

Efficacy of invasive techniques in physical therapy for migraine treatment and prevention: a systematic review of randomized controlled trials

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INTRODUCTION

Approximately 14% of the world population suffers from migraine, a highly debilitating idiopathic primary headache¹.

The classification and diagnosis of migraines are carried out according to the International Classification of Headache Disorders (ICHD-3), based primarily on monthly migraine frequency and the manifestation of aura. More than 15 attacks per month is considered chronic and ≤ 15 episodic².

The etiology of this autonomic dysfunction is unclear, but a plausible hypothesis suggests peripheral and/or central sensitization. Generally, a migraine attack develops in three or four successive stages in which the onset of pain is determined by the trigeminal-vascular system. Parasympathetic activity increases in the intracranial arteries and fires the first-order neurons of this structure, sending nociceptive information from the durometer to the trigeminal ganglion. The information is then forwarded to the brainstem, in the spinal trigeminal nucleus (STN), via second-order trigeminal vascular neurons. The trigeminovascular neurons of the third-order STN are located in the thalamus, and from there, the nociceptive information is finally sent to the somatic-sensory cortex³.

Migraine medication is known to induce moderate-to-severe adverse effects, and the prophylactic treatments' effectiveness is only 50–60%, further decreasing in the chronic modality^{4,5}. Nonpharmacological treatments for migraine prophylaxis include physical activity, relaxation, and physiotherapy. Physiotherapy, in particular, includes treatments such as neuromodulation, acupuncture, and myofascial release techniques.

Neuromodulation refers to any intervention (drug or physical agent) that can induce a stimulating or inhibiting effect on a neurological function⁶.

Another treatment with neuromodulatory effects is acupuncture—a Traditional Chinese medicine therapy that obtains

therapeutical benefits by stimulating specific points in the body (acupoints)⁵. Acupoints usually correspond with nerve fibers and terminals, which, when stimulated, modulate the information they emit⁷.

Myofascial treatment is another physiotherapy approach used for migraine prevention. This therapy, through techniques such as dry needling (DN), treats pain induced by myofascial trigger points (TrPs), and hyperirritable loci caused by dysfunctional motor endplates. When palpated or when the muscle harboring them gets activated or stretched, TrPs induce referred and/or local pain⁸. TrPs in the craniocervical area constantly emit nociceptive inputs to the STN, facilitating its sensitization and, therefore, predisposing both the onset and chronification of migraine¹.

Despite being a recent systematic review on the subject, the articles included are not recent, which justifies an update on the subject.

OBJECTIVES

The main objective of this systematic review was to update scientific knowledge regarding invasive physiotherapy techniques for migraine prophylaxis. Secondary objectives include identifying which of the therapies has greater clinical relevance and implies the best risk-benefit assessment. A comparison among techniques, and, possibly, with drug therapies, will be made.

METHODS

Study design

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statements⁹.

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This systematic review has been registered in PROSPERO (International prospective register of systematic reviews) in November 2021, with registration number CRD42021287200.

Literature search strategy

Randomized controlled trials (RCTs) included in the review were selected from three different databases: Academic Search Ultimate, CINAHL with Full Text, and Medline Complete. Initially, PubMed, Cochrane, and Google Scholar were searched to identify the latest systematic reviews on migraine prevention via invasive physiotherapy techniques using key terms such as migraine prevention/prophylaxis, invasive physiotherapy, dry needling, acupuncture, and percutaneous electrostimulation. References from included studies were also searched for any relevant study.

The utilized MESH terms for identifying RCTs were acupuncture OR electroacupuncture OR dry needling OR percutaneous nerve stimulation AND migraine.

Inclusion criteria

RCTs published in the last 5 years and available on Academic Search Ultimate, CINAHL with Full Text, and Medline Complete were identified.

Inclusion criteria were the following:

1. RCTs including participants aged between 18 and 80 years and diagnosed with episodic or chronic migraine with or without aura according to the ICHD-3.
2. PEDro score $\geq 6/10$.
3. Main purpose of the study: to evaluate the preventive effects of invasive physiotherapy techniques compared with other treatments (placebo or pharmacology).
4. Type of interventions: acupuncture, DN, and percutaneous electrostimulation.
5. Types of outcome measures: change in monthly migraine days (frequency, intensity, and duration), acute medication intake, adverse events, pain pressure threshold, cervical range of motion (ROM), or muscle thickness.

Data extraction

Two researchers (GL, DDB) autonomously carried out the data selection and extraction. If disagreement occurred at any stage, a third author considered the available information, or if necessary, the study authors were contacted for clarification. When eligibility could not be determined in cases of disagreement, both researchers discussed the study based on its relevance to inclusion and exclusion criteria, interventions used, and outcomes measured to reach an accord. We obtained the aid of a third reviewer in instances when common ground could not be attained.

Quality assessment

RCT quality was assessed based on the PEDro scale criteria. All studies scored $\leq 6/10$ on PEDro.

RESULTS

Study selection

A total of 1,465 articles were identified using the keywords and MESH terms; 190 articles were dismissed in the primary phase, and later 370 titles and abstracts were analyzed. Finally, nine articles satisfied eligibility criteria (Figure 1).

Study characteristics

This review included nine randomized controlled trials that comprehensively analyzed 1,054 participants. Acupuncture was compared with pharmacotherapy in three studies, combined with pharmacotherapy in two, and compared with sham or no treatment in four studies. Overall results outlined acupuncture to be significantly effective in reducing migraine frequency. Acupuncture's effectiveness was significantly higher than sham or no treatment; compared to pharmacotherapy, it was at least as effective.

Finally, both DN and percutaneous electrostimulation obtained similar results for decreasing migraine frequency compared to sham treatment. Table 1 describes a detailed summary of this section, in which we can make a detailed comparison of the most relevant studies of invasive physiotherapy treatment for migraine.

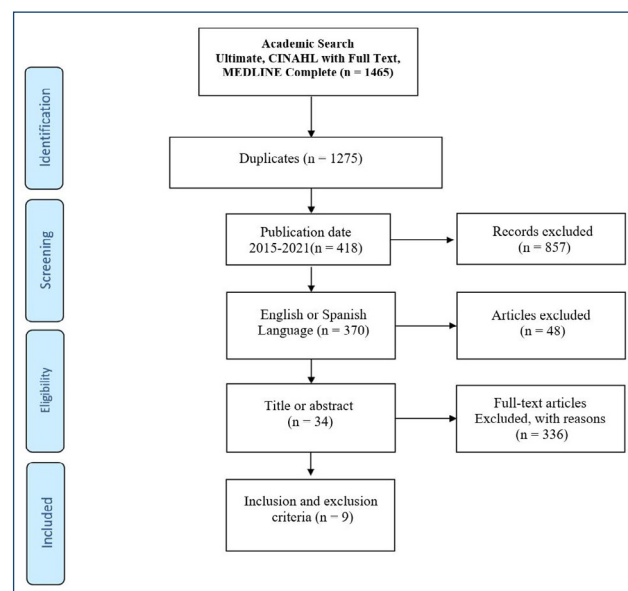


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart.

Table 1. Summary of invasive physiotherapy for migraine prevention.

Authors	Study	Participants	Outcomes	Interventions	Results
Li and Xu ¹⁷	RCT	n=62 Monthly migraine frequency ≥ 2 Migraine history >3 months Age 18–70 years	Migraine days/month. Episodes/month RR 50% per month Headache days/month. Acute medication intake/month. Follow-up immediately post treatment.	12 weeks treatment. Group 1: PES 30'/day, 5 days/week' 12 weeks. Group 2: placebo PES 30'/day, 5 days/weeks' 12 weeks.	PES: \downarrow migraine frequency versus placebo and baseline.
Rezaeian et al. ¹²	RCT	n=40 Migraine of myofascial origin.	Monthly frequency, intensity, and migraine duration. Acute medication intake. Muscle thickness of SCM. Pain pressure threshold (PPT) in the SCM. Active cervical ROM. Follow-up up to 1-month post treatment.	Group 1: 3 DN sessions in the sternocleidomastoid muscle (SCM) in 1 week. 48 h between sessions. 8–10 functions/session. Group 2: 3 sham DN sessions (no penetration). Same frequency as group 1.	Group 1: migraine frequency, intensity, duration \downarrow , PPT \uparrow , active cervical ROM \uparrow and muscle thickness of SCM \uparrow compared to baseline and to CG. Results persisted in the 1-month follow-up.
Musil et al. ¹⁹	RCT	n=86 Migraine history ≥ 12 months ≥ 4 migraines in the last 4 weeks. Migraine with and without aura.	Migraine days/4 weeks. RR 50%. Acute medication intake/4 weeks. Quality of Life (MIDAS) 6 months post-treatment follow-up.	*Preventive drugs allowed in both groups. 12 w of treatment. Group 1: 14 sessions of 25' semi-standardized acupuncture. 2 sessions/w in w 1–4, 1 session/w in w 5–8, 1 session/14 days in w 9–12. Group 2: waiting list.	Group 1: migraine frequency \downarrow , acute medication intake \downarrow , 50% RR \uparrow versus group 2 and baseline.
Wang et al. ²⁰	RCT	n=50 Migraine history ≥ 12 months ≥ 5 migraine days/4 weeks. Age of 18–80 years.	Migraine days/4 weeks. Migraine duration. Migraine intensity. RR 50%. Acute medication intake. Quality of life (McGill questionnaire and MSQ). Pressure pain threshold. 1-year post-treatment follow-up.	20 w treatment. Preventive drugs allowed in both groups. Group 1: 16 25' semi-standardized acupuncture reaching "de qi." 2 sessions/1 in w 1–4, 1 session/w in w 5–8, 1 session/2 w in w 9–12, 1 session/ month in w 13–20. Group 2: same protocol of sham acupuncture (insertion and no insertion).	Group 1: migraine days \downarrow , attack intensity \downarrow , 50% RR \uparrow , pressure pain threshold \uparrow . Results persisted in the 3 months follow-up but not in the 1-year follow-up.
Zhao et al. ⁵	RCT	n=249 2–8 migraines/month Age 18–65 years	Change in migraine frequency from baseline to w 16. Migraine days/month. Average migraine intensity/month. Average acute medication intake/every 4 weeks for 24 weeks. Anxiety (SAS) Depression (SDS) Quality of life (MSQ). 20 weeks post-treatment follow-up.	4 w of treatment; no preventive drugs allowed Group 1: 20 30' semi standardized electro-acupuncture, reaching De qi. 5 session/w – 2 days' rest' 4 w. Frequency 2/100 Hz (alternating every 3 s) intensity 0.1–1.0 mA. Group 2: sham electro-acupuncture in not acupoints. Same parameters of electrostimulation as group 1, but without reaching de qi. Group 3: waiting list.	True acupuncture: migraine frequency \downarrow versus sham and baseline.
Xu et al. ²¹	RCT	n=147 Migraine without aura, Age 15–65 years. Migraine history >12 months. Onset <50 years. 2–8 attacks/month. Not being familiarized with acupuncture.	Change in number of migraine days/4 weeks cycles from baseline to week 20 after randomization. RR 50% in weeks 17–20. Attack intensity. Quality of life (MSQ and MIDAS) Sleep quality (PSQI) Anxiety (BAI) Depression (BDI-II) Change in acute medication intake from baseline to week 20. Expectations on acupuncture efficacy. 3 months post-treatment follow-up.	8 w of treatment. Group 1: 20'30' session of semi-standardized acupuncture. Frequency: 10 days alternating/9 days rest/10 days alternating + usual care. Group 2: 20'30' sham acupuncture without needle penetration. Usual care. Same protocol as group 1. Group 3: usual care.	Real acupuncture: quality of life \uparrow , migraine days \downarrow , migraine attacks \downarrow versus baseline and other groups.

Continue...

Table 1. Continuation.

Authors	Study	Participants	Outcomes	Interventions	Results
Naderinabi et al. ¹⁶	RCT	n=150 Chronic migraines. Ages 20–60 years. No liver or coagulation dysfunctions.	Pain intensity. Migraine days/month. Lost days (work, school, family) due to migraine. Acute medication intake. Associated symptoms. Follow-up 1-, 2-, and 3-months post-treatment.	127 days duration. Group 1 and 2 without drug prevention. Group 1: 60'30' sessions of manual acupuncture. Reaching De qi. 2 cycles of 30 sessions carried out in 60 days. 1 w rest between cycles. Group 2: botulinum toxin in 31 facial and pericraneal acupoints. Group 3: sodium valproate 500 mg/day for 3 months.	Group 1: average pain intensity ↓, migraine days ↓ vs group 2 and 3. *All 3 groups significantly benefitted versus baseline; group 1 demonstrated more efficacy and less AEs.
Nie et al. ²³	RCT	n = 135 Migraine with or without aura. migraine history ≥12 months. Frequency of ≥2. ≤6 attacks/month. Onset < 50 years of age. Age 18–65 years.	Monthly migraine frequency. Average migraine duration/month. Migraine intensity. Acute medication intake. Associate symptoms. Quality of life (PRO). Clinical efficacy. Follow-up 1-month post-treatment.	12 w duration. Group 1: 14'30' semi-standardized acupuncture reaching de qi + 10' Tuina massage therapy. 2 sessions/w in w 1–4, 1 session/w in w 5–8 and 1 session/14 days in w 9–12. Group 2: only acupuncture, same protocol as group 1. Group 3: drug prevention.	All outcomes improved significantly in all groups. Groups 1 and 2 improved significantly more than group 3. Group 1 improved significantly more than group 2. Tuina therapy improves acupuncture's efficacy.
Giannini et al. ¹⁸	RCT	n=135 Episodic migraines with or without aura. No previous preventive treatment in the last 3 months. Ages >18 years.	Headache frequency. Migraine frequency. Acute medication intake. Quality of life and of migraines (MIDAS y SF-36). Treatment satisfaction. RR 50%. Withdrawals from trial. Depression and anxiety (SDS y SAS). 3 y 6-month follow-up.	4 months duration. Group 1: 12 semi-standardized acupuncture sessions. 2 in the 1st week and then 1 session/w. Group 2: personalized preventive drugs 4 months.	Migraine and headache frequency ↓ significantly in both groups, (↔ difference between groups). In the 3rd and 6th months follow-up benefits persisted significantly ↑ in the acupuncture group. No AEs in group 1.

RCT: randomized controlled trials; N: number of patients; AEs: adverse effects; PES: percutaneous electro-stimulation; RR 50%: 50% responders' rate; ROM: range of movement; SCM: sternocleidomastoid; MSQ: migraine-specific quality of life questionnaire; SAS: Zung self-rating anxiety scale; PSQI: Pittsburg quality sleep index; BAI: Beck anxiety inventory; BDI-II: Beck depression inventory-II; SF-36: short form health survey 36 items; PRO: patient reported outcome (for quality of life); PPT: pressure pain threshold; CG: control group; MIDAS: migraine disability assessment score.

DISCUSSION

Despite having relatively low effectiveness and the common adverse effects it implies, pharmacological treatment is still the first-line therapy for migraine prophylaxis and acute management. The low tolerability of this therapy is the reason why researchers have been seeking for alternatives in the past years. In this regard, specific invasive physiotherapy techniques have been the subject of study for migraine prevention; these therapies include neuromodulation via PES, acupuncture, and DN⁶⁻⁸.

TrPs are more preponderant and appear to be contributing notably to migraine¹⁰. Their treatment in muscles associated with the STN has demonstrated to be effective in improving conditions of migraine patients¹¹.

The study included in this review supports DN for migraine prophylaxis as it significantly reduced migraine frequency and was significantly superior to placebo. In addition, DN improved cervical ROM, muscle belly thickness, and reduced acute medication intake¹².

Considering migraine frequency and comparing DN with acupuncture and PES, DN obtained significant benefits with only three sessions performed in 1 week, which, in addition, persisted throughout the follow-up month. Considering the abovementioned techniques, DN appears to be the fastest to decrease migraine frequency and acute medication intake when compared to the other analyzed techniques.

PES is one of the most validated neuromodulation techniques for migraine prevention⁶. The study included in this review¹³ used PES on the Taiyang EX-HN 5 acupoint, coinciding with the zygomaticotemporal nerve derived from the zygomatic nerve (branch of CN V2). Most acupoints of the face and forehead correspond to cutaneous or terminal branches of the facial and trigeminal nerves, both anatomically related to migraine¹⁴.

Analgesic electrostimulation applied in these locations stimulates the production of serotonin and substances

analogous to endogenous morphine, lacking in migraine patients and essential to improve their condition¹⁵. The analyzed study did not consider such a parameter, but it is likely that the reduction in migraine frequency was favored by it. This study had only a short-term follow-up and demonstrated that PES significantly improved migraine frequency and 50% of the RR parameters.

The main limitation is that the implemented protocol had an extremely high volume of sessions (60) carried out with a 5 days/week frequency for 12 weeks. Surprisingly, the abandon rate was only $\approx 11\%$. An acupuncture study¹⁶ shared the total number of sessions, but diluted them in 4.5 months, impacting less on daily life.

Acupuncture differs from conventional neuromodulation due to its different clinical reasoning and foundational theories. Among its various application modalities are manual and electroacupuncture. The latter seems to achieve faster and longer-lasting analgesia¹⁷. In the analyzed study⁵, electroacupuncture induced significant preventive effects for migraine in only 4 weeks; these persisted up to 5 months post-treatment. Compared to manual acupuncture studies¹⁸⁻²⁰, even though the total number of sessions (20) and its duration (25–30 min) were similar, electroacupuncture prescribed a higher treatment frequency (5 days/week) during a shorter intervention period (4 weeks). Additionally, in contrast to other acupuncture protocols, which gradually diluted treatment frequency¹⁸⁻²⁰, the intervention was interrupted abruptly.

Considering efficacy compared to placebo, manual acupuncture is significantly superior to sham acupuncture after 12–13 weeks from baseline^{5,20,21}; meanwhile, electroacupuncture is superior already after 4 weeks⁵. Concerning significant improvements from baseline, both manual²² and electroacupuncture⁷ are effective after approximately 4 weeks, but with different statistical values ($p=0.026$ and $p<0.001$, respectively).

According to the reviewed acupuncture studies^{16,18-20,23}, this therapy significantly decreased acute medication intake in all cases except one, in which baseline levels were already extremely low¹⁸. On the contrary, drug intake improved in the short term and during the 1-month follow-up in all analyzed studies. These results persisted in the long term, except for one study, in which the dropout rate in follow-up was particularly high²⁰. As for DN¹² and PES¹³, which also effectively improved this parameter, benefits were traceable only in the short term due to a lack of long-term follow-up.

Some of the acupuncture studies included in the current review^{5,13,21} also analyzed parameters related to quality of life and migraine impact on life. In this regard, variables such as sleep quality and migraine-related missed workdays¹⁶ were also included.

Quality of life was measured either with MSQ (*Migraine-specific quality of life questionnaire*) or MIDAS (*migraine disability assessment scale*). All analyzed acupuncture protocols recorded improvements of such parameters.

PES and DN studies did not include quality of life or migraine impact on life as dependent variables^{12,13}.

LIMITATIONS

This review has a number of limitations. First, some studies only include patients whose migraine depended directly on the TrPs of the sternocleidomastoid. Second, the terms of the use of prophylactic drugs were not specified; a detail that could mainly distort the results.

CONCLUSION

According to the analyzed studies, all investigated techniques are promising options for migraine prophylaxis, either in combination with or in substitution of pharmacotherapy.

Since most of the studies assessed acupuncture, a rigorous comparison with the other considered therapies was not viable.

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AUTHORS' CONTRIBUTIONS

GL: Investigation (equal), Methodology (equal), Writing – original draft (equal). **VAP:** Formal Analysis (equal), Investigation (equal), Project administration (equal), Software (equal), Writing – review & editing (equal). **ÁGF:** Methodology (equal), Writing – review & editing (equal). **GGPS:** Formal Analysis (equal), Investigation (equal), Writing – review & editing (equal). **JADBM:** Methodology (equal), Writing – review & editing (equal), Supervision (equal). **DDB:** Methodology (equal), Supervision (equal), Writing – review & editing (equal).

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