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Efficacy and Safety of Acupuncture for the Postoperative Analgesia after Lumbar Vertebrae Surgery: A Protocol for Systematic Review and Meta-Analysis

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Abstract: The increasing frequency of lumbar vertebrae surgery has heightened the need for effective postoperative pain management. Acupuncture, globally acknowledged for its analgesic efficacy, emerges as a potential intervention for addressing postoperative pain following lumbar spine surgery. Despite its widespread use, a comprehensive evaluation of the efficacy and safety of acupuncture in this specific context is currently lacking. To address this knowledge gap, the development of a systematic review and meta-analysis protocol is crucial to synthesizing existing evidence rigorously. Eight databases are searched since they were created until November 2023: PubMed, Cochrane Library, Web of Science, Embase, China National Knowledge Infrastructure (CNKI); Chinese Scientific Journal Database (VIP), Wanfang Database, Chinese Biological Medicine Database (CBM). We utilize the STATA software (16.0, Texas, USA) for statistical analysis. The primary outcomes of the study are the efficacy rate and pain score. The result of this study is that acupuncture treatment is effective for analgesia after lumbar spine surgery and we will also observe the safety and any side effects. This review presents new evidence to assess the efficacy and safety of acupuncture for postoperative analgesia after lumbar vertebrae surgery.

1. Introduction

Abbreviation: LBP=low back pain, RCTs = randomized controlled trials, TCM =traditional Chinese medicine, CI = confidence interval, MD = mean difference, RR = relative risk, CI = confidence interval, MD = mean difference, SMD = standard mean difference, VIP = China Science

and Technology Journal Database.

Low back pain (LBP) is a prevalent issue worldwide, with reported prevalence rates ranging from 12% to 40% in the general adult population. It affects 60-80% of individuals at some point in their lives.[1,2] With the aging population, spine surgery has steadily become one of the primary therapies during the past few decades[3-6] Nevertheless, there is no ignoring that lumbar spine surgery is commonly characterized by diffuse and severe pain in the postoperative period. Postoperative pain occurs in about 80% of patients who undergo surgery [3-7]. Inadequate control of postoperative pain is a common phenomenon with widespread implications. It can affect postoperative recovery, lead to many complications(e.g., deep vein thrombosis, coronary ischemia, pulmonary embolism), decrease quality of life, and even prolong hospitalizations.[8-10] One research has revealed that Postoperative pain control is a crucial factor in reducing the rate of 30-day readmission after lumbar spine surgery. It is the second most common cause of readmission (22.4%), surpassed only by wound complications (38.6%).[11] According to one survey, patients with chronic pain often suffer from depression, with rates ranging from 17.8% to 92.4%.[12] It is important to note the negative impact that chronic pain can have on mental health. In addition to bringing patients physical and mental pain, but also brings a tremendous economic burden to patients and society.[13,14] Therefore, the management and treatment of postoperative pain are critical. However, after much searching, we found that most studies in lumbar spine surgery focus on pain treatment before and in spine surgery. There is insufficient research on postoperative pain, which is the innovation of this meta-analysis.

Many therapeutic interventions have been suggested for the management of postoperative pain, in the lumbar vertebrae, including drug therapy, local anesthetic infiltration, surgery, conservative treatment, and other alternative treatments. Drug therapy is currently widely used as the primary treatment, such as Opioid's mainstay for treating postoperative pain.[15] Nevertheless, these medications frequently give rise to various complications, including respiratory depression, cardiovascular stress, cognitive changes, urinary and gastrointestinal dysfunction, the potential for addiction and abuse, and acquired tolerance.[16,17] Patient-controlled analgesia(PCA) is mainly composed of opioids. It also has the same side effects as opioids (e.g., nausea and vomiting, pruritus, sedation, and, less commonly, respiratory depression and confusion).[18,19] Non-steroidal anti-inflammatory drugs (NSAIDs) are also commonly used to help manage postoperative pain. Still, their adverse effects include gastrointestinal bleeding and ulceration, cardiovascular events, and renal dysfunction.[20] For gabapentin and pregabalin, Nearly two-thirds of patients had adverse events leading to drug discontinuation, such as dizziness (19%), somnolence (14%), and gait disturbance (14%).[21,22] Currently, regional analgesic techniques such as erector spine plane block(ESPB) and Thoracolumbar interfacial plane block(TLIP) are commonly used for providing long-lasting postoperative analgesia.[23-27] However, it is worth noting that while these techniques have demonstrated a high success rate when performed under ultrasound guidance, they may not always be straightforward or cost-effective in certain cases.[28] A study has indicated that almost 40% of patients did not benefit from undergoing spinal reoperation. Furthermore, the increased costs associated with this treatment pose a problem.[29]

Conservative treatments include Chiropractic, physiotherapy, massage, exercise, herbs, and acupuncture. However, further research is needed to better define the effectiveness of complementary therapies in improving postoperative pain control.[30] All of these lumbar spine analgesic techniques have inherent advantages and disadvantages that restrict their universal applicability.[31] Therefore, we are committed to investigating whether a postoperative analgesic technique is convenient, effective, economical, simple, and less time-consuming, with few side effects.

Acupuncture is one of the oldest medical practices based on Traditional Chinese Medicine (TCM)

fundamentals theory.[32] It has a long history, The theory of acupuncture is systematically presented in “The Yellow Emperor's Classic of Internal Medicine" which dates back to 200 BC.[33] Acupuncture has several advantages, including its simplicity of operation, high tolerability, low risk of severe adverse effects, and low economic cost.; Acupuncture is also universally recognized for its analgesic effects and is increasingly being used as an integrative or complementary therapy for the treatment of pain.[34,35] A systematic review of Roger Chou presented that acupuncture may provide more effective pain relief than certain medications, such as NSAIDs.[36] The mechanism of acupuncture analgesia has made significant progress in these years. However, the specific mechanisms need to be further investigated. Mechanisms may include endogenous pain control systems, brain plasticity, and non-specific effects.[37] One prevailing theory has shown that acupuncture analgesia is a comprehensive effect that transmits signals induced by acupuncture to the relevant areas of the brain and the spinal cord, thereby increasing or reducing neurotransmitters and achieving the purpose of analgesia.[38] Some researchers have suggested that acupuncture could be a viable alternative to oral medication for managing low back and leg pain in pre-and postoperative patients with LDH.[39] However, whether acupuncture can satisfactorily and safely relieve the pain in lumbar spine postoperative patients has yet to be definitively concluded. So, this is the reason and importance of this meta-analysis. We will perform a comprehensive published literature search of each database, committed to gathering extensive evidence. It also aims to evaluate the efficacy and safety of acupuncture for the treatment of postoperative pain after lumbar vertebrae surgery and to bring new evidence to inform clinical practice.

2. Methods

2.1. Study Registration

The protocol has been registered in PROSPERO (CRD42022376727). This protocol conforms to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA-P) guidelines.

2.2 Search Methods

2.2.1. Electronic Searches

We're going to search the following eight databases from when they were created until November 2023: PubMed, Cochrane Library, Web of Science, Embase, China National Knowledge Infrastructure (CNKI); Chinese Scientific Journal Database (VIP), Wanfang Database, Chinese Biological Medicine Database (CBM).

2.2.2. Other Resources Searches

For unpublished trials and ongoing studies, we will review the platforms used to register trials, including the WHO International Clinical Trials Registry Platform (ICTRP) and the Chinese Clinical Trials Registry Centre. To ensure that studies meeting all inclusion criteria are fully included, we will also hand-search grey literature. Identified publications, references, and relevant systematic reviews will also be researched.

2.2.3. Search Strategy

The following Mesh terms were used: (“acupuncture” OR “three-edged needle” OR “fire needle” OR “skin needle” OR “intradermal needle” OR “electroacupuncture” OR “acupuncture with electrical nerve stimulation” OR “ear acupuncture” OR “auricular therapy” OR “auricular point

sticking" OR "plum blossom needle") AND ("total knee arthroplasty" OR "total knee replacement") AND ("pain" OR "acute pain" OR "pain management" OR "analgesia") AND ("randomized controlled trial" OR "random*").

The search strategy will adhere to the PRISMA guidelines. The authors will use a combination of Medical Subject Headings (Mesh) and free words to ensure a comprehensive search for all relevant articles. The key search terms will include: "acupuncture", "acupuncture analgesia", "lumbar vertebrae/spine surgery," "postoperative pain", and "randomized controlled trial". Table 1 displays the Search strategy used in PubMed. We will employ this same approach when searching other databases.

Table 1: The search strategy used in the PubMed database. (From establishment to Novermber 2023)

Table 1

Pubmed will be searched from their inception to February 2023:

Search Number	Query
#1	randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract])
#2	"acupuncture analgesia"[MeSH Terms] OR "analgesia acupuncture"[Title/Abstract] OR "acupuncture anesthesia"[Title/Abstract] OR "anesthesia acupuncture"[Title/Abstract] OR ("Acupuncture"[MeSH Terms] OR "Acupuncture Therapy"[MeSH Terms] OR ("acupuncture treatment"[Title/Abstract] OR "acupuncture treatments"[Title/Abstract] OR "treatment acupuncture"[Title/Abstract] OR "therapy acupuncture"[Title/Abstract] OR "pharmacoacupuncture treatment"[Title/Abstract] OR (("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "Treatments"[All Fields] OR "Therapy"[MeSH Subheading] OR "Therapy"[All Fields] OR "Treatment"[All Fields] OR "treatment s"[All Fields]) AND "Pharmacoacupuncture"[Title/Abstract]) OR "pharmacoacupuncture therapy"[Title/Abstract] OR (("therapeutics"[MeSH Terms] OR "therapeutics"[All Fields] OR "therapies"[All Fields] OR "Therapy"[MeSH Subheading] OR "Therapy"[All Fields] OR "therapy s"[All Fields] OR "therapys"[All Fields]) AND "Pharmacoacupuncture"[Title/Abstract]) OR "Acupotomy"[Title/Abstract] OR "Acupotomies"[Title/Abstract]))
#3	"Failed Back Surgery Syndrome"[MeSH Terms] OR ("Failed Back Surgery Syndrome"[MeSH Terms] OR ("failed"[All Fields] AND "back"[All Fields] AND "surgery"[All Fields] AND "syndrome"[All Fields]) OR "Failed Back Surgery Syndrome"[All Fields] OR "FBSS"[All Fields]) OR (("persist"[All Fields] OR "persistance"[All Fields] OR "persistant"[All Fields] OR "persisted"[All Fields] OR "persistence"[All Fields] OR "persistences"[All Fields] OR "persistencies"[All Fields] OR "persistency"[All Fields] OR "persistent"[All Fields] OR "persistently"[All Fields] OR "persistents"[All Fields] OR "persister"[All Fields] OR "persisters"[All Fields] OR "persisting"[All Fields] OR "persists"[All Fields]) AND ("spinal"[All Fields] OR "spinalization"[All Fields] OR "spinalized"[All Fields] OR "spinally"[All Fields] OR "spinals"[All Fields]) AND ("somatoform disorders"[MeSH Terms] OR ("somatoform"[All Fields] AND "disorders"[All Fields]) OR "somatoform disorders"[All Fields] OR ("pain"[All Fields] AND "syndrome"[All Fields]) OR "pain syndrome"[All Fields])) OR ("spine"[MeSH Terms] OR "vertebral column"[Title/Abstract] OR "column vertebral"[Title/Abstract] OR (("Column"[All Fields] OR "column s"[All Fields] OR "Columns"[All Fields]) AND "Vertebral"[Title/Abstract]) OR "vertebral columns"[Title/Abstract] OR "spinal column"[Title/Abstract] OR "column spinal"[Title/Abstract] OR "columns spinal"[Title/Abstract] OR "spinal columns"[Title/Abstract] OR "Vertebra"[Title/Abstract] OR "Vertebrae"[Title/Abstract] OR "lumbar vertebrae"[MeSH Terms])
#4	"postoperation"[All Fields] OR "postoperational"[All Fields] OR ("postoperative period"[MeSH Terms] OR ("postoperative"[All Fields] AND "period"[All Fields]) OR "postoperative period"[All Fields] OR "postop"[All Fields] OR "postoperative"[All Fields] OR "postoperatively"[All Fields] OR "postoperatives"[All Fields]) OR ("pain, postoperative"[MeSH Terms] OR "post surgical pain"[Title/Abstract] OR "pain post surgical"[Title/Abstract] OR "post surgical pain"[Title/Abstract] OR "pain post operative"[Title/Abstract] OR "pain post operative"[Title/Abstract] OR "postsurgical pain"[Title/Abstract] OR "pain postsurgical"[Title/Abstract] OR "post operative pain"[Title/Abstract] OR "post operative pain"[Title/Abstract] OR "post operative pains"[Title/Abstract] OR "postoperative pain"[Title/Abstract] OR "postoperative pain chronic"[Title/Abstract] OR "pain chronic postoperative"[Title/Abstract] OR "chronic postoperative pain"[Title/Abstract] OR "chronic post surgical pain"[Title/Abstract] OR "chronic post surgical pain"[Title/Abstract] OR "pain chronic post surgical"[Title/Abstract] OR "post surgical pain chronic"[Title/Abstract] OR "chronic postsurgical pain"[Title/Abstract] OR (("Chronic"[All Fields] OR "chronical"[All Fields] OR "chronically"[All Fields] OR "chronicities"[All Fields] OR "chronicity"[All Fields] OR "chronicization"[All Fields] OR "chronics"[All Fields]) AND ("Postsurgical"[All Fields] OR "postsurgically"[All Fields]) AND "Pains"[Title/Abstract]) OR "pain chronic postsurgical"[Title/Abstract] OR "postsurgical pain chronic"[Title/Abstract] OR "persistent postsurgical pain"[Title/Abstract] OR (("Pain"[MeSH Terms] OR "Pain"[All Fields]) AND "persistent postsurgical"[Title/Abstract]) OR "postsurgical pain persistent"[Title/Abstract] OR "post operative pain chronic"[Title/Abstract] OR "pain chronic post operative"[Title/Abstract] OR "post operative pain chronic"[Title/Abstract] OR "chronic post operative pain"[Title/Abstract] OR "chronic post operative pain"[Title/Abstract] OR "postoperative pain acute"[Title/Abstract] OR "pain acute postoperative"[Title/Abstract] OR "acute postoperative pain"[Title/Abstract] OR "acute post operative pain"[Title/Abstract] OR "acute post operative pain"[Title/Abstract] OR "post operative pain acute"[Title/Abstract] OR "pain acute post operative"[Title/Abstract] OR "post operative pain acute"[Title/Abstract])
#5	#1 AND #2 AND #3 AND #4

2.3. Eligibility Criteria

2.3.1. Types of Studies

All randomized controlled trials (RCTs) of acupuncture in treating postoperative analgesia

following lumbar vertebrae surgery were included in this meta-analysis. There were no language restrictions in the study. If the articles are in a non-English or Chinese language, we will use translation software to complete the review.

2.3.2. Types of Participants

All adults (18 years or over) presenting with postoperative pain after lumbar vertebrae surgery, regardless of ethnicity, gender, age, race, disease duration, or economic status. Inclusion criteria for lumbar spine surgery should include any lumbar single or combined procedure, also this includes all anterior, posterior, and combined approaches.[40]

2.3.3. Type of Interventions

We included trials where the acupuncture treatment was based on the theory of Traditional Chinese Medicine (TCM). Acupuncture must be the main treatment or combined with other conservative treatments. All acupuncture methods will be included (e.g., electroacupuncture, fire needle, acupuncture point injection, auricular acupuncture, etc.) Meanwhile. We will strictly exclude moxibustion treatment, needle-knife therapy, acupoint pasting therapy, and transcutaneous electrical nerve stimulation (TENS). What calls for special attention is that we only included the study with acupuncture as the intervention rather than moxibustion, which sometimes needs to be distinguished. Moreover, there are no restrictions on acupoint selection, treatment time, duration, or course.

2.3.4. Types of Comparisons

The control group will receive conventional treatment consisting of the following:
1) Acupuncture vs. no treatment.
2) Acupuncture vs. drug therapy.
3) Acupuncture + other common therapy vs. other common therapy.
4) Acupuncture vs. placebo or sham acupuncture
5) Acupuncture vs. other active therapies;
We excluded studies that only compared different methods of acupuncture (e.g., electroacupuncture compared with acupoint catgut embedding)

2.3.5. Outcomes

2.3.5.1. Primary Outcomes

The primary outcomes include the efficacy rate and the pain scale. For the pain scale, there are visual analogue scales [VAS], numeric rating scale [NRS], present pain intensity [PPI], pain rating index [PRI], and so on.

2.3.5.2. Secondary Outcomes

Secondary outcomes include: Functional status (e.g., Oswestry Disability Index [ODI], Roland-Morris disability questionnaire [RMDQ]), Japanese Orthopaedic Association [JOA], recurrence rate during follow-up and adverse eve

2.4. Exclusion Criteria

1) Patients with pain caused by other diseases.

2) Patients who are not suitable for acupuncture or who are at risk of developing acupuncture-related safety complications (e.g. patients with bleeding, infectious tendencies, severe skin diseases, and patients on anticoagulation therapy).[41]

3) Patients with disease affect the outcome (e.g., diabetic neuropathy, epilepsy, mental illness).

4) Non-RCT studies will be excluded: Systematic review, meta-analysis, case report, and conference papers.

5) Repeated publications and missing data research will be excluded.

6) Studies with obvious errors in data and animal experiments will be excluded.

2.5. Data Collection and Analysis

2.5.1. Selection of Studies

All literature retrieved from the electronic database is imported into NoteExpress V.3.7.0 software (Beijing Aiqihai Software Company) for categorization and administration. Two authors (BQL, ZJ) will independently screen the titles and abstracts first and sort the studies for inclusion, exclusion, or uncertainty. For the uncertain records, we will read full texts for the uncertain studies to check and exclude literature that does not meet the inclusion criteria. In the case of publications with insufficient or unclear data, we will endeavor to obtain the data with the authors by e-mail or phone. In case of disagreement, consult No 3. Author (HGF) assists in judging. The flow chart of PRISMA shows the process of the primary selection (Figure 1).

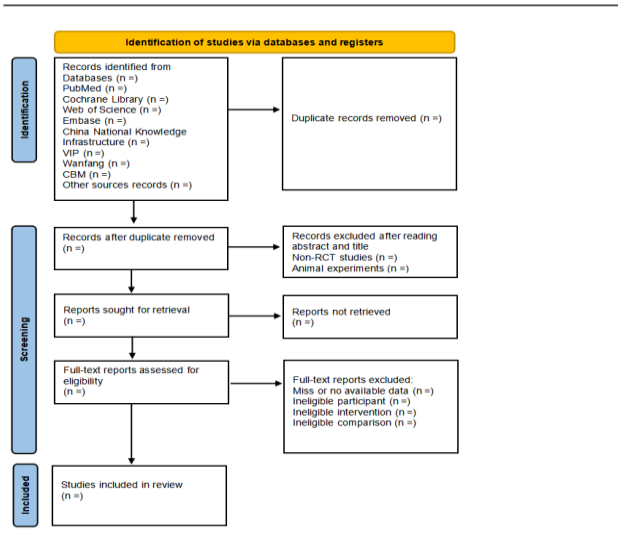

Figure 1. PRISMA flow chart of the study selection process. PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-analysis, RCT=randomized controlled trial.

Figure 1: PRISMA flow chart of the study selection process. RCT = randomised controlled trial.

2.5.2. Data Extraction and Management

Two authors (BQL, ZJ) will extract the characteristics of each primary study using a standard, pre-piloted data extraction form to collect the following details, and design a data extraction form (Excel, Microsoft Corporation, USA). The data mainly includes:

(1) publication year, name of the first author, number of patients in each group, average age in each group;

(2) name of the lumbar vertebrae surgery, interventions, comparisons;

(3) main outcome and additional outcomes;

(4) duration of follow-up, missing data, blinding.

If the data extraction process is experiencing problems and inconsistencies, any disagreements are resolved by the third author (HGF).

2.5.3. Assessment of Risk of Bias

Two authors (BQL.ZJ) will follow the Cochrane risk of bias 2.0 to independently assess the risk of study bias.[42] There are six factors for evaluation in Rob 2: random sequence generation, deviations from intended interventions, lack of outcome data, measurement of outcomes, selection of reported outcomes, and overall bias. And it contains three levels: "low risk", "some concern", and "high risk".

2.5.4. Measurement of Treatment Effect

For dichotomous data, the measurement should be conducted using relative risk (RR) or odds ratio (OR) along with a 95% confidence interval (CI). In the case of continuous variable data, mean difference (MD) or standard mean difference (SMD), accompanied by a 95% confidence interval (CI), should be employed for measurement.

2.5.5. Dealing with Missing Data

We will endeavor to communicate with the primary author to obtain the necessary data that is not currently available. If it is not possible to obtain the data, the study will ultimately be subject to exclusion.

2.5.6. Assessment of Heterogeneity

1) If $P>0.01$, $I^2 < 50\%$, indicating the absence of significant heterogeneity, the fixed-effects model will be employed.

2) If $P<0.01$, $I^2 \geq 50\%$, suggesting the presence of heterogeneity, the random-effects model will be applied.

If heterogeneity is found, a sensitivity analysis or subgroup is performed analysis to determine the source of heterogeneity.

2.5.7. Assessment of Reporting Biases

We will use the funnel plot to assess the reporting biases. If the funnel plot asymmetry exists, we will analyze the reasons for the outcome. It indicates that there may be a publication bias, low literature quality, or negative unpublished results. If necessary, we will evaluate it with Begg's and Egger's tests to evaluate it more accurately.[43]

2.5.8. Data Synthesis

The STATA software (16.0, Texas, USA) will operate the data synthesis. Based on the Assessment of heterogeneity. If there is no significant heterogeneity, the fixed-effects model will be used for data synthesis. If significant heterogeneity is detected, the random-effects model will be employed. If necessary, the subgroup or sensitivity analysis will be generated to evaluate its origin.

2.5.9. Subgroup Analysis

If heterogeneity exists, we will conduct the subgroup analysis according to the different outcomes, such as different types of acupuncture, acupoint selection, and acupuncture combined

with other treatments, to find the sources of heterogeneity.

2.5.10. Sensitivity Analysis

To assess the source of heterogeneity and the reliability of the meta-analysis results, we will perform a sensitivity analysis.

2.5.11. Quality of Evidence

According to the GRADE approach to evaluate the quality of evidence. The quality of evidence is divided into four levels: very low, low, moderate, and high quality. The following five aspects will degrade the quality of evidence, including the risk of bias, publication bias, consistency, indirectness, and inaccuracy.[44]

2.5.12. Ethical Approval

Ethical approval is unnecessary because this is a systematic literature research without patients involved.

3. Discussion

With the increase of lumbar spine surgery, the problem of postoperative pain is becoming increasingly severe. A study revealed a notable finding: over fifty percent of the surveyed patients expressed apprehension regarding postoperative pain, with some individuals opting to defer their surgeries as a consequence.[3] Despite the increasing emphasis on pain management and the development of some guidelines for managing pain, a large number of patients still suffer from the intolerable pain they continue to suffer after surgery.[7] Nowadays, our prolonged exposure to 4G and 5G electromagnetic radiation leads to immunodeficiency, and the use of anti-inflammatory drugs or other highly concentrated medications impairs the energy of these patients, and surgery only treats the symptoms of low back pain and does not address the energy deficiencies that exist within the five organs of the Five Elements Theory of Traditional Chinese Medicine (TCM)[45,46], which is another reason why we have chosen acupuncture as a method of treatment.

More and more researchers support using acupuncture as adjuvant therapy in treating postoperative pain.[47,48] However, due to the lack of evidence analysis of acupuncture for postoperative analgesia after lumbar spine surgery, many clinicians need help to accurately grasp the efficacy of acupuncture and apply acupuncture in clinical practice. According to our search, there are currently no articles conducting meta-analyses on this topic, so we wrote this article intending to provide more convincing evidence for clinicians to make decisions and to better help patients with lumbar surgery to relieve pain.

Author contributions

The protocol has been read and approved for publication by all authors.
Conceptualization: Qingling Bian, Guofu Huang.
Data curation: Jing Zou, Yueyu Zhang. Guofu Huang.
Validation: Jing Zou, Yueyu Zhang.
Investigation: Qingling Bian, Jing Zou.
Methodology: Qingling Bian, Jing Zou.
Software: Qingling Bian, Jing Zou, Yueyu Zhang.
Supervision: Jing Zou, Guofu Huang.

Writing – original draft: Qingling Bian.
Writing – review & editing: Qingling Bian, Guofu Huang.

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