INPLASY PROTOCOL

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Conflicts of interest:
None.

Orbital Decompression versus Intravenous High-dose Glucocorticoids in Treatment for Dysthyroid Optic Neuropathy. A Systematic Review of the Literature

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Review question / Objective: **P: Dysthyroid Optic Neuropathy; I: surgical decompression; C: intravenous high-dose glucocorticoids therapy; O: visual function; S: RCT and case series.**

Condition being studied: **Dysthyroid optic neuropathy (DON), secondary to thyroid-associated ophthalmopathy (TAO), is the most common cause of visual loss in TAO , whose incidence is 4% to 8% among TAO patients. So far, the exact pathogenesis of DON remains unclear. Admittedly, DON is a condition that the crowding of the orbital apex leads to optic nerve compression, causing vision loss . The treatment of DON mainly includes drug decompression, radiotherapy and surgical decompression. Steroid is most commonly applied in drug decompression. Currently, the majority of the literature supports initial treatment of DON with high dose intravenous steroids. If the response is poor or when high dose steroid therapy is not tolerated, surgical decompression is recommended. However, deviations from this management strategy were documented and there is no consensus on the treatment of DON with high-dose steroids or direct surgical decompression. So far, most studies have reported results of mainly combined approaches while only a few have been conducted evaluating the effectiveness and the safety of purely surgical decompression or purely steroid treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 May 2020 and was last updated on 02 May 2020 (registration number INPLASY202050005).

INTRODUCTION

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METHODS

Participant or population: Studies fulfilling the following criteria were eligible for inclusion:The patients were considered as a decreased visual acuity to be due to dysthyroid optic neuropathy and not due to corneal problems alone or other pre-existing eye diseases when we found a combination of the following: apical crowding on computed tomography (CT) scan of the orbit, and/or disturbances in visual fields examination compatible with optic neuropathy, and/or a low score in the Ishihara colour test, and/or an increased latency of visual evoked potential, and/or papilloedema on fundoscopic examination.

Intervention: Studies were supposed to include purely surgical decompression approaches. Any study evaluating combined approaches and treated by OD or steroids without interruption before was excluded from our systematic review.

Comparator: Studies were supposed to include purely medical decompression with steroids. Any study evaluating combined approaches and treated by OD or steroids without interruption before was excluded from our systematic review.

Study designs to be included: All randomized and nonrandomized controlled studies were included, as well as prospective or retrospective case series of at least 10 decompressed orb.

Eligibility criteria: Reviews, conference abstracts, animal studies, studies with incomplete experimental data, and duplicate publications were excluded.

Information sources: PubMed, EMBASE, the Cochrane Library databases as well as other sources were searched by two independent reviewers followed by extensive hand-searching for the identification of relevant studies.

Main outcome(s): The primary outcome measures of interest included the improvement of visual acuity and response rate. Outcomes were evaluated from 1 to 6 months following the intervention.

Additional outcome(s): Secondary outcomes in our study included proptosis reduction, change in diplopia and clinical activity score (CAS).Adverse outcomes were considered complications of steroid or orbital decompression surgery.

Quality assessment / Risk of bias analysis: The Cochrane risk-of-bias tool was used to evaluate the randomized controlled trials (RCTs) study. Case series reports using case series bias evaluation tools.The studies were classified as low, high, and uncertain risk of bias.

Strategy of data synthesis: We assessed the risk of bias and then extracted data from included studies. Visual acuity and proptosis reduction were considered as key outcomes in this systematic review. We used χ^2 test to compare the number of patients with improved visual acuity in the ivGC group and OD group. And through

analyzing and calculating, we got a weighted mean in proptosis reduction in two groups respectively.

Subgroup analysis: We did not plan to conduct a subgroup analysis. We investigated heterogeneity by careful review of the study reports.

Sensibility analysis: We did not plan to conduct a sensibility analysis.

Language: The search was restricted to only articles published in English were included in the study.

Country(ies) involved: China.

Keywords: dysthyroid optic neuropathy, glucocorticoid, orbital decompression.

Contributions of each author:
Author 1 - Mingna Xu - Author 1 conceived and designed the review, and collected data for it.
Author 2 - Zhaoqi Pan - Author 2 co-ordinated the review and did the data collection for it.
Author 3 - Yunhai Tu - The author contributed to the development of the selection criteria.
Author 4 - Wencan Wu - The author provided general advice on the review and secured funding for it.