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<td>Dr. Subhadra Antherjanam</td>
<td>Dr.Gopinathan G</td>
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PROFORMA FOR REGISTRATION
OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI [M.S] IN SHALAKYATANTRA

“OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE EFFICACY OF
CHANDRAPRABHA VARTHI ANJANA IN KAPHAJA KACHA( SENILE
IMMATURE CATARACT)”

By
DIVYA V BHANU
1ST YEAR P.G SCHOLAR
DEPARTMENT OF P.G. STUDIES IN SHALAKYA TANTRA
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KOLLAM.

( SESSION-2013-14 )
From
Divya.V.Bhanu
Preliminary M.S. (Ayu) Scholar,
Department of Shalakya Tantra,
Amrita school of Ayurveda,
Vallikkavu P.O
Kollam.

To
The Registrar,
Amrita Vishvavidya Peetham Deemed University,
Coimbatore, Tamilnadu.

Through,
The Principal and Head of the Department of Shalakya Tantra,
Amrita school of Ayurveda,
Vallickavu P.O, Kollam.

Respected Sir,

Sub: Submission of completed Proforma for Registration of Subject for dissertation

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita Vishwavidya Peetham Deemed University, Coimbatore for partial fulfilment of M.S. (Ayurveda) Shalakya Tantra.

Title of the Dissertation:

“OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE EFFICACY OF CHANDRAPRABHA VARTHI ANJANA IN KAPHAJA KACHA(SENILE IMMATURE CATARACT)”

Herewith I am enclosing a completed proforma of synopsis for registration of subject for dissertation.

Thanking you,

Place: Vallickavu
Date: 28.05.2014

Your’s faithfully,
Divya.V.Bhanu
Completed Proforma for Registration of Subject for Dissertation for Ayurveda vachaspati
(M.S) in Salakya Tantra

1. NAME OF THE CANDIDATE : DIVYA.V.BHANU
   AND ADDRESS (IN BLOCK LETTERS) : PRELIMINARY M.S. (AYU) SCHOLAR.
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3. NAME OF THE INSTITUTION: AMRITA SCHOOL OF AYURVEDA,
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4. COURSE OF THE STUDY AND: M.S. (AYURVEDA) – SHALAKYA
   SUBJECT

5. DATE OF ADMISSION TO THE COURSE : 18TH NOV 2013

6. TITLE OF THE TOPIC :
   “OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE EFFICACY OF
   CHANDRAPRABHA VARTHI ANJANA IN KAPHAJA KACHA (SENILE
   IMMATURE CATARACT)”
1. BRIEF RESUME OF THE INTENDED WORK

I. Need of the study

Kacha is a Drushtigata Neteroga told by Ayurveda Acharyas in clinical text like Ashtangahrudaya and Sushruta Samhita. Acharya Vagbhata has mentioned that in kaphaja kacha person perceives object as covered by diminished sun, moon and lamp and the drishtimandala of eye appears as swetha in colour. In the initial stages of the disease, kapha vitiated. It’s snigdha, sheeta and dravagunas are increased and are confined to rasadhatu. Later sthira and gurugunas are increased. As a result, the transparent structure turns to dense white opacity. Acharya sushruta mentioned kacha as a synonym of linganasa. Acharya vangasena has also explained the same. Considering the signs and symptoms and histological changes in the lens, different stages of senile cataract may be compared to kaphaja kacha and linganasa. Various medical measures have been advised in different classical text books of ayurveda to manage kaphaja kacha. Surgery is mentioned in the final stage of kaphaja linganasa where there is total loss of vision.

Senile cataract is one of the major causes for the age related visual impairment and blindness. It affects 12 to 15 million persons worldwide. It is a disease of common occurrence in all geographical area and in all races. The incidence is distinctly more in developing tropical countries. In India, approximately 38 million persons become blind from cataract each year. Conventional medical system is yet to offer a convincing therapeutic management for this disorder with surgery being the only alternative offered.

Owing to the increased rate of incidence of senile cataract, non availability of effective medical measures and the possible complications and contra indications of surgery, Ayurveda can offer an avenue of research for the need of drugs which can effectively manage this condition.

In describing the treatment of Timira, Vagbhata Acharya says that kaphaja timira is a sadhya vyadhi, kaphaja kacha as yapya and kaphaja linganasa as sastra sadhya. Here the treatment for kaphaja kacha can be the same as kaphaja timira except siravedha.

Chandraprabhavarthi Anjana is an ophthalmic preparation mentioned in Bhaishajya ratnavaly. It is the combination of Anjana, Swethamaricha, Pippali, Yashti madhu, Vibheethaka Madhya, Sankha nabhi & Manashila which are to be triturated in Aja ksheera and prepare Vati.
Then it is dried in chaya. At the time of usage the vati can be diluted with water and that can be used as Anjana.

The current study is undertaken to evaluate the efficacy of Chandraprabhavarthi Anjana in the treatment of Kaphaja kacha (Senile Immature Cataract).

II. Review of Literature

A) Description of kacha nidana, lakshana and chikitsa in ayurvedic classics.

B) Description of senile immature cataracts in modern medicine

C) Description of Anjana kriya karma in ayurvedic classics

D) Description of Chandraprabhavarthi Anjana in ayurvedic classics

A) Description of kacha nidana, lakshana and chikitsa in ayurvedic classics.

Timira is a drushtigataroga. Samanyanidana of netraroga can be taken as the nidana of thimira. Vagbhata Acharya says that doshas get vitiated by the specific causes mentioned for the individual vitiation of doshas. Those causes which are especially achakshushya in nature and pithaprakopakara, propagate through the siras upwards and localizes in netra avayava which includes anyone or all of sandhi, vartma, sita, Krishna, drushti and sarvakshi.

Acharya vagbhata mentioned that, if Kaphaja Thimira not treated in correct time, it will lead to kaphaja Kacha. In kaphaja kacha, persons sees objects as covered by diminished sun, moon and lamp and the Drushti Mandala of eye appears as white in colour.

B) Description of senile immature cataracts in modern medicine

Senile Cataract is also called as age related Cataract. It is rare in persons under 50 years of age unless associated with some metabolic disturbances. By the age of 70 years, over 90% of individuals develop senile cataract. It occurs equally in men and women and is frequently bilateral, although one eye may be affected earlier than the other. Senile cataract may be broadly divided into 2 groups depending on the part of the lens affected by the opacity Nuclear cataract, consisting 20 – 25% and cortical cataract comprising 75
– 80% of all senile cataracts. In senile cortical cataracts, pre-senile changes are the rule. Clinically the progress of a senile cortical cataract may be classified into 3 stages – Immature stage, mature stage and Hyper mature stage.

Immature stage can be further divided into 3 stages – stage of Lamellar separation, Incipient stage and Intumescent stage. Subjective symptoms of Incipient stages are polyopia, rain bow haloes and impairment of vision. The symptoms of Intumescent are same as in previous stage, but in addition, the patient develops myopia due to alteration of lental curvature.

C) Description of Anjana kriya karma in ayurvedic classics

Anjana is one among seven netra kriya kalpas. Anjana is a procedure of applying medicinal paste or powder to the inner side of lower eye lid. It should be applied from the kaneenaka sandhi to the apanga sandhi and viceversa. It can be done either with finger tip or with anjana salaka either in the morning or in the evening followed by netra kshalana. Based up on the number of medicines used, Anjana is classified into three-lekhana,ropana and drushti prasadana. For lekananjana kshara amla teekshana drugs, for ropananjana tikta kashaya drugs and for prasadana madhura seetha drugs are used.Based on the form of usage anjana is classified into three-gudika, rasakriya and choorna. Here lekhananjana is used in this study.so the matra is one harenu.

D) Description of Chandra;phabhavarthi Anjana in ayurvedic classics

This anjana is mentioned in the text BhaishajyaRatnavali. The ingredients of this anjana are anjanam, swethamaricham,pippaly, yashtimadhu,vibheethaka- madhyam,sankhanaabhy and manasila which are to be triturated in aja ksheera and prepare vati.Then it is dried in chaya.At the time of usage ,varthi can be diluted in water and can use as anjana.

