INPLASY PROTOCOL

To cite: Jin et al. Efficacy and safety of Traditional Chinese Medicine for external use as adjuvant treatment of diabetic periodontitis: A Systematic review and meta-Analysis. Inplasy protocol 202220054. doi: 10.37766/inplasy2022.2.0054

Received: 14 February 2022

Published: 15 February 2022

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Support: **2021MS133, 2021MS061, XSGG2019.**

Review Stage at time of this submission: **Data extraction.**

Conflicts of interest:
None declared.

Efficacy and safety of Traditional Chinese Medicine for external use as adjuvant treatment of diabetic periodontitis: A Systematic review and meta-Analysis

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Review question / Objective: **Meta Analysis of the effectiveness of Randomized controlled Trials of traditional Chinese Medicine for external use as adjuvant treatment of diabetic periodontitis.**
Condition being studied: **Periodontitis is a chronic periodontal inflammation caused by dental plaque, which can lead to the formation of periodontal pockets, loss of periodontal attachment, alveolar bone absorption, and even the loosening and falling off of teeth. Diabetes mellitus is a metabolic disease characterized by hyperglycemia, which causes various complications and extensive harm. Some scholars believe that diabetes is the sixth major complication of periodontitis, and both of them are risk factors. At present, western medicine mostly uses periodontal basic treatment and oral anti-inflammatory drugs to treat this disease. However, taking anti-inflammatory drugs for a long time can easily cause adverse reactions such as drug resistance. In recent years, traditional Chinese medicine has increasingly shown its advantages in the treatment of this disease, and with the development of science and technology, traditional Chinese medicine has gradually been processed into a more convenient and effective external dosage form for clinical treatment of this disease, and related clinical studies have found that it has good clinical efficacy. Therefore, we will make a systematic evaluation and meta-analysis on the efficacy and safety of external adjuvant treatment of diabetic periodontitis with traditional Chinese medicine.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 February 2022 and was last updated on 15 February 2022 (registration number INPLASY202220054).

INTRODUCTION

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by dental plaque, which can lead to the formation of periodontal pockets, loss of periodontal attachment, alveolar bone absorption, and even the loosening and falling off of teeth. Diabetes mellitus is a metabolic disease characterized by hyperglycemia, which causes various complications and extensive harm. Some scholars believe that diabetes is the sixth major complication of periodontitis, and both of them are risk factors. At present, western medicine mostly uses periodontal basic treatment and oral anti-inflammatory drugs to treat this disease. However, taking anti-inflammatory drugs for a long time can easily cause adverse reactions such as drug resistance. In recent years, traditional Chinese medicine has increasingly shown its advantages in the treatment of this disease, and with the development of science and technology, traditional Chinese medicine has gradually been processed into a more convenient and effective external dosage form for clinical treatment of this disease, and related clinical studies have found that it has good clinical efficacy. Therefore, we will make a systematic evaluation and meta-analysis on the efficacy and safety of external adjuvant treatment of diabetic periodontitis with traditional Chinese medicine.

METHODS

Participant or population: The subjects of the study should meet the diagnostic criteria of western medicine, there are no restrictions on the sex, age, ethnic, background, occupation, course of disease.

Intervention: Traditional Chinese medicine for external use, combined with conventional western medicine. We will not set limitations on dosages and course of treatment.

Comparator: Western medicine routine treatment.

Study designs to be included: RCTs with or without blind methods, that report the application of Traditional Chinese medicine for external use for diabetic periodontitis will be included.

Eligibility criteria: Reported in Chinese and English ,and meet the "PICOS" will be taken into account, Details are as follows: 1. The subjects of the study should meet the diagnostic criteria of western medicine, and the sex, age, ethnic, background, occupation, course of disease of the diabetes mellitus patient with periodontal disease unlimited; 2. The experimental group was treated with Traditional Chinese medicine for external use, with western medicine routine treatment; 3. The control group was treated with routine western medicin alone; 4. The outcomes included main outcomes(probing pocket depth (PPD) and/or clinical attachment loss (CAL) and/or plaque index (PLI) and/or sulcular bleeding index (SBI)) and/or secondary outcomes(Tooth mobility (TM) and/or glycosylated hemoglobin A1c (HbA1c) and/or fasting blood-glucose (FPG) and/or bleeding on probing (BOP) and/or Interleukin-16 (IL-6) and/or tumor necrosis factor-α (TNF-α) and/or total effective rate and/or adverse effects). 5. The type of study is randomized controlled trial, clinical study, whether using blind method or not.

Information sources: The computer searches the databases of PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure(CNKI), VIP Datebase, Chinese Biometical Datebase,Wangfang Database.

Main outcome(s): Probing pocket depth (PPD) and/or clinical attachment loss (CAL) and/or plaque index (PLI) and/or sulcular bleeding index (SBI).

Data management: Tooth mobility (TM) and/or glycosylated hemoglobin A1c (HbA1c) and/or fasting blood-glucose (FPG) and/or bleeding on probing (BOP) and/or Interleukin-16 (IL-6) and/or tumor necrosis factor-α (TNF-α) and/or total effective rate and/or adverse effects.

Quality assessment / Risk of bias analysis: Two authors will independently assess the

risk of bias, The bias risk assessment tool of Cochrane system evaluator manual 5.4 was used to assess the bias risk of the included RCT, which including 7 items: random sequence generation, allocation concealment, blinding method, incomplete outcome data, selective reporting, and other biases.The quality of each trial will be divided into 3 levels: low bias risk, high bias risk, and unclear bias risk.Two authors will exchange assessment results and check whether the assessment results are consistent. If there is a disagreement, the third author will participate in the discussion and determine the final result.

Strategy of data synthesis: Meta analysis will be performed using Rev Man5.4.0 software. The odds ratio (OR) and its 95% Confidence Interval (CI) will be used as the counting data, while the weighted mean difference (WMD) and its 95% CI will be used as the measurement data. The I2 test will be used to assess statistical heterogeneity. Results of the meta-analysis will be visualised by forest plots. Sensitivity and subgroup analyses will be performed to explore the potential origins of significant heterogeneity.

Subgroup analysis: The heterogeneity test will be carried out first among all studies, I2 test will be used. When P>0.1 and I2 < 50%, the fixed effect model will be used; otherwise, If there is statistical heterogeneity among the results (p50%), the random effect model is used to estimate the combined effect, and a subgroup analysis will be conducted to explore the source of the heterogeneity, including different outcomes.

Sensitivity analysis: To ensure the stability and reliability of the results, a sensitivity analysis will be performed by excluding the low-quality or high-weight studies one by one, and the results will be compared and discussed.

Language: No restriction.

Country(ies) involved: China.

Keywords: diabetic periodontitis; Traditional Chinese Medicine for external use; meta-analysis; protocol.

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Author 4 - Qianrong Xu.
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