

Efficacy of nasal endoscopic dacryocystorhinostomy for chronic dacryocystitis

A systematic review protocol of randomized controlled trial

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Abstract

Background: This study aims to assess the efficacy and safety of nasal endoscopic dacryocystorhinostomy (NED) for patients with chronic dacryocystitis (CD).

Methods: The following 7 electronic databases will be searched from inception to the present: Cochrane Library, EMBASE, MEDLINE, Cumulative Index to Nursing and Allied Health Literature, Web of Science, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. In addition, the clinical trials registry and reference lists of included studies will also be searched. We will only include randomized controlled trials of NED for CD in this systematic review. Two review authors independently carry out the study selection, data extraction, and methodological quality assessment. Whenever it is possible, we will pool the data and conduct meta-analysis by using RevMan 5.3 software.

Results: This study will evaluate the efficacy and safety of NED for patients with CD. The primary outcome includes success rate of ostial patency. The secondary outcomes consist of duration of surgery, quality of life, postoperative complications, and surgeon's comfort.

Conclusion: The findings of this study may summarize the latest evidence of NED for patients with CD.

PROSPERO registration number: PROSPERO CRD42019123664.

Abbreviations: CD = chronic dacryocystitis, NED = nasal endoscopic dacryocystorhinostomy, RCTs = randomized controlled trials.

Keywords: chronic dacryocystitis, efficacy, nasal endoscopic dacryocystorhinostomy, randomized controlled trial, safety, systematic review

1. Introduction

Chronic dacryocystitis (CD) is a common infection disorder of the lacrimal sac typically associated with nasolacrimal duct obstruction (NLDO).^[1–3] The cause of NLDO consists of idiopathic or secondary to various infections, inflammations, traumatic injuries, as well as the neoplasms.^[4,5] This condition ultimately results in stagnation of tears and accumulation of

mucoïd secretions, which contributes to the bacterial infections and genesis of dacryocystitis.^[6,7] Previous study has reported that this condition often affects adults above 30 years old, especially among female population.^[8]

Nasal endoscopic dacryocystorhinostomy (NED) are reported to treat CD by numerous clinical trials.^[9–28] However, up to date, the efficacy and safety of NED for the treatment of CD is still inconclusive. Additionally, no systematic review has addressed this issue. Therefore, the protocol of this systematic review will evaluate the efficacy and safety of NED for patients with CD.

2. Methods

2.1. Study registration

This protocol study has registered with PROSPERO (CRD42019123664), and it has designed and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol statement guidelines.^[29]

2.2. Eligibility criteria for study selection

2.2.1. Types of studies. All relevant randomized controlled trials (RCTs) regarding the NED for patients with CD will be fully considered for inclusion without any language and publication status restrictions. However, any other studies, including non-clinical trials, non-controlled studies, non-RCTs, and quasi-RCTs will be excluded.

This study does not need ethics approval, because no individual patient data will be involved in this study. The results of this study will be published in peer-reviewed journals.

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The authors have no conflicts of interest to disclose.

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2.2.2. Types of interventions. The experimental group includes NED monotherapy. However, the studies will not be considered if the combination of NED with other treatments was utilized in the experimental group. The control group can receive any therapies, except the NED.

2.2.3. Types of patients. Patients clinically diagnosed with CD will be included in this study, regardless the race, sex, and age.

2.2.4. Types of outcome measurements. The primary outcome includes success rate of ostial patency. The secondary outcomes consist of duration of surgery (as recorded by minutes), quality of life (as assessed by any scales, such as Short Form Health Survey is a 36-item), postoperative complications, and surgeon's comfort (as measured by any related instruments).

2.3. Search strategy for identification studies

We will search the following 7 electronic databases from their inception to the present: Cochrane Library, EMBASE, MEDLINE, Cumulative Index to Nursing and Allied Health Literature, Web of Science, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. Moreover, we will also search clinical trials registry and reference lists of included studies. Any relevant RCTs on assessing the efficacy and safety of NED for CD will be fully considered in this systematic review. The search strategy sample of electronic database Cochrane Library is shown in Table 1. Similar search strategy for other electronic databases will also be built and applied.

2.4. Data collection and analysis

2.4.1. Study selection. Two review authors will independently scan the title, and abstract for each study according to the predefined eligibility criteria. The full texts will be read if there is insufficient information to judge a study from the title and abstract. Any disagreements regarding the study selection between 2 review authors will be resolved by consulting a third review author. The whole process of study selection is shown in Figure 1.

2.4.2. Data collection and management. Two review authors will independently extract the data according to the predefined data extraction sheet. It will consist of study characteristics,

patient characteristics, and study methods, details of treatments in both experimental and control groups, and all outcome measurements. Any divisions regarding the data extraction will be solved by a third review author through discussion.

2.4.3. Risk of bias assessment for included studies. Two review authors will independently assess the methodological quality for each included study by using the Cochrane risk of bias tool. It comprises of 7 domains. Each domain will be judged as low risk of bias, unclear risk of bias, or high risk of bias. Any divergences regarding the methodological assessment will be resolved by a third review author through discussion.

2.4.4. Treatment effect measurement. In this study, the continuous data will be expressed as mean difference and 95% confidence intervals (CIs), while the dichotomous data will be expressed as risk ratio and 95% CIs.

2.4.5. Missing data dealing with. If there is missing data or insufficient information, we will contact the primary corresponding authors to require them. If those data is unachievable, we will only analyze the available data, and will discuss its impacts.

2.4.6. Heterogeneity assessment. We will use I^2 test to identify the heterogeneity. Reasonable heterogeneity will be considered if $I^2 \leq 50\%$. Otherwise, significant heterogeneity will be regarded if $I^2 > 50\%$ is identified.

2.4.7. Data synthesis. If $I^2 \leq 50\%$, a fixed-effect model will be used to pool the data and meta-analysis will be conducted. If $I^2 > 50\%$, a random-effect model will be used, and data pooled and meta-analysis will be carried out according to the results of the subgroup analysis. Under such situation, subgroup analysis will be conducted. If there is still substantial heterogeneity after the subgroup analysis, then data will not be pooled and meta-analysis will not be performed. Instead, a narrative summary will be described.

2.4.8. Subgroup analysis. Subgroup analysis will be carried out to detect any possible reasons that may cause significant heterogeneity. It will be conducted in accordance with the different characteristics, types of experimental and control interventions, or the outcome measurement instruments.

2.4.9. Sensitivity analysis. Sensitivity analysis will be conducted to check the robustness and stability of pooled outcome

Table 1

Search strategy for Cochrane Library.

Number	Search terms
1	Mesh descriptor: (dacryocystitis) explode all trees
2	((chronic dacryocystitis) or (nasolacrimal sac*) or (blockage*) or (nasolacrimal duct*)):ti, ab, kw
3	Or 1-2
4	Mesh descriptor: (nose) explode all trees
5	Mesh descriptor: (endoscopy) explode all trees
6	Mesh descriptor: (dacryocystorhinostomy) explode all trees
7	((nasal endoscopic dacryocystorhinostomy*) or (nasal*) or (endoscopy*) or (endoscopic*) or (surgery*) or (treatment*) or (therapy*) or (intervention*)):ti, ab, kw
8	Or 4-7
9	MeSH descriptor: (randomized controlled trials) explode all trees
10	((random*) or (randomly*) or (allocation*) or (random allocation*) or (control*) or (placebo*) or (single blind*) or (double blind*) or (randomized control trial*) or (RCT*) or (clinical trials*) or (controlled clinical trials*)):ti, ab, kw
11	Or 9-10
12	3 and 8 and 11

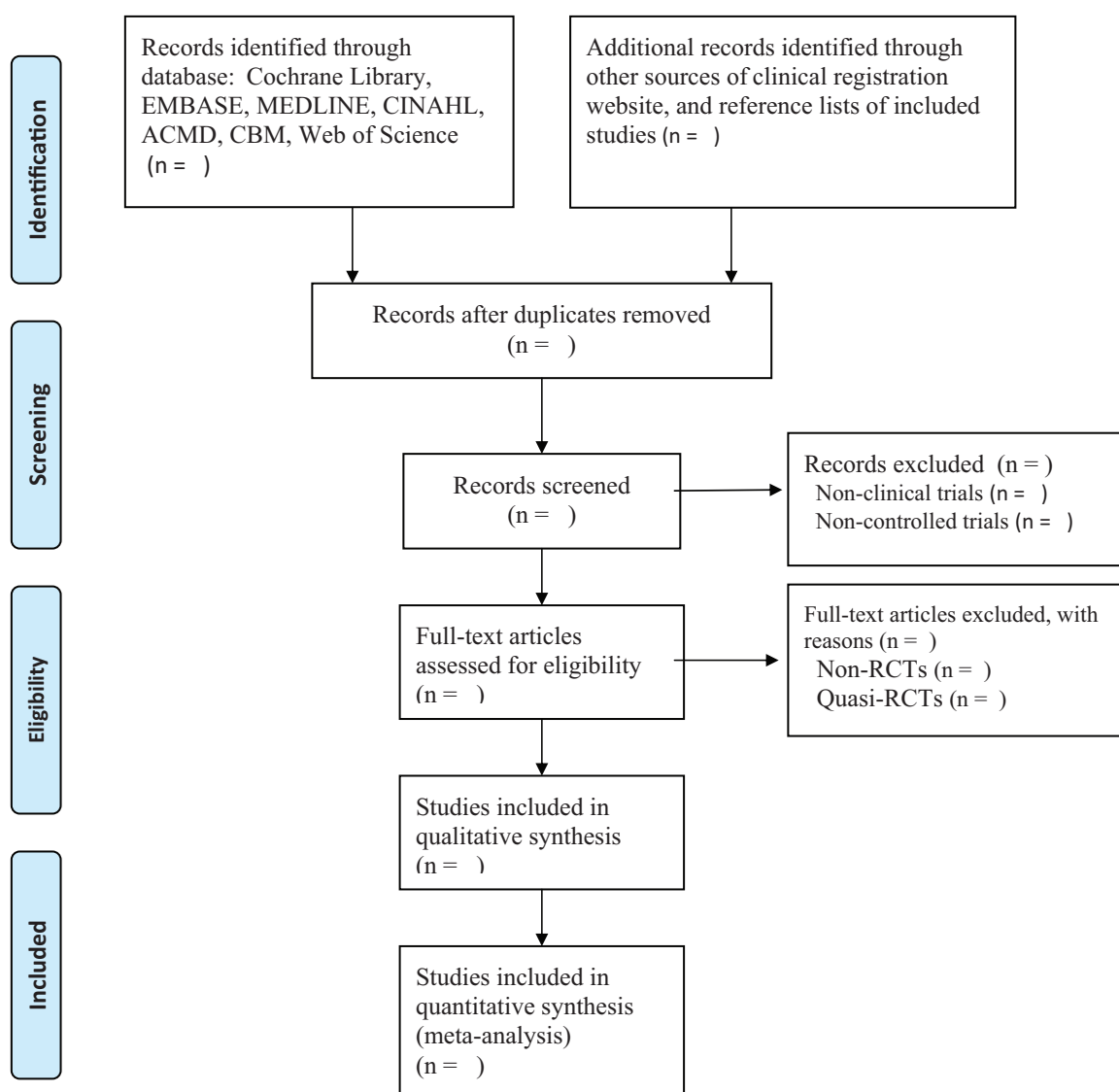


Figure 1. Process of study selection.

results, methodological quality, and the potential impacts of missing data.

2.4.10. Reporting bias. If more than 10 qualified RCTs are included, we will conduct the funnel plot^[30] and Egg regression test to check the possible reporting bias.^[31]

3. Discussion

Researchers hypothesize that NED plays an important role in the treatment of patients with CD. However, until currently, only literature on the efficacy and safety of NED for CD has been conceptual. Given emerging clinical trials on NED for CD have reported, we aim to carry out a systematic research synthesis to inform the efficacy and safety of NED for CD. We are expected to establish the current knowledge base regarding the efficacy and safety of NED for the treatment of CD. The findings of this study will be disseminated to a variety of stakeholders interested in NED treatment to inform both the researchers for further studies

and clinicians focusing on the public health approach to education.

Author contributions

Conceptualization: Xiao Chen, Yang Liu.

Data curation: Xiao Chen, Yang Liu.

Formal analysis: Xiao Chen.

Funding acquisition: Yang Liu.

Investigation: Yang Liu.

Methodology: Xiao Chen.

Project administration: Yang Liu.

Resources: Xiao Chen, Yang Liu.

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Supervision: Yang Liu.

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