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

A thesis submitted by

Manuel Joseph Vivera

in partial fulfilment of the requirements for the Degree of

Master of Clinical Science (MClinSc)

Joanna Briggs Institute

Faculty of Health Sciences
University of Adelaide

January 2016

Table of Contents

Declaration	iv
Acknowledgements	v
Abstract	vi
List of tables and figures	ix
Definition of Ayurvedic terms	xi
Acronyms	xiii
Chapter 1: Background	1
1.1 Introduction	1
1.2 Ardita: definition, cause and prevalence	1
1.3 Treatment for Ardita: Ayurvedic and conventional	3
1.3.1 Conventional treatment	3
1.3.2 Ayurvedic treatment	3
1.4 Introduction to systematic reviews	4
1.4.1 Emergence of systematic reviews as part of the evidence-based	healthcare movement 4
1.4.2 Features of and steps in a systematic review	4
1.5 Ayurvedic medicine and systematic reviews	8
1.6 Review objectives	8
Chapter 2: Systematic review methods	10
2.1 Introduction	10
2.2 Inclusion criteria	10
2.2.1 Types of participants	10
2.2.2 Types of intervention(s) and comparator(s)	10
2.2.3 Types of studies	11
2.2.4 Types of outcomes	11
2.3 Search strategy	13

2.4 Assessment of quality of included studies	15
2.5 Data collection	15
2.6 Data analysis and synthesis method	15
Chapter 3: Results of the Systematic Review	16
3.1 Description of studies	16
3.1.1 Search and study selection	16
3.1.2 Key characteristics of included studies	17
3.1.3 Methodological quality of included studies	21
3.2.1 Ardita symptom 1: Facial distortion (Mukha Vakrata/Vaktradhavakrata)	24
3.2.2 Ardita symptom 2: Speech disorder (Vaksanga)	25
3.2.3 Ardita symptom 3: Dribbling of saliva (Lalasrava)	26
3.2.4 Ardita symptom 4: Inability to shut eyelids (Akshinimesha Asamarthya/ Netravikurti)) 27
3.2.5 Ardita symptom 5: Facial pain (Mukhaparshwa Greevavedana)	29
3.2.6 Ardita symptom 6: Earache (Karna Vedana)	30
3.2.7 Ardita symptom 7: Absence of facial wrinkles (Lalata Vali Nasha)	31
Chapter 4: Discussion	33
4.1 Summary of findings	33
4.2 Knowledge gaps and limitations	34
4.3 Reflection on the difficulties confronting reviewers synthesising evidence on effectivene Ayurvedic treatments	
4.4 Implications for practice	36
4.5 Implications for research	36
4.6 Conclusion	37
Conflict of interest	37
References	38
Appendices	41
Appendix I: Databases searched and search strategy	41
Appendix II: Critical appraisal tool	43

44
46
47

Declaration

I certify that this work contains no material which has been accepted for the award of any degree or diploma in my name, in any university or other territory institution, and, to the best of my knowledge and belief, contains no material previously published or written by any person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any degree or diploma in any university or other territory institution without the prior approval of the University of Adelaide, and, where applicable, any partner institution responsible for the joint-award of this degree.

I give consent to this copy of my thesis, when deposited in the University library, to be made available for loan and photocopying, subject to the provisions of the Copyright Act 1968.

I also give permission for digital version of my thesis to be made available on the web, via the University's digital research repository, the Library Search and also through web search engines, unless permission has been granted by the university to restrict access for a period of time.

Manu	el Joseph	Vivera:	 	 	
	•				
Date:					

Acknowledgements

I extend my gratitude to my primary supervisor, Dr Judith Gomersall, for her support and assistance in the development of this systematic review. I also thank Dr Alla Grynevych and Dr Karolina Lisy who officiated as secondary supervisors and the Joanna Briggs Institute staff for their support and expertise at various stages of the development of this review. Further to this, I wish to thank Dr Morné Stephan Scheepers for serving as the second assessor of this review.

A special thank you is reserved for my wife, Merly, who supported me unconditionally and assisted in all possible ways throughout my research work.

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

Table 1:	Characteristics of participants in the included studies	18		
Table 2:	Symptoms presented by participants in the study by Gupta A			
Table 3:	Outcomes and outcome measures	21		
Table 4:	Assessment of quality of included studies for randomised controlled randomised controlled trials	ed trials/pseudo- 22		
Table 5:	Change in symptoms for the interventions and comparators (% reclassification/description)	lief reported and		
Table 6:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating facial distortion in the study by the Gupta			
Table 7:	Relative efficacy of Mahamasha Taila Nasya intervention and Ksh intervention for alleviating facial distortion	eerabala Shirobasti		
Table 8:	Effectiveness of Mahamasha Taila Nasya intervention and Ksheerabala Shirobasti intervention in alleviating speech disorder (Vaksanga) in the Gupta study25			
Table 9:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti25		
Table 10:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating dribbling of saliva (Lalasrava) in the Gup			
Table 11:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti27		
Table 12:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating inability to shut eyelids (Akshinimesha A Gupta study			
Table 13:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti28		
Table 14:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating facial pain (Mukha Parshwa Greevaveda study			
Table 15:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti29		
Table 16:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating earache (Karna Vedana) in the Gupta st			
Table 17:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti 30		
Table 18:	Effectiveness of Mahamasha Taila Nasya intervention and Kshee intervention in alleviating absence of facial wrinkles (Lalata Vali N study			
Table19:	Relative efficacy of Mahamasha Taila Nasya and Ksheerabala Sh	irobasti32		

Figure 1: Flowchart of search and study selection17

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.