Previous research done on Senile Immature Cataract

1) Gupta AM. Role of Svarna Gairikanjanam in Timira w.s.r to Immature Cataract. Jamnagar: Gujarat Ayurveda University; 1997.

2) Rao Prasad. Clinical evaluation of Nayanamrita Anjana in Timira (Immature Cataract) with or without ghrita. Vijayawada: AP University; 1994

3) Jayashri K Rayakar ,Govt. Ayurveda Medical College Bangalore . A Comparative study on choornanjana and ksheeridrumadi Ghruta Tarpan in the management of kacha.
III. AIM AND OBJECTIVE OF THE STUDY

1) To evaluate the effect of Chandraprabhavarthi Anjana in Kaphaja Kacha.

2) MATERIALS AND METHODS

I. SOURCES OF DATA:

a) Literary Source: The details of Kaphaja Kacha and Senile Immature Cataract will be incorporated in great detail from Samhitas and other Ayurvedic and Modern reference books.

b) Clinical Source: 30 patients with the classical signs and symptoms of kaphaja kacha will be selected from OPD and IPD of Shalakya Tantra Department of Amrita School of Ayurveda, Vallickavu, Kollam for the clinical study

c) Drug Source: Chandraprabhavarthi Anjana will be prepared by mixing Anjana, swethamaricha, pippaly, yashtimadhu, vibheethakamadhyam, sankha naabhi and manashila and do bhavana in aja ksheera, prepare varti and it is dried in chaya. At the time of usage, the varti can be triturred in water and that can be used for anjana.

II. MATERIALS REQUIRED FOR THE STUDY

I. METHOD OF COLLECTION OF DATA.

1. Sample:

Open label single arm study of 30 patients who are fulfilling the criteria will be selected for the present clinical study.

2. Inclusion Criteria:

- Patients of age group of 50 to 70 years
- Patients of either gender
- Visual acuity of 6/9 or less

3. Exclusion Criteria:\(^5\)

- Senile Mature and Hyper Mature Cataract
ii. PROCEDURE AND DESIGN OF THE STUDY

1. **Materials and Methods**

   a) Patients with senile immature cataract

   b) Chandraprabhavarthi Anjana

2. **Design of the study**

   According to ayurveda classics, Anjana should be done only after kaya sodhana followed by sirovirechana. After getting proper kaya and sira sodhana, Anjana should be administered twice daily for the period of one month.

   Follow-up - After completion of the treatment the patients will be advised to report Salakyam OPD for a period of one month with an interval of 15 days to assess the sustained effect of treatment.

3. **Grouping and Treatment / Procedure**

   Grouping: In a group 30 patients who are fulfilling the criteria will be selected for the present clinical study.

   Treatment procedure: 30 patients of Kaphaja Kacha will be treated with Chandraprabhavarthi Anjana twice daily with the dosage of 1 harenu matra (approximately 50 mg) for 30 consecutive days.

4. **Assessment criteria**

   Effect of the Anjana will be assessed by the signs and symptoms before and after the procedure. It will be on the basis of self formulated scoring scale according to signs and symptoms. Before and after treatment, the visual acuity, refraction, direct
ophthalmoscopy and Slit lamp examination will be done. Periodic follow up of the patient at an interval of 15 days for one month will be done.

a) Subjective Parameter

1) Glare
2) Diplopia- Uniocular
3) Blurred vision
4) Floaters
5) Dark and bright adaptation

b) Objective Parameter

1) Visual Acuity by Snellen’s Chart
   - Distant Vision
   - Near Vision
   - Pinhole Test
2) Slit Lamp Examination
3) Direct Ophthalmoscopic Examination

5. STATISTICAL METHODS

The data obtained will be tabulated and statistically analysed using paired T-Test.

3. Does the study require any investigations or interventions to be conducted on patients, Healthy volunteers, cadaver or animals? If so please describe briefly:

Yes, Study will be conducted on patients with senile immature cataract only. No animal experiments will be conducted.

4. Has ethical clearance been obtained from your institution in case of (3)? (Human /Animal)

Yet to be obtained
5. LIST OF REFERENCES


Name of the researcher : Divya.V.Bhanu

Signatures

Name and designation of the guide : Dr. Venkateswara Reddy
Professor
Department of Shalakya tantra
Amrita School of Ayurveda

Remarks of the guide :

Signatures with official seal :

Name and designation of the co-guide : Vd. Gopinathan.G
Assistant Professor
Department of shalakya tantra
Amrita school of Ayurveda

Signatures with official seal :

Name and designation of Head of Department : Dr.K.V.Subhadra Antherjanam
Professor and HOD
Department of Shalakya tantra
Amrita school of Ayurveda

Signatures with official seal :

Name and designation of Head of Institution : Dr. M. R. Vasudevan Namboothiry
Principal,
Amrita school of Ayurveda

Signatures with official seal :

TOP
PROFORMA FOR REGISTRATION
OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI [M.S] IN SHALAKYATANTRA

“AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE
EFFICACY OF CHANDANASAINDHAVĀDI AṆJANA IN ARMA(PTERYGIUM)”

By
SREEVIDYA .T.R
1ST YEAR P.G SCHOLAR
DEPARTMENT OF PG STUDIES IN SHALAKYATANTRA
AMRITHA SCHOOL OF AYURVEDA, VALLICKAVU, CLAPPANA P.O
KOLLAM

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AMRITA SCHOOL OF AYURVEDA, VALLICKAVU, CLAPPANA P.O
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ASSISTANT PROFESSOR
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(SESSION-2013-14)
From,

SREEVIDYA.T.R
Preliminary M.S.(Ayu) Scholar,
From Department of Shalakya Tantra
Amrita school of Ayurveda,
Vallikkavu P.O
Kollam.

To,

The Registrar,
Amrita Vishwavidya Peetham University,
Coimbatore, Tamilnadu.

Through,

The Principal and Head of the Department of Shalakya Tantra,
Amrita school of Ayurveda,
Vallickavu P.O, Kollam.

Respected Sir,

Sub: Submission of completed Proforma for Registration of Subject for dissertation

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita Vishwavidya Peetham Deemed University, Coimbatore for partial fulfillment of M.S. (Ayurveda) Shalakya Tantra.

Title of the Dissertation

“AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF CHANDANASAINDHAVĀDI AṆJANA IN ARMA(PTERYGIUM)

Herewith I am enclosing a completed Performa of synopsis for registration of subject for dissertation.

Thanking you,

Place: Vallickavu
Date: .28.05.2014

Your’s faithfully,

SREEVIDYA.T.R
Completed Performa for Registration of Subject for Dissertation for Ayurveda vachaspati (M.S) in Salakya Tantra

1. NAME OF THE CANDIDATE : SREEVIDYA .T.R
   AND ADDRESS (IN BLOCK LETTERS) : PRELIMINARY M.S. (AYU) SCHOLAR. DEPT. OF SHALAKYA TANTRA,
   AMRITA SCHOOL OF AYURVEDA,
   VALICKAVU P.O KOLLAM.

2. PERMENANT ADDRESS : SREERANGAM (H)
   NJEEZHOOR .P.O KOTTAYAM
   PIN-686612

3. NAME OF THE INSTITUTION : AMRITA SCHOOL OF AYURVEDA,
   VALICKAVU P.O KOLLAM

4. COURSE OF THE STUDY AND SUBJECT : M.S. (AYURVEDA) – SHALAKYA

5. DATE OF ADMISSION TO THE COURSE : 18TH NOV 2013

6. TITLE OF THE TOPIC :

   “AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF CHANDANASAINDHAVĀDI AṆJANA IN ARMA(PTERYGIUM)”
1. BRIEF RESUME OF THE INTENDED WORK

I. NEED FOR THE STUDY:

In Ayurveda shalakya tantra is the branch dealing with sense organs. Among all the indriyas, nayana is considered as pradhana. Arma is one among shuklagata roga that is explained by both acharya susrutha and vagbhata. Arma is a membrane like growth developing either from kaneenika or apanga sandhi, may or may not progress into Krishna bhaga.

Arma can be compared with Pterygium which is a degenerative condition of subconjunctival tissues which proliferates as vascularised granulation tissues to invade cornea destroying the superficial layers of stroma and bowmans membrane, within interpalpebral fissure. The epidemiological studies around the world have shown that the prevalence rates ranges from 0.3% to 37.46%.

Arma seldom gives any symptoms, but it can become inflamed and cause ocular surface irritation. Pterygium may become cosmetically unpleasant for the patient and further growth may cause visual symptoms due to induced astigmatism or direct encroachment onto visual axis. Rarely in pterygium neoplastic changes occur. A leading theory proposes that the prevalence of pterygium among people in equato regions is due to the damaging effect of ultra violet radiation specifically UV-B radiation. Pterygium is common in hot climate, dusty and dry environment. Due to global warming pterygium is becoming a burning problem as it is mainly causing ozone layer depletion. It is a major public health concern in rural areas.

As per acharyas in netraroganidana Rajonishevana, dhoomanishevana etc can be the cause of arma. Eventhough disease is gradually progressing ignorance of the patient about the treatment can lead it into complicated stage. For this prevention of progression acharyas had explained different lekhana anjana. Among 3 types of anjana, lekhana anjana is explained by acharya susrutha, sarngadhara. Acharya susrutha only recommending surgery, when arma becomes charmatulya, bahala, snayu mamsa ghanavrutha and reaching Krishna mandala.

Chandana saindhavadi anjana is one among lekhana anjana which is explained in bhaishajya ratnavali. This contains chandana, saindhava, pathya and palasha tarushonitha which having vilekhana property. Properties of this drug can arrest further progression and also helps in the removal of dooshitha kaphadi doshas which causes mamsa dushti.
present study is undertaken to assess the effect of **chandana saindhavadi anjana** in the management of arma.

**II. REVIEW OF LITERATURE:**

**ARMA**

- Arma is one among 11 netra vikara studied under shulagatha roga by acharya sushrutha\(^2\) and 13 explained by vagbhata\(^1\).
- Arma is mainly classified into 5 types: Prasthari, Shuklarma, Khatajarma, Adhimamsa arma, Snayu arma\(^2\).
- Arma\(^7\) is a membraneous growth that forms in shuklamandala.
- Different treatments are explained for the management of arma mainly lekhana, chedhana, anjana, ghrithapana and lepa\(^1\).
- Arma is also explained in bhavaprakasha\(^7\) madhyama khanda, netra roga chikistadhikara of yogaratnakara\(^6\), and in 3 chapter of gada nigraha.
- Madhava kara explained about arma in madhyamakhanda, also netra roga and chikitsa explained in sahasra yoga and chikitsamanjari.

**PTERYGIUM:**

- Pterygium is characterized by elastotic degeneration of collagen and fibrovascular degeneration.\(^5\)
- It has an advancing portion called head, which is connected to body by neck.
- Sometimes iron deposits can be seen adjacent to head of pterygium which is called as STOCKER’S LINE.
- Location of the line indicates the pattern of the growth.

**ANJANA:**

- Anjana is one of kriyakalpas\(^2\) used widely in the treatments of netravikaras.
- Anjana is mainly of 3 types: lekhana, ropana, snehana.\(^2\)
- Again its preserved as gudika, rasakriya & choorna,
- Netra, vartma, sirakosha, srota, and srungataka marmaasrita doshas are taken out by anjana.\(^2\)

**CHANDANA SAINDHAVADI ANJANA\(^3\):**

- It is a lekhana anjana that explained in bhaishajya ratnavali.\(^3\)
- It is mainly indicated in arma and sukla rogas.
• Drugs present in this anjana are 1 part chandana, 2 part saindhava, 3 part pathya and 4 parts palasha taru shonitha.

**PREVIOUS RESEARCH DONE ON ARMA**

• Study on arma and its management with shanmakshika varti by sushama .v in 1979 from government ayurveda college trivandrum.

• Chandrodaya varti dwara arma chikitsa by Pandey p.s. in 1978 from IMS faculty of ayurveda BHU Varanasi

• Role of chandrodaya varti in prevention of recurrence after arma chedana by Nath Meenakshi in 2003 from H.G institute of PGE &RA Paprola (H.p)

• Role of marichadi anjana and vimala varti in the management of arma .a clinical study by Rashmi.m.v in 2001 from government ayurveda medical college ,Bangalore.

