INPLASY PROTOCOL

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Conflicts of interest:

No conflicts of interest.

INTRODUCTION

Review question / Objective: The patient population, intervention, comparison, and outcome framework was used to formulate

Revascularization Versus Apexification for the Treatment of Immature Necrotic Teeth based on periapical healing and root development outcomes: a systematic review and meta-analysis

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Review question / Objective: The patient population, intervention, comparison, and outcome framework was used to formulate the following questions: 1. For the treatment of immature necrotic teeth with open apices, does revascularization result in better periapical healing compared with apexification? 2. For the treatment of immature necrotic teeth with open apices, does revascularization result in better overall effective rate compared with apexification? 3. For the treatment of immature necrotic teeth with open apices, does revascularization result in better changes in root length, root thickness, and size of the apical foramen compared with apexification?

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 September 2020 and was last updated on 03 September 2020 (registration number INPLASY202090013).

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apexification? 2. For the treatment of immature necrotic teeth with open apices, does revascularization result in better overall effective rate compared with apexification? 3. For the treatment of immature necrotic teeth with open apices, does revascularization result in better changes in root length, root thickness, and size of the apical foramen compared with apexification?

Condition being studied: The treatment of immature necrotic teeth with incomplete root formation is extremely challenging. Apexification is mainly adopted in the traditional treatment, but it can't solve the problem of the thin and weak root canal walls. Recently, revascularization as a new treatment, has been reported in clinical trials and shown good efficacy in promoting root development. Althought revascularization may be a more ideal treatment, it has a lower success rate compare with apexification according to some research. Furthermore, adverse events such as a measurable change in crown colour associated with revascularization was also observed. As no consensus has been reached with respect to the use of revascularization or apexification. The purpose of this research was to carry out a meta-analysis to compare these two different treatments available in the management of immature teeth and determine which one provides better outcomes. In our study, we will not simply compare the success rate, but also conduct a statistical analysis of periapical healing and overall effective rate for the first time. Meanwhile, the imaging results will used for comprehensive analysis of important indicators of root development included the changes in root length, root thickness and apex closure, considered having better levels of scientific evidence.

METHODS

Participant or population: Patients with immature necrotic permanent teeth.

Intervention: revascularization.

Comparator: Apexification.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Study inclusion criteria were: (1) study: prospective randomized controlled trials (2) Participants: patients with immature necrotic permanent teeth (3) Intervention: regenerative endodontic therapy; (4) Comparison: apexification therapy; (5) Outcomes: reported clinical and radiographic outcomes. Case reports, proceedings, letters, comments, editorials, and personal communications were excluded.

Information sources: We will search articles in three electronic database including PubMed, Web of Science, and Cochrane Library. All the publications from 1 Jan 2001 to 4 Sept 2020 will be searched without any restriction of countries or article type. Reference list of all selected articles will independently screened to identify additional studies left out in the initial search.

Main outcome(s): The main outcomes of interest were periapical healing, overall effective rate, the changes in root length, root thickness and apex closure after intervention.

Additional outcome(s): Adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials, items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: (1) random sequence generation; (2) allocation concealment; (3) blinding of patients and personnel; (4) blinding of outcome assessment; (5) incomplete outcome data; and (6) selective reporting risk. Other biases results from these questions will be graphed and assessed using Review Manager 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark).

Strategy of data synthesis: The metaanalysis was conducted using using Cochrane RevMan version 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark). A random-effect models was presented as forest plot with 95% Confidence Interval (CI). Pooled-effect estimates were obtained comparing the periapical healing, overall effective rate and indicators of root development between groups, and it was reported as risk ratio (RR). A p-value <0.05 was considered statistically significant (Z test). The Cochran Q test was used to assess heterogeneity among studies, with a threshold p-value of 0.1, and the inconsistency i2 test, in which values between 25-50% were considered indicative of low heterogeneity, between 50-75% moderate and greater than 75% of high heterogeneity.

Subgroup analysis: We will consider subgroups such as jurisdiction, clinic type and location.

Sensibility analysis: Sensitivity of the metaanalysis was assessed using the leaveone-out approach. A two-sided p value < 0.05 was considered to indicate statistical significance.

Country(ies) involved: China.

Keywords: Immature permanent teeth, pulp revascularization, apexification, periapical healing, overall effective rate, root development.

Contributions of each author:

Author 1 - Yirui Xie - drafted the manuscript.

Author 2 - Yao Lin - provided statistical expertise and project design.

Author 3 - Junbing He - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 4 - Furong Lu - The author read, provided feedback and approved the final manuscript.