The effectiveness of Ayurvedic oil based nasal instillation (Nasya) medicines in the treatment of facial paralysis (Ardita)

A thesis submitted by

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Abstract

Background

Ardita (facial paralysis) is a medical condition that disfigures or distorts the facial appearance of the sufferer, causing facial asymmetry and malfunction. Ardita patients may benefit from considering alternative treatments such as Ayurveda, including Taila Nasya (nasal instillation of medicated oil).

Objectives

To synthesize the best available evidence regarding the effectiveness of different Nasya oils in the treatment of Ardita. Secondly, to draw evidence based recommendations from the synthesis for practitioners and Ardita sufferers.

Inclusion criteria

Types of participants

Studies conducted with adult sufferers (18-70 years of age) of Ardita (chronic or acute) in any setting were considered. Studies including participants who were pregnant or suffered allergic rhinitis, fever, intracranial tumour/haemorrhage and bilateral facial palsy were excluded.

Intervention(s)/comparator(s)

Taila Nasya (at all dosages and frequencies), either as a standalone treatment or in combination with other Ayurvedic treatments, was the intervention considered. Comparators considered were different Taila Nasya stand-alone treatments, Taila Nasya in combination with other Ayurvedic interventions and Ayurvedic interventions that did not include Taila Nasya.

Outcomes and measures

The outcomes of interest were changes in Ardita symptoms including facial distortion, speech disorders and facial pain. All measures of these symptoms were considered. .

Types of studies

All quantitative study designs (experimental, quasi-experimental and observational) were considered.

Search strategy

A three-step search strategy was initially used to identify published and unpublished studies. Studies published in the English language were considered, irrespective of publication date. Following an initial limited search of MEDLINE and CINAHL, the text words contained in the title and abstract, and of the index terms used to describe each articles were analysed. From the identified keywords and index terms, searches were undertaken across all relevant databases. Thirdly, reference lists of identified thesis and articles were searched for additional studies. Universities and website operators related to Ayurvedic research in India were contacted, including the National Institute of Ayurveda for relevant studies. Besides this, the University of Adelaide librarian was contacted to retrieve those studies identified in the reference lists of thesis and articles. Due to the dearth of studies identified, a

fourth step was added to the search strategy commonly used for systematic reviews based on the Joanna Briggs Institute systematic review methodology. This involved contacting Indian universities and relevant institutions to locate and obtain studies that match the inclusion criteria of this review.

Methodological quality

Studies matching the inclusion criteria were independently assessed by the author and a secondary reviewer using the relevant standardised critical appraisal instrument from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (MAStARI).

Data extraction and synthesis

Data was extracted by the primary reviewer using a standardised data extraction tool from the Joanna Briggs Institute. The intention was to conduct a meta-analysis. However, this was not possible because only two studies were identified, and these examined different interventions and comparators. A narrative synthesis was therefore conducted, aided by tables.

Results

Only two pseudo-randomised studies, with a small number of participants and which met the inclusion criteria, were accessible and included in the review. One study with 20 participants, divided equally into two groups, compared the effectiveness of two alternative nasal instillations, namely Anu Taila and Mashadi Taila for alleviating four Ardita symptoms. Although the researchers claimed that Anu Taila Nasya is better than Mashadi taila Nasya for controlling facial distortion, they stated that Mashadi taila Nasya offered statistically highly significant outcome values. Furthermore, they made an unsupported statement that Mashadi taila Nasya if administered with Shamana medicines will give better results in short duration. The second study, which included 30 participants split evenly between the intervention and comparator groups, compared the effectiveness of Nasya with Shirobasti for alleviating seven Ardita symptoms. Both studies used observational measurements and graded Ardita symptoms as ‘mild’, ‘moderate’ or ‘marked’ at baseline and after one month. In the study that included 30 participants, the 15 patients who received the Nasya intervention experienced relief from the symptoms of facial pain, speech disorder and earache within the range of 78.2% to 90.9%, graded as ‘marked’. The review found scant and low level of evidence favouring the Taila Nasya intervention compared to Shirobasti.

Conclusions

This systematic review presents extremely limited evidence, from only two small experimental studies, that administration of Nasya oil alone may provide some relief from Ardita symptoms of facial distortion, speech disorder, inability to shut eyelids and dribbling of saliva in adult patients. Of the two studies, one had very weak methodology and did not offer any robust results. No strong conclusions may be drawn from the evidence included in this review due to the limited number of studies, limited number of participants and poor quality of studies.

Inferences for practice

Practitioners should advise Ardita patients that there is extremely limited evidence that suggests that

Mahamasha Taila Nasya alone may provide some relief from Ardita symptoms of facial distortion, speech disorder, inability to shut eyelids/upward eye rolling, and dribbling of saliva in adult patients. Given the absence of a strong evidence base, practitioners should be guided by clinical wisdom and patient preference.

Inferences for research

Well controlled clinical trials comparing the effects of standalone Nasya therapy and Nasya combined with other Ayurvedic treatments and/or conventional medicine on Ardita symptoms should be conducted. High quality clinical trials examining the relative effectiveness of different Nasya oils for treating Ardita are also required.

List of tables and figures

Definition of Ayurvedic terms

General

Amla – Sour.

Churna - Dry ground herbs (fine powder form). According to the requirement, Churnas are administered either orally, nasal (snorting) or externally (topical application).

Dosha - The basic psycho-physiological functional principle of an individual.

Kashaya – Astringent taste**.** The word Kashaya is sometimes used as a synonym for Kwatha

Katu – Pungent.

Kerala Panchakarma - An Ayurvedic purification procedure that originates from the state of Kerala in India known as Kerala Panchakarma. It is distinct from the general Panchakarma. Kerala Panchakarma includes Shirobasti, Dhara (controlled continuous flow of liquid medicine in the body), Pizhicil (dripping medicinal oil on the body by wringing a cloth soaked with the oil), Pinda Sweda (application of a bolus of medicines by fomenting the patient with the medicines tied in a piece of cloth and warmed in oil), Netra Basti also known as Tarpanam (an eye treatment where the eyes are bathed in herbal juices or medicinal oil using a donut-like container made with flour), Karnapurana (medicinal eardrop instillation), and Shirolepa (medicinal poultice application on the body. Navara Kizhi (bio-stimulation of whole or part of the body using a bolus bundle of cooked Shastika rice) is a sub class of Pinda Sweda.

Kwatha - A herbal decoction (Also called ‘Quatha’, ‘Kashayam’, ‘Kwatham’ or ‘Kwath’.). This is generally prepared by refluxing (controlled boiling) a required quantity of prescribed herbs in water in the ratio 1:8 until the contents reduce to a quarter of the original quantity.

Lavana – Salty.

Madhura – Sweet.

Marsha Nasya - When medicated oil is used for Nasya, there is dose wise differentiation. When a higher dose of oil is used for Nasya, the term Marsha Nasya is used. The higher dose is meant for quick action. When a lower dose of oil is used, the term Pratimarsha Nasya is used.

Nasya - Nasal instillation of Ayurvedic medicine (Also called ‘Nasyam’.). It is one of the five panchakarma procedures used as part of Ayurvedic treatment.

Panchakarma - The five prong modality of purification treatment employed as a part of Ayurvedic treatment. The word Panchakarma is a combination of two words, Pancha and Karma. Pancha means five and Karma means procedure. This includes Vasti (enema, administered with medicinal liquid), Nasya, Raktamoksha (bloodletting), Vamana (emesis) and Virechana (purgation).

Poorvakarma - Preparatory procedures employed prior to administering Panchakarma.

Prakriti - The primordial psycho-physiological quality of an individual that is present at birth.

Raktamoksha – Bloodletting. This is one of the Panchakarma procedures used in treating

hematoma, blood clots or in a detoxification regimen.

Rasa – Taste.

Shirobasti - One of the five modalities of treatment that is used in Ayurveda where about 1 litre of medicated oil is held within a tight circular container on the patient's head. The oil is retained for an average period of one hour and subsequently removed.

Taila - Medicated oil. Taila is generally prepared in two stages. Firstly, a kwatha is made by refluxing (controlled boiling) of prescribed herbs in water. Secondly, the liquid decoction thus obtained is heated with a required amount of vegetable oil or animal fat (usually butter oil). The aqueous part is evaporated leaving behind a mixture of oil and solid mass, which is then filtered to obtain Taila. In some Taila preparations, herbal juices are preferred over kwatha.

Taila Nasya - Nasal instillation of oil based medicine.

Tikta – Bitter.

Vamana - Emesis or controlled induced vomiting with prescribed medicines. This is one of the Panchakarma procedures for treating general Kapha disorders.

Vasti - One of the Panchakarma procedures, also known as Basti. This is generally medicated enema with a Kwatha, Taila or practitioner prescribed liquid. Most often Vasti is prescribed for treating Vata disorders.

Virechana - One of the Panchakarma procedures where medicines are used to induce controlled purgation.

Symptoms

Akshinimesha asamarthya and Netravikriti - Inability to shut eyelids or upward rolling of eyes.

Ardita – Facial paralysis.

Karna vedana – Earache.

Lalasrava - Dribbling of saliva.

Lalata vali nasha - Absence of facial wrinkles.

Mukhaparshwa greevavedana - Facial pain.

Vaksanga - Speech disorder.

Vaktrardhavakra and Mukha vakrata - Facial distortion.

Shamak - Easing vitiation.

Balya - That which strengthens the body.

Brimhaniya – Nutritious.

Acronyms

AYUSH - The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy of the Government of India.

CINAHL - Cumulative Index to Nursing and Allied Health Literature.

DARE - The Database of Abstracts of Reviews of Effects.

DHARA - Digital Helpline for Ayurveda Research Articles.

EBM - Evidence Based Medicine.

EMBASE - Excerpta Medica Database.

HTA - Health Technology Assessment.

IPD - In patient department (of a hospital).

JBI - Joanna Briggs Institute.

JBISRIR - JBI Database of Systematic Reviews and Implementation Reports.

MEDLINE - Medical Literature Analysis and Retrieval System Online.

OPD - Outpatient department (of a hospital).

PICO - The pneumonic for Population, Intervention, Comparison intervention and Outcomes.

PRISMA - Preferred Reporting Items for Systematic Review and Meta-Analyses.

RCT - Randomised controlled trials.

TRIP – Turning Research into Practice.

Chapter 1: Background

1.1 Introduction

This dissertation is based on a systematic review that aimed to determine the effectiveness of nasal instillation of Ayurvedic medicine (Nasya) for the treatment of facial paralysis, Ardita, in Ayurvedic terminology. The systematic review used the Joanna Briggs Institute (JBI) methodology for conducting systematic reviews. It was preceded by the publication of a protocol[1] and the systematic review report from the evidence review is soon to be published in the JBI Database of Systematic Reviews and Implementation reports.

The JBI methodology for systematic reviews is designed to identify and synthesize primary healthcare research for the purpose of informing better healthcare practice and policy. The JBI offers guidance to assist reviewers to identify and synthesise diverse forms of evidence addressing diverse questions for which health policy makers and practitioners require answer to support their decision making. This review used the JBI guidance on reviews of quantitative evidence on intervention effectiveness.[2]

The dissertation is structured as follows: This chapter provides a background to the review, chapter two presents the method used in the review, chapter three presents the results, and Chapter four comprises the discussion, conclusion and implications for practice and research.