• Role of anjana/aschothana in netra roga w.s.r to arma with nishamarchi anjana by Rao .G.k in 1996 from Dr.B.R.K.R government ayurveda college ,Hyderabad.

• Study of prasthari arma excision w.s.r to sushrutha by Raskar sameer in 2003.

• Effect of sithamanashiladi anjana after arma chedana by dr.kannadas,Trivandrum ayurveda college

• Guluchyadi anjana in the management of arma by dr mini ,tvm ayurveda college.

**III. AIMS AND OBJECTIVES**

• To study the concepts of arma and pterygium in detail.

• To study the efficacy of **chandana saindhavadi anjana** in the management of arma.

**2. MATERIALS AND METHODS**

**I. SOURCE OF DATA**

**LITERARY SOURCE:** The details of arma and pterygium are collected from samhitas and other ayurvedic and modern reference books.

**CLINICAL SOURCE:** Patient attending OPD &IPD of AMRITHA AYURVEDA MEDICAL COLLEGE, will be taken for the study.

**DRUG SOURCE:** Chandana saindhavadi is prepared from the choorna of chandana, saindhava, pathya, palasha taru shonitha in increasing quantity.
II. MATERIALS REQUIRED FOR THE STUDY

i. METHOD OF COLLECTION OF DATA

1. SAMPLE

30 patients fulfilling all the inclusion criteria will be selected for study.

2. INCLUSION CRITERIA:

- Age group-20-60 years
- Sex-Either sex
- Pterygium encroaching to cornea
- Clinical features as per classics

3. EXCLUSION CRITERIA

- Arma with any other ocular pathologies
- Pseudopterygium
- Those contra indicated for anjana therapy

ii. PROCEDURE AND DESIGN OF THE STUDY

1. MATERIALS AND METHODS

- Arma patients fulfilling all inclusion criteria
- Chandana saindhavadi anjana

2. DESIGN OF THE STUDY

30 patients of arma is taken for study. As per classics the anjana should be done only after doing kaya shudhi. So here also the shodhana is done and later nasya is done for uttamanga shudhi. Thereafter anjana is done in the specific dose. After the treatment patient is asked to attend the OPD at regular intervals of 15 days for a period of 2 month for the follow up.

3. GROUPING AND TREATMENT/PROCEDURE

GROUP: A single group of 30 patients is taken.
PROCEDURE: After doing proper snehana and shodhana of the individuals the anjana should be done.¹

Medicine: CHANDANA SAINDHAVADI ANJANAM

Dose-2 shalaka

Time period- 1 month

4. ASSESSMENT CRITERIA
Patient will be assessed with subjective and objective parameters formulated for arma before and after treatment.

A. SUBJECTIVE PARAMETER:
  - Redness
  - Foreign body sensation
  - Watering
  - Blurred Vision
  - Discomfort in the affected eye

B. OBJECTIVE PARAMETER:
  - Visual Acuity
  - Slit lamp Biomicroscope
  - Pictorial presentation

5. STATISTICAL METHODS:
The data obtained will be tabulated and statistically calculated using Paired T-test.

3. Does the study requires any investigations or interventions to be conducted on patients, healthy volunteers, cadavers or animals?
   Yes. the present study requires investigations and interventions on patients.

4. Has ethical clearance been obtained from your institution in case of (3)?
   (Human/animal):
   Yet to be obtained
5. LIST OF REFERENCES:


Name of the researcher : Sreevidya T.R

Signatures : 

Name and designation of the guide : Dr.K.V.Subhadra Antherjanam

Professor and HOD

Department of Shalakya tantra

Amrita School of Ayurveda

Remarks of the guide :

Signatures with official seal :

Name and designation of the co-guide : Dr.K.Sivabalaji

Assistant professor

Department of shalakya tantra

Amrita school of Ayurveda

Signatures with official seal :

Name and designation of Head of Department : Dr.K.V.Subhadra Antherjanam

Professor and HOD

Department of Shalakya tantra

Amrita school of Ayurveda

Signatures with official seal :

Name and designation of Head of Institution : Dr. M. R. Vasudevan Namboothiry

Principal,

Amrita school of Ayurveda

Signatures with official seal :

TOP
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI [M.D]/[MS] IN SHALAKYA

OPEN LABEL CLINICAL STUDY TO ASSESS THE COMPARATIVE
EFFECTIVENESS OF GHRITAMANDA ASCYOTANA AND TARPANA IN
COMPUTER VISION SYNDROME

BY
SUMITHA PRAKASH. C
1ST YEAR P.G SCHOLAR
DEPARTMENT OF P.G. STUDIES IN SHALAKYA TANTRA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O.
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GUIDE
Dr.K.V.SUBHADRA ANTERJANAM
PROFESSOR AND HOD
DEPARTMENT OF SHALAKYA TANTRA
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CO-GUIDE
DR.K.SIVA BALAJI

SESSION-2013-14
From
Sumitha Prakash.C
Preliminary M.S. (Ayu) Scholar,
Department of Shalakya Tantra,
Amrita school of Ayurveda,
Vallikkavu P.O Kollam.

To
The Registrar,
Amrita Vishwavidya Peetham Deemed University,
Coimbatore, Tamilnadu.

Through
The Principal and Head of the Department of Shalakya Tantra,
Amrita school of ayurveda,
Vallikkavu P.O Kollam.

Respected Sir,

Sub: Submission of completed Proforma for Registration of Subject for dissertation

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita Vishwavidya Peetham Deemed University, Coimbatore. for partial fulfillment of M.S. (Ayurveda) shalakya tantra.

Title of the Dissertation:
“OPEN LABEL CLINICAL STUDY TO ASSESS THE COMPARATIVE EFFECTIVENESS OF GHRITAMANDA ASCYOTANA AND TARPANA IN COMPUTER VISION SYNDROME”

Herewith I am enclosing a completed Proforma of synopsis for registration of subject for dissertation.

Thanking you,

Place: Vallikkavu
Date: 28.05.2014

Your’s faithfully,

Sumitha Prakash C
Completed Proforma for Registration of Subject for Dissertation for Ayurveda vachaspati (M.S) in shalakya tantra

1. NAME OF THE CANDIDATE : SUMITHA PRAKASH C AND ADDRESS PRELIMINARY M.S. (AYU) SCHOLAR. (IN BLOCK LETTERS) DEPT. OF SHALAKYA TANTRA, AMRITA SCHOOL OF AYURVEDA, VALLIKAVU P.O KOLLAM.

2. PERMANENT ADDRESS : D/O K.G PRAKASH SURYA PRABHA, PUTHIYAKAVU, TRIPUNITHURA P.O, ERNAKULAM, KERALA

3. NAME OF THE INSTITUTION : AMRITA SCHOOL OF AYURVEDA, VALLIKAVU P.O KOLLAM

4. COURSE OF THE STUDY AND : M.S. (AYURVEDA)- SHALAKYA SUBJECT

5. DATE OF ADMISSION TO THE COURSE : 18TH NOV 2013

6. TITLE OF THE TOPIC : “OPEN LABEL CLINICAL STUDY TO ASSESS THE COMPARATIVE EFFECTIVENESS OF GHRITAMANDA ASCYOTANA AND TARPANA IN COMPUTER VISION SYNDROME”
1. BRIEF RESUME OF THE INTENDED WORK

I. NEED FOR THE STUDY

Computer vision syndrome (CVS) is one among the lifestyle disorder in the present era. About 88% of people who use computers everyday suffer from this problem. CVS is a complex of ocular and visual problem due to near work which is experienced during the use of computer and television. Therefore, an Ayurvedic approach in understanding the management thereafter is hypothesized for CVS

One of the most simple and therapeutic modes of therapy are lubricating eye drops or ascytanawhich is intended to relieve the symptoms of dry and tired eyes due to decreased blink rates. One study indicates that higher viscosity eye drops may be more beneficial than balanced salt solutions. Higher viscosity drops normalize the interblink interval and relieved ocular discomfort more efficiently than balanced salt solutions following computer use. Common artificial tears lack the proteins which are found in natural tears. Long term use of preservatives present in some lubricating drops tears may harm the eye or the patients of CVS may get only symptomatic relief. Also the effect of ghrita manda is mentioned as netra soolaghna (Su Su 105/45) as well as the corneal epithelium is lipoidal ie epithelium is lipophilic drug-friendly so Goghrita is Snehonattam. It is Rasayana and Chakshushya. It has properties of Snigdha, Guru and Mrudu. Because of these properties Goghrita is very useful for vitiated pitta and vatta dosha in CVS (Tripathi, 1999, p. 264-265). So, to find a better approach to this problem, this study to evaluate the efficacy of ascytanawith ghrita manda in computer vision syndrome was designed.

II. REVIEW OF LITERATURE:

The review of literature includes screening of classical Ayurvedaliteratures, contemporary literatures, modern literatures, journals and internet sources to collect sufficient data for the study.

DEFINITION:

According to ‘American Optometric Association’, Complex of eye and visual problems related to the activities, which stress the near vision, experienced during or related to computer use are collectively called as ‘Computer Vision Syndrome’. Despite these contributions to the society, prolonged exposure to VDTs has been the cause of a visual and ergonomic disorder called “Computer Vision Syndrome” (CVS).

SYMPTOMS

1. Eye strain
2. Dry eyes
3. Eye irritation  
4. Blurred vision  
5. Headaches  
6. Watering of eyes  
7. Redness  
8. Double vision  

Though ‘Computer Vision Syndrome’ has no direct reference in Ayurveda classics, however an Ayurveda approach can be given on the basis of the fundamentals of Ayurveda, on the basis of clinical symptoms it can be deduced as Vata paithikadisease. As per (Ayurvedic Pharmacopia, Part-1Vol-IV) Ayurveda properties of Goghrita are as follows: 

Rasa: Madhura  
Guna: Guru, Snigdha, Mirdu  
Veerya: Seeta  
Vipaka: Madhura  

In Ashtanga Hridaya sutra sthana and Sushruta Sutras also the properties of ghee is mentioned mainly as snehottam and ratapittaghna.

PREVIOUS WORKS DONE:
1. Dr. Siddapur Chandrashekhar: “Study on CVS and its management with indigenous drugs” G.A.M.C, Bangalore, RGUHS, 2002
3. A clinical study on the efficacy of “Chandanadi Ghrita Tarpana” and Lodhradi arka aschyotana in Computer Vision Syndrome by Dr. JYOTI. S. P.G. Scholar, Department of Shalaka tantra, G.A.M.C Bangalore.
III. AIM AND OBJECTIVE OF THE STUDY

1. To evaluate the efficacy of ‘Go ghritamanda Tarpana’ and Ascyotana in Computer Vision Syndrome.
2. To compare, discuss and draw conclusions on the efficacies of the both the line of treatments

2. MATERIALS AND METHODS

I. Source of data

- **Patient’s source:** The patients with the signs and symptoms of CVS attending the OPD and IPD of Shalakya Tantra in Amrita school of Ayurveda. After being scrutinized patients will be registered under present study.
- **Literary source:** Samhita, modern books of surgery, medicine, physiology, & pharmacology. Journals, magazines, seminars, conferences, digital library & web sites.
- Vision testing lab attached to laboratory.

II. Materials required for the study

Trial drug: Go Ghrita Manda Sneihika tarpana and ascyotana.

i. Method of collection of data

1. **Sample:**
   - 30 patients who are fulfilling the criteria will be selected by simple random sampling for the present clinical study.
   - It will be divided into 2 groups irrespective of age, sex, marital status, educational status and nature of work.
   - 15 people in each group.

b. **Diagnostic Criteria:**
   - Clinical features of computer vision syndrome.
   - Schirmer’s Test
   - Tear film break up Test
   - Visual acuity

2. **Exclusion criteria:**
   - Any clinical condition containing ocular pathology including Patients with local and systemic infective disorders of eye, cataracts, glaucoma, degenerative disorders.
- Other systemic disorders like Diabetes Mellitