Effectiveness of acupuncture for the treatment of postoperative pain
A protocol for a systematic review of randomized controlled trial
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Abstract

Background: This aim of this study is to assess the effectiveness and safety of acupuncture for the treatment of patients with postoperative pain (PPP).

Methods: We will carry out a systematic review of the published literature and will comprehensively search Cochrane Library, MEDLINE, EMBASE, CINAHL, PsyCINFO, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from inception to the present with no language restrictions. Randomized controlled trials comparing acupuncture with other interventions or sham acupuncture will be included. Two reviewers will independently conduct study selection, data collection, and study quality. A third reviewer will resolve any discrepancies. We will apply RevMan 5.3 software for statistical analysis.

Results: The protocol of this study will systematically assess the effectiveness and safety of acupuncture for patients with PPP. The primary outcome is postoperative pain intensity. The secondary outcomes comprise of: analgesic consumption, postoperative recovery parameters, vital signs, quality of life, and treatment related adverse events.

Conclusion: This study will summarize the current evidence base for the effectiveness and safety of acupuncture for patients with PPP.

Abbreviations: PPP = postoperative pain, RCTs = randomized controlled trials.

Keywords: acupuncture, effectiveness, postoperative pain, randomized controlled trial, safety

1. Introduction

Postoperative pain (PPP) is one of the most frequent symptoms encountered by patients following surgery.\cite{1,2,3} It has been estimated that about 86% of surgery patients experience moderate to severe PPP.\cite{6} In addition, more than 50% of these patients still experience persistent chronic PPP.\cite{7} These conditions may also restrict physical activity, prolong recovery time, and affect quality of life.\cite{8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31} Furthermore, PPP may also lead to postoperative complications, increase postoperative morbidity, extend hospital stay, and increase health care costs.\cite{8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31}

Acupuncture has been demonstrated to be useful in the management of a variety of pain disorders, including headache, migraine, neck pain, shoulder pain, elbow pain, back pain, hip pain, knee pain, leg pain, and ankle pain.\cite{10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31} In addition, numerous randomized clinical trials have also reported that it can effectively decrease PPP.\cite{19,20,21,22,23,24,25,26,27,28,29,30,31} However, to date no study has systematically explored its effectiveness and safety for patients with PPP. Thus, this study will aim to systematically assess the effectiveness and safety of acupuncture for patients with PPP.

2. Methods and analysis

2.1. Ethics and dissemination

Ethical approval is not needed, because individual data will not be involved. This study will be published in a peer-reviewed journal.

2.2. Study inclusion and exclusion criteria

2.2.1. Types of studies. All randomized controlled trials (RCTs) of the application of acupuncture in the treatment of patients with PPP will be included with no language limitation. However, animal studies, case reports, case series, commentaries, reviews, non-controlled trials, and non-RCTs will be excluded.
2.2.2. Types of interventions. The participants in the intervention group have received acupuncture treatment alone, in addition to standard medical care. The patients in the control group have received other interventions or sham acupuncture in addition to the same standard medical care as the intervention group.

2.2.3. Types of participants. We will include patients diagnosed with PPP with no limitations of race, gender, and age.

2.2.4. Types of outcome measurements. The primary outcome is pain intensity, which can be measured by numerical rating scales or any other scales. The secondary outcomes include analgesic consumption, postoperative recovery parameters, vital signs, quality of life, and treatment related adverse events.

2.3. Search methods for the identification of studies

2.3.1. Electronic database searches. With the assistance of a librarian, we will comprehensively search relevant literature from Cochrane Library, MEDLINE, EMBASE, CINAHL, PsycINFO, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from inception to the present with no language restrictions. We will include RCTs on assessing effectiveness and safety of acupuncture for the treatment of patients with PPP. The retrieval strategy for Cochrane Library is showed in Table 1. In addition, similar search strategy will be adapted to other electronic databases.

2.3.2. Other literature sources search. We will also search dissertations, conference proceedings, and reference lists of relevant included studies.

2.4. Data collection and analysis

2.4.1. Study selection. After retrieving initial results by scanning titles and abstracts of all records, irrelevant studies and duplicated studies will be removed. After that, the full-texts of the remaining studies will be further evaluated according to the previously described inclusion criteria. Two authors will independently carry out study selection. A third author will be consulted where consensus is not reached between 2 authors. The flowchart of study selection process will be showed in Figure 1.

2.4.2. Data extraction and management. All data will be extracted based on the customized data extraction form by 2 independent authors. Any conflicts between 2 authors will be solved by discussion with the help of a third author where consensus is not reached. Variables to be extracted include the following information: study data (first author, year of publication, study type, country, journal, study setting, etc), patient data (age, gender, diagnosis criteria, eligibility criteria, etc), study methods (randomization, concealment, blinding, etc), intervention details (treatment types, dosage, frequency, etc), and outcome measurements (primary and secondary outcomes, adverse events, follow-up results, etc).

2.4.3. Missing data dealing with. Any unclear or missing data from eligible studies will be inquired from primary authors using email. We will analyze available data if those data cannot be obtained.

2.5. Study quality assessment

Methodological quality of all eligible RCTs will be evaluated using Cochrane risk of bias tool for evaluating risk of bias. There are 7 domains, and each domain is further judged as low, unclear, and high risk of bias.

2.6. Measures of treatment effect

Mean difference or standard mean difference and 95% confidence intervals will be utilized as the effect measures of continuous variables. For dichotomous values, Risk ratio and 95% confidence intervals as the effect measures of binary variables will be presented.

2.7. Assessment of heterogeneity

Heterogeneity will be estimated by $I^2$ test among included studies. When the value of $I^2$ is 50% or less, heterogeneity is acceptable, and a fixed-effects model will be utilized for data synthesis. Otherwise, when the value of $I^2$ is more than 50%, heterogeneity is high, and a random-effects model will be used for data synthesis.

2.8. Statistical analysis

RevMan 5.3 software will be applied for statistical analysis. If the heterogeneity is acceptable, meta-analysis will be performed. If the heterogeneity is significant, it is inappropriate to carry out meta-analysis.
meta-analysis, and subgroup analysis will be conducted. If there is still such substantial heterogeneity among those included studies, we will not pool the data and provide a narrative summary instead of meta-analysis.

2.9. Additional analysis

2.9.1. Subgroup analysis. We will investigate whether heterogeneity resulted from other confounders, such as different characteristics, treatments and compactors, and outcomes.

2.9.2. Sensitivity analysis. We will assess the robustness of outcome results by excluding studies with high risk of bias.

2.9.3. Reporting bias. In order to detect reporting bias, funnel plot and Egger regression test will be used for quantitative assessments if more than 10 eligible RCTs are included.[32–33]

3. Discussion

The current literature maintains that acupuncture is effective at decreasing PPP in postoperative patients. However, the evidence for the effectiveness improvement of postoperative recovery and safety for patients with PPP is still inconclusive. Therefore, this study will aim to systematically and comprehensively search literature records. It will address a new aspect related to published studies to explore the effectiveness and safety of acupuncture for PPP. Its results will provide the latest evidence of acupuncture for PPP in both clinical practice and to further research in the field.

Author contributions

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References

[1] Gan TJ. Poorly controlled postoperative pain: prevalence, consequences, and prevention. J Pain Res 2017;10:2287–98.
[2] Cachemaille M, Blanc C. Chronic postoperative pain. Rev Med Suisse 2016;12:1225–6.
[3] Rawal N. Current issues in postoperative pain management. Eur J Anaesthesiol 2016;33:160–71.
[4] Hines R, Barash PG, Wattrous G, et al. Complications occurring in the postanesthesia care unit: a survey. Anesth Analg 1992;74:503–9.
[5] Dimova V, Lautenbacher S. Chronic postoperative pain. Epidemiology and psychological risk factors. Anaesthesiol Intensivmed Notfallther 2010;45:488–93.
[6] Taghavi R, Tabasi KT, Mogharabian N, et al. The effect of acupuncture on relieving pain after inguinal surgeries. Korean J Pain 2013;26:46–50.
[7] Brown AK, Christo PJ, Wu CL. Strategies for postoperative pain management. Best Pract Res Clin Anaesthesiol 2004;18:703–17.
[8] Yates P, Dewar A, Edwards H, et al. The prevalence and perception of pain amongst hospital in-patients. J Clin Nurs 1998;7:321–30.
[9] Chang LH, Hsu CH, Jong GP, et al. Auricular acupressure for managing postoperative pain and knee motion in patients with total knee replacement: a randomized sham control study. Evid Based Complement Alternat Med 2012;2012:7.
[10] Farahmand S, Shafazand S, Alinia E, et al. Pain management using acupuncture method in migraine headache patients: a single blinded randomized clinical trial. Anesth Pain Med 2018;8:e81688.
[11] Seo SY, Lee KB, Shin JS, et al. Effectiveness of acupuncture and electroacupuncture for chronic neck pain: a systematic review and meta-analysis. Am J Chin Med 2017;45:1573–95.
[12] Chau JPC, Lo SHS, Yu X, et al. Effects of acupuncture on the recovery outcomes of stroke survivors with shoulder pain: a systematic review. Front Neurol 2018;9:30.
[13] Gadau M, Yeung WF, Liu H, et al. Acupuncture and moxibustion for chronic knee pain: a systematic review of randomized controlled trials. BMC Complement Altern Med 2014;14:136.
[14] Xu T, Zhou S, Zhang Y, et al. Acupuncture for chronic uncomplicated musculoskeletal pain associated with the spine: a systematic review protocol. Medicine (Baltimore) 2019;98:e14055.
[15] Che Y, Lee S, Kim J, et al. Thread embedding acupuncture for musculoskeletal pain: a systematic review and meta-analysis protocol. BMJ Open 2018;8:e015461.
[16] Xiang Y, He JY, Li R. Appropriateness of sham or placebo acupuncture for randomized controlled trials of acupuncture for nonspecific low back pain: a systematic review and meta-analysis. J Pain Res 2017;11:83–94.
[17] Zhang Q, Yue J, Golianu B, et al. Updated systematic review and meta-analysis of acupuncture for chronic knee pain. Acupunct Med 2017;35:392–403.
[18] Clark RJ, Tigné M. The effectiveness of acupuncture for plantar heel pain: a systematic review. Acupunct Med 2012;30:298–306.
[19] Chen SC, Lu SN, Lai CT, et al. Aqueous acupuncture for postoperative pain—a matched controlled trial. Gaoxiong Yi Xue Ke Xue Za Zhi 1991;7:466–70.
[20] Li QS, Cao SH, Xie GM, et al. Combined traditional Chinese medicine and Western medicine. Relieving effects of Chinese herbs, ear-acupuncture and epidural morphine on postoperative pain in liver cancer. Chin Med J (Engl) 1994;107:289–94.
[21] Kotani N, Hashimoto H, Sato Y, et al. Preoperative intradermal acupuncture reduces postoperative pain, nausea and vomiting, analgesic requirement, and sympathoadrenal responses. Anesthesiology 2001;95:349–56.
[22] Sun ZH, Feng CX. The clinical observation on acupuncture at Xuanzhong (GB 39) and Ashi points for treatment of orthopedic postoperative pain. Zhongguo Zhen Jiu 2007;27:895–7.
[23] Grube T, Uhlemann C, Weiss T, et al. Influence of acupuncture on postoperative pain, nausea and vomiting after visceral surgery: a prospective, randomized comparative study of metamizole and standard treatment. Schmerz 2009;23:370–6.
[24] Xu YH, Wang QY, Yu ZB, et al. Clinical observation on acupuncture for treatment of abdominal postoperative pain. Zhongguo Zhen Jiu 2010;30:904–6.
[25] Holzer A, Lettgeb U, Spacek A, et al. Auricular acupuncture for postoperative pain after gynecological surgery: a randomized controlled trial. Minerva Anestesiol 2011;77:298–304.
[26] Langenbach MR, Aydemir-Dogruyol K, Issel R, et al. Randomized sham-controlled trial of acupuncture for postoperative pain control after stapled haemorrhoidopexy. Colorectal Dis 2012;14:e486–91.
[27] Kramer S, Zaps D, Kutz DF, et al. Impact of surgical intervention and postoperative pain on electrical skin resistance at acupuncture points: an exploratory study. Acupunct Med 2012;30:129–60.
[28] Gavrionsky S, Koeniger-Donohue R, Steller J, et al. Postoperative pain: acupuncture versus percutaneous electrical nerve stimulation. Pain Manag Nurs 2012;13:150–6.
[29] An LX, Chen X, Ren XJ, et al. Electro-acupuncture decreases postoperative pain and improves recovery in patients undergoing a supratentorial craniotomy. Am J Chin Med 2014;42:1099–109.
[30] Vase I, Baram S, Takakura N, et al. Can acupuncture treatment be double-blind? An evaluation of double-blind acupuncture treatment of postoperative pain. PLoS One 2015;10:e0119612.
[31] Ribeiro MR, de Carvalho CB, Pereira RHZ, et al. Yamamoto New Scalp Acupuncture for postoperative pain management in cats undergoing ovariohysterectomy. Vet Anaesth Analg 2017;44:1236–44.
[32] Sutton AJ, Duval SJ, Tweedie RL, et al. Empirical assessment of effect of publication bias on meta-analyses. BMJ 2000;320:1557–7.
[33] Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629–34.