The effectiveness of Ayurvedic oil based nasal instillation (Nasya) medicines for the treatment of facial paralysis (Ardita): a systematic review protocol

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Review question/objective
The objective of this review is to establish the effectiveness of oil based nasal instillation medicines in the treatment of Ardita (facial paralysis).

The question that will be asked in the review is:

Which of the commonly used Ayurvedic nasal instillation medicated oils is the most effective for treating Ardita either solely or in combination with other Ayurvedic medical interventions?

Background
Facial paralysis is a medical condition that disfigures or distorts the facial appearance.¹ Besides causing asymmetry of the face, it limits the functioning of facial muscles of the sufferer. The condition could be congenital or could be caused as a result of infection, stroke, toxicity, physical trauma, neoplastic, iatrogenic or idiopathic aetiologies.² Facial paralysis can be unilateral or bilateral. Among the causes of facial paralysis, Bell's palsy cases are the highest.³ The eponym Bell's palsy is used when the peripheral facial nerve paralysis is caused by idiopathic reasons.³,⁴ In certain cases facial paresis is caused as a result of the central nervous system disorder or brain injury, leading to facial paralysis. Bell's palsy, which as indicated above is paralysis disorder that is most common, affects men and women equally and can occur at any age, but it is rare before age of 15 or above the age of 60.⁵ It is estimated that bell's palsy constitutes 60 to 70%
cases among all facial paralysis, followed by trauma and infection related ones. The condition is resultant of damage caused to the seventh cranial nerve which travels through the bony Fallopian canal in the skull, providing nerve impulse to the muscles on each sides of the face and tear glands. Additionally, the facial nerve also transmits taste sensations from the tongue.

The Ayurvedic term for facial paralysis irrespective of the aetiology is Ardita.

Cause-based classification of facial paralysis according to conventional medicine is:

Idiopathic: Bell’s palsy, sarcoidosis, inherited Bell’s palsy, myasthenia gravis, multiple sclerosis, temporal arteritis.

Infection: External otitis, varicella zoster, syphilis, otitis media, poliomyelitis, botulism, mastoiditis, coxsackievirus, tetanus, diptheria, HIV, cholesteatoma, Lyme disease.

Neoplastic: Schwannoma, teratoma, meningioma, von Recklinghausen’s disease, hemangioma, parotid tumour, acoustic neuroma, sarcoma, carcinoma (metastatic).

Metabolic: Diabetes mellitus, Hypertension, Acute porphyria.

Congenital: Möbius syndrome, Dystrophia myotonica.

Autoimmune syndrome: Thrombotic thrombocytopenic purpura, Kawasaki disease, Guillian barre/Miller–Fisher syndrome.

Neurological: Opercular syndrome, Wernicke-Korsakoff syndrome, pseudo-tumour cerebri, lacunar infarct.

Iatrogenic: Post-immunisation, Antitetanus serum, Vaccine for rabies.

Trauma: Traumatic delivery, parotid surgery, mastoid surgery, forceps delivery, anaesthetic nerve block, mandible fracture, penetrating injury, scuba diving.

Toxins: Ethylene glycol, ethanol, Carbon monoxide, thalidomide.

Patho-physiological classification of facial paralysis is of two types namely supranuclear palsy and infranuclear palsy. The former is identified as the involvement of the central nervous system when the fibres of facial nerve proximal to facial nucleus in pons are involved. The causes are mainly due to cerebrovascular stroke, haemorrhage or tumour in the region. In infranuclear palsy, the involvement of peripheral nervous system is identified, when the facial nerve is affected after its nucleus in pons. Bell’s palsy and parotid tumours are most common in this category.

Evidence of knowledge of facial paralysis has been known since ancient times and has been transcribed in present day scientific literature. Ancient cultures like the Incas, Egyptians, Greeks and the Indians had a fair bit of understanding of this medical condition and attempted medical interventions available at that time. The great Indian sage Caraka, in his medical tome scripted in the second century BC describes the aetiology and management of Ardita. He describes clinical features of Ardita with symptoms manifested such as face, nose, eyebrows and jaws become distorted, food in mouth loses direction, tongue becomes crooked on trying to raise, voice becomes weak and hearing weakness. Ayurvedic science identifies the psycho-physiological nature of a person on the bases of subtle bio-energies known as Doshas. Basically, there are
three doshas, namely Vata, Kapha and Pitha. The simplest equivalence for Vata substrate in the human body is the nervous system. Caraka attributes the root-cause of Ardita to perturbed Vata dosha. However, other Ayurvedic experts like Sodhala classifies Ardita on doshic influence of Kapha and Pitha besides Vata.

