INPLASY PROTOCOL

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Effectiveness comparison of nonpharmacological analgesia delivery methods: A protocol for systematic review and network meta-analysis

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Review question / Objective: **Labor pain and methods to relieve it are a major concern for the mother and child, with considerable implications for intra- and postpartum care. At present, there are mainly drug analgesia and nonpharmacological analgesia for maternal labor. The commonly used drugs for labor analgesia include opioids, non-opioids, nitrous oxide, and patient-controlled analgesia (PCA). It has been reported that drug analgesia can cause adverse reactions such as nerve depression, respiratory depression and heart rate slowing in newborns, and the long-term effects on newborns need to be systematically evaluated.In addition, for the mother, drug analgesia can cause a series of adverse reactions, such as pruritus, fever, drowsiness, nausea and vomiting, loss of consciousness and respiratory disorders. The nonpharmacological therapies for pain relief include a variety of techniques, not only to relieve the physical sensations of pain but also to prevent suffering by enhancing the psychoemotional and spiritual components of care. In this study,network meta- analysis was used to evaluate the efficacy and safety of different nonpharmacological analgesia.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 August 2020 and was last updated on 23 August 2020 (registration number INPLASY202080097).

INTRODUCTION

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Condition being studied: Childbirth is a complex and special physiological process. Pain often accompanies the whole process of delivery. Long term pain will affect the physiological and psychological of pregnant women, and severe pain will affect the delivery process and the life of maternal and fetal. There are two ways to relieve delivery pain: drug analgesia and nonpharmacological analgesia. Nonpharmacological analgesia has less effect on the fetus than drug analgesia and is currently a more popular method for labor analgesia. Due to the lack of randomized trials comparing the efficacy of various nonpharmacological analgesia, it is still difficult to judge the relative efficacy. Therefore, we intend to conduct a network meta-analysis to evaluate the benefit among these nonpharmacological analgesia.

METHODS

Search strategy: #1 "Parturition" [MeSH] OR "Parturitions" [Title/Abstract]OR "Birth" [Title/Abstract] OR "Births" [Title/Abstract] OR "Childbirth" [Title/Abstract] OR "Childbirths" [Title/Abstract] #2 "Music therapy" [MeSH] OR "Therapy, Music" [Title/Abstract] #3 "Massage" [MeSH]OR "Zone Therapy" [Title/Abstract] OR "Zone Therapies" [Title/Abstract]OR "Therapy, Zone" [Title/Abstract] OR "Massage Therapy" [Title/Abstract] OR "Massage Therapies" [Title/Abstract]OR "Therapies, Massage" [Title/Abstract] OR "Therapy, Massag" [Title/Abstract] OR "Therapies, Zone" [Title/Abstract] #4 "Doula" [MeSH] OR "Labor Coaches" [Title/Abstract]OR "Coaches, Labor" [Title/Abstract] OR "Labor Coach" [Title/Abstract] OR "Coach, Labo" [Title/Abstract] #5 "Electric Stimulation, Transcutaneous" [MeSH] OR "Stimulation,Transcutaneous Electric" [Title/Abstract]OR "Transcutaneous Electric Stimulation" [Title/Abstract] OR "Percutaneous Electric Nerve Stimulation" [Title/Abstract].OR "TENS" [Title/Abstract] OR "Electrical Stimulation, Transcutaneous" [Title/Abstract]OR "Transcutaneous Electrical Stimulation" [Title/Abstract] OR "Transdermal Electrostimulation" [Title/Abstract]OR "Electrostimulation, Transdermal" [Title/Abstract] OR "Percutaneous Electrical Nerve Stimulation" [Title/Abstract] OR "Transcutaneous Electrical Nerve Stimulation" [Title/Abstract]OR "Transcutaneous Nerve Stimulation" [Title/Abstract]OR "Stimulation, Transcutaneous Nerve" [Title/Abstract]OR "Nerve Stimulation, Transcutaneous" [Title/Abstract]OR "Percutaneous Neuromodulation Therapy" [Title/Abstract] OR "Neuromodulation Therapy, Percutaneous" [Title/Abstract] OR "Percutaneous Neuromodulation Therapies" [Title/Abstract] OR "Therapy, Percutaneous Neuromodulation" [Title/Abstract]OR "Percutaneous Electrical Neuromodulation" [Title/Abstract] OR "Electrical Neuromodulation, Percutaneous" [Title/Abstract]OR "Electrical Neuromodulations, Percutaneous" [Title/Abstract] OR "Neuromodulation, Percutaneous Electrical" [Title/Abstract]OR "Neuromodulations, Percutaneous Electrical" [Title/Abstract]OR "Percutaneous Electrical Neuromodulations" [Title/Abstract]OR "Analgesic Cutaneous

Electrostimulation" [Title/Abstract] OR "Cutaneous Electrostimulation, Analgesic" [Title/Abstract]OR "Electrostimulation, Analgesic Cutaneous" [Title/Abstract] OR "Electroanalgesia" [Title/Abstract]OR "Electroanalgesias" [Title/Abstract]OR "Neuromodulations, Percutaneous Electrical" [Title/Abstract]OR "Percutaneous Electrical Neuromodulations" [Title/Abstract] #6 "Aromatherapies" [MeSH] OR "Aroma Therapy" [Title/Abstract]OR "Aroma Therapies" [Title/Abstract]OR "Therapies, Aroma" [Title/Abstract]OR "Therapy, Aroma" [Title/Abstract] #7 " Training, Autogenic" [MeSH] OR "Progressive Muscle Relaxation" [Title/Abstract]OR "Muscle Relaxation, Progressive" [Title/Abstract]OR "Relaxation, Progressive Muscle" [Title/Abstract]OR "Progressive Relaxation" [Title/Abstract]OR "Relaxation, Progressive" [Title/Abstract] #8 "Hypnoses" [MeSH] OR "Hypnotism" [Title/Abstract]OR "Hypnotherapy" [Title/Abstract]OR "Hypnotherapies" [Title/Abstract]OR "Mesmerism" [Title/Abstract] #9 "Yoga" [MeSH] #10 #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 #11 #1AND #10 #12 Randomized controlled trial [Title/Abstract] OR Controlled clinical trial [Title/Abstract]OR "RCT" [Title Abstract] #13 #11 AND #12.

Participant or population: The diagnosis of parturient delivery is based on the Clinical Practice Guidelines Guidelines For Normal Delivery (2020) and Guidelines For Normal Delivery (2020).In order to reduce the occurrence of heterogeneity, all the subjects were primiparas.

Intervention: On the basis of conventional nursing care, the experimental group was added with analgesic measures. The commonly used nonpharmacological analgesia measures include: music therapy, massage, doula, Electric Stimulation, Training, hypnoses, acupuncture-moxibustion and so on.

Comparator: The control group was routine education and routine nursing.

Study designs to be included: The included studies will be RCTs in this systematic review regardless of publication status and language. Animal trials, systematic review, case reports and studies with incorrect designs or incomplete data will be excluded.

Eligibility criteria: According to the principle of PICOS, the inclusion and exclusion criteria of literature were determined.

Information sources: Studies will be obtained from the China National Knowledge Infrastructure (CNKI), Wan Fang Data, Chinese Scientific Journals Database (VIP), PubMed, CBM, Embase, Web of science and Cochrane Library, regardless of publication date or language. The databases will be retrieved by combining the subject words with random words. The search terms will be adapted appropriately to conform to the different syntax rules of the different databases.

Main outcome(s): The primary outcomes should include the VAS score.

Additional outcome(s): Secondary outcomes will include the active stage of labor, the second stage of labor, postpartum hemorrhage volume and neonatal Apgar score.

Quality assessment / Risk of bias analysis: Two researchers will be designated to assess the quality of included RCTs independently by utilizing the Cochrane risk of bias assessment tool. As specified by Cochrane Handbook V.5.1.0, the following sources of bias were considered: random sequence generation, allocation concealment, participant blinding, intervention blinding, outcome assessor blinding, incomplete outcome data, selective reporting, and other sources of bias. Each domain was rated as having a high-risk, low-risk or unclear-risk of bias as appropriate. The two reviewers resolved any differences through discussion. If no consensus can be reached, consult experts in the field and refer to their opinions.

Strategy of data synthesis: A network evidence diagram will be drawn to visually represent the comparisons between the studies. The size of the nodes represents the number of participants, and the thickness of the edges represents the number of comparisons. Stata14 and OpenBUGS14 Software will be used to carry out Bayesian network meta-analysis. Bayesian inference will carried out using the Markov chain Monte Carlo (MCMC) method, the posterior probability will be inferred from the prior probability, and estimation and inference will be assumed when MCMC reaches a stable convergence state. As a result, the grade of analgesic effect of different measures will be represented by the curve area or bar graph under the cumulative ranking curve (SUCRA).

Subgroup analysis: If there is high heterogeneity in the included studies, we will perform subgroup analyses to explore the differences in age, sex, race, lesion location, and course of the Intervention time.

Sensibility analysis: To ensure robustness of the combined results, sensitivity analyses will be performed to assess the impact of studies with a high risk of bias. We will compare the results to determine whether lower-quality studies should be excluded.

Country(ies) involved: China.

Keywords: network meta-analysis, delivery, nonpharmacological analgesia, protocol.

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