1.2 Ardita: definition, cause and prevalence

Facial paralysis, hereafter referred to using the Ayurvedic term, Ardita, is a medical condition that disfigures or distorts the facial appearance[3] either unilaterally or bilaterally. Besides causing asymmetry of the face, it also limits the functioning of facial muscles of the sufferer. Ardita may be congenital or a result of infection, stroke, toxicity, physical trauma, neoplastic, iatrogenic or idiopathic aetiologies.[4]

Among the causes of Ardita, Bell's palsy constitutes 60% to 70% of cases.[5-8] Bell's palsy is a peripheral facial nerve paralysis of idiopathic origin,[5,6] although in certain cases facial paresis is a result of a central nervous system disorder or brain injury. Damage is observed in the seventh cranial nerve, which travels through the bony Fallopian canal in the skull. The seventh cranial nerves provides nerve impulses to the muscles on each side of the face and tear glands, as well as transmitting taste sensations from the tongue.[7] Bell's palsy affects men and women equally, and while it can occur at any age, it is rare before the age of 15 or above the age of 60.[7]

The cause-based classification of Ardita according to conventional medicine is[4, 9, 10]:

- 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, diphtheria, HIV, cholesteatoma, Lyme disease.

- Neoplastic: schwannoma, teratoma, meningioma, Von Recklinghausen's disease, haemangioma, 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.

Facial paralysis may be classified as supranuclear palsy and infranuclear palsy. The former is identified as the involvement of the central nervous system when the fibres of facial nerves proximal to facial nucleus in the pons are involved. The causes are mainly 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 the pons (i.e. below the nucleus of facial nerves). Bell's palsy and parotid tumours are most common in this category.[11]

The Ayurvedic term for facial paralysis irrespective of the aetiology is Ardita.[12] Ardita has been reported since ancient times and the description has been transcribed in present day scientific literature. Ancient cultures including the Incas, Egyptians, Greeks and Indians referred to this medical condition and also described the medical interventions used in its treatment.[5] The great Indian sage, Caraka, in his medical tome written in the second century BC, described the aetiology and management of Ardita.[12] He described clinical features of Ardita with symptoms such as distortion of the face, nose, eyebrows and jaws, inability to chew, crooked tongue upon protrusion, and weakened voice and hearing.[12, 13]

Ayurvedic science identifies the psycho-physiological nature of a person on the basis of subtle bio-energies known as Doshas. There are three Doshas: Vata, Kapha and Pitta. The simplest equivalent of Vata substrate in the human body is the nervous system.[13-15] Caraka attributed the root cause of Ardita to perturbed Vata Dosha.[12] An alternative view attributes Ardita to the doshic influence of Kapha and Pitta rather than Vata.[16]

1.3 Treatment for Ardita: Ayurvedic and conventional

1.3.1 Conventional treatment

Conventional medicine offers various treatments for Ardita depending on its etiology. In the management of Ardita, including Bell's palsy, initial measures recommended by clinicians typically involve eye protection, including application of eye ointment or lubricant[17] and the wearing of watch-glass bandages.[18] These bandages prevent dehydration of the cornea and/or alteration to normal eye movement. Mime therapy (gesture, expression and movement), physiotherapy (including massage and relaxation techniques) or medication (steroid and antiviral agents) may also be used to control the condition. In some cases, acupuncture, transcutaneous electrical stimulation, transmastoid decompression, surgical methods (gold weight implant, facial nerve cable grafting, subperiostal facial suspension (face lifting) or botulinum toxin injections are performed in an attempt to remedy persistent Ardita.[19, 20]

Some studies have found that facial paralysis is treatable with conventional medicine and that a complete cure is possible if treatment is done in the early stages of development of symptoms.[19,20] The current evidence base on the effectiveness of conventional medicine treatments suggests that there is no single treatment that universally suits all aetiologies of Bell's palsy, and unless medical/surgical intervention is provided within two years of first development of symptoms, cases go uncured with resultant permanent facial disfigurement.[19] In the light of this, guidance on evidence-based alternative medication options may be of benefit to sufferers of Ardita.

1.3.2 Ayurvedic treatment

The administration of nasal instillation medicine in Ayurveda is called Nasya which belongs to the five-pronged Ayurvedic treatment modality known as Panchakarma. The other four modalities are Vasti (rectal medication), Raktamoksha (bloodletting), Virechana (induced purging) and Vamana (emesis). In the author's experience, from interacting with patients suffering from Ardita, Nasya is regarded as patient friendly because it can be administered in the comfort of the patient's residence even without help or supervision by practitioners, and patients do not commonly suffer side effects. In the literature reviewed, Nasya medication has not been reported to cause any side effects.[21] The dosage of Nasya recommended by Ayurvedic medicine practitioners commonly varies between two to 10 drops in each nostril, once or twice daily.[22]

The medication for Ardita is described in the compendium of Susruta Samhita,[23] a renowned Ayurvedic surgeon of ancient times and father of discrete surgery who lived in the first century AD. Susruta's Ardita treatment protocol gives special emphasis to Nasya,[23] and he recommends an oil extract made out of herbal classes called Trinapanchamoola, Mahapanchamoola, Kakolyadi and Vidarigandhadi.

Generally, Nasya forms part of an overall treatment protocol for various health conditions. Guided by the holistic approach to treatment that informs Ayurvedic medicine, Ayurvedic practitioners often prescribe oral medication and other forms of therapy simultaneously with Nasya. In some cases

practitioners may recommend Shirobasti, which is known as one of the Kerala Panchakarma treatments.[22] Kerala Panchakarma means a group of five treatment modalities namely, Dhara (streaming of a medicated decoction or oil on the body), Phizichil (dripping of a medicated decoction or oil on the body), Navara Kizhi (bio-stimulation of the whole or part of the body using a bolus bundle of cooked Shastika rice), Shirobasti (pooling of medicated oil on the head, which is held for a prescribed time) and Shirolepa (application of medicinal poultice on the body). [24]

It is understood that conventional medicine does not offer a complete cure for Ardita, especially in chronic condition,, and has its own limitations in treatment.[19,20] Some Ardita sufferers choose to Ayurvedic treatment over conventional medication due to their belief in holistic health management. The motivation for this review was to provide practitioners of Ayurveda and Integrative medicine, as well as patients suffering from Ardita, with evidence informed recommendations on the most effective Naysa oil treatment for Ardita and the effectiveness of Nasya oil compared to other treatment options.

1.4 Introduction to systematic reviews

1.4.1 Emergence of systematic reviews as part of the evidence-based healthcare movement

The evidence-based healthcare movement originated in the mid 19th century in Europe.[25] Clinicians came to rely on published scientific studies in guiding their diagnoses and decision making. The application of knowledge thus gained was extended to management of medical conditions although it had limitations. The knowledge gained was not always robust enough and tended to be biased towards the researchers' interests or those who commissioned the research. The interpretation of results and conclusions was sometimes misleading. The findings and conclusions were therefore more akin to expert opinions and this reliability came into question. To overcome these shortcomings, literature reviews were developed so as to gather findings of studies on specific topics, analyse them and report the critique in a meaningful way.

Literature reviews are different from systematic reviews. Literature reviews are based on articles that describe and discuss a specific topic or topics from a contextual or theoretical point of view. Literature reviews have drawbacks because they tend to rely on the author's knowledge and experience. They provide a limited view on a topic, are often subjective, and are based on selective references chosen from the studies.[26] The limitations evinced in such reviews led to the development of systematic reviews which aim to provide a more comprehensive, unbiased synthesis of all the relevant studies, with its findings given in a single document.[26] Evidence-based medicine implies application of current best evidence that is explicit and judicious in decision making in respect the of individual's healthcare.[25] Evidence-based healthcare practice entails the merging of clinicians' professional judgment with the best available evidence from systematic reviews.[25]

1.4.2 Features of and steps in a systematic review

The core purpose of a systematic review is to find relevant evidence befitting practice of medicine/healthcare from all available sources whereas in a literature review the focus is only on the

available literature.[26,,27,28] Another salient feature of systematic reviews is the critical appraisal of selected studies/literature. The reviewer is guided through set criteria of well defined methodology that would include gathering evidence from primary studies and assimilating findings to reaching a conclusion. The clarity and robustness of the methodology enables repeatability and reproducibility.

Systematic reviews follow well defined steps that describe review method.[26, 29] The key components of the systematic review are:

- A well defined review question or hypothesis with clearly articulated objectives
- Clear inclusion and exclusion criteria that are pre-published in a protocol
- Comprehensive search criteria for published and unpublished studies
- Reporting of exclusion of studies with reasons based on sound considerations
- Assessment of methodological quality of included studies
- Analysis of data extracted from the included studies
- Presentation and synthesis of the extracted findings
- Transparency of reporting of the methodology and methods used.

The systematic review methodology is principally based on the way the evidence is gathered, synthesised and the methodological quality of the included studies appraised. Evidence could be qualitative, quantitative, economic, or text and opinion-based. The methodology adopted in the systematic review that forms the basis of this thesis is provided in chapter 2 below. A series of steps are used in systematic reviews regardless of the type of evidence being synthesised. These are as follows:

Step 1. Framing of review question and inclusion criteria

The critical part of any systematic review is to have a well defined and structured review question that states the problem to be assessed. This sets the quality of the review and the direction for the conduct of the review.[30] The framing of the review question may vary depending on whether a qualitative or quantitative review is being conducted.

A free form review question describes the focus of the review in simple language; however this may be vague. This can be converted into a structured review question with a clear and explicit format using a structured approach. Generally, to have a structured, robust and meaningful systematic review question, review authors follow the components of PICO, which is a pneumonic for Population, Intervention, Comparison intervention, and Outcomes. PICO is the JBI recommended path for developing the systematic review question.[2]

The basic thrust of a quantitative systematic review question generally is one of effectiveness of a medicine, treatment or clinical practice. The review authors normally engage in analysing the effectiveness of an intervention compared to another for the medical condition cited, and for a set population. The review may vary to include comparing and analysing multiple interventions or

treatments as the reviewer chooses.

Setting up of a clear structured systematic question enables the reviewer to draft a review protocol. The protocol is an overview of the review that minimises bias and ensures scientific rigour throughout the review process.[30] An important aspect of the protocol is the selection criteria that define the parameters for the inclusion/exclusion of studies, generally referred to as the inclusion criteria. According to the PICO format, the review question needs to consider some fundamental elements to justify the inclusion criteria. These are:

- Type of studies to be included
- Intervention under investigation
- Any other interventions or treatments for comparison
- Outcomes
- Population
- Publication language
- Time period.

Having clear inclusion criteria enables the reviewer to answer the review question accurately and precisely. This offers repeatability/reproducibility of the review under the set conditions.[30]

Step 2. Developing a search strategy and seeking evidence

To undertake a robust, clear and comprehensive systematic review, a detailed search strategy is essential. This involves following a set logical process for identifying all available literature that is published and unpublished. [20]

Initially, searching multiple databases using key words or terms is conducted to examine the potential outcomes of the search. This enables the reviewer to have an idea of the extent of available literature, which in turn facilitates the optimisation of the search for all relevant evidence. A good understanding of the number of relevant studies that are available allows the reviewer to either widen or narrow the search as the review proceeds. Accordingly, the reviewer could reassess and refine the search strategy. [26]

The refinement of the search strategy based on the review question allows identification of the key terms in a precise way. In addition to searching selected databases, reviewers often conduct hand searches of citations and reference lists in studies or journals to locate more relevant studies.[26] Subsequently, it is recommended to search unpublished or grey literature, including manuscripts, to ensure that the search is as comprehensive as possible, and that no potential relevant studies are missed out.

The quality of systematic review rests on the repeatability of review. This means that the

comprehensive search needs to be clearly reported so that another reviewer who may wish to conduct the same review will arrive at similar results and conclusions.[26] To help the reviewer in logically reporting the search steps, the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) guideline is recommended.[26] The guideline directs the reviewer to include the search strategy of at least one major database in the review.

Step 3. Study selection and critical appraisal

A decision to include or exclude studies is made after examining the full texts of selected studies and relevant citations. Every article that is selected has to be screened to ascertain if they are relevant to the review question and whether the inclusion criteria have been met. In the process of critical appraisal of studies, therefore, the limitations of studies are identified.[31] The reviewing of full texts allows the final selection of studies relevant to the review question. It is recommended that the excluded studies detailing the reasons for each exclusions is tabulated.[27]

The core aims of critical appraisal are to exclude low quality studies, and to identify the strength and weakness of the included studies. The robustness of the review is indicated by the conduct of a meticulous critical appraisal.[31] To ensure a rigorous and meaningful critical appraisal, the JBI offers checklists. The critical appraisal also helps the reviewer to identify and eliminate potential bias in the review that might otherwise influence the results. In order to eliminate such bias, the JBI recommends appraisal of the articles by two reviewers. In cases of significant disagreements between the two reviewers, the help of a third reviewer could be sought. [31]

Step 4. Data extraction and synthesis

Key data from the selected studies are retrieved and collated after the critical appraisal. A feature of systematic reviews that is distinct from traditional literature reviews is the process of data extraction and synthesis.[32] Standardised data extraction tools are employed by the reviewer so that relevant data is accurately retrieved from all selected studies.

The outcome of the data synthesis forms the result section of the systematic review.[32] It is recommended that a meta-analysis of the collated data be conducted for quantitative systematic reviews. The process involves statistically combining the results of the studies to calculate a summary effect.[32] Heterogeneity of studies is often encountered by reviewers, which prevents the use of meta-analysis. In such cases, a narrative summary is recommended to convey the findings and results of the review.

Step 5. Interpreting and reporting findings

Interpreting the significance of a review's findings is said to be both an art and a science. [27] Translating the findings of a systematic review to offer meaningful and practical answers is based on the strength of the evidence and the results being presented in a clear and succinct way. It needs to be presented in a reasonably simplified manner so that the review is understood by readers with

different backgrounds. It is therefore essential to use plain language wherever possible.[33] The applicability or usefulness of the review in evidence-based practice can be enhanced by providing meaningful recommendations as well as mentioning the implications for research.[27]

1.5 Ayurvedic medicine and systematic reviews

It has been suggested by Ayurvedic experts that evidence informed practice should be based on classical textual sources as well as current clinical practice of Ayurveda.[29] In this regard, validation of textual sources could be undertaken along with critical analysis of research studies on the topic to measure and evaluate the application of findings to inform evidence-based practice.

Due to the non-conventional diagnostic methods such as dosha diagnosis involved in Ayurveda, the current practice of adopting research models used for conventional medicine may not be suitable for research in Ayurvedic clinical studies.[29,34] This means that the diagnosis and evaluation of a patient goes beyond the measurement of symptoms and pathology. Therefore there is a need to develop new research models for primary research and accordingly modify systematic review methodology to give meaningful recommendations for evidence-based clinical practice in Ayurveda. Efforts have been made by experts in recent times to overcome such shortcomings and to provide better outcomes for evidence-based Ayurvedic clinical practice.[34,35] These include organising a group of interdisciplinary experts to create list for inclusion and exclusion of diseases, disorders, syndromes, or symptoms in each of these phases according to Ayurvedic practice, and facilitating development of Ayurvedic research formats for case reports, case series, cohort, case controlled, observational, or controlled clinical studies.

The inclusion criteria model, Population Intervention, Control, and Outcome (PICO), adopted in conventional systematic reviews for considering studies have limitations when used for Ayurvedic systematic reviews. This is because the title and methodology of primary studies may not always be similar.[36] To overcome such shortcomings, it is recommended that outcome measures be categorised into four categories: primary outcome, secondary outcome, adverse events and time of outcome assessment. This would satisfy the particular requirements of Ayurvedic comprehensive etiological evaluations and enable pooling of studies accordingly.[37]

1.6 Review objectives

Practitioners of Ayurvedic medicine often come across patients with various sorts of health conditions seeking a cure or relief from their symptoms. From the experience of the author, it can be said that patients often ask about the effectiveness of medication or the treatment protocol. As Ayurvedic medicine is a traditionally evolved science, which has not been widely researched in scientific cause-effect relationship studies, including clinical studies, the practitioner's only resource is ancient textual sources on medicines. In the light of this, a scientific back-up armed with a systematic review of primary studies was felt as a necessity. There have been continued efforts by Ayurvedic scholars to integrate EBM with Ayurveda as well as to practise evidence based Ayurveda.[34,35] It is therefore imperative to undertake a systematic review to ascertain the best treatment for Ardita using Taila

Nasya. Being frequently consulted by Ardita sufferers, and in view of the absence of systematic reviews on Ayurvedic treatment of Ardita, the author was prompted to conduct a systematic review on this topic.

The objective of this review was to identify and synthesise the best available evidence on the effectiveness of Nasya oil for treating Ardita and to draw evidence-based recommendations thereby for the benefit of practitioners and Ardita sufferers. The motivation for this systematic review was to initiate steps in developing a guideline by combining outcomes of primary studies and also identifying limitations and gaps in the evidence available on this topic.

Chapter 2: Systematic review method

2.1 Introduction

As was explained in chapter 1, best practice systematic review methodology is to develop and publish a protocol for the review to be conducted. A protocol for this review was published in the JBI Database of Systematic Reviews and Implementation Reports and the systematic review has been accepted for publication in the database.

This chapter presents the method used in the systematic review. It describes the inclusion criteria, search strategy, assessment of methodological quality, and data collection and synthesis methods.

2.2 Inclusion criteria

The inclusion criteria set the parameters for the systematic review, and guided the reviewer in the inclusion or exclusion of studies. This process is also known as study selection.[31]

2.2.1 Types of participants

This review considered studies that included adults (18-70 years of age) with Ardita (chronic or acute). An inclusive approach was adopted with respect to geographical location of the participants (rural and urban areas considered), socio-economic status, sex and ethnicity. Studies conducted in any health or research/laboratory setting was considered.

Studies whose participants were pregnant women, adults older than 70 years and patients with allergic rhinitis, fever, intracranial tumour/haemorrhage and bilateral facial palsy were excluded from the review.

Patients younger than 18 were also excluded, as according to the ancient textual source, Astanga Hridaya Sootra Sthanna,[22] oil-based Nasya is not usually administered to children.

2.2.2 Types of intervention(s) and comparator(s)

The review considered all available quantitative studies that examined the effectiveness of nasal instillation of Ayurvedic oil-based herbal medicine, either as a stand-alone therapy or as part of the holistic Ayurvedic treatment approach. Studies examining Nasya administered by a therapist and/or self-administered Nasya were considered. All dosages and frequencies of Nasya administration were considered. Preliminary investigation on availability of studies comparing Ayurvedic Nasya oils with placebo or no treatment gave no favourable result and hence the scope of review had to be limited.

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

With respect to comparators, studies comparing the effectiveness of one Ayurvedic oil based nasal instillation medicine with another were considered. In addition, studies examining the effectiveness of any one or more Ayurvedic oil based nasal instillation medicines compared to other Ayurvedic

interventions were considered.

Originally the comparator was defined more broadly, and included conventional treatments. It was subsequently decided to exclude conventional medical comparator(s) and limit the comparators to other Ayurvedic nasal oil based and other treatments. This was because the search identified no studies examining the effectiveness of Nasya either as a stand-alone treatment or in combination with other interventions compared to conventional medicine. The issue of lack of evidence comparing Ayurvedic treatment with conventional treatment modalities is addressed further in the discussion and recommendations section of the review.

2.2.3 Types of studies

The review considered all quantitative study designs measuring the effectiveness of Taila Nasya for treating Ardita, including but not limited to, randomized controlled trials, non-randomized controlled trials, quasi-experimental studies, before and after studies, prospective and retrospective cohort studies, case control studies and analytical cross sectional studies.

2.2.4 Types of outcomes

All Ardita symptoms were considered and these include: Vaktardhavakra/Mukha Vakrata (facial distortion), Vaksanga (speech disorder), Akshi Nimesha Asamarthya/Netravikriti (inability to shut eyelids/upward rolling of eyes) Lalasrava (dribbling of saliva), Karnavedana (earache), Lalata Vali Nasha (absence of facial wrinkles) and Mukha Parshwa Greevavedana (facial pain).[38-41] In both conventional and Ayurvedic medicine, changes in Ardita symptoms are commonly measured though observation – such studies were therefore included in this review.

Measurement of observable changes in Ardita symptoms in conventional medicine was undertaken using the House-Brackmann scale.[16,40] The House-Brackmann grading of facial function measure/scale ranges from Grade I (normal) to Grade VI (no movement), as follows:

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 no disfigurement

May not be able to lift eyebrow(s)

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 of corner of mouth

Synkinesis, contracture, and spasm usually absent

Grade VI

No movement, loss of tone, no synkinesis, contracture or spasm

A commonly used grading system for measuring Ardita symptoms in studies of Ayurvedic treatment effects is as follows (with four example symptoms):

- *Vaktrardhavakra* (facial distortion)

  Complete Mukhavakrata (3)

  Half Mukhavakrata (2)

  Mild Mukhavakrata (1)

  Normal (0)

- *Vaksanga* (speech disorder)

  Complete Vaksanga (3)

  Pronouncing with great effort (2)

  Pronouncing with less effort (1)

  Normal speech (whistling) (0)

- *Netravikriti* (inability to shut eyelids)

  Complete upward rolling of eye (3)

  Upward rolling (halfway) of eye (2)

  Partial (less than half) upward rolling of eye (1)

Normal (0)

- *Lalasrava* (dribbling of saliva)

  Constant (profuse) Lalasrava (3)

  Intermittent (moderate) Lalasrava (2)

  Partial (mild) Lalasrava (1)

  No Lalasrava (0)

There are three symptoms for grading Ardita which are occasionally used. These are:

- *Karna vedana* (earache)

  Constant pain (3)

  Intermittent pain (2)

  Partial pain (1)

  No pain (0)

- *Lalata Vali Nasha* (absence of facial wrinkles)

  Complete absence of facial wrinkles (3)

  Minimal appearance of wrinkles (2)

  Moderate appearance of wrinkles (1)

  Normal symmetrical appearance of wrinkles (0)

- *Mukha Parshwa Greevavedana* (facial pain)

  Constant pain on the affected side (3)

  Intermittent pain on half of the affected side (2)

  Site-specific pain on the affected side for part of the day (1)

  No pain (0)

2.3 Search strategy

This review was conducted according to *a priori* published JBI review protocol.[1] and the databases searched and search strategy has been appended as Appendix 1.

Holistic treatments are generally prescribed to control diseases as well as related co-morbidities. Besides controlling symptoms, holistic treatments are usually intended for overall wellness of the patient. This means that the treatments may not always be single disease specific. The use of Nasya as part of a holistic treatment for Ardita complicates conducting a systematic review that aims to

identify and synthesise evidence on the effectiveness of Nasya as a stand-alone treatment for treating this condition.

During the protocol development stage of this review a small number of studies examining the effectiveness of Nasya and other Ayurvedic medicines for treating Ardita were identified, most of which were conducted by students undertaking postgraduate studies at Indian universities.[42-50]

The search strategy for this review involved three steps and aimed to find studies of published and unpublished studies. An initial limited search of MEDLINE and CINAHL was undertaken, followed by an analysis of the text words contained in the title and abstract, and the index terms used to describe each article. A second search of all identified keywords and index terms was undertaken across all databases as listed below. Finally, reference lists of identified theses and articles were searched for additional studies.

The following databases were searched to identify published studies:

PubMed

CINAHL

Cochrane (CENTRAL)

Scopus

Centre for Review and Dissemination databases

TRIP

EMBASE

EBM Reviews

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

To identify unpublished studies the following search engines, commonly used to identify grey literature in systematic reviews, were searched: Google Scholar, MedNar and ProQuest Dissertations and Theses.

Very few relevant articles were identified using the initial search strategy, and as a result, additional strategies were employed:

1. Searching of the websites (1) www.rguhs.ac.in/ and, (2) nia.nic.in/ that index studies and postgraduate student dissertations (Masters and PhD) completed in India. The second website is the official website of the National Institute of Ayurveda, the apex institute of the Department of AYUSH, Ministry of Health and Family Welfare, Government of India, which is known to be a key repository for studies on the effectiveness of Ayurvedic medicine.
2. Email contact with Dr Girish KJ, an expert in Ayurvedic medicine, to assist with the identification and retrieval of relevant studies for this review. Details of his services are available at www.ayurvedahealthcare.info/content/researches-ayurveda-riai. The website not

only includes studies conducted by PhD and Masters students on Ayurvedic medicine topics undertaken at Indian universities but also offers guidance in conducting research on Ayurveda.

3. The University of Adelaide librarian was contacted to assist in retrieving studies identified in the reference lists of theses and articles as mentioned in third stage of the search.

Only studies published in the English language were considered for inclusion for the systematic review. Investigation on finding studies in languages other than English was initially conducted, but gave no favourable result.

The initial keywords used in the early stage of this review were 'nasya', 'taila nasya', 'ardita', and 'panchakarma'. As these keywords are Sanskrit or vernacular terminology, spelling variations to sound similar to the words were also used. For example: the word 'nasya' was also searched for 'nasyam', both meaning the same due to regional usage variation. The keywords finally used were Nasya, errhine therapy, Marsha Nasya, Taila Nasya, Ardita, facial paralysis, and Panchakarma.

2.4 Assessment of quality of included studies

Papers initially selected were assessed independently by the lead reviewer and the secondary reviewer prior to inclusion in the review using the standardised critical appraisal instrument from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix II). Although not specified in the review protocol, it was agreed by both reviewers that in light of the very small evidence base identified, studies would be included regardless of their score from the quality assessment. The implications of poor methodological quality/risk of bias was to be considered in the evidence interpretation and drawing of recommendations.

2.5 Data collection

Data was extracted by the primary reviewer using the pre-determined standardised data extraction tool from JBI-MAStARI (Appendix III). The data extracted included specific details about the interventions, populations, study methods and outcomes of significance to the review question.

2.6 Data analysis and synthesis method

The data available from the selected studies[36,39] was heterogeneous due to different interventions and populations. Selected studies did not equally provide details on the characteristics of the included participants, such as similarities/differences in the age, demographics, ethnicity and clinical presentation of the intervention and the control groups. Authors of one study[38] also failed to provide crucial information regarding participants, such as symptom severity, and duration of suffering from Ardita. The study[38] also did not provide information about participants excluded from the groups.

The results of the studies have therefore been summarised using tables and narrative summary. The nature of the evidence identified from the heterogeneous studies precluded meta-analysis.

Chapter 3: Results of the systematic review

3.1 Description of studies

This chapter deals with identification and retrieval of primary research papers for the systematic review from various sources including contacting authors overseas.

3.1.1 Search and study selection

A total of 4309 records were identified from the initial database search and a further 12 from the hand search giving an overall number of 4321. From these, 1197 records were identified as duplicates and removed, leaving 3124 records whose abstracts and titles were assessed against the inclusion criteria. A total of 3112 of these records were excluded following review of the titles and abstracts as they did not fit the inclusion criteria. This left a total of 12 studies identified for full text retrieval and examination. The University of Adelaide Librarian was contacted to retrieve one of the studies, which was made available. This study lacked necessary study details including any statistical assessment and therefore was excluded. One of the other studies retrieved had insufficient data on outcome measures and was also excluded. Out of the 10 remaining studies, the authors of eight studies were contacted by email and telephone to obtain full texts of their studies, but the attempts were futile. Finally, two studies with full text were included for consideration. Figure 1 shows the study selection process and Appendix IV lists the studies identified and excluded, with reasons for exclusion.

Since only two studies were available that met inclusion criteria, a decision was made to include them in the review regardless of their quality and considering the implications of their methodological flaws in the analysis.

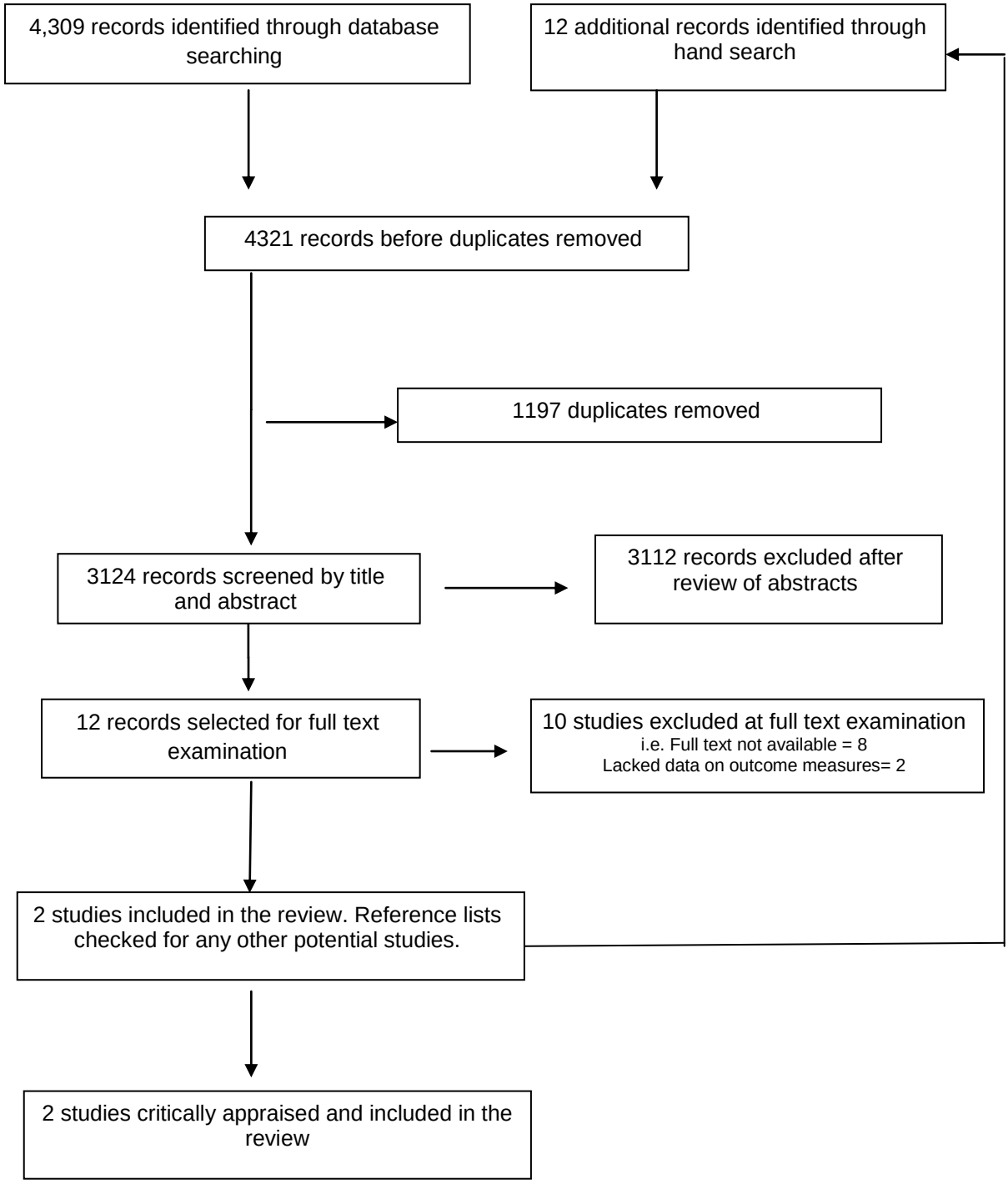

Figure 1: Flowchart of search results and study selection process

3.1.2 Key characteristics of included studies

Appendix V provides a summary of the characteristics of the two included studies.

Study design

The included studies[38,41] were pseudo randomised studies (small clinical trials). Both lacked true random assignment of participants to intervention and control groups, and used observational measurement to measure changes in Ardita symptoms.

Study settings and participants

Both studies were conducted in hospitals in India and included participants attending inpatient and outpatient departments.

Table 1 provides details of the age, education status, occupation and marital status of the study participants. One of the two included studies[38] had 20 adult participants, comprising both males and females. The authors of this study provided no further details on the characteristics of the included participants, such as similarities/differences in age, demographics, ethnicity and clinical presentation of the intervention and control groups. The authors also failed to provide crucial information regarding participants, such as symptom severity, how long each patient had been suffering from Ardita and the suspected aetiology. The study also did not provide information about who was excluded from the participant group (Table 1).

Table 1: Characteristics of participants in included studies[38,41]

Citation	Participant's characteristics									
	Gender		Age		Education status		Occupation		Marital status	
	M	F	Age group	No:	Group	No:	Group	No:	Group	No:
Thanki et. al.[38]	Not specified		Not specified		Not specified		Not specified		Not specified	
Gupta[41]	16	14	20-30yrs	9	Illiterate	6	Labourer	3	Married	21
			31-40yrs	8	Primary	15	Business	1		
			41-50yrs	1	Higher Secondary	3	Agriculture	3	Unmarried	7
			51-60yrs	3	Graduate	6	Ex-service	5		
			61-70yrs	9	Post graduate	0	Housewife	9	Widow	2
							Student	4		
							Other	5		

The second study[41] had a sample size of 30 participants. All the participants were adults, aged between 20 and 70 years. Of the 30 participants in this study, there were four males and 11 females allocated to the group treated with Nasya, and 12 males and three females treated with Shirobasti. The 2-30 and 61-70 year age groups had the highest number of study participants, (30% of total participants each), followed by the 31-40 year age group (26.7%). Across both groups, 63.3% were

Hindus and 30% were Muslims; the remaining participants were Christians. The educational background classification showed that of 80% of participants were literate and 20% were illiterate. A total 70% of participants of both groups were married and the remainder were either unmarried or widows.

In this study conducted by Gupta,[41] some of the Ayurvedic qualities of the participants were assessed. Among the 30 participants, 17 individuals were strict vegetarians and the rest were non-vegetarian. The Rasa-wise classification of the study subjects showed half of the participants predominantly consumed Katu (pungent) foods, whereas 14 people preferred Tikta (bitter) foods. Other tastes that the study subjects enjoyed were Madhura (sweet; 13 participants), Kashaya (astringent; 13 participants), Lavana (salty, seven participants) and Amla (sour; six participants). The author failed to classify the mixed tastes of foods consumed by the participants and it appeared that participants consumed foods of multiple tastes. Gupta[39] also classified the Prakriti (basic body constitution) of the study subjects; they had binary Prakriti attributes with 15 having Vata-Pitta, 10 with Vata-Kapha and five with Kapha-Pitta.

Although Gupta[41] stated that all 30 participants suffered Ardita, he did not specify which of the participants with multiple medical conditions were chronically ill with Ardita. Unilateral symptoms and signs of Ardita were shown on the right side (14 individuals) and the left side (16 individuals) of the face. Excluding the symptoms of facial distortion (Mukha vakrata) and an inability to close the eyelids/upward rolling of eyes (Akshinimesha asamarthya), the remaining five symptoms presented in the intervention and control groups did not have an equal number of participants (Table 2). Although pre-intervention gender wise classification and demographic characteristics before treatment were available in the study of Gupta A[41]**,** no such classification data was made available of the intervention/ comparator groups after treatment.

Table 2. Symptoms presented by participants in the study by Gupta A[41]

Ardita symptoms	**Number of participants**	
	Intervention (Nasya) group	**Comparator (Shirobasti) group**
Facial distortion (Mukha Vakrata)	15	15
Speech disorder (Vaksanga)	10	9
Dribbling of saliva (Lalasrava)	9	6
Inability to shut eyelids (Akshinimesha Asamarthya)	15	15
Facial pain(Mukhaparshwa Greevavedana)	6	5
Earache(Kana Vedana)	7	4
Absence of facial wrinkles(Lalata Vali Nasha)	8	12

Interventions and comparators

In the study by Thanki et al. [38] (20 participants), the effectiveness of one Nasya oil for treating Ardita was compared with that of another oil. More specifically:

- **Mashadi Taila** Nasya was administered to 10 patients in the intervention group. The dosage of six drops of the oil was instilled in the nostrils of the subjects. This was continued for 15 days, followed by a check-up at one month.
- **Anu Taila** Nasya was administered to 10 patients in the control group. The dosage of six drops of the oil was instilled in the nostrils of the subjects. This was continued for 15 days, followed by a check-up at one month.

The authors selected the two oils on the basis of similar Ayurvedic pathophysiological properties, such as Vata-Kapha Shamak (easing Vata and Kapha vitiation), Balya (strengthening the body) and Brimhaniya (nutritional value).

In the study conducted by Gupta[41], the intervention group of 15 patients received:

(i) Preparatory treatment: Oral medication of 5-10g of Avipattikara Churna twice daily, up to five days until Nirama Lakshana (digestive normalcy) was observed.

(ii) Core treatment: Nasya with Mahamasha Taila for seven days.

The comparator group of 15 patients received:

(i) Preparatory treatment: Oral medication of 5-10g of Avipattikara Churna twice daily, up to five days until Nirama Lakshana (digestive normalcy) was observed.

(ii) Core treatment: Shirobasti with Ksheerabala Taila for seven days.

The final evaluation of effectiveness of interventions was made after the follow-up check at the end of 30 days.

Additionally, as a preparatory treatment, both the intervention and comparator group participants were simultaneously administered with the oral medications, Brihat Vata Chintamani Rasa tablet and Dhanadhanayanadi Kwath, whilst being treated with the designated medicine for the group.

The preparatory interventions given to the participants in the study by Gupta[41] were generally done in the context of Panchakarma treatments[22] where Nasya was one of the five modalities. Here, groups undergoing different interventions were compared in order to identify the most effective treatment for Ardita. The treatment used for the comparator group was a topical application of oil on the head (Shirobasti with Ksheerabala Taila), whereas the intervention group was treated with Mahamasha Taila Nasya. In administering Shirobasti, about one litre of medicated oil was held within a tight fitting circular container on the patient's head, with the oil drenching the scalp. The oil was retained for an average duration of one hour and subsequently removed.[22]

Outcome measures

The study by Thanki et. al.[38] measured four Ardita symptom outcomes: 'facial distortion', 'speech disorder', 'dribbling of saliva' and 'inability to shut eyelids/upward rolling of eyes'. In addition to these symptoms, the study by Gupta[41] measured facial pain (Mukhaparshwa Greevavedana), earache (Karna Vedana), and absence of facial wrinkles (Lalata Vali Nasha). Both studies used observational measurement (see Table 3).

Table 3. Outcomes and outcome measures

Study	Outcomes	How outcomes were measured
Gupta. A, 2011[41]	Facial distortion (Mukha Vakrata) Dribbling of saliva (Lalasrava) Inability to shut eyelids (Akshinimesha Asamarthya) Speech disorder (Vaksanga) Facial pain (Mukhaparshwa Greevavedana) Earache (Karna vedana) Absence of facial wrinkles (Lalata Vali Nasha)	Subjective measurement: Observation with assessment by the researcher. Ardita symptoms assessed graded and scored prior to intervention administration and after one month using the researcher defined scale as 'mild', 'moderate' or 'marked' relief for each group. Change in symptom/outcome measured for comparator and intervention and statistical testing (*t*-test and *p*-value calculation) to establish whether difference was statistically significant. Measurement of effect after one month of intervention initiation.
Thanki H.K, Joshi P.N, Shah N.B, 2009[38]	Facial distortion (Vaktrardhavakrata) Dribbling of saliva (Lalasrava) Inability to shut eyelids (Netravikriti) Speech disorder (Vaksanga)	Subjective measurement: Observations by the researchers: Ardita symptoms assessed and graded as 'mild', 'moderate' and 'marked' difference in reduction of outcomes. The pre-intervention score (baseline) was not given. Measurement of effect after one month.

3.1.3 Methodological quality of included studies

The quality of the two key studies[38,41] was assessed using the JBI MAStARI critical appraisal tool. Whilst both studies rated poorly, that of Gupta[41] was of slightly higher quality than Thanki et al..[38] Table 4 presents the results of the critical appraisal.

Allocation of participants to treatment and comparator groups was not truly random in either studies, placing that result at a risk of bias. Whilst the studies did not mention whether the participants were aware of the full details of the interventions, it is highly likely that they were aware of the kind of treatment being administered. The study authors reported no specific steps taken to conceal any aspect of the treatment, such as the type of Nasya oil administered. Participant behaviour in response to knowledge about the treatment administered could have once again biased the results. Further

bias could have resulted from the fact that trial investigators were also the assessors, and that treatment outcomes were measured observationally.

The study by Thanki et al..[38] did not incorporate appropriate statistical analysis when assessing the effectiveness of treatments either within groups or when comparing different interventions. Furthermore, the authors of the studies[38,41] did not provide a comprehensive description of the measures used to draw conclusions about the relative effectiveness of the different interventions (Table 4).

Table 4. Assessment of quality of included studies for randomized controlled trials/pseudo-randomized controlled trials

	Assessment questions	Thanki et al.[38]	Gupta[41]
1	Was the assignment to the treatment groups truly random?	N	N
2	Were the participants blinded to treatment allocation?	Unclear	Unclear
3	Were allocations to treatment groups concealed from the allocator?	Unclear	N
4	Were the participant attrition details described?	NA	NA
5	Were those assessing outcomes blind to the treatment allocations?	N	N
6	Were the control and the treatment groups comparable at entry?	Unclear	Y*
7	Were the groups treated identically other than for the named interventions?	Unclear	Unclear
8	Were the outcomes measured in the same way for all groups?	Y	Y
9	Were the outcomes measured in a reliable way?	No	No
10	Was appropriate statistical analysis used and reported?	NA**	Y
Overall		Very low quality	Low quality

*Although there was difference in gender composition, both female and male participants were treated alike because Ardita treatment using Nasya is the same for either gender.

****** Although the study says that statistical analysis was conducted, details were not included in the assessment.

Note: (1) There was no attrition in the studies and hence quality criterion 4 on the checklist was not applicable.

3.2 Findings

The effectiveness of Nasya interventions in the studies presented by Gupta A[41] and Thanki et al.[38] is presented in Table 5. The data reports the percentage decrease in symptom severity for both interventions and comparators. Although the classifications used to describe the change in Ardita symptoms following treatment varied between the authors[38,41] (see table legend), it can be seen that Nasya administration improved all Ardita symptoms to some degree.

Table 5. Change in symptoms for the interventions and comparators (% relief reported and classification/description)

Ardita symptom	Gupta				Thanki *et al*.			
	Mahamasha Taila Nasya (N=15)		Ksheerabala Taila Shirobasti (N=15)		Anu Taila Nasya (N=10)		Mashadi Taila Nasya (N=10)	
	%	Description	%	Description	%	Description	%	Description
Facial pain (Mukhaparshwa Greevavedana)	83.3	Marked	66.6	Moderate	-		-	
Speech disorder (Vaksanga)	78.2	Marked	57.14	Moderate	70	Marked	70	Marked
Earache (Karna Vedana)	90.9	Marked	75	Moderate	-		-	
Facial distortion (Mukha Vakrata)	38.09	Mild	26	Mild	62.5	Marked	56.25	Marked
Inability to shut eyelids (Akshinimesha Asamarthya)	56	Moderate	36	Mild	68.75	Marked	86.66	Marked
Absence of facial wrinkles (Lalata Vali Nasha)	27.27	Mild	56.52	Moderate	-		-	
Dribbling of saliva (Lalasrava)	72.72	Moderate	66.66	Moderate	77.77	Marked	77.77	Marked

Note 1:

In the study by Gupta[41], the descriptive measure of relief from Ardita symptoms was based on the percentage relief value: up to a 50% relief of symptoms equated to ‘mild relief’, between 51-75% relief equated to ‘Moderate relief’, and greater than 75% relief was reported as ‘marked relief’**.**

In the study by Thanki et al.[38], the measure of relief from Ardita symptoms was also based on the percentage relief value: < 25% relief equated to ‘mild improvement’, 26-50% relief equated to a ‘moderate response’, and > 50% was reported as ‘marked relief’.

Note 2:

Measurement values were reported based on one month follow-up in both studies.

3.2.1 Ardita symptom 1: Facial distortion (Mukha Vakrata/Vaktradhavakrata)

Table 6 presents data from Gupta[41] that documents this study's findings on the effect of Nasya and Shirobasti treatment on facial distortion. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in facial distortion following treatment with either Nasya or Shirobasti. Of interest, the percentage improvement in facial distortion observed after administration of Mahamasha Taila Nasya (38.09%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (26.0%) (Table 5), suggesting that Nasya may be more effective than Shirobasti for treating facial distortion in Ardita patients.

Table 6. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating facial distortion in the study by the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	1.4	0.87	1.6	1.2
Mean difference	0.53		0.4	
SD	0.51	0.7	0.51	0.68
Difference in SD	0.19		0.17	
SE	0.13	0.18	0.13	0.18
Difference in SE	0.05		0.05	
't' value	4		3.06	
'*p*' value	<0.01		<0.01	
Assessment	Significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating facial distortion, as reported by Gupta[41], are presented in Table 7. It shows that there was no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in controlling facial distortion in Ardita sufferers.

Table 7. Relative efficacy of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention for alleviating facial distortion

Outcome	**Intervention group (Nasya)**			**Comparator group (Shirobasti)**			***'t'* value**	***'p'*value**	**Remarks***
	Mean	**SD**	**SE**	**Mean**	**SD**	**SE**			
Facial distortion (Mukha Vakrata)	0.53	0.52	0.13	0.4	0.51	0.13	0.72	>0.1	NS

* NS = Not statistically significant

Although Thanki et al.[38] reported a 56.25% relief from facial distortion following treatment with Mashadi Taila Nasya (Table 5) and a 62.5% relief from facial distortion following treatment with Anu

Taila Nasya (Table 5), data showing pre- and post-treatment values were not included. Results from statistical analysis of the measures were also not reported.

In summary, the two studies[38,41] presented limited evidence that Nasya combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, and Nasya with Anu Taila and Nasya with Mashadi Taila, may be effective for addressing facial distortion in patients suffering from Ardita.

3.2.2 Ardita symptom 2: Speech disorder (Vaksanga)

Table 8 presents data from Gupta[41], and documents the effect of Nasya and Shirobasti treatment on speech disorder. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in speech disorder following treatment with either Nasya or Shirobasti. Of interest, the percentage improvement in speech disorder observed after administration of Mahamasha Taila Nasya (78.2%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (57.14%) (Table 5), suggesting that Nasya may be more effective for treating speech disorder in Ardita patients.

Table 8. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating speech disorder (Vaksanga) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	1.53	0.33	1.4	0.60
Mean difference	1.2		0.8	
SD	1.25	0.67	1.3	0.74
Difference in SD	0.58		0.56	
SE	0.32	0.17	0.34	0.19
Difference in SE	0.15		0.15	
't' value	4.94		4	
'*p*' value	<0.001		<0.01	
Assessment of statistical significance	Significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating speech disorder, as reported by Gupta[41], are presented in Table 9. It shows that there was no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in controlling speech disorder in Ardita sufferers.

Table 9. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti (n=30)

Outcome	**Intervention group (Nasya)**			**Comparator group (Shirobasti)**			**'t' value**	***'p'*value**	**Remarks** *
	Mean	**SD**	**SE**	**Mean**	**SD**	**SE**			

Speech disorder (Vaksanga)	1.20	0.94	0.24	0.8	0.77	0.20	1.27	>0.1	NS

* NS = Not statistically significant

Although Thanki et al.[38] reported a 70% relief from speech disorder following treatment with Mashadi Taila Nasya (Table 5) and a 70% relief from speech disorder following treatment with Anu Taila Nasya (Table 5), data showing pre- and post-treatment values were not included. Results from statistical analysis of the measures were also not reported.

In summary, the two studies[38,41] present limited evidence that Nasya combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, and Nasya with Anu Taila and Nasya with Mashadi Taila, may be effective for addressing speech disorder in patients suffering from Ardita.

3.2.3 Ardita symptom 3: Dribbling of saliva (Lalasrava)

Table 10 presents data from Gupta[41], and documents the effects of Nasya and Shirobasti treatment on dribbling of saliva. Values are presented for both pre-and post-treatment, and demonstrate a statistically significant improvement in dribbling of saliva following treatment with either Nasya or Shirobasti. Of interest, the percentage improvement in dribbling of saliva observed after administration of Mahamasha Taila Nasya (72.72%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (66.66%) (Table 5), suggesting that Nasya may be more effective for treating dribbling of saliva in Ardita patients.

Table 10. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating dribbling of saliva (Lalasrava) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	1.47	0.4	1.0	0.3
Mean difference	1.07		0.7	
SD	1.3	0.63	1.31	0.72
Difference in SD	0.67		0.59	
SE	0.34	0.16	0.34	0.19
Difference in SE	0.18		0.15	
't' value	4		2.9	
'*p*' value	<0.01		<0.02	
Assessment of statistical significance	Significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating dribbling of saliva, as reported by Gupta[41], are presented in Table 11. It shows that there was no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in controlling dribbling of saliva in Ardita sufferers.

Table 11. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti (n=30)

Outcome	Intervention group (Nasya)			Comparator group (Shirobasti)			*'t'* value	*'p'*value	Remarks*
	Mean	SD	SE	Mean	SD	SE			
Dribbling of saliva (Lalasrava)	1.07	1.03	0.27	0.7	0.9	0.23	1.13	>0.1	NS

* NS = Not statistically significant

Thanki et al..[38] only presented the percentage change/relief for the symptom, dribbling of saliva (Table 5). Whilst the authors reported that there was a 77.77 **%** improvement from the use of Mashadi Taila Nasya and 77.77 **%** relief from Anu Taila Nasya, no measures of the symptoms before the intervention were presented. Results from statistical analysis of the measures were also not reported.

To sum up the findings for the third outcome, the two studies[38,41] presented some limited low quality evidence that Nasya, combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, and Nasya with Anu Taila and Nasya with Mashadi Taila, may be effective for addressing facial distortion in patients suffering from Ardita.

3.2.4 Ardita symptom 4: Inability to shut eyelids (Akshinimesha Asamarthya/ Netravikurti).

Table 12 presents data from Gupta[41], and documents the effects of Nasya and Shirobasti treatment on inability to shut eyelids. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in inability to shut eyelids following treatment with either Nasya or Shirobasti. Of interest, the percentage improvement in inability to shut eyelids observed after administration of Mahamasha Taila Nasya (56.0%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (36.0%) (Table 5), suggesting that Nasya may be more effective for treating inability to shut eyelids in Ardita patients.

Table 12. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating inability to shut eyelids *(*Akshinimesha Asamarthya) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	1.67	0.73	1.67	1.07
Mean difference	0.94		0.6	
SD	0.49	0.46	0.49	0.59
Difference in SD	0.03		0.10	
SE	0.13	0.12	0.13	0.15
Difference in SE	0.01		0.02	
't' value	4.53		3.67	
'*p*' value	<0.001		<0.01	
Assessment of statistical significance	Highly significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating inability to shut eyelids, as reported by Gupta[41], are presented in Table 13. It shows that there was no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for controlling the inability of Ardita sufferers to shut their eyelids.

Table13. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti. (n=30)

Outcome	**Intervention group (Nasya)**			**Comparator group (Shirobasti)**			***'t'* value**	***'p'*value**	**Remarks***
	Mean	**SD**	**SE**	**Mean**	**SD**	**SE**			
Inability to shut eyelids (Akshinimesha Asamarthya)	0.94	0.8	0.21	0.6	0.63	0.16	1.27	>0.1	NS

* NS = Not statistically significant

Thanki et al..[38] only presented the percentage of change/relief from the symptom inability to shut eyelids (Table 5). Whilst the authors reported that there was a 68.75**%** improvement from the use of Anu Taila Nasya and 86.66**%** relief from Mashadi Taila Nasya, no measures of before or after symptoms were presented. Results from statistical analysis of the measures were also not reported.

To sum up the findings for the fourth outcome, the two studies[38,41] presented some limited low quality evidence that Nasya combined with the oral medicines Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, and Nasya with Anu Taila and Nasya with Mashadi Taila may be effective in addressing the inability in patients suffering from Ardita to shut their eyelids.

3.2.5 Ardita symptom 5: Facial pain (Mukhaparshwa Greevavedana)

Table 14 presents data from Gupta[41], and documents the effects of Nasya and Shirobasti treatment for facial pain. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in facial pain following treatment with either Nasya or Shirobasti. Of interest, the percentage improvement in facial pain observed after administration of Mahamasha Taila Nasya (83.3%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (66.6%) (Table 5), suggesting that Nasya may be more effective for treating facial pain in Ardita patients.

Table 14. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating facial pain (Mukha Parshwa Greevavedana) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	0.8	0.13	0.8	0.27
Mean difference	0.67		0.53	
SD	1.15	0.44	1.21	0.6
Difference in SD	0.71		0.61	
SE	0.30	0.11	0.31	0.15
Difference in SE	0.19		0.16	
't' value	2.87		2.48	
'*p*' value	<0.02		<0.05	
Assessment of statistical significance	Significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating facial pain, as reported by Gupta[41], is presented in Table 15. It shows that there was no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in controlling facial pain in Ardita sufferers.

Table 15. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti. (n=30)

Outcome	**Intervention group (Nasya)**			**Comparator group (Shirobasti)**			***'t'* value**	***'p'*value**	**Remarks***
	Mean	**SD**	**SE**	**Mean**	**SD**	**SE**			
Facial pain (Mukha Parshwa Greevavedana)	0.67	0.90	0.23	0.53	0.83	0.22	0.42	>0.1	N S

* NS = Not statistically significant

Thanki et al..[38] did not present any observation on this symptom (Table 5).

To sum up the findings for the fifth outcome, among the two studies[38,41] only Gupta[41] presented some limited low quality evidence that Nasya combined with the oral medicines Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath may be effective for addressing facial pain in patients suffering from Ardita.

3.2.6 Ardita symptom 6: Earache (Karna Vedana)

Table 16 presents data from Gupta[41], and documents the effects of Nasya and Shirobasti treatment on earache. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in earache following treatment with Nasya and statistically insignificant with Shirobasti. Of interest, the percentage improvement in earache observed after administration of Mahamasha Taila Nasya (90.9%) was greater than that following treatment with Shirobasti using Ksheerabala Taila (75.0%) (Table 5), suggesting that Nasya may be more effective at treating earache in Ardita patients.

Table 16. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating earache (Karna Vedana) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	0.73	0.07	0.53	0.13
Mean difference	0.66		0.4	
SD	0.96	0.37	0.99	0.35
Difference in SD	0.59		0.64	
SE	0.25	0.1	0.26	0.09
Difference in SE	0.15		0.17	
't' value	3.16		2.10	
'*p*' value	<0.01		<0.10	
Assessment of statistical significance	Significant		Not significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila for alleviating earache, as reported by Gupta A[41], are presented in Table 17. They show that no difference in the effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in controlling earache of Ardita sufferers.

Table 17. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti. (n=30)

Outcome	**Intervention group (Nasya)**			**Comparator group (Shirobasti)**			***'t'* value**	***'p'*value**	**Remarks***
	Mean	**SD**	**SE**	**Mean**	**SD**	**SE**			
Earache (Karna Vedana)	0.66	0.82	0.21	0.4	0.74	0.19	0.94	>0.10	NS

* NS = Not statistically significant

Thanki et al..[38] did not present any observation on this symptom (Table 5).

To sum up the findings for the sixth outcome, among the two studies[38,41] only Gupta[41] presented some limited low quality evidence that Nasya combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, may be effective for addressing earache in patients suffering from Ardita.

3.2.7 Ardita symptom 7: Absence of facial wrinkles (Lalata Vali Nasha)

Table 18 presents data from Gupta[41], and documents the effects of Nasya and Shirobasti treatment on absence of facial wrinkles. Values are presented for both pre- and post-treatment, and demonstrate a statistically significant improvement in absence of facial wrinkles following treatment with either Nasya and highly statistically significant improvement with Shirobasti. Of interest, the percentage improvement in absence of facial wrinkles observed after administration of Mahamasha Taila Nasya (27.27%) was lesser than that following treatment with Shirobasti using Ksheerabala Taila (56.52%) (Table 5), suggesting that Shirobasti may be more effective at treating absence of facial wrinkles in Ardita patients.

Table 18. **Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating absence of facial wrinkles (Lalata Vali Nasha) in the Gupta study[41]**

	Nasya group (n=15)		Shirobasti group (n=15)	
	Before treatment	After treatment	Before treatment	After treatment
Mean	1.47	1.07	1.53	0.67
Mean difference	0.4		0.86	
SD	1.46	0.88	1.06	0.72
Difference in SD	0.58		0.34	
SE	0.38	0.23	0.27	0.19
Difference in SE	0.15		0.08	
't' value	3.05		6.5	
'*p*' value	<0.01		<0.001	
Assessment of statistical significance	Significant		Significant	

The relative effectiveness of Mahamasha Taila Nasya compared to Shirobasti using Ksheerabala Taila in alleviating absence of facial wrinkles, as reported by Gupta[41], is presented in Table 19. It shows that Shirobasti using Ksheerabala Taila is slightly more effective compared to Mahamasha Taila Nasya for controlling absence of facial wrinkles of Ardita sufferers.

Table19. Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Shirobasti. (n=30)

Outcome	Intervention group (Nasya)			Comparator group (Shirobasti)			*'t'* value	*'p'*value	Remarks*
	Mean	SD	SE	Mean	SD	SE			
Absence of facial wrinkles(Lalit vali nasha)	0.4	0.51	0.13	0.86	0.52	0.13	2.50	>0.02	S

* S = Statistically significant

Thanki et al..[36] did not present any observation on this symptom (Table 5).

To sum up the findings for the seventh outcome, among the two studies[38,41] only Gupta[41] presented some limited low quality evidence that Shirobasti combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Danadanayanadi Kwath, may be effective for addressing absence of facial wrinkles in patients suffering from Ardita.

Chapter 4: Discussion

The principal aim of this review was to identify and analyse the best available evidence on the effectiveness of Nasya treatment in general, as well as specific Nasya oils, in alleviating the symptoms of Ardita, either solely or in combination with other Ayurvedic medical interventions. Secondly, this review intended to draw evidence based recommendations for practitioners and Ardita sufferers.

4.1 Summary of findings

It is a common practice in Ayurveda to administer preparatory medication before the core intervention of Nasya is administered. This means that the final outcome may reflect the combined effect of the preparatory medicine as well as the core medicine. As a result, identification of which of the interventions (preparatory or core) was effective, and to what extent it was effective, is challenging, particularly as medications may act synergistically and additively, or even potentiate each other. The use of Nasya as part of a holistic treatment for Ardita complicates any attempts to review the effectiveness of Nasya as a stand-alone treatment for treating this condition.

This review examined the effects of various Ayurvedic treatments on seven common Ardita symptoms, namely facial distortion (Mukha Vakrata), dribbling of saliva (Lalasrava), inability to shut eyelids/upward rolling of eyes (Akshinimesha Asamarthya), speech disorder (Vaksanga), facial pain (Mukhaparshwa Greevavedana), earache (Karna Vedana), and absence of facial wrinkles (Lalata Vali Nasha). The results reflected the findings from the studies presented by Gupta[41] and Thanki et al.[38] and presented some limited evidence that Taila Nasya combined with the oral medicines, Brihat Vata Chintamani Rasa tablet and Dhanadhanayanadi Kwath, may be effective for addressing six of the above mentioned symptoms (except absence of facial wrinkles) in patients suffering from Ardita.

The study by Gupta[41] had different comparators such that the effectiveness of Nasya was compared to another modality, namely Shirobasti. There is no standard preparatory treatment in Panchakarma that could be used for all aetiologies and patient types.[22,24] Therefore, selection of preparatory treatment medication is always the professional judgment of the practitioner. In his study Gupta[41] did not provide before and after measurements for the preparatory oral medication of Avipattikara Churnam. This limited identification of the actual effect of either Nasya with Mashadi Taila or Shirobasti using Ksheerabala Taila meant that the effects of the treatment could be of those of a concomitant medical intervention and not exclusively those of the main intervention. Therefore, the bearing of each (preparatory and main) intervention on the overall treatment of both the groups is unknown.

The study by Thanki et al.[38] had several flaws, such as failure to provide any details of statistical analysis and not presenting before and after intervention outcome values. The study also lacked key data points, such as baseline measurements for the individual participants and changes achieved after the treatment for each outcome. Results were only presented for the percentage decline in

symptoms observed in the participants. Thanki et al.[38] did not specify whether the participants were suffering from acute or chronic Ardita, although both the intervention and comparator were involved administration of Nasya oil. Beyond this, the authors claimed that Anu Taila Nasya was better than Mashadi Taila Nasya for controlling facial distortion, yet stated that Mashadi Taila Nasya offered statistically highly significant outcome values. Finally they made an unsubstantiated statement that Mashadi Taila Nasya, administered with Shamana medicines, would give better results in a short duration.

Due to the high risk of bias in the two studies[38,41] and the limited number of participants, the results should be treated with extreme caution. Consequently, conclusive evidence-based recommendations to guide practitioners about which of the Nasya and/or other treatments to administer in order to relieve Ardita symptoms cannot be made.

4.2 Knowledge gaps and limitations

This review had a number of crucial limitations. Firstly, only English studies were included. Secondly, a number of relevant existing studies were inaccessible and hence not assessed for their eligibility based on the inclusion criteria and for possible inclusion in the review. Thirdly, the two studies[38,41] which formed the focus of this review were of a very low standard/methodological quality and were fraught with a high level risk of bias.

Ayurvedic diagnostic appraisal is based on body constitution as well as symptomatology, whereas conventional medicine focuses primarily on symptomatology. The two included studies were analysed using an appraisal tool based on notions of study quality/validity (conventional research methods) based western science, which limit the universal applicability of their findings to Ayurveda.

This review did not include any studies examining the effectiveness of Nasya compared to conventional treatment for Ardita. The lack of evidence comparing the Ayurvedic treatment with conventional treatment modalities limits the range of available studies. The review intended to include studies irrespective of publication date/year. A source of relevant studies was identified at http://indianmedicine.nic.in/index2.asp?slid=648&sublinkid=242&lang=1. However, availability of research papers through http://indianmedicine.nic.in was limited for the period 2010-11 to 2013-14.

4.3 Reflection on the difficulties confronting reviewers synthesising evidence on effectiveness of Ayurvedic treatments

Research on Ayurvedic medicine and treatment gained attention in the scientific community in the mid 20th century and has been gradually developing.[54,55] Unlike conventional medicine where drugs and treatments are subject to stringent evaluation and legislation before they are recommended for public use, Ayurvedic treatments and medicines evolved out of traditional practices and folklore through the ages. The basis for the acceptance of an Ayurvedic medicine for practice was generally an ‘expert

opinion' of a senior practitioner or a teacher (Guru). Tests and trials have not been a part of Ayurvedic medical practice as Ayurvedic medicine has always been an inherent aspect of Indian cultural and Hindu rituals and beliefs,. The orations and advice of gurus were later scripted by disciples and handed down the generations.[12,23]

In the light of modern scientific development and critical thinking, practitioners of Ayurvedic medicine, universities in India and Ayurvedic medicine manufacturers have attempted to incorporate, if not implement, modern scientific evaluations on Ayurvedic treatments and medicine. With the backing of the supportive ministries of the Government of India, steady but slow progress has been made in evaluating and standardising some medicines. The challenges and obstacles that the researchers in this field endure is multi-factorial. This means that rigorous clinical trials cannot be performed mainly due to three reasons. Firstly, there are insufficient funds available for Ayurvedic research unlike those for modern pharmaceutical medicines. Secondly, there is lack of standardisation and quality control of the herbs used in manufacturing Ayurvedic medicine. Thirdly, disease classification and diagnostics in Ayurveda is different from modern medicine. This means that, beyond pronounced measurable signs and symptoms, Ayurvedic diagnosis rely on subtle changes in the body that are assessed by the medical intuition of the practitioner. This implies there is a risk of human error or variation as each individual practitioner's intuition varies. True Ayurvedic research then becomes partially scientific and partially metaphysical. This is evident in almost all published Ayurvedic research papers and most researchers remain complacent with the outcome of their research. Systematic reviews are then faced with the problem of the availability and the poor quality of studies and the difficulty in assessing studies.

Finding Ayurvedic research papers for systematic reviews according to the research tools of modern medicine and clinical trials is a difficult task. Identifying good primary research papers fulfilling all aspects of Ayurvedic diagnostic paradigms and satisfying modern critical assessment tools of research are therefore rare. Researchers in Ayurvedic medicine are aware of these difficulties which stem from the development of primary research itself.[55,56] Some of the points cited are:

- Use of non-standardised medicines in trials.
- Variations in dosage of herbal drugs.
- Inefficiencies in selection of study populations.
- Low number of participants in studies.
- Difficulties in establishing placebos (food being part of medication).
- Variations in drug response with individuals of different Prakriti (The primordial psycho-physiological quality of an individual that is present at birth).
- Variation in duration of interventions.

To sum up, the difficulties in conducting good clinical trials and primary research is in itself a major factor in finding primary research papers for systematic review. It appears that evidence-based treatments in Ayurvedic medicine similar to that of conventional medicine is at present difficult to achieve, given the complexities involved.

4.4 Implications for practice

Some patients choose to have Ayurvedic treatment instead of conventional medication for treating Ardita due to their belief in the concept of holistic health management. Therefore, the need for knowledge on the various treatment options for Ardita with details of its effectiveness is important so that both practitioners and patients can make a well-informed decision. There are no reports of adverse effects caused by Nasya medication.[21]

The bias inherent in the design of the two included studies[38,41], as well as the lack of similarity of the interventions, precluded reliable analysis of the effectiveness of a particular Nasya medication to alleviate Ardita symptoms. The poor quality of included studies prevents drawing valid evidence-based recommendations to guide practitioners and patients in making decisions about which Nasya treatment to select to alleviate Ardita. In the absence of reliable evidence, practitioners and patients should be guided by patient preference and clinical wisdom.

4.5 Implications for research

- Since Ayurveda is regarded as a personalised treatment approach, it is recommended that randomised controlled trials on Ayurvedic medicine and treatments be designed with the trial participants grouped on the basis of their individual body constitution (Prakriti) type rather than adopting the conventional design. Also, dosha assessments for all participants need to be recorded before and after the trials along with measurements of any co-morbidity. This would enable reproducible research and its findings could be adapted to Ayurvedic evidence based practice.
- Nasya, being one of the safe Panchakarma procedures, is widely used by practitioners and researchers for conducting studies. In the case of Ardita, there is no standard format for determining outcome measures to rule out possible biases and to offer credible repeatable research data. It is suggested that all symptoms of Ardita be included for outcome measures and the results be statistically analysed.
- It is also suggested that if Poorvakarma is administered prior to Nasya, the same outcome measures need to be taken before and after Poorvakarma. This would eliminate the possibility of incorrect interferences and establish that the effect of Poorvakarma is independent of Nasya administration. Alternatively, participant groups may be treated with and without Poorvakarma.
- Research needs to be conducted to examine the effectiveness of Ayurvedic medicines, especially Nasya oils compared to conventional medicines in treating Ardita.
- It is recommended that more research be conducted to examine the effectiveness of Nasya

compared to other traditional medicine modalities as a priority to guide practitioners in regards to evidence-based treatments.

- It is also recommended to investigate and account for what proportion of Ardita cases get resolved spontaneously, with the time duration measured.
- Researchers in Ayurvedic medicine should to be encouraged to publish their studies in all popular databases and journals so as to provide easily accessible research data for systematic reviews and hence enhance evidence-based practice.

Ayurveda is regarded as a personalised medicine[49] that views and treats individuals from a holistic mental and physical health perspective. This is in contrast to conventional medicine, where the practitioner focuses on specific treatment of the disease symptom or pathology. This difference in approach suggests that conventional study designs (e.g. RCTs) may be inadequate in addressing the holistic approach to the management of a person's health that is inherent in Ayurveda. Therefore, the outcome measures of these studies would not be complete to describe relevant Ayurvedic aspects.[42-45] To compensate for the deficiencies of the conventional RCTs when applied to Ayurveda, research design that accommodates for symptom classification according to the participant's basic body constitution (Prakriti) is needed. In practice, a modified RCT that could include classification of participants according to their Prakriti dosha state and measurements of co-morbidity would be more appropriate.

4.6 Conclusion

The systematic review that forms the basis of this thesis offers extremely limited evidence collected from only two small experimental studies that administration of Nasya oil alone may provide some relief from Ardita symptoms of facial distortion, speech disorder, inability to shut eyelids and dribbling of saliva in adult patients. Of the two studies included for the systematic review, one was comparatively weak methodologically and did not offer any robust results. Due to the limited number of studies included in the review, the limited number of their participants and their poor quality, no strong conclusions should be drawn to guide patients and practitioners from the evidence included in the systematic review.

Conflict of interest

The author of this thesis and systematic review is an Ayurvedic medicine practitioner.

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Appendices

Appendix I: Databases searched and search strategy

PUBMED

Ardita[tw] OR ardittam[tw] OR arditta[tw] OR ardid[tw] OR facial paralysis[mh] OR facial paralys*[tw] OR facial pals*[tw] OR bell's palsy[tw] OR bell palsy[tw] OR bell palsy[mh] OR facial neuropathy[tw]

AND

Medicine, ayurvedic[mh] OR siddha[tw] OR ayurved*[all] OR ayur veda[tw] OR nasya[tw] OR nasyam[tw] OR hindu medicine[tw] OR nasya[tw] OR nasyam[tw] OR panchakarma[tw]

Limits : Humans and English

CINAHL

TX ardittam OR TX Ardita OR TX ardid OR TI facial paralysis MW Ardita OR TI palsy OR TI "Bells palsy" OR AB bell palsy OR Facial paralysis AND TI ayurveda OR TI nasya OR TI nasyam OR TI taila OR TI anu taila OR MW Ardita vata* OR TI shadbindu OR TI shadbindu taila OR Ayurvedic oil

Limits : Adults, English

SCOPUS

Ardita OR nasya OR ayurveda

Limits: English, Human

EMBASE

'ayurveda' OR ayurvedic AND 'facial paralysis' OR Ardita AND 'facial paralysis' OR 'taila nasya' OR 'Ardita' AND 'nasya' OR 'ayurvedic medicine'

Limits: Male, Female, English

COCHRANE

'Facial Paralysis bell's palsy Ardita Facial paresis AND ayurveda anu taila nassya taila nasya nasal instillation OR nasya

WEB OF SCIENCE

Ardita OR nasya

Limits: English

DHARA

Taila nasya

GOOGLE SCHOLAR

Ardita, taila nasya

HAND SEARCH

Free access websites www.rguhs.ac.in/ and http://nia.nic.in/ were searched using key words ‘Ardita, Nasya, Taila nasya’.

On demand website organiser Dr Girish KJ was contacted through email to identify and access MD/PhD thesis -Dissertations from http://www.ayurvedahealthcare.info/content/researches-ayurveda-ria.

The University of Adelaide librarian was contacted for obtaining three relevant studies, of which one was made available.

Appendix II: Critical appraisal tool

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

Reviewer _____ Date _____

Author _____ Year _____ Record Number _____

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix III: Data extraction tool

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:

_____

_____

_____

Study results

Dichotomous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Continuous data

Outcome	Intervention ( ) number / total number	Intervention ( ) number / total number

Appendix IV: List of studies identified and excluded with reasons

No:	Citation	Publication type	Reason for exclusion
1	Vivekananda K. – The Clinical management of Ardita Vata with Bhunag-taila nasya along with Ekangaveera Rasa (internally). Dr B.R.K.R Government Ayurvedic College, Hyderabad-500 038, INDIA. [A.P University, Vijayawada,] 1997.	Thesis	Full text unavailable
2	Laxman P. H. –The clinical study of the effect of Vata Gajankush Rasa (internally) and Anu taila nasya in Ardita Vata. DR B.R.K.R Government Ayurvedic College, Hyderabad-500 038, INDIA. [A.P University, Vijayawada], 1998.	Thesis	Full text unavailable
3	Venkatesh R – Role of Nasya Karma in Ardita w.s.r to Ksheer Bala Taila. S D G M Ayurvedic Medical College, Gadag- 582118, INDIA. [Rajiv Gandhi University Of Health Sciences, Bangalore], 1999.	Thesis	Full text unavailable
4	Asha S. I. – A clinical study to evaluate the effect of Nasya in the management of Ardita w.s.r to Bell`s palsy. Govt. Ayurvedic Medical College Mysore, Karnataka -570001, INDIA.[Rajiv Gandhi University of Health Sciences, Bangalore], 2003.	Thesis	Full text unavailable
5	Prashant C.S. – Clinical study on the effect of Mahamashadi taila nasya Karma in Ardita (Upper motor neuron lesion palsy). S.D.M college of ayurveda Udupi- 574240, INDIA. [Rajiv Gandhi University Of Health Sciences, Bangalore], 2003.	Thesis	Full text unavailable
6	Nitin B Tatpuje – A Clinical Study on Ardita Roga with special reference to Navana Nasya and Shiro Pichu. HASS's Ayurveda Mahavidyalaya Hubli, Karnataka - 580024, INDIA. [Rajiv Gandhi University of Health Sciences, Bangalore], 2003.	Thesis	Full text unavailable
7	Venkat Ravikrishna- Effect of Mashabaladi Nasya with and without Balaksheera Dhoom in Ardita, S.N.K. Jabashetty Ayurvedic medical college, Bidar-585403, INDIA. 2005.	Thesis	Full text unavailable
8	Tatapuje Nitin B- A clinical study of Ardita roga w.s.r. to Navan nasya and shiropichu, A.V. Samitis Ayurvedic mahavidyalaya, Bijapur – 586101, Karnataka, INDIA. [Rajiv Gandhi University of Health Sciences, Bangalore] 2002.	Thesis	Full text unavailable
9	Vidyanath, R. Title: Effect of lasuna kalka and shadbindu taila nasya in Ardita vata [Bell's palsy]. Renaissance. Nagarjuna Herbal Concentrates Ltd, Alakkode, Kalayanthani P.O., Thodupuzha, Idukki Dist., Kerala, India, 2009.	Journal article	Lack of data on outcome measures
10	Pooja K, Tribhuvan P, Vikas S and Pareek R.K. 2014, Role of Kukkutanda Swedna and Nasya in the Management of Ardita- A Pilot Study, Int J Ayurveda & Altern Med. 4:5 . pp.1602-1607.	Journal article	Insufficient data on outcome measures

Appendix V: Characteristics of included studies

Study	Method	Participants	Settings	Intervention	Comparator	Outcomes	Measures	Comment: study quality
Gupta. A, 2011[41]	Pseudo-randomized Trial	30 participants of age group 20 to 70 years.	OPD and IPD of Post Graduate Department, Kaya Chikitsa, Ayurveda Mahavidyalaya, Hubli	Nasya with Mahamasha Taila (6-8 drops) for 7 days. Oral administration of 125mg Brihat Vata Cintamani Rasa tablet with Dhanadanayadi Kwatha as adjutant for one month.	Shirobasti with Ksheerabala Taila for 7 days; oral administration of 125mg Brihat Vata Cintamani Rasa tablet with Dhanadanayadi Kwatha as adjutant for one month.	Mukhaparshwa greevavedana (facial pain) *Vaksanga (speech disorder) Karna Vedana(earache) *Mukha vakrata(facial distortion) *Akshinimesha Asamarthya (inability to close eyes) Lalata Vali Nasha (absence of facial wrinkles) *Lalasrava (dribbling of saliva)	Observational measurement. Symptoms graded as Mild, Moderate or Marked Measurement at baseline and after one month.	Low.
Thanki H.K, Joshi P.N, Shah N.B, 2009[38]	Pseudo-randomized Trial	20 participants suffering from Ardita.	OPD and IPD of Govt. Akhandanad Ayurveda College Hospital and Govt. Maniben Ayurveda College, Ahmadabad.	15 day Nasya with Anu Taila.	15 day Nasya with Mashadi Taila.	*Vaksanga (speech disorder) *Mukha Vakrata(facial distortion) *Akshinimesha Asamarthya (inability to close eyes) *Lalasrava (dribbling of saliva)	Observational measurement. Symptoms graded as Mild Moderate or Marked. Follow-up at 30 days	Very low. Lack of data on symptom measures before treatment and insufficient presentation of results from statistical analysis.