The renowned Ayurvedic surgeon of ancient times and father of discrete surgery Susruta who lived in the first century AD, describes medication for Ardita in his compendium – Susruta Samhita. His treatment protocol gives special emphasis to Nasya.

Conventional medicine offers various treatments for facial paralysis according to the aetiology. In the management of facial paralysis which include Bell’s palsy, acute measures are normally taken first. These typically include eye protection such as application of eye ointment or lubricant and wearing watch-glass bandages to prevent dehydration of the cornea or from aberrations. Subsequently, Mime and physiotherapy including massage and relaxation may be advised to control the condition. Further, medication with steroids or antiviral agents may be prescribed. In some cases, acupuncture, transcutaneous electrical stimulation, transmastoid decompression, surgical methods such as Gold weight implant, facial nerve cable grafting, subperiostal facial suspension (face lifting), or Botulinum toxin injection are performed.

The conventional medical treatment and management of facial paralysis has its own limitations. It has been reported that in some cases up to 10% of patients are reported to have no recovery from the condition. Some studies have found that the facial paralysis is treatable to a complete cure in the early stages of development of symptoms. However, there are no known definite recommendations favoring any specific medication that could be regarded as the best. In the light of this fact, availability of evidence based alternative medication would be of help to the patients.

The administration of nasal instillation medicine in Ayurveda is called Nasya which belongs to the 5-prong Ayurvedic treatment modality known as Panchakarma. Nasya is regarded as patient friendly because it can be done even in the comfort of patients’ residence. Moreover, the use of Nasya medication has not been reported as causing any side effects. The usual dose varies between two to 10 drops in each nostril, once or twice daily.

Currently there is a dearth of easy to access evidence on the prevalence of use of Nasya for treating facial paralysis as well as on the effectiveness of Nasya for treating facial paralysis. A search of leading databases of published medical studies, including PubMed, Cochrane and DHARA found no systematic review on either the prevalence of use of Nasya for treating facial paralysis or / and the effectiveness of different nasal instillation Ayurvedic medicines for treating facial paralysis. In the absence of a systematic review existing on the topic, the review will fill a knowledge gap and facilitate practitioners of Ayurveda and Integrative medicine using Nasya as an alternative treatment modality in a way that is informed by evidence.

Keywords

Ayurveda; Nasya; Ardita; Facial paralysis; Vata
Inclusion criteria

Types of participants

Adults (18-70 years of age) with Ardita (chronic or acute) are the participants to be included in this review. More specifically, the review will consider for inclusion studies that have examined the effectiveness of Nasya for treating acute or chronic Ardita in adults. An inclusive approach will be adopted with respect to geographical location of the participants with patients located in any country, and both rural and urban areas to be considered. Participants of any socio-economic status, both sexes and all ethnic origins will be considered.

Studies whose participants have been pregnant women, adults older than 70 years and patients with allergic rhinitis, fever, intracranial tumour/haemorrhage and bilateral facial palsy will be excluded from the review. The reason for the lower age limit of 18 is because oil based Nasya is not usually administered to children, according to the ancient textual source Astanga Hridaya Sootra Sthanna.23

Types of intervention(s) and comparator(s)

The review will include for consideration all quantitative studies conducted worldwide that have examined the effectiveness of nasal instillation of Ayurvedic oil-based herbal medicine. All studies that quantified the effectiveness of Nasya either administered by a therapist or by self-administration in treating facial paralysis will be considered for inclusion. All dosages and frequencies of Nasya use will be considered and if possible how effectiveness varies with dosage and frequency of use will be detailed in the analysis.

All studies in which the comparator was conventional medical management or placebo will be considered for inclusion. However, studies of Ayurvedic Nasya medicine in conjunction with conventional medicine, if any, will be excluded. As the objective is not only to shed light on the effectiveness of Nasya for treating facial paralysis, but also the effectiveness of one kind of Nasya medicine compared to another, all studies that have compared the effectiveness of one Nasya instillation medicine compared to another will be considered.

Types of outcomes

The review will consider both Ayurvedic and Conventional medicine outcome assessment criterion as described in the research papers. With respect to the conventional medicine this will include, but not be limited to facial function as measured by the House-Brackmann grading24,25 of facial function measure. With respect to the Ayurvedic medicine approach this will include but not limited to Ayurvedic diagnostic scoring.14,22

The House-Brackmann scale ranges between I (normal movement) and VI (no movement).25

Grade I
Normal symmetrical function
Grade II
Slight weakness noticeable only on close inspection
Complete eye closure with minimal effort
Slight asymmetry of smile with maximal effort
Synkinesis barely noticeable, contracture, or spasm absent
Grade III
Obvious weakness, but not disfiguring
May not be able to lift eyebrow
Complete eye closure and strong but asymmetrical mouth movement
Obvious, but not disfiguring synkinesis, mass movement or spasm
Grade IV
Obvious disfiguring weakness
Inability to lift brow
Incomplete eye closure and asymmetry of mouth with maximal effort
Severe synkinesis, mass movement, spasm
Grade V
Motion barely perceptible
Incomplete eye closure, slight movement corner mouth
Synkinesis, contracture, and spasm usually absent
Grade VI
No movement, loss of tone, no synkinesis, contracture, or spasm
The Ayurvedic facial function grading is done as follows, with a full score of 3 for complete, 2 for Half, 1 for Mild and a score of 0 for normal.22
1. Vaktrardhavakra :
   Complete Mukhavakra
   Half Mukhavakra
   Mild Mukhavakra
   Normal
2. Vaksanga :
   Complete Vaksanga
   Pronouncing with great efforts
   Pronouncing with less efforts
   Normal speech (whistling)
3. Netravikriti:
   Complete upward rolling of eye
   Half of the upward rolling of eye
   Partial upward rolling of eye
   Normal

4. Lalasrava:
   Constant (profuse) Lalasrava
   Intermittent (moderate) Lalasrava
   Partial (mild) Lalasrava
   No Lalasrava

**Types of studies**

To answer the questions of whether Nasya is effective for treating facial paralysis in the population of interest and the relative effectiveness of the different Nasya that emerge as effective, the review will consider experimental and epidemiological study designs including randomized controlled trials, non-randomized controlled trials and quasi-experimental studies.

**Search strategy**

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in the review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe articles. Second, a search using all identified keywords and index terms will then be undertaken, across all databases. Thirdly, the reference list of identified reports and articles will be searched for additional studies. If missing information in studies are found all efforts will be made to obtain them. A limitation of the proposal is that even though it is understood that there may be a number of studies that are published in languages besides English, only studies published in English will be considered. This is due to concerns about the cost and feasibility associated with translation.

The following databases will be searched to identify published studies:

- PubMed
- CINAHL
- Cochrane (CENTRAL)
- Scopus
- Centre for Review and Dissemination databases
- Turning Research into Practice TRIP
- EMBASE

doi: 10.11124/jbisrir-2013-1147
EBM Reviews

DHARA, DARE, AYUSH Research Portal (Govt of India) and HTA database.

To identify unpublished studies the following will be searched:

Google Scholar

Online clinical trials registers:

MedNar

ProQuest Dissertations

Theses

Studies published in English language will be considered for inclusion.

Examples of initial keywords that will be used in the exploratory stage of the search for studies in electronic databases are: Nasya, Ardita, Panchakarma and Ayurveda.

Informed by the findings from the initial exploratory searches in the range of databases to be covered, further key words will be identified and a detailed search strategy will be developed and implemented for each database.

**Assessment of methodological quality**

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

**Data collection**

Data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

**Data synthesis**

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Where statistical pooling is not possible the findings will be presented in narrative form. Tables and figures will be used to aid in data presentation where appropriate.
Conflicts of interest

There are no conflicts of interest to report.

Acknowledgements

The primary reviewer would like to thank Morne Scheepers, fellow Master of Clinical Science Student, for agreeing to assist with critical appraisal in the proposed review.
References


Appendix I: MASTARI critical appraisal checklist

**JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
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<td>2. Were participants blinded to treatment allocation?</td>
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<td>3. Was allocation to treatment groups concealed from the allocators?</td>
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<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6. Were the control and treatment groups comparable at entry?</td>
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<td>7. Were groups treated identically other than for the named interventions</td>
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<td>8. Were outcomes measured in the same way for all groups?</td>
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<td>9. Were outcomes measured in a reliable way?</td>
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<td>10. Was appropriate statistical analysis used?</td>
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Overall appraisal: Include □ Exclude □ Seek further info. □

Comments (Including reason for exclusion)


Appendix II: MASTARI data extraction instrument

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _______________________ Date _________________________

Author _______________________ Year _________________________

Journal _______________________ Record Number _________________________

Study Method
RCT ☐ Quasi-RCT ☐ Longitudinal ☐
Retrospective ☐ Observational ☐ Other ☐

Participants
Setting

Population

Sample size
Group A _______________________ Group B _______________________  

Interventions
Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions: