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SYSTEMATIC REVIEW

Effect of miniscalpel-needle on relieving the pain of myofascial pain syndrome: a systematic review

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Abstract

OBJECTIVE: To evaluate the effect and safety of miniscalpel-needle (MSN) on reducing the pain of myofascial pain syndrome (MPS).

METHODS: We reviewed the available literatures inception up to February 2014 using Pubmed, EMBASE, Cochrane Library, Chinese National Knowledge Infrastructure Database, Chinese Biomedical Database and Wanfang Database.

RESULTS: Eight randomized controlled trials were finally identified. The main controls involved acupuncture, medications, injection, massage and cupping. We found that all of the studies agreed on the potential benefit of MSN as a strategy for MPS and the superiority compared to the controls, however, randomized methods applied in most of the trials could be criticized for their high or unclear risk of bias. Further research is also needed to clarify questions around the appropriate frequency and number of treatment sessions of MSN.

CONCLUSION: This review shows that MSN might have the effect on MPS, even though there were some limitations in the studies included in the review. Studies with robust methodology are warranted to further test its pain-relieving effect on MPS.

Key words: Myofascial pain syndromes; Miniscalpel-needle; Treatment outcome; Review

INTRODUCTION

Myofascial pain syndrome (MPS), is characterized by the existence of trigger points within muscles, it could be defined as a regional muscular pain syndrome. The myofascial trigger points (MTrPs), as Simons and Travell[1] described, are highly localized hyperirritable spots in a palpable, taut band of skeletal muscle fibers. MPS may be the most common causes of persistent musculoskeletal pains,[2, 3] and it may cause many functional and psychiatric complications such as anxiety, depression, and loss of functional capacity.[4]

There are many treatment therapies proposed for this disease, including pharmacological and nonpharmacological interventions. Pharmacological treatments consist of anti-inflammatory, analgesic and narcotic medications which is been used for symptom control.[5] For non-pharmacological treatment we have ultrasound

therapy,[6] electrotherapy,[7] stretching exercise,[8] dry needling,[9] acupuncture,[10] local injection of botulinum toxin.[11] However, all the aforementioned methods just perform a function of inactivation of MTrPs, and they will recur frequently if the underlying etiological lesion is not completely removed.[12,13]

Miniscalpel-needle, a new kind of needle with a sharp edge, was invented by a Chinese doctor named Zhu Hanzhang in 1976. It is rooted in traditional channel tendon theory,[14] and its release technique combines the therapeutic role of acupuncture and microinvasive operation.[8] It causes not only a stimulation to the acupoint but also a release of the taut band in MPS.[15] Thus, it may provide successful relief of pain for a significantly long period for its release of adhesive soft tissues between the tendon sheath and the periosteum.[16] To date, there are not any systematic reviews investigating the effect of MSN for MPS. The primary objective of this systematic review is to determine the evidence base for the potential therapeutic effect of MSN on MPS.

MATERIALS AND METHODS

Reference search

To review the existed evidence base for the effect of MSN on MPS, a systematic computerized search of electronic databases inception up until February 2014 was performed sequentially in PubMed, EMBASE, Cochrane Library, Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Database (CBM) and Wanfang Med Online. The keywords searched were "Miniscalpel-needle", "needle knife", "small needle scalpel" or "acupotomology" combined with "myofascial pain syndrome", "fasciitis" or "trigger points".

Inclusion criteria

Randomized controlled clinical trials that assessed the efficacy or effectiveness of miniscalpel-needle for MPS were included. MSN combined with other interventions and compared with other interventions alone were also included. Main outcomes were pain intensity measured by VAS, effective rate measured by number of patients with improved symptoms, and range of motion (ROM).

Exclusion criteria

Animal studies, and duplication of published papers were excluded. Studies concentrated on comments were also excluded. Our initial aim was to appraise the immediate effect of MSN on MPS, so studies that looked at MSN combined with another therapy, such as cupping, compared with no treatment or other therapies were also excluded.

Data extraction and quality assessment

Study selection was screened independently by two reviewers based on the predetermined inclusion and exclusion criteria with disagreement resolved by discussion and adjudication. The following key information was extracted from each study: first author, publication year, study design, sample size, characteristics of participants, main acupoints/sites selected, duration and sessions of treatment, outcome measures, results reported, and adverse events.

A risk of bias assessment was conducted using the Cochrane Collaborations tool for assessing risk of bias,[17] which included six aspects, namely, adequate sequence generation, allocation concealment, blinding, incomplete data, selective reporting, and other forms of bias. Two authors (Liu and Peng) completed the risk of bias assessment for each study independently, with any divergence resolved through discussion. Three levels naming low/unclear/high risk of bias were determined for each study according to Cochrane Handbook.[17]

Data analysis

Binary outcomes were summarized using risk ratio (*RR*) with 95% confidence intervals (*CI*) while continuous outcomes using mean difference (*MD*) with 95% *CI*. RevMan 5.0.20 software was used for data analysis. Meta-analysis was used for the trials with good homogeneity, which was assessed by examining I^2 on study design, participants, interventions, control, and outcome measures.

RESULTS

After screening and scrutinising, 8 clinical studies[8,18-24] meet the inclusion criteria. Of the 8 studies reviewed, 6 studies[19-24] were published in Chinese and 2 studies[8,18] in English. Data collection process was shown in Figure 1. All of the studies were parallel design. Six[18-21,23,24] trials had 2 groups and 2 trials[8,22] had 3 groups. Sample size ranged from 43 to 100. All of the studies were applied in China. Only 4 trials[19-21,24] mentioned the diagnostic criteria of MPS. All of the researchers applied MSN on MTrPs as the intervention while the controls varied considerably. Two[19,21] used acupuncture, one[8] applied acupuncture and self neck-stretching exercises, one[18] employed injection, one[20] used medication, one[22] used acupuncture and blocking therapy, one[23] used medication and massage, and the last one[24] used acupuncture and cupping. VAS was reported in two trials,[18,23] effective rate was reported in six trials,[19-24] and ROM was reported in two trials.[8,18] A summary of the author, years, number of patients, age, intervention and control, intervention duration and sessions, outcome measures, result and adverse events were shown in Table 1.

Methodological quality of RCTs

According to our pre-defined methodological quality criteria, 7 trials were evaluated as unclear risk of bias and one was high risk of bias (Table 2). Three trials[8,20,24]

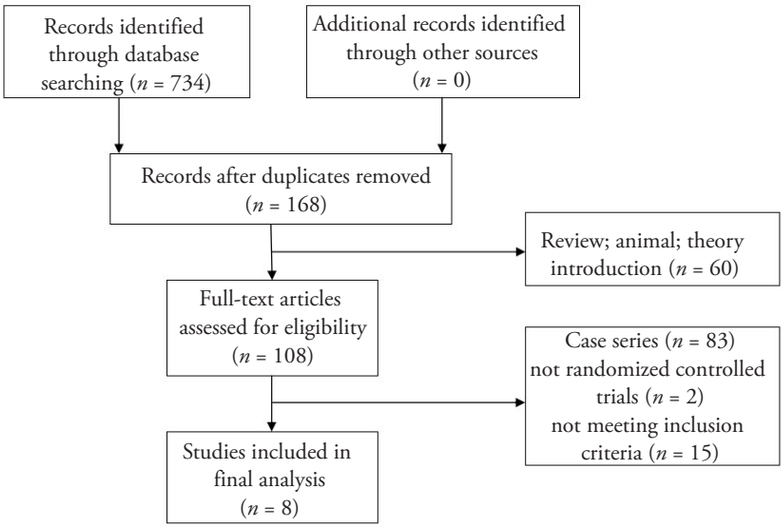

Figure 1 Flow chart of report selection process

reported randomization procedures, but none of them described allocation concealment clearly. Blinding was unavailable in all the trials. Four trials[8,18,20,22] reported dropouts, but none of them used intention-to-treat analysis.

Estimate effects of RCTs

Most of the researches could not be synthesized by quantitative method according to the variations in study quality, participants, intervention and control and outcome measures. Despite of positive results of all the studies, they can be criticized for their poor quality. Therefore, large and rigorously-designed RCTs are warranted to confirm the beneficial effect of MSN on MPS.

MSN versus acupuncture

Three trials[19,21,22] compared MSN to acupuncture and applied effective rate as the outcome measures after treatment. They reached converse conclusions. Fang[21] found that MSN was superior (*RR* 1.27, 95% *CI* 1.07 to 1.52, *P* = 0.007) to acupuncture in terms of the number of patients with improved symptom while Wei[19] (*RR* 1.06, 95% *CI* 0.97 to 1.15, *P* = 0.19) and Zhou[22] (*RR* 1.23, 95% *CI* 0.97 to 1.55, *P* = 0.08) didn't.

MSN plus other treatments versus other treatments

Ma *et al* [8] designed the trial using three groups, MSN and SNS (self neck-stretching exercises) group, acupuncture and SNS group, SNS group. It was indicated that MSN was better than acupuncture on VAS (*MD* 1.80, 95% *CI* − 3.05 to − 0.55, *P* = 0.005) and ROM (*MD* 2.60, 95% *CI* 0.15 to 5.05, *P* = 0.04) at 3 month follow-up but no difference was found at 2 weeks.

MSN versus other treatments

One trial[18] comparing MSN to injection of a mixture of lidocaine and 1.5 mL saline found significant difference on VAS and ROM at half a month, 2 months, and 3 months after treatment. However, original data was unavailable and an analysis was impossible.

Three trials[20,23,24] compared MSN to medication, medication and massage, acupuncture and cupping, respectively. All the trials reported significant difference in effective rate between MSN and control (Table 3).

Adverse events

No information could be seen in 5 studies[19,21-24] and 2 studies[8,18] reported no adverse events. 1 case of needle sickness was involved in one study.[20]

DISCUSSION

Miniscalpel-needle, as a new technique has been widely applied clinically to treat various diseases in China, and could make long-term effect according to immense amount of researches. Four steps consist of incision, stripping, release and cutting are involved in the basic approach of MSN, while the most important point is paralleling to the muscle fibers, nerves and blood vessels to avoid injury.[25] Compared to the filiform needle, it occupies an extra blade and a thicker body, thus accomplishing its role of acupuncture stimulation and soft tissue release. Yang[26] and Zhang[27] proved that thick filiform needles made strong stimulation while thin needles made weak stimulation. Therefore, MSN, coarseness of which is several times thicker than the common filiform needle, is more prone to induce a strong needle sensation and obtain excellent curative effect. In a study, Zhang and Guo pronounce that the MSN release technique is a returning to the ancients and innovation of acupuncture.[16] Unfortunately, no relevant studies and application could be seen abroad.

Exactly, there has been a lot of systematic reviews examining the effect of MSN.[28-32] One trial studies on frozen shoulder, two on cervical spondylosis, and another two on knee osteoarthritis. All the above reviews affirm the

Table 1 Summary of the randomized controlled clinical trials

Study	Number of patients	Age (treatment / control)	Intervention and control	Treatment duration (times)	Outcome measures	Results	Adverse events
Ma *et al* 2010[8]	43	NR	MSN and SNS (A) *vs* Acupuncture and SNS (B) *vs* SNS (C)	MSN: 1 or 2 times at week 0 and 1 (1 or 2) Acupuncture: 1 or 2 times at week 0 and 1 (1 or 2) SNS: 3 times per day during 3 months follow up (90)	PI, PPT, ROM	A and B is significantly better than C in terms with both outcomes at 2 weeks and 3 months endpoints. A is better than B at 3 months follow-up only	NO
Wang *et al* 2007[18]	72	NR	MSN *vs* Injection (a mixture of lidocaine and 1.5 mL saline)	Only 1 time	VAS, ETP, Cb, Cr, Ir	MSN group has significantly improvement on ETP, VAS and Cb at all time points than control group	NO
Wei 2001[19]	60	24-60/23-63	MSN *vs* Acupuncture	MSN: 1 time a week, 3 weeks, (3) Acupuncture: 1 time a day, 5 times a week, 3 weeks, (15)	Effective rate	MSN group is better than acupuncture group and MSN shorten the curative period.	NR
Zhang and Lv 2008[20]	62	17-55	MSN *vs* Medication (chlorzoxazone)	MSN: only 1 time Medication: 2 tablets a time, 3 times a day, 1 week, (21)	Symptom score, EMG,Effective rate	MSN group is better than control group on effective rate, but don't report EMG^{m} and symptom score	1 case of needlesickness
Fang 2007[21]	46	26-64/31-66	MSN *vs* Electro-acupuncture	MSN: 1 time a week, 3 weeks, (3) Electro-acupuncture: 1 time a day, 3 weeks, (21)	Effective rate	MSN is better than electro-acupuncture.	NR
Zhou *et al* 2009[22]	100	25-65	MSN *vs* Acupuncture *vs* Blocking therapy	Only 1 time	Effective rate	MSN is better than acupuncture at 1st week, and 3rd month, but only superior to blocking the-rapy at 3rd month	NR
Han *et al* 2011[23]	100	25-58	MSN *vs* Medication and massage	MSN: 1 time a week, 4 weeks, (4) Medication: 1 tablet a time, 2 times a day Massage: once every other day, 10 times a course, 3 courses (30)	VAS, Effective rate	MSN is better than the control in terms with both the outcomes	NR
Zhao 2012[24]	80	46.74/47.20	MSN *vs* Acupuncture and cupping	MSN: 1 time per 5 days, 15 days (3) Acupuncture and cu -pping: 1 time a day, 10 days (10)	Effective rate	MSN is better than the control	NR

Notes: NR: not reportead; MSN: miniscalpel-needle; SNS: self neck-stretching exercises; *VS*: versus; PI: pain intensity; PPT: pressure pain threshold; ROM: range of motion; VAS: visual analog scale; ETP: evaluation of the Trigger Points; Cb: contralateral bending; Cr: contralateral rotation; Ir: ipsilateral rotation; EMG: electromyography; NO: no adverse events.

Table 2 Risk of bias assessment for the included studies

Study	Adequate sequence generation?	Allocation concealment	Blinding of participants, personnel, and outcome assessor	Incomplete outcome data?	Selective outcome reporting	Other sources of bias?	Risk of bias
Ma *et al* [8]	Computer -generated	Unclear	Unclear	Low	Low	Low	Unclear risk of bias
Wang *et al* [18]	Unclear	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias
Wei[19]	Unclear	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias
Zhang *et al* [0]	Table of random numbers	Unclear	Unclear	Low	High	Unclear	High risk of bias
Fang[21]	Unclear	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias
Zhou *et al* [22]	Unclear	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias
Han *et al* [23]	Unclear	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias
Zhao[24]	Registration order	Unclear	Unclear	Low	Low	Unclear	Unclear risk of bias

Table 3 Effect estimates in 8 RCTs

Item	Trial	Comparison	Effect estimate (95% *CI*)	*P* value
Numbers of patients with effective symptoms after treatment	Wei[19]	MSN versus Acupuncture	RR 1.06 [0.97, 1.15]	0.19
	Zhou *et al* [22]	MSN versus Acupuncture	RR 1.23 [0.97, 1.55]	0.08
	Fang[21]	MSN versus Acupuncture	RR 1.27 [1.07, 1.52]	0.007
	Zhang *et al* [20]	MSN versus Chlorzoxazone	RR 1.12 [0.96, 1.30]	0.16
	Zhou *et al* [22]	MSN versus Blocking therapy	RR 2.05 [1.09, 3.86]	0.66
	Zhao[24]	MSN versus Acupuncture and Cupping	RR 1.33 [1.11, 1.59]	0.002
	Han *et al* [23]	MSN versus Medications and Massage	RR 1.23 [1.06, 1.41]	0.006
Visual analogue scale	Ma *et al* [8]	MSN and SNS versus Acupuncture and SNS	MD − 1.80 [− 3.05, − 0.55]	0.005
	Ma *et al* [8]	MSN and SNS versus SNS	MD − 3.70 [− 4.88, − 2.52]	<0.000 01
	Han *et al* [23]	MSN versus Medications and Massage	MD − 1.66 [− 2.00, − 1.32]	<0.000 01
Range of motion	Ma *et al* [8]	MSN and SNS versus Acupuncture and SNS	MD 2.60 [0.15, 5.05]	0.04
	Ma *et al* [8]	MSN and SNS versus SNS	MD 3.70 [0.82, 6.58]	0.01

Notes: RCTs: randomized controlled trials; MSN: miniscalpel-needle; SNS: self neck-stretching exercises.

effect of MSN. This review firstly identifies and analyses the effect of MSN for MPS. As most of the trials report positive results, it seems that MSN appears to be effective for MPS, and is superior to acupuncture, medications and injection. However, it should be interpreted with caution because of high risk of bias.

Only eight trials with 670 patients were involved in this review, seven of which were evaluated as unclear risk of bias, and the last one was high risk of bias. Although three trials reported randomization, no trial described allocation concealment. Definite information of blinding was not available in all the trials. Despite difficulty in blinding patients with regard to MSN, the method of blinding can be practiced on those in charge of evaluating outcome indices and data. Four trials reported dropouts, but none of them used intention-to-treat analysis. The safety has become a primary issue and a top challenge of the development of MSN.[33] However, only three trials reported adverse events, no information was available in other five trials.

There are a few limitations in our review. Firstly, the overall quality of the included studies is not satisfied. The results of most studies should be interpreted carefully due to missing information on randomization concealment and blinding method, and inappropriate methods for dealing with missing data. Then, samples are too small in the included studies, which will result in a lack of statistical power. However, too many samples will consume manpower, resources and time, consequently, calculation of the sample is warranted. Thirdly, variations in the treatment duration and frequency of MSN may also influence the treatment effect, and the variability between intervention and control treatment are fairly different, which enlarge the heterogeneity. Then, the choose of outcome measures should be internationally recognized such as VAS,

ROM, and the composite outcome measures such as cure, markedly effective, effective or ineffective is not standard and is hard to interpret, thus limiting the generalization of the findings. Only three trials[8,18,22] described long-term effect. The parameters of the MSN should also be described so that other clinicians could get the same result. As all of the researches are done by Chinese, papers written by researchers of other countries are not available, which may lead to publication bias.

In conclusion, the findings of this review suggest that MSN was more effective for MPS than acupuncture, medications and injection though there were some limitations in the studies included in the review and nearly all of them was evaluated with unclear risk of bias.

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