MIDAS** (Migraine Disability Assessment) questionnaire was put together to help you measure the impact your headaches have on your life. The information on this questionnaire is also helpful for your primary care provider to determine the level of pain and disability caused by your headaches and to find the best treatment for you.

INSTRUCTIONS

Please answer the following questions about **ALL** of the headaches you have had over the last 3 months. Select your answer in the box next to each question. Select zero if you did not have the activity in the last 3 months. Please take the completed form to your healthcare professional.

- _____ 1. On how many days in the last 3 months did you miss work or school because of your headaches?
- _____ 2. How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school.)
- _____ 3. On how many days in the last 3 months did you not do household work (such as housework, home repairs and maintenance, shopping, caring for children and relatives) because of your headaches?
- _____ 4. How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)
- _____ 5. On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?
- _____ Total (Questions 1-5)

What your Physician will need to know about your headache:

- _____ A. On how many days in the last 3 months did you have a headache? (If a headache lasted more than 1 day, count each day.)
- _____ B. On a scale of 0 - 10, on average how painful were these headaches? (where 0=no pain at all, and 10=pain as bad as it can be.)

Scoring: After you have filled out this questionnaire, add the total number of days from questions 1-5 (ignore A and B).

MIDAS Grade	Definition	MIDAS Score
I	Little or No Disability	0-5
II	Mild Disability	6-10
III	Moderate Disability	11-20
IV	Severe Disability	21+

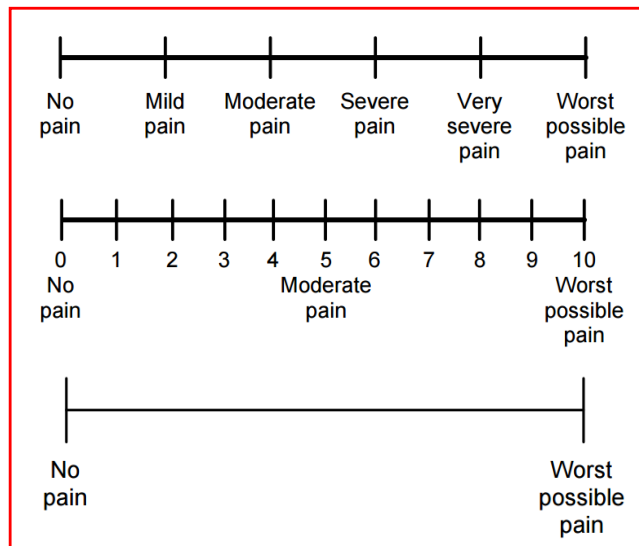
If Your MIDAS Score is 6 or more, please discuss this with your doctor.

VISUAL ANALOG SCALE (VAS) QUESTIONNAIRE

Word Descriptor Scale:

On a scale of 0 to 10, with 0 meaning no pain and 10 meaning the worst pain you can imagine, how much headache pain have you had this past week?

Visual Analog Scale



Graphic Scale



Certificate of Consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant (Print)

Name of Witness (Print)

Signature of Participant

Signature of Witness

Date: Day/Month/Year

Date: Day/Month/Year

Statement by the researcher/person taking consent:

I have accurately explained the information sheet to the potential participant. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant

Print Name Researcher (Print)

Signature of Researcher

Date: Day/Month/Year