



Review Article

Analysis of Clinical Research Trends for Acupotomy Treatment of Peripheral Facial Palsy



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ABSTRACT

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The purpose of this review was to investigate acupotomy treatment for peripheral facial palsy. By reviewing recent clinical trends, this may contribute to standardizing acupotomy treatment methods. There were 7 randomized controlled trials and 6 case series using acupotomy treatment for peripheral facial palsy published between January 01, 2014 and April 05, 2021, which were retrieved from 9 online databases. The number and characteristics of participants, main treatment sites, combination treatments, size of acupotomy needle, frequency and total period of treatment, evaluation indices, efficacy, and adverse events were analyzed. "Tender point or induration," "infraorbital foramen," and "buccal mucosa" were the most used treatment sites. The sizes of acupotomy needles varied from 20 mm to 80 mm in length, and 0.35 mm to 1.0 mm in diameter. One treatment cycle was performed every 3 to 5-7 days, and the number of treatments per treatment session ranged from 3 to 5-9 cycles. The results were evaluated using 1 to 4 evaluation indices and 9 different evaluation indices were used overall. The efficacy rate was the most used index, followed by the House-Brackmann grade, and electrocardiography. The "Risk of Bias 2" categorized most studies as having "some concerns." There were few adverse events reported.

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Introduction

Peripheral facial palsy is a cranial nerve condition/disease characterized by symptoms of paralysis or weakened facial muscles including a reduction in the affected-side forehead wrinkles, ptosis, dry eye or epiphora, and sagging corners of the mouth [1]. In the 2019 National Health Insurance Statistical Yearbook, 111,089 people with facial palsy visited Oriental medicine institutions, resulting in an annual expenditure of about 41.4 billion won [2]. In the National Health Insurance Review and Assessment Service in the 2020 list of frequent conditions/diseases statistics, facial nerve disorders and facial palsy specifically ranked 21st and 24th, respectively, in the total number of inpatients and outpatients at Oriental medical institutions. Oriental medicine treatment of facial nerve disorders and facial palsy have a large socio-economic impact [3].

In Oriental medicine, facial palsy has been treated by a variety of conservative treatments including acupuncture, pharmacopuncture, thread-embedding therapy, Pyung-Hyung acupuncture, Miso facial rejuvenation acupuncture, the scratching method, and Chuna therapy [4-9]. However, it has been reported that if the appropriate treatment was not given within 72 hours after acute onset of facial palsy, various sequelae may occur in about 30% of cases [10]. This requires appropriate studies for more effective therapies to minimize neurodegeneration [10].

Acupotomy is a type of acupuncture which was developed by combining Oriental acupuncture and Western medicine surgery. Due to its simpler manipulation, shorter treatment period, and less damage to the relevant tissues than the surgical treatment, studies have been focused upon its therapeutic effect in the musculoskeletal system such as the cervical and lumbar spine, and joints [11]. Studies where acupotomy has been applied to

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the treatment of facial palsy have been steadily published both nationally and internationally.

In this review, acupotomy treatment of peripheral facial palsy and the latest clinical research trends were assessed to examine the use and standardization of acupotomy treatment methods.

Materials and Methods

Study materials

Articles reporting acupotomy treatment of peripheral facial palsy which had been published from 2014 to April 05 2021 were reviewed. The initial design of this study was to review studies published in the last 10 years. However, in the 7 relevant articles published from 2010 to December 2013, 1 article did not have the full text available, 1 article was determined to be irrelevant after checking its title and abstract, and the remaining articles were all case series (CS) of < 20 cases. Randomized controlled trial (RCTs), non-RCTs, and CSs containing ≥ 20 were reviewed in this study, while in vivo or vitro studies, CSs containing < 20 cases, systematic reviews, and protocol articles were excluded. Facial palsy which occurred due to cerebrovascular conditions/diseases, injury, and tumor, or facial palsy which developed into bilateral symptoms were excluded from this review. Studies which reported using acupotomy singly or in combination with other treatments were selected.

This study was a retrospective study and so informed consent was not necessary.

Literature search

Online databases

The literature search was conducted until April 05, 2021 using 4 international databases [PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI)], and 5 national databases [Oriental medicine Advanced Searching Integrated System (OASIS), Science ON, DBPIA, Korean Studies Information Service System (KISS), and Research Information Sharing Service (RISS)].

Search words and terms

In international databases, the search words were English terms of “facial palsy,” “facial paralysis,” “Bell’s palsy,” “facial neuritis,” “acupotomy,” “needle knife,” “mini-scalpel,” and “stiletto needle.” Other similar words such as “facial paresis,” “Bell’s paralysis,” “acupotome,” and “acupotomology” were also used. In Chinese and Korean databases, in addition to the English terms, Chinese words and Korean words were also used. Search terms were surveyed both in the titles and the abstracts, and search terms and formulas were modified and combined to suit the characteristics of each database.

Data screening and extraction

Two independent researchers checked the titles and abstracts, and selected final articles by reviewing the full texts, after considering the predefined inclusion and exclusion criteria. Disagreements which could not be resolved were referred to a 3rd researcher to determine the suitability of an article.

Data analysis and management

The 2 researchers used EndNote X8 to retrieve information the title, author, publication year, study type, sample sizes,

treatment sites, combined therapies, mean morbidity period, size of acupotomy needles, treatment cycle and frequency, evaluation indices, therapeutic effect, and adverse event reports.

Revised risk-of-bias tool for RCT

Two researchers assessed the risk of bias by applying the revised Cochrane Risk-of-Bias tool (RoB 2) to 7 RCT articles [12]. In response to each of relevant questions about bias, “high risk of bias,” “some concerns” or “low risk of bias” were observed, and if there were any disagreements between the 2 researchers, a 3rd researcher was consulted to reach a final agreement.

Results

Outcome

A total of 58 articles were retrieved from international databases: PubMed ($n = 0$), Cochrane Library ($n = 1$), EMBASE ($n = 2$), and CNKI ($n = 55$). A total of 30 articles were retrieved from national databases: OASIS ($n = 0$), RISS ($n = 1$), Science ON ($n = 1$), DBPIA ($n = 1$), and KISS ($n = 18$). A total of 88 articles were reviewed. Amongst them, 23 articles were removed due to duplication. Forty articles were published prior to 2014 and those whose titles and abstracts were irrelevant to acupotomy for peripheral facial palsy were ruled out. After screening, 1 article, whose full text could not be found, and 3 CSs with < 20 cases were also excluded, which led to the final selection of 13 articles. The literature selection process was plotted in the form of a flow diagram of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Fig. 1).

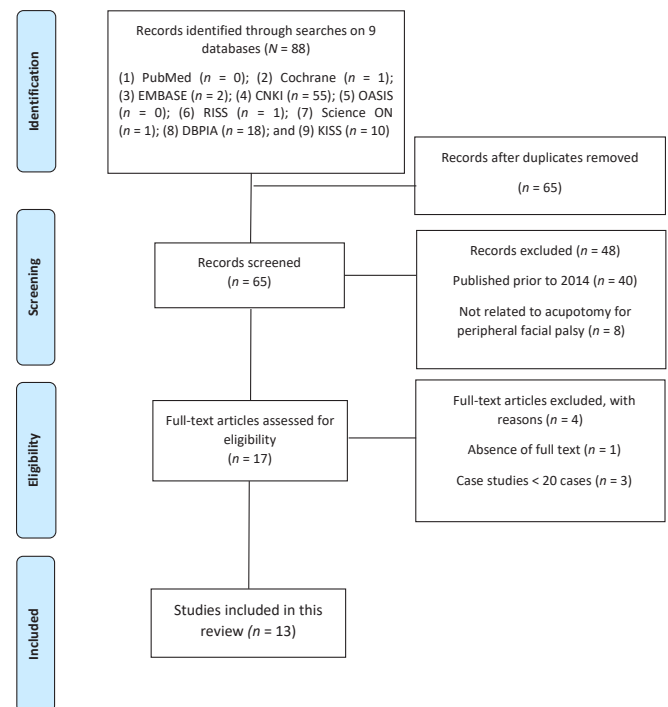


Fig. 1. The flow diagram according to preferred reporting items for systematic reviews and meta-analyses.

Abstract

Out of 13 articles, 12 articles were published in China, and 1 article was published in Korea. One article was published in 2014 and 2019. Two articles were published in 2015, 2016, 2018, and 2020. Three articles were published in 2017, indicating that the most articles were published in that year. In terms of the study type of the 13 articles, there were 7 RCTs and 6 CSs.

Analysis of selected articles

Sample size of study

In the selected 13 studies, an overall total of 655 participants were involved which consisted of 329 males and 326 females. Seven articles (2 RCTs and 5 CSs) had < 50 participants, 5 articles (5 RCTs) had > 50 < 100 participants, and 1 article (1 CS) had > 100 participants. Studies with the smallest, and largest number of participants were CSs which consisted of 23 and 128 participants, respectively (Tables 1 and 2).

Table 1. The Analysis of the Characteristics of Treatment.

First author (y) [reference]	Study type N (I:C)	Sample age (y) (I/C)	Sample (M:F) (I/C)	Course of condition/disease (I/C)	Acupoints (I)	Size (L × D; mm)	Treatment session & total period (I)
1. Lee (2014) [13]	RCT 30 (15:15)	50.80 ± 4.18 / 54.07 ± 4.04	6:9 / 7:8	≤ 10 D	- MP+C7 SP: SCM, SC, TE17 - NL - C2 SP+FJ - C1 TP - C1, C3 FJ	50 × 0.5	- Inpatient: 2 Tx/D - Outpatient: 2-3 Tx/ W (Total 3 W)
2. Zhao (2015) [14]	CS 25	17-72 (Mean: 45.2)	16:9	2 H-3 D (Mean 1.5 D)	- BC of affected side - Meridian of newly paralyzed region	-	-
3. Yang (2015) [15]	CS 23	18-64 (39.16 ± 8.25)	8:15	5 D-10 Y (2.49 ± 0.79 Y)	TP of cervical region	-	-
4. Tang (2016) [16]	CS 42	15-73	18:24	3.04 ± 0.28 M	ST07, TE17, ST02, EX-HN16, SI18, ST06, EX-HN4, GB14, ST04 (Choose 4-6 points)	40 × 0.5 (Type 1, No. 4)	- 1 Tx /5-7 D - 3 Tx /1 session (Min 2 Tx, Max 6 Tx)
5. Zhang (2016) [17]	RCT 42 (21:21)	50.0 ± 5.6 / 52.0 ± 6.0	9:12 / 8:13	≥ 2 M	- MP - Lower point of zygomatic arch - Infraorbital foramen - BC	50 × 0.6 (No. 4) 80 × 1.0 (No. 3)	- 1 Tx/4 D - 4 Tx/1 session (Next Tx after 5 D)
6. Zhang (2017) [18]	CS 25	Mean 37.6	17:8	3 D-6 M (Mean 4.32 M)	TE17, GB04, ST02, CV24, EX-HN8, ST05, ST07, LI04 (+) LR03, BC against induration (3 points)	30 × 0.4	2 nd Tx after 5 D of 1 st Tx (Not exceed 3 Tx)
7. Zhang (2017) [19]	RCT 52 (26:26)	45.21 ± 8.10 / 45.55 ± 8.46	16:10 / 15:11	≥ 1-3 M	ST07, TE17, ST02, EX-HN16, SI18, ST06, EX-HN4, GB14, ST04 (Choose 4-6 points)	40 × 0.5 (Type 1, No. 4)	- 1 Tx/5-7 D - 3 Tx /1 session
8. He (2017) [20]	RCT 70 (35:35)	32.26 ± 9.47 / 31.55 ± 9.21	19:16 / 18:17	15-51 D (29.28 ± 6.34) / 16-54 D (28.77 ± 6.62)	TD, nodule on 3 Yang meridians of hand and foot	40 × 0.35	1 Tx per 3 D (Total 10 Tx for 30 D)
9. Xu (2018) [21]	CS 128	28-75 (38.1 ± 9.5)	72:56	-	-	-	2 nd Tx after 5-7 D of 1 st Tx (3-4 Tx)
10. Hong (2018) [22]	RCT 60 (30:30)	25-47 (43.03 ± 5.27) / 28-65 (39.05 ± 6.43)	20:10 / 16:14	2.79 ± 1.30 D / 2.10 ± 0.85 D	- 2.5 cm outer of midpoint of inferior nuchal line - C2 SP - Midpoint & outer 1/3 point of C2 SP- MP line - C3-C6 SP - 3-4 cm outer of C7 SP - Medial border of subclavicular fossa - BC (1 W after o/s)	20 × 0.35	- Tx at intervals of 3-5 D - 5-9 Tx/1 session (+) BC: (1 Tx/W, 3 Tx/1 session)
11. Chen (2019) [23]	RCT 62 (31:31)	21-68 (44.5 ± 23.5) / 21-67 (44.0 ± 23.0)	15:16 / 16:15	-	STP	50 × 1.0	Next Tx after 1 W depending on progress
12. Wang (2020) [24]	CS 36	23-61 (18.45 ± 6.48)	16:20	3 M-25 Y (5.5 ± 2.6 M)	① Face: EX-HN4, GB14, ST02, BL02, GB01, EX-HN8, CV24, ST04, BC ② Neck: - C1-C7 TP & FJ - C2 SP - TP or induration on FJ, muscle	Type 1, No. 4	- 1 Tx/5-7 D - 3 Tx/1 session
13. Lu (2020) [25]	RCT 60 (30:30)	42.86 ± 13.62 / 42.42 ± 13.06	9:21 / 8:22	5.26 ± 3.18 D / 5.18 ± 3.22 D	- STP (Ant. & post. margin) - TP (Ant. & post. tubercle)+C2 SP - Facial TP, induration	50 × 0.8 (No. 4) 50 × 0.6 (No. 4)	- 1 Tx/3 D - 5 Tx/1 session (Total 15 D)

I, intervention group; C, control group; RCT, randomized controlled trial; CS, case series; MP, mastoid process; SP, spinous process; SCM, sternocleidomastoid muscle; SC, splenius capitis; NL, nuchal ligament; FJ, facet joint; TP, transverse process; STP, styloid process; TP, tender point; BC, buccal mucosa.

Table 2. Assessment and Main Results of the Studies.

First author (y)	Intervention group	Control group	Evaluation index	Main result (I/C)	Adverse events
1. Lee (2014) [13]	NKT+CA+PATx+HM+WM	CA+PATx+HM+WM	1. Y-score 2. VAS	1. ① I) Significant improvement in all periods (P01, P12, P23, P02, P03) ($p < 0.05$) C) Significant Improvement in all periods ($p < 0.05$) except P12 ($p = 0.085$) ② Comparison of improvement - P01, P23: I > C ($p > 0.05$), P12, P02, P03: I > C ($p < 0.05$) 2. ① Significant improvement in all periods ($p < 0.05$) except P12 (I: $p = 0.116$, C: $p = 0.359$) ② Comparison of improvement - P01, P12, P02: I > C ($p > 0.05$), P23, P03: I > C ($p < 0.05$)	Few cases of dizziness and poor condition (Recovered within 3 days)
2. Zhao (2015) [14]	NKT+WNA+PT+HM+WM	-	1. H-B 2. ER	1. Gr. I : 17 cases, Gr. II : 6 cases, Gr. III : 2 cases, Gr. IV-VI : 0 cases 2. 100%	No occurrence
3. Yang (2015) [15]	NKT+CA	-	1. ER	1. ① After 1 st Tx: 95.65% ② After 2 nd & 3 rd Tx: 100%	Not mentioned
4. Tang (2016) [16]	NKT+modified flash cupping method	-	H-B ER	1. Gr. I : 27 cases, Gr. II : 11 cases, Gr. III : 2 cases, Gr. IV-VI : 2 cases 2. 95.23%	No occurrence
5. Zhang (2016) [17]	NKT	FNA	1. ER	1. 100% / 66.7% ($p < 0.05$)	Not mentioned
6. Zhang (2017) [18]	NKT	-	1. ER	1. 96%	Not mentioned
7. Zhang (2017) [19]	NKT+HOT+MNGF+WM	MNGF+WM	1. H-B 2. ER	1. Gr. I : 0→8 / 0→3, Gr. II : 2→7 / 2→4, Gr. III : 7→7 / 6→3, Gr. IV : 7→2 / 7→5, Gr. V : 6→1 / 5→6, Gr. VI : 4→1 / 6→5 ($p < 0.05$) 2. 84.6% / 38.5% ($p < 0.05$)	No occurrence
8. He (2017) [20]	NKT+WM	CA+WM	1. ER 2. SFGS 3. EMG 4. IC	1. 91.4% / 80.0% ($p < 0.05$) 2. $44.22 \pm 10.45 \rightarrow 76.64 \pm 10.06 / 46.25 \pm 10.32 \rightarrow 68.18 \pm 12.15$ ($p < 0.05$) 3. ① CMAP pulse width: $0.85 \pm 0.43 \rightarrow 1.24 \pm 0.46$ ($p < 0.05$) / $0.89 \pm 0.47 \rightarrow 1.01 \pm 0.35$ ② R1 latent period: $12.18 \pm 1.98 \rightarrow 8.78 \pm 1.85$ ($p < 0.05$) / $12.61 \pm 2.63 \rightarrow 10.66 \pm 2.27$ ($p < 0.05$) 4. 11.43% / 20% ($p > 0.05$)	Not mentioned
9. Xu (2018) [21]	NKT+CA+HM	-	1. ER	1. 98.44%	No occurrence
10. Hong (2018) [22]	NKT+CA (CA: taiji six-he acupuncture)	WM	1. ER	1. 96.67% / 83.33% ($p < 0.05$)	Not mentioned
11. Chen (2019) [23]	NKT+CA+WM+Chuna	CA+WM+Chuna	1. ER 2. TCM 3. EMG	96.77% / 58.06% ($p < 0.05$) 2. ① Mouth & eye deviation: $0.45 \pm 0.23 / 2.17 \pm 0.44$ ② Facial numbness: $0.51 \pm 0.25 / 2.20 \pm 0.41$ ③ Eyelid insufficiency: $0.42 \pm 0.27 / 2.22 \pm 0.38$ ④ Facial convulsion: $0.52 \pm 0.21 / 2.35 \pm 0.40$ ($p < 0.05$) 3. ① OO: $59.31 \pm 11.56 \rightarrow 98.54 \pm 9.62 / 58.34 \pm 12.94 \rightarrow 75.88 \pm 8.63$ ② FB: $18.39 \pm 4.33 \rightarrow 48.66 \pm 4.93 / 19.27 \pm 3.35 \rightarrow 34.56 \pm 3.87$ ③ LLS: $21.35 \pm 7.22 \rightarrow 82.51 \pm 9.78 / 22.18 \pm 7.57 \rightarrow 55.37 \pm 8.61$ ($p < 0.05$)	Not mentioned
12. Wang (2020) [24]	NKT+Facial scraping	-	1. H-B 2. ER	1. $1.47 \pm 0.73 \rightarrow 4.56 \pm 0.83$ 2. 94.4%	Not mentioned
13. Lu (2020) [25]	NKT	WM	1. FFAS 2. ER	1. $9.84 \pm 4.68 \rightarrow 27.16 \pm 2.86 / 9.86 \pm 4.66 \rightarrow 23.68 \pm 6.12$ ($p < 0.05$) 2. 86.67% / 73.33% ($p < 0.01$)	Not mentioned

NKT, needle knife treatment; CA, common acupuncture; PATx, pharmacopuncture; PT, physiotherapy; HM, herbal medicine; WM, western medicine; Y-score, Yanagihara score; VAS, visual analogue scale; Paβ, period from the α th visit to β weeks later; WNA, warm needling acupuncture; H-B, House-Brackmann grade; ER, efficacy rate; Tx, treatment; FNA, fire needling acupuncture; HOT, hyperbaric oxygen therapy; MNGF, mouse nerve growth factor; TCM, TCM syndrome score; EMG, electromyography; SFGS, Sunnybrook facial grading scale; IC, the incidence of complications; OO, orbicularis oris; FB, frontal belly; LLS, Levator labii superioris; FFAS, facial nerve function assessment scale.

Table 3. The Frequency of Mentioning Acupotomy Treatment Sites.

Frequency	Treatment points
5	Tender point or induration, Buccal mucosa of affected side, ST02 (Infraorbital foramen)
4	GB14, ST07 (Lower point of zygomatic arch), C2 Spinous process
3	TE17, EX-HN4, ST04
2	EX-HN8, CV24, EX-HN16, ST06, SI18, C1-3 Facet joint, Styloid process, Mastoid process
1	ST05, LI04, LR03, BL02, GB01, Anterior & posterior tubercle of transverse process of cervical spine, C1 Transverse process, C3-6 Spinous process, C4-C7 Facet joint, C7 Spinous process and its 3-4 cm outer point, Midpoint & outer 1/3 point of C2 spinous process-mastoid process line, Nuchal ligament, Medial edge of subclavian fossa 2.5 cm outer of midpoint of inferior nuchal line

Treatment sites and combination therapies

In performing acupotomy, 4 articles described their treatment points based on the anatomical structure site alone, 2 studies based it on the acupoint alone, and 2 studies based it on the facial or posterior cervical induration alone. Both the anatomical structure and the acupoint were used as the treatment points in 3 studies, and 1 study treated both acupoints and the induration. One article had no specific description of the treatment site in their article (Table 3).

In the intervention group, 3 studies applied only acupotomy, and 7 articles used a combination of acupotomy and other acupuncture therapies: 1 study used pharmacopuncture, 1 study used fire needling, and 5 studies used acupuncture.

Among the concurrent treatments in the intervention group in the studies reviewed, with the exception of acupuncture, there were 3 articles that described herbal medicine treatment and 5 articles which mentioned Western medicine treatment. Facial Scratching, physiotherapy, the cupping method, and Chuna therapy were mentioned in 1 article, each.

Mean morbidity period and intractable facial palsy

Of the 8 articles that reported the mean morbidity period clearly, 3 articles mentioned an average mean morbidity period of < 10 days, 1 article mentioned an average of ≥ 10 days < 3 months, 3 articles mentioned an average of > 3 months < 1 year, and 1 article mentioned an average of ≥ 1 year.

A total of the 5 articles mentioned intractable facial palsy was an inclusion criteria or the described symptoms similar to intractable facial palsy.

Size of acupotomy needles

Ten out of 13 articles specified the needle length and diameter, and the remaining article only mentioned the needle type and model number. Out of articles which reported the needle length and diameter, 2 studies used needles of 2 different sizes, depending on treatment points, in the same case (Table 4).

Treatment cycle and frequency

The treatment cycle was reported either 3 days, or 5-7 days, and the number of treatments for each treatment session was reported as 3 cycles, or 5-9 cycles in 10 articles which mentioned treatment cycle or session.

The total number of treatment cycles performed during the study period ranged from 2-10 cycles, and there were 3 articles

Table 4. The Size of Acupotomy Needle and Frequency of use.

Size (mm)*	Frequency
20 × 0.35	1
40 × 0.35	1
30 × 0.40	1
40 × 0.50	2
50 × 0.50	1
50 × 0.60	2
50 × 0.80	1
50 × 1.00	1
80 × 1.00	1

*Length × diameter.

with the total study period specified: 15 days, 3 weeks, and 30 days.

Evaluation index

All articles were assessed based on at least 1 index and at most 4 indices, and a total of 9 evaluation indices were used. The total efficacy rate, which was the most used, was applied 12 times, followed by the House-Brackmann grade, and electromyography which were used 4 times and 2 times, respectively. Each of the remaining 6 evaluation indices were used once.

When analyzing the number of evaluation indices used per study, 6 articles used 2 evaluation indices, and 5 articles used 1 evaluation index. One article used 3 evaluation indices, and 1 article used 4.

Therapeutic effect

In Lee's study [13], 1 of the 7 articles where statistics was performed on the efficacy rate, the treatment group had a greater improvement in symptoms compared with the control group (based on the Yanagihara score), 1 week after the initial visit, and

for the period 2 to 3 weeks following the initial visit, however, this difference was not statistically significant. In addition, postauricular pain intensity (measured by the Visual Analogue Scale score) did not significantly improve for the period 1 to 2 weeks following the initial visit, and when compared with the improvement to the control group, there was also no significant improvement 1 week after the initial visit, for the period 1 to 2 weeks following the initial visit, and 2 weeks after the first visit [13]. He et al [20] reported that in assessing the therapeutic effect, there was a significant improvement compared with the control group, based on the evaluation indices including the total efficacy rate, the Sunnybrook Facial Grade System, and the electromyography though the incidence of complications showed no significant improvement. The remaining therapeutic effects in the studies of Lee et al [13] and He et al [20] were all assessed to be significant, and the articles [14-16,18,21,24] where statistical analysis was not performed had a total efficacy rate of between 94.4% and 100%.

Adverse events

Amongst the 13 articles, 8 articles did not mention safety, accidents, or adverse events, however, 4 articles specifically stated no safety concerns. Lee et al [13] only reported dizziness and poor conditions were sometimes observed which mostly disappeared within 3 days in sensitive patients, and there were no adverse events due to hematoma or nerve damage, and dropouts.

Assessment of the risk of bias

Seven of the 13 articles, which were RCT, were assessed for risk of bias in 5 assessment items using RoB 2. The results of assessing the risk of bias were plotted with Risk-of-Bias Visualization (ROBVIS) [26] (Figs. 2 and 3).

1. Bias arising from the randomization process

Only 1 article noted the allocation sequence, which was reported as random and concealed, so this article was categorized as a “low risk of bias.” The remaining 6 articles only briefly mentioned the randomization, so they were categorized as “some concerns” arising from the randomization process.

2. Bias due to deviations from the intended interventions

In 7 articles, bias was introduced into the study because deviations from the protocol had occurred in the blinding of the intervention from the participants and the researchers and a sham control was not implemented. Six of these articles, with no missing values, were categorized as “some concerns,” and 1 study which was conducted on half of the participants (after drop out) was categorized as “high risk of bias” due to a deviation from the intended patient number for intervention of the study.

3. Bias due to missing outcome data

Six articles described intervention results measured on all participants, and so these articles were categorized as “low risk of bias” due to missing data. The remaining article was categorized as “high risk of bias,” because the results were analyzed for half the participants (excluding the dropouts).

4. Bias in measurement of the outcome

In 6 articles, because the measurement of outcome was assessed by facial muscle functionality or the total efficacy rate, which is relatively objective, these studies were classified as “low risk of bias.” The remaining article was categorized as “some concerns” due to the use of the Visual Analogue Scale score, which is a subjective measurement of pain, that could affect the assessment of intervention outcome with patient knowledge of the intervention.

5. Bias in selection of the reported result

In 7 articles there was no mention of a separate protocol or prior plans, but they were categorized as “some concerns” of bias

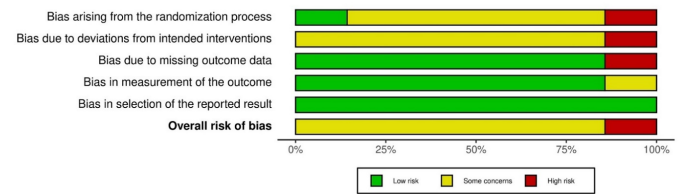


Fig. 2. Risk of bias graph.

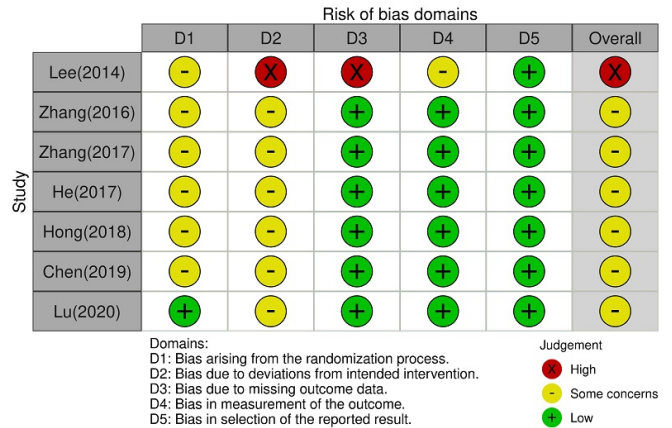


Fig. 3. Risk of bias summary. (X): High risk of bias, (+): Low risk of bias, (-): Some concerns.

in selection of the reported result because there was no clear evidence of selectively reporting only specific intervention results or analyses estimating the results of specific interventions.

Discussion

Facial nerve palsy is largely divided into supranuclear central palsy and infranuclear peripheral palsy, and 70% of facial palsy was reported to fall into peripheral facial palsy [27,28]. The facial nerve (the 7th cranial nerve), tends to be easily damaged because it has a longer pathway than any other cranial nerves, and passes through the narrow facial canal [29]. Inflammatory changes due to viral infection of the facial nerve can cause segmental demyelination and the resultant edema may apply pressure on the nerve within the facial canal causing facial nerve palsy [28].

Western medicine treatments for peripheral facial palsy include high-concentration oral steroids, and antiviral agents applied at the initial treatment, with painkillers concurrently administered when accompanied by neuralgia. When indicated, surgical treatments such as facial nerve decompression, and nerve transplantation are performed [30,31]. In particular, the nerve decompression has recently emerged as a solution for cases where > 90% of neurodegeneration occurs within 14 days from the onset [32].

The sites for acupotomy treatment in the intervention group were largely described in 3 ways: the anatomical structure, the acupoint, and the facial or posterior cervical induration. According to traditional acupoints and meridians, there are acupoints in the

stomach, gallbladder, bladder, large intestine, and a triple energizer meridian which have been frequently used to treat facial palsy. In addition, from an anatomical point of view, as the facial nerve receives blood from adjacent blood vessels such as the stylomastoid artery, persistent ischemia occurs due to inflammatory edema triggering neurodegeneration and causing facial dysfunction including facial palsy [33]. Acupoints like TE17, EX-HN16, ST07, SI18, ST04, TE23 and CV24 are influenced by the facial nerve, because they are located on the pathway of the facial nerve or in its vicinity [34]. It can be expected that acupotomy would not only provide the meridian-associated therapeutic effect through the relevant acupoints, but also create nerve decompression, and normalized blood supply to the relevant facial nerve. When treating buccal mucosa with acupotomy, similar effects as described above can be expected because it is also located on the pathway of the facial nerve. On the other hand, cervical vertebra spinous process, transverse process, and facet joints are the origins and insertions of several posterior cervical muscles, so acupotomy stimulation of those parts may remove facial nerve inflammation, edema, dehydration, and entrapment of adjacent blood vessels [35,36].

In 11 studies, the course of facial nerve palsy treatment was specified, varying from 10 days to > 1 year. Five articles mentioned intractable facial palsy in the participant inclusion criteria or described similar symptoms.

Ten articles stated length and diameter of acupotomy needles used in the treatment, and 2 studies used acupotomy needles of 2 different sizes, depending upon the treatment sites in the same study. Zhang et al [17] used a No. 4 needle measuring 50 mm × 0.6 mm and a No. 3 needle measuring 80 × 1.0 mm. It can be assumed that thicker and longer needles were used to ensure therapeutic facilitation with the same force to reach deeper structures such as the buccal mucosa. Lu reported a No. 4 needle which was 0.8 mm wide was inserted to the anterior and posterior borders of the styloid process, and a No. 4 needle which was 0.6 mm wide was inserted into the tender point, and the induration of the facial muscle, respectively. It can therefore be assumed that the tender point, and the induration on the face, are in a more superficial layer rather than the styloid process [25].

In He's study, an acupotomy needle, and an acupuncture needle of the same size, 0.35 × 40 mm, were used in the treatment group and the control group, respectively. The control group received 1 treatment cycle daily, whereas 1 treatment cycle for the intervention treatment group was performed every 3 days. It can be assumed that more days were required for the treatment site recovery following acupotomy [20]. However, since only 3 articles specifically mentioned the total study period and the total number of treatment cycles, which varied from 2 cycles to 10 cycles, it was considered that studies in the future should design the total study period and the number of treatment cycles more specifically.

Among the 9 evaluation indices used in the 13 articles reviewed, the total efficacy rate was most frequently applied. It can be assumed that efficacy rate has the advantage of being a simpler, quicker assessment. However, it also has the disadvantage of possibly producing different values depending upon the assessor's subjectivity in assessing facial functionality. Thus, evaluation indices should be itemized in more detail and more objective numerical values should be presented.

Regarding safety, accidents, or adverse events, only the study by Lee et al [13] reported dizziness and poor conditions were sometimes observed. However, as acupotomy is an invasive therapy that involves creating a stronger stimulation than achieved using acupuncture. Thus, concerns about infection, and damage to adjacent nerves and blood vessels, and imposing a physical burden,

and an acupuncture-associated vasovagal response in sensitive patients, it is necessary to monitor the patient longer-term and on a more elaborate basis.

Bias indicates systematic errors created in the study, possibly overestimating or underestimating the study findings [37]. There were 7 RCT out of 13 articles assessed for risk of bias for 5 items. In assessing the bias arising from the randomization process, only 1 article was categorized as "low risk of bias," suggesting that randomization of participants, especially the concealment of the allocation sequence should be designed more systematically. In blinding, only the study by He et al [20] inserted acupuncture needles to the control group which were the same size as the intervention group, while the remaining articles did not present any sham therapy. It was considered that it would be difficult to blind the participants and the intervention providers due to the shape of acupotomy needles and the invasive nature of acupotomy. As a result, 7 articles were categorized as "some concerns" in terms of the overall risk of bias.

It was reported that applying acupotomy to peripheral facial palsy improves facial expression muscle dysfunctions. However, all of 13 articles selected for this study were published in non-English speaking countries, and there may be more articles published in English or other languages which the search terms did not capture in the databases. This study also has the limitation that all 13 selected articles were not RCTs and therefore, a sufficient number of studies have not yet been published on acupotomy treatment of peripheral facial palsy. In addition, the risk of bias in many of the selected articles were not low risk, thus more systematic design of randomization and blinding is required.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Ethical Statement

This research did not involve any human or animal experiment.

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