Effect of Kinesio Taping on Low Back Pain During Pregnancy: A Protocol for Systematic Review and Meta-Analysis

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Protocol

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Abstract

Background: Low back pain during pregnancy can affect the daily living activities of pregnant women to a certain extent, and even lead to fetal agitation and threatened abortion. Kinesio taping (KT) can improve tissue circulation and provide elastic supports, which is a reliable method to treat low back pain. At present, there is a lack of high-level clinical evidence for the treatment of low back pain during pregnancy with KT. Therefore, this study will systematically review and analyze currently available randomized controlled trials to evaluate the efficacy and safety of KT in the treatment of low back pain during pregnancy.

Methods and analysis: This protocol is guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols. We will search the following database sources of the Randomized controlled trials: PubMed, the Cochrane Library, EMBASE, Web of Science, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Science, and the Wanfang Database. From the establishment of the database to April 2021. Two independent investigators will conduct an electronic literature search, study selection, data extraction, and quality assessment to summarize and evaluate the efficacy of KT in the treatment of low back pain during pregnancy. and risk of bias will be assessed using the Cochrane bias risk tool. All data analysis will be conducted using Revman5.3 software.

Result: This study will objectively and comprehensively evaluate the efficacy and safety of randomized controlled trials of KT for low back pain during pregnancy, and submit the results to a peer-reviewed journal for publication.

Conclusion: This study will provide clinicians with the latest high-quality evidence for the use of KT in the treatment of low back pain during pregnancy.

Systematic review registration: PROSPERO CRD42021250373

1. Background

Rationale

Pregnancy-related low back pain (PLBP) is a common problem of pregnant women during pregnancy. It is a physiological pathology that only appears during pregnancy and postpartum. The etiology is not clear, but the main potential factors are hormones, biomechanics, post-traumatic or degenerative diseases, low back pain during pregnancy, and psychosocial factors [1]. Up to 70 percent of pregnant women have reported low back pain at some point during pregnancy [2, 3]. And the pain with the progress of pregnancy and becoming very serious, on the pregnant woman's daily life, sleep and so on have a great impact, seriously reducing the quality of life [4–7]. It also increases the risk of postpartum anxiety and depression [8]. Due to the lack of information on treatment options available to pregnant women and

clinicians, and concerns that treatment may have harmful effects on fetal development, the treatment currently offered for low back pain during pregnancy is mainly physiotherapy [9].

Kinesio Taping (KT) is a non-invasive therapeutic technique developed by Dr. Kenzo Kase in 1973 [10]. Applied to patient skin under tension in the form of an elastic braid, it can be lengthways extended to 140 percent of its original length to treat a variety of musculoskeletal problems, such as injury, pain, dysfunction, and a variety of other conditions, without limiting joint mobility [11, 12]. KT can correct joint dislocation, provides muscle support, activates the endogenous analgesia system, and eliminates congestion and effusion [13, 14]. The main manifestations are, KT can inhibit muscle overextension, relieve muscle spasticity and fatigue, reduce abnormal muscle spasticity, and enhance joint stability; Through sensorimotor stimulation, information is transmitted to the cerebral cortex, and then the motor response is generated; By stimulating the skin mechanoreceptors, improving the sensory feedback on the attached area, strengthening the input of proprioceptive sensory information, achieving indirect regulation of nerve and muscle activities, enhancing sensory input and other advantages [12, 15].

With the continuous innovation and progress of rehabilitation methods, KT has been applied to improve low back pain during pregnancy. Some studies have shown that KT can reduce pregnancy-related low back pain problems [16–18]. However, the evidence is still insufficient. Some studies have found that the improvement effect of KT on low back pain is not significant [19, 20]. Therefore, this study conducted a comprehensive evaluation of relevant research results from home and abroad through systematic evaluation and meta-analyze, to provide an evidence-based basis for the effect of KT on low back pain during pregnancy.

Objectives

The purpose of this study was to systematically evaluate the efficacy of KT for low back pain during pregnancy. Based on the results of our study, we aim to provide some helpful suggestions and information for future clinical studies.

2. Methods

2.1. Study protocol registration

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42021250373). The consent of this protocol report is based on the preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement guidelines [21].

2.2 Inclusion criteria for study selection

2.2.1 Types of studies. Randomized controlled trials (RCTs) on the treatment of low back pain during pregnancy with KT were included in either Chinese or English, whether blind or assigned concealment was used.

2.2.2 Types of patients. Participants with 14 to 40 weeks gestation, no recent history of medications, no previous back surgery, no serious back injury (spondylolisthesis), local tenderness, and unilateral or bilateral lumbar muscle tension.
2.2.3 Type of intervention. The intervention measures for the experimental group were to receive KT intervention, while the control group received conventional rehabilitation training analgesics or placebo treatment.
2.2.4 Types of outcome measurements. Main outcome measures: Roland Morris Dysfunction Questionnaire (RMDQ); Secondary outcome measure: Visual Analogue Scale of pain (VAS).
2.2.5 Inclusion criteria.

We used the PICOS (Participants, Intervention, Comparator, Outcome, and Study design) model to select studies for this review.

(1) Participants: patients with low back pain during pregnancy;

(2) Intervention: patients received KT;

(3) Comparator: patients received other treatment;

(4) Outcomes: low back pain function and lumbar function improvement score;

(5) Study design: Randomized clinical trial.
2.2.6 Exclusion criteria.

(1) Non-Chinese and English literature;

(2) Lack of outcome indicator data;

(3) Duplicate studies, studies reporting too little information, studies with incomplete data.

2.3.1 Data sources. The following electronic databases will be searched from inception to April 2021: PubMed, the Cochrane Library, EMBASE, Web of Science, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Science, and the Wanfang Database. In addition, reference lists of the included studies were manually searched to identify additional relevant studies.
2.3.2 Other resources. We will search the following registration website of the clinical trial: WHO ICTRP and ISRCTN Register. Moreover, the relevant grey literature from the Health Management Information Database (HMIC), Open SIGLE Database, and the National Technical Information Service (NTIS) will be searched.

2.4 Search strategy.

The search was carried out by combining theme words with free words. The search terms on PubMed are as follows: Kinesio tape (e.g., Athletic Tape); Pregnancy (e.g., Pregnancies or Gestation); Randomized controlled trial (e.g., Randomized or Randomly). Combinations of Medical Subject Headings (MeSH) and text words will be used. The same search term is used in other electronic databases. Taking PubMed as an example, the retrieval strategy is shown in Table 1.

2.5 Data collection and analysis

2.5.1. Selection of studies. The retrieved studies will be imported into Endnote X8 to remove duplicates. Two researchers (XXL and YXW) will independently screen the titles and abstracts according to the pre-established inclusion and exclusion criteria. After that, the full text will be screened as a second filtration. Two researchers will crosscheck the included studies, and the third researcher (LN) will be involved if disagreements occur. The literature screening flow chart is shown in Fig. 1.

2.5.2. Data extraction and management. Two researchers (TH and DZY) will independently extract the data and fill it in a predesigned form. Information includes author, year of publication, participant characteristics, details of interventions and comparisons, specific data, outcomes, conclusions, follow-up, adverse events, etc. The extracted data will be cross-checked. If there is a disagreement, consult a third researcher (LN) to reach a consensus. The study authors will be contacted for further information if necessary.

2.5.3 Risk of bias in individual studies. Two researchers (MXR and CY) independently evaluated the risk of bias of the included studies and cross-checked the results. Disagreements were resolved by consulting a third party. The quality of the included studies was assessed using the Cochrane Collaboration risk assessment tool for RCTs [22]. The risk of bias (low, unclear, or high) was assessed based on random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases.

2.5.4. Management of missing data. When the data is missing, the first author or author of the article will be able to use the sensitivity analysis to assess the impact of the missing data on the results. If the effect is significant, we will remove the incomplete data experiment. After the data integrity is guaranteed, the descriptive analysis replaces the meta-analysis.

2.5.5. Assessment of heterogeneity. Statistical heterogeneity will be investigated using tests and statistics. A fixed-effect model will be applied when heterogeneity is low ($I^2 < 50\%$) and a random-effects model will be used for moderate heterogeneity ($50\% < I^2 < 75\%$). When heterogeneity is considerably high, meta-analysis will not be performed.

2.5.6. Assessment of reporting biases. Funnel plots will be performed to assess potential reporting bias when more than ten studies are included. In addition, Egger regression and the Begg correlation test will be conducted to identify the funnel plot asymmetry.

2.5.7. Assessment of reporting biases. In this study, if there are more than ten studies the funnel diagram will be used to determine whether there are reporting biases.

2.5.8. Subgroup analysis. We will conduct subgroup analysis according to the intervention measures, intervention cycle, length of pregnancy cycle, and different details of outcome indicators of the experimental group and the control group.

2.5.9. Sensitivity analysis. Sensitivity analysis will be performed according to sample size, study design, heterogeneous quality, and statistical model. Trials with quality defects will be excluded to ensure the stability of the analysis results.
2.5.10. Assessment of reporting biases. This study will carry out funnel plots to evaluate any potential reporting bias.
2.5.11 Grading the quality of evidence. This study will use the evidence quality rating method to evaluate the results obtained from this analysis. GRADE will be assessed across the domains of risk of bias, consistency, directness, precision, and publication bias. In the context of the system review, quality reflects our confidence in the effectiveness of the assessment. It has four evaluation levels, namely, high (further research is very unlikely to change our confidence in the estimate of effect), moderate (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate), low (further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate), or very low (very uncertain about the estimate of effect) [23].

2.6 Statistical analysis

All data were statistically analyzed using RevMan 5.3 software. Effect sizes for studies using the same result measurements were presented as the mean difference (MD) and the corresponding 95% confidence interval (CI). For studies using different outcome measures, the effect size was presented as the standardized mean difference (SMD), i.e., the change in the mean value of the selected outcome measure expressed as the weighted standard deviation mean difference. The chi-square test was used to determine whether the combined statistics of several similar studies were significantly different. Subgroup analysis or meta-regression will be performed to assess the potential sources with reasonable explanations if heterogeneity is considerably high. The meta-analysis was set to a significant level of $P < 0.05$. The basic features of the articles included will be filled in Table 2.

2.7 Ethics and dissemination

The present study will use published data and does not require ethics approval.

3. Discussion

As low back pain is a condition with high incidence and prevalence in the general population, pregnancy-related low back pain is common during pregnancy [24, 25]. At present, the pathophysiological mechanisms associated with low back pain during pregnancy are unclear. The main accepted factors include weight gain during pregnancy, changes in postural position, and hormonal fluctuations that may cause musculoskeletal system problems, destabilizing the spine and sacroiliac joints, and connective tissue [26]. As a non-invasive form of treatment, KT is highly acceptable and harmless to the body. Therefore, it is of great significance and role to judge the efficacy and safety of KT in the intervention of low back pain during pregnancy [27].

Some studies have shown that KT can effectively reduce the symptoms of low back pain during pregnancy [9, 17], but its efficacy has not been systematically evaluated scientifically. This study will systematically evaluate and meta-analyze the effect of KT on low back pain during pregnancy from four aspects of literature collection, literature screening, data extraction, and data analysis. We believe that the results of this systematic review will help to improve the clinical evidence of KT in the treatment of low back pain during pregnancy and provide a basis for clinical decision-making.

However, this systematic review has some limitations. due to the limitation of language, we only searched Chinese and English literature. In the included studies, there were differences in the time and way of KT intervention among patients, which may have certain clinical heterogeneity.

4. Abbreviations

PLBP
Pregnancy-related low back pain; KT:Kinesio taping; RCTs:Randomized controlled trials; CI:Confidence interval; MD:Mean difference; SMD:Standard mean difference; GRADE:Grading of Recommendation, Assessment, Development, and Evaluation

5. Declarations

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Author contributions

Conception and design: XXL, YXW, and LN; Collection and assembly of data: MXR, CY, and TH; Data analysis and interpretation: TH and DZY; Manuscript writing: XXL. Revised the language/article: All authors; Final approval of manuscript: All authors.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

6. Referencess

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7. Tables

Table 1. Search strategy for the PubMed database.

Number	Search items
#1	Kinesiotape [MeSH]
#2	Kinesio Tape [Title/Abstract]
#3	Kinesio Tapes [Title/Abstract]
#4	Tape, Kinesio [Title/Abstract]
#5	Tapes, Kinesio [Title/Abstract]
#6	Athletic Tape [Title/Abstract]
#7	Tape, Athletic [Title/Abstract]
#8	Orthotic Tape [Title/Abstract]
#9	Tape, Orthotic [Title/Abstract]
#10	#1 OR #2 - #9
#11	Pregnancy [MeSH]
#12	Pregnancies [Title/Abstract]
#13	Gestation [Title/Abstract]
#14	#11 OR #12 - #13
#15	Randomized controlled trial [Publication Type]
#16	Randomized [Title/Abstract]
#17	Randomly [Title/Abstract]
#18	#15 OR #17
#19	#10 AND #14 AND #18

Table 2. Characteristics of the published studies included in the meta-analysis.

Study	Country	Mean age T/C	Sample size T/C	Number of pregnancies (week)	Type of intervention T/C	Duration of trial period	Outcomes

Figures

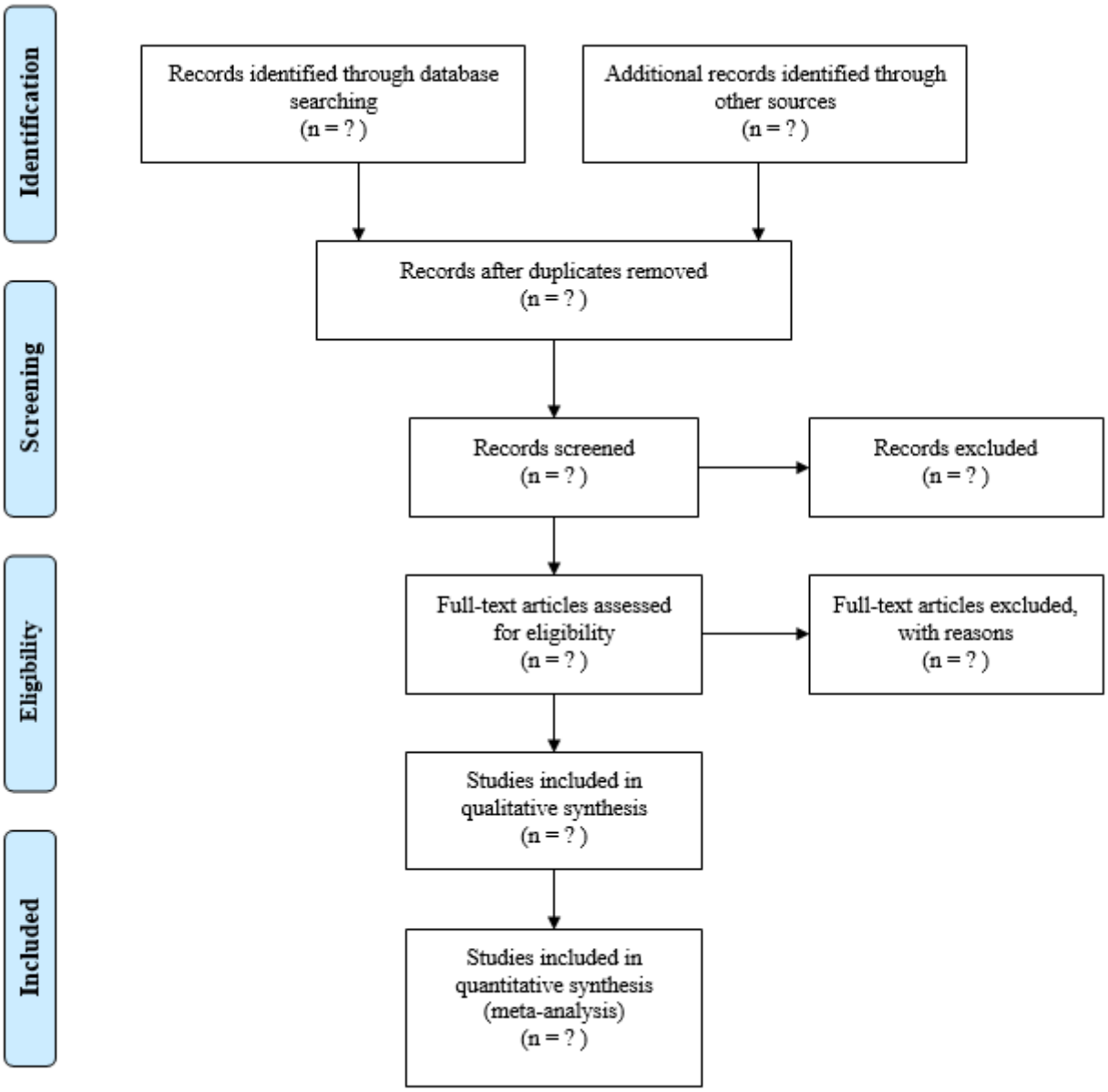

Figure 1

Flow diagram of the study selection process.

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- PRISMAPchecklist.doc