# Effectiveness and Safety of Korean Medicine for Trigeminal Neuralgia: A Case Report\*

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### [Abstract]

- **Objectives :** This study aims to report the effectiveness and safety of Korean medicine with thread embedding acupuncture in the treatment of trigeminal neuralgia (TN).
- **Methods :** A 73-year-old man who had suffered from severe facial pain for one year and who had had a healthy tooth extracted due to the pain is reported. He could not eat or sleep due to the severe pain. Acupuncture, thread embedding acupuncture, cupping, herbal steam, and herbal medicines were used for the treatment. Numeric Rating Scale (NRS) and adverse events were checked daily, and other outcomes (Baseline Evaluation, Visual Analogue Scale [VAS], Short Form Health Survey 36-Bodily Pain [SF-36 BP], and Patient Global Assessment [PGA]) were measured at hospital admission and discharge. During the follow-up examinations, his pain was evaluated roughly, without using any formal measurements, on the basis of a global assessment.
- **Results :** All measured parameters, including pain, quality of life, and patient satisfaction were noted to have improved at the time of discharge compared to admission: VAS from 10 to 1.5, NRS from 7-8 to 1-2, and SF-36 BP from 0 to 22.5, and the patient's global assessment was somewhat improved. He did not take any analgesics after discharge and noted only mild adverse events, like pain where the acupuncture and thread embedding acupuncture needles were inserted. His pain relief was maintained for 6 months.
- **Conclusion :** Korean medicine with thread embedding acupuncture might be a safe and effective treatment for TN. In the future, larger sample sizes and high quality randomized clinical trials are warranted to confirm its efficacy and safety.

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# I. Introduction

Trigeminal neuralgia (TN) is characterized by recurrent unilateral brief electric shock-like pains. It is limited to one or more divisions of the trigeminal nerve and is triggered by innocuous stimuli<sup>1</sup>.

The annual incidence rate of TN is 4 to 13 per 100,000 and this condition gradually becomes more common with increasing age; most cases present after the age of 50 years<sup>2,3)</sup>. Almost all (80~90%) cases are caused by vascular compression of the trigeminal nerve at its entry into the pons. Other causes include meningioma, epidermoid and other cysts, saccular aneurysms, and arteriovenous malformations<sup>2,4,5)</sup>.

The diagnosis of TN is based on its characteristic clinical features (primarily paroxysms of pain in the trigeminal nerve), but it is difficult to distinguish from dental pain. Classic TN pain is intermittent and sharp, whereas dental pain is continuous and dull.

Carbamazepine is considered the gold standard for the initial medical treatment of TN<sup>6</sup>. Several other drugs have shown some evidence of effectiveness as well, including oxcarbazepine, baclofen, lamotrigine, and pimozide<sup>7</sup>. If patients are not responsive to these medical therapies, surgery can be considered. Surgical treatments can be divided into 2 categories: ablative procedures that include microvascular decompression and non-ablative procedures that include radiofrequency thermocoagulation, chemical (glycerol) injections, balloon compression, stereotactic radiosurgery, and peripheral neurectomy and nerve blocking<sup>7</sup>.

Acupuncture trials for TN were retrieved from 5 Korean web databases, the Research Information Sharing Service (RISS). Korean studies Information Service System (KISS), Oriental Medicine Advanced Searching Integrated System (OASIS), Korea Institute of Science and Technology Information (KISTI), and National Digital Science Library (NDSL). We found no studies similar to ours, which used thread embedding

acupuncture. Here, we report this approach using the data from the medical records of Pusan National University (Korean Medicine Hospital).

# II. Case study

# 1. Patient

Lee O.O., 73 years

# 2. Symptoms

- 1) The chief complaint was pain over the left lower face.
- 2) Other symptoms were insomnia and anorexia (secondary to pain)

### 3. Onset

May 2014

# 4. Patient's Past Medical History

- Cerebral infarction in 2012 for which he underwent a vascular surgery; he has been on medication since then.
- Dementia diagnosed in 2014; he has been on medication since then.
- Periodontitis was diagnosed in 2010 at the Pusan National University (Dental Hospital); thereafter, he was on medication for 6 to 7 months.

# 5. Family History

None

# 6. Present Medication

NEUROCEPT 5 mg (Donepezil hydrochloride), 1 Tablet hora somni (nootropic and neurotonic)

ALBIS 300 mg, 1 Tablet (Sucralfate hydrate, potassium bismuth citrate and ranitidine hydrochloride) quaque die (other antiulcerant) BONALING-A 50 mg, 1 Tablet (Dimenhydrinate) quaque die (antiemetic) CRESTOR 10 mg, 1 Tablet (Rosuvastatin calcium) quaque die (antilipidemic agent) NEUROMED 800 mg, 1 Tablet (Oxiracetam)

quaque die (nootropics and neurotonics) PLAVITOR 97,875 mg, 1 Tablet (Clopidogrel

hydrogen sulfate) quaque die (antithrombotic antiplatelet agent)

PLETAAL 50 mg, 1 Tablet (Cilostazol) quaque die (antithrombotic antiplatelet agent)

# 7. Present History

- May 2014: The patient experienced idiopathic pain over the left lower face. He went to a local hospital and was diagnosed with TN. Despite taking medication prescribed, the pain was not relieved.
- 2) July-August 2014: After making a rough guess that the pain might be due to a dental problem, he got his tooth extracted at a dental hospital to get relief from the pain; however, there was no improvement.
- December 2014: The patient visited the Pusan National University (Dental Hospital), but was unable to understand the reason for his pain and diagnosis.
- May 2015: The patient visited the Pusan National University (Korean Medicine Hospital) for the treatment of his facial pain.

# 8. Examination

#### 1) Baseline evaluation

The patient was asked to grade his pain intensity at presentation as severe, moderate, mild, or none. His self-evaluated pain intensity at admission was moderate.

#### Short Form Health Survey 36–Bodily Pain (SF–36 BP)

The SF-36 BP measures the state of bodily pain and disability over the past 4 weeks. It consists of 2 sections, and each scale is transformed into a 0-100 scale. The mean of the 2 values indicates the patient's degree of discomfort. (A higher score indicates a lower level of disability). Physical function and bodily pain are graded using this quality of life questionnaire.

### 3) Visual Analogue Scale (VAS)

The VAS is a graphically represented continuous scale that is 10 cm in length. Pain intensity grading ranges from 0 (no pain) to 10 (the worst pain imaginable), and the patients mark a point on the line that represents their perceived pain. The VAS is determined by measuring it from the starting point of 0 to the marked point. Upon admission, the patient-reported VAS was 10.

#### 4) Numeric Rating Scale (NRS)

Using the NRS, the patient-reported pain is verbally assessed by using a scale ranging from 0 to 10 (0 = no pain, 10 = the worst pain imaginable). As it is more convenient for evaluating the pain intensity compared to the VAS, we evaluated the patient using the NRS scale daily. On hospitalization, his NRS was 7-8.

# 9. Intervention

- 1) Acupuncture (Table 1)
- Herbal Medicine (Table 2)
   2015.05.11~19 'Gagamwiryeongtang' was pre-

1. Acupuncture rationale		
1a) Style of acupuncture	Classic acupuncture theory and Master Dong's acupuncture theory	
1b) Reasoning for treatment provided	Based on historical context and literature sources (e.g., The Textbook of Acupuncture and Moxibustion Medicine)	
1c) Extent to which treatment was varied	Semi-fixed formula; individualized acupuncture regimen according to the patient's symptoms and conditions	
2. Details of needling		
2a) Number of needle insertions per subject per session	10 $\sim$ 15 points; practitioner adjusted the number of needle insertions according to patient's symptoms and conditions	
2b) Names of points:	ST4, ST6, TE17, Ll2, Ll3, Ll4, LR3, LR2, and Ashi-point	
2c) Depth of insertion	$30 \sim 90$ mm (according to the expected tissue depth on acupuncture points)	
2d) Response sought	Subjective De-qi sensation	
2e) Needle stimulation	Manual stimulation of rotation, lifting and thrusting	
2f) Needle retention time	$0 \sim 20$ minutes	
2g) Needle type	Dong-bang stainless steel disposable acupuncture needle 0.40 $\times$ 60 mm, 4090 mm, 40 x 135 mm, 50 $\times$ 60 mm,	
3. Treatment regimen		
3a) Number of treatment sessions	31	
3b) Frequency and duration of treatment sessions	Twice daily until discharge (excluding the admission day)	
4. Other components of treatment		
4a) Details of other interventions administered to the acupuncture group	Dry-cupping, herbal steam therapy on face, herbal decoction, and thread embedding acupuncture	
5. Practitioner background		
5a) Description of participating acupuncturists	Two Korean medicine doctors,	
	<ol> <li>Resident trainee in acupuncture and moxibustion medicine with 3 years of experience</li> <li>Specialist of acupuncture and moxibustion medicine with more than 10 years of experience</li> </ol>	
6. Control or comparator interventions	No control intervention	

#### Table 1. Standards for Reporting Intervention in Clinical Trials of Acupuncture (STRICTA)

#### Table 2. Herbal Medicine Treatment

Date	Herbal medicine
2015.05.11~19	Forsythiae Fructus 16 g, Lonicerae Flos 16 g, Uncariae Ramulus et Uncus 12 g, Ulmi Cortex 8 g, Angelicae Dahuricae Radix 8 g, Astragali Radix 8 g, Gleditsiae Semen 6 g, Platycodi Radix 6 g, Atractylodis Rhizoma 6 g, Magnoliae Flos 6 g, Zingiberis Rhizoma 6 g, Saposhnikovia Radix 4 g, Notopterygii Rhizoma 4 g, Ligustici Sinense Radix 4 g, Cimicifugae Rhizoma 4 g, Puerariae Radix 4 g, Schizonepetae Spica 4 g, Glycyrrhizae Radix 4 g, Xanthii Fructus 4 g, Jujubae Fructus 4 g, Amomi Fuctus 4 g, Crataegii Fructus 4 g, Aconitum Koreanum 4 g, Cnidii Rhizoma 3 g, Ephedrae Herba 2 g, Asari Herba Cum Radix 2 g, Menthae Herba 2 g, Gardeniae Fructus 2 g
2015.05.19~26	Forsythiae Fructus 12 g, Lonicerae Flos 12 g, Paeoniae Radix 8 g, Rehmannia Glutinosa 6 g, Scrophularia Buergeriana 6 g, Angelicae Gigantis 6 g, Cnidii Rhizoma 4 g, Angelicae Dahuricae Radix 4 g, Astragali Radix 4 g, Schizonepetae Spica 4 g, Cimicifugae Rhizoma 4 g, Lycii Radicis Cortex 4 g, Phellodendri Cortex 4 g, Scutellariae Radix 4 g, Asari Herba Cum Radice 3 g

scribed 3 times a day, 2 hours after meal. 2015.05.19~26 'Chieunyangbang' was prescribed 3 times a day, 2 hours after meal. Additionally, sometimes, he was administered 'Uhwang cheongsimwon' to relieve the pain.

- Herbal Steam: Steam was applied to the face for 20 minutes twice daily. The steam consisted of Agastachis herba, Artemisiae Vulgaridis Folium, and Menthae Herba.
- 4) Cupping: Ten cups were placed on the upper back for 5 minutes, 1 or 2 times per day, for 7 days. This was repeated a total of 10 times.
- 5) Thread embedding Acupuncture August 26, September 16, and December 30, 2014: We performed thread embedding acupuncture 3 times, (29 G × 25 mm), and 10 thread embedding acupunctures were performed each time. Three thread embedding acupuncture needles were inserted in the frontal region, 3 in the zygomatic region, and 4 in the corner of his lip.

# 10. Treatment Period

May 11~26, 2015: Inpatient treatment May 27, 2015~January 13, 2016: Outpatient follow up treatment

#### 11. Results (Table 3)

We assessed the patient's NRS and adverse events daily, and other outcomes were measured at admission and discharge. His daily NRS showed fluctuations, but was never worse than at the time of hospitalization. After 15 days of treatment, all outcomes were better than at the initial admission.

- 1) Baseline Evaluation
- 2) SF-36 BP
- 3) VAS
- 4) NRS (Fig. 1)
- 5) Patient Global Assessment (PGA)

The patient's assessment of recovery after

	Admission (2015.05.11)	Discharge (2015.05.26)
Baseline evaluation	Moderate pain	Mild pain
SF-36 BP*	0	22.5
$VAS^{\dagger}$	10	1.5
NRS <sup>†</sup>	7–8	1–2
PGA§		Somewhat improved

Table 3. Changes in Outcomes after Treatment

\*: Short Form Health Survey 36-Bodily Pain.

†: Visual Analogue Scale.

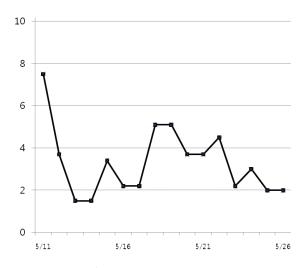
\* Numeric Rating Scale.

§: Patient Global Assessment.

treatment was evaluated at discharge. Response options included very much improved, somewhat improved, no change, somewhat worsened, and very much worsened. His response was "somewhat improved", and he had experienced a pain reduction of 70-80% as a result of the treatment.

6) Adverse Events

There were some adverse events, such as bleeding, pain, and bruising where the acupuncture or thread embedding acupunc– ture needles were inserted, but these were mild and transient events.





\* If patient reported his pain intensity as 7–8, it is regarded as 7.5 in this graph.

7) Follow Up

From May 27, 2015 through January 13, 2016, the patient continued to receive treatment (for a period of 35 weeks). He was administered weekly treatment; thus, he had a total of 35 sessions. Thread embedding acupuncture was performed 3 times in all, on August 26, September 16, and November 30, 2015. The patient reported that he was almost pain-free from October 17, 2015.

# III. Discussion

In the past six years, the number of patients visiting hospitals in Korea has exceeded 42,000 annually, and medical care benefit costs had increased to 5.5 billion won in 2015<sup>8</sup>. There is a growing need for appropriate treatment.

The prognosis of TN is variable because it is the intensity of pain that causes patients to seek treatment. Recurrence is common, and a single episode of pain may vary from 1 day to 4 years. Severe pain reduces a patient's quality of life.

Carbamazepine is the first-line treatment for classical TN. Based on 2 placebo-controlled studies that evaluated the use of carbamazepine in TN, a Cochrane systematic review concluded that carbamazepine is probably effective in some people with chronic neuropathic pain, including TN. However, in 4 studies, 65% (113/173) participants experienced at least 1 adverse event in the carbamazepine group, compared to only 27% (47/173) in the placebo group<sup>6</sup>. The adverse events included giddiness, unsteadiness, drowsiness, dizziness, blood dyscrasias, cutaneous problems, interference with other drugs, impaired mental and motor function in older people, skin rash, renal dysfunction, increase in liver transaminases, hyponatremia, ataxia, nausea, and cardiac arrhythmia<sup>9</sup>.

A Cochrane systematic review reported that all neurosurgical interventions produced variable pain relief, but their efficacy could not be confirmed because of the poor quality of the 11 included trials. Further, many of them resulted in several adverse events, including paresthesia or reduced sensation, reduced corneal reflexes, corneal keratitis, masseter dysfunction, cerebrospinal fluid leak, a transient rise in blood pressure and others<sup>10</sup>.

Concerning non-antiepileptic drugs, only low quality evidence is available regarding their efficacy in the treatment of TN, and there are several side effects. For example, 83.3% of pimozide users experienced at least 1 adverse event, such as physical and mental impairment, hand tremors, memory impairment, involuntary movements during sleep, and slight manifestations of Parkinson's disease.

There were no studies on microvascular decompression; observational data suggested that this treatment modality provided the longest-lasting pain relief.

There is little evidence to help aid comparative decision-making efforts regarding the best surgical procedure for treating TN. Well-designed studies are urgently needed to facilitate the same.

Acupuncture is broadly used for the relief of low back pain, neck pain, knee pain, headaches, and so on. The mechanism of analgesia is unclear, but it is assumed that it 1) harmonizes energy flow (Qi) and stimulates the body's natural healing mechanisms;<sup>10</sup> 2) allows for a variable combination of local effects; 3) induces the release of  $\beta$ -endorphins, endomorphins, and enkephalin, and brings about heightened levels of serotonin and dopamine in the blood and brain;<sup>12)</sup> 4) releases immune-modulators to induce the release of adrenaline and nor-adrenaline; and 5) promotes pain sensory inhibition at the spinal cord level.

Thread embedding acupuncture is a technique that provides longer stimulation to the acupoints than standard acupuncture. It acts as a foreign substance in the body that causes mechanical and biochemical effects, and results in aseptic inflammation. Persistent stimulation from the embedded acupuncture boosts the body's self-defense mechanisms and helps it become self-sustaining. It is known to be effective in the treatment of various chronic pains and functional diseases and has recently found application in facial palsy treatment, plastic surgery, obesity treatments, and a musculoskeletal disease treatment<sup>10</sup>.

In Korean medicine, we treat TN by addressing acupoints such as Hagwan (ST7), Hapgok (LI4), Chanjuk (BL2), Hyeopgeo (ST6), Taeyang (EX– HN15), and Sabaek (ST2). In particular, the third branch of trigeminal nerve pain is treated with Hyeopgeo (ST6), Hagwan (ST7), Daeyeong (ST5), and Seungjang (CV24)<sup>13</sup>.

A systematic review of acupuncture for TN suggested that it has an efficacy rate similar to that of carbamazepine, but with fewer adverse events; however, these results should be interpreted cautiously because the methodological quality of the reviewed studies were low<sup>14</sup>. Further, chuna combined with acupuncture has shown favorable results for TN compared to carbamazepine in a systematic review conducted in 2016, but this review also included studies with a high risk of bias.

This study has the following limitations:

- Only 1 case, a retrospective one, was considered; hence, the findings cannot be generalized.
- 2) We have an incomplete outcome assessment: we measured the patient's outcomes using VAS, NRS, SF-36 BP, and PGA, but the pain frequency and duration should also have been measured. Further, in this study, the patient's 24-hour mean pain intensity was measured using VAS, although the maximum pain, 24-hour mean pain, and minimum pain could have been measured separately. A Cochrane review considered complete pain relief without medication one year after randomization and pain intensity reduction of 30%, 50%, or greater as the primary outcomes.
- 3) The outcome was incomplete. At follow-up, no outcome measurements were used.
- 4) Several interventions were performed:

acupuncture, cupping, herbal steam, herbal medicine, and thread embedding acupuncture were used. For this reason, it is unclear as to which intervention was the most effective.

Despite the above limitations, this case report also has several strengths:

- We saw a rapid treatment effect; the patient had been suffering from severe pain for 1 year and had lost both his appetite and ability to sleep due to the pain. He even got his tooth extracted due to the pain, but experienced no relief. After one session of Korean medicine treatment, his pain intensity reduced by 50%, and his sleeping time increased from 2-3 hours to 6 hours. After 14 days of treatment, his pain, based on VAS, decreased from 10 to 1.5, with minimal adverse events like pain at the sites of acupuncture needle insertion. He has not taken any analgesics after being discharged.
- 2) Long-term follow-up was performed. The patient's hospitalization was for 15 days, but we continued his treatment and observation for 8 months. His pain intensity and adverse events were checked at every visit. During his treatment, pain levels were fluctuating. Sometimes his pain increased for no reason, or due to the cold, but the pain intensity was the worst when he first checked into the hospital. Sometimes after getting discharged, he even felt no pain.
- 3) The report about thread embedding acupuncture for the treatment of TN is the first of its kind in Korea. There have been several reports about Korean medicine and TN, but none of them focused on thread embedding acupuncture. We used thread embedding acupuncture for this patient's treatment and found it to be effective and safe; hence, we decided to report it.

Based on these results, we can suggest that Korean medicine with thread embedding acupuncture may be an effective and safe treatment modality for TN; however, this is just a case report. A randomized controlled trial is the gold standard for evaluating an intervention's true efficacy. There is no evidence to assess the effectiveness and safety of Korean medicine, and no evidence of its true economic costs. In the future, larger sample sizes and high quality randomized clinical trials are needed to confirm the effectiveness and safety of Korean medicine for TN. Future studies should report their methods in detail and use clear inclusion criteria, allocation concealment, randomization, double-blinded assessments, and adequate outcome measurements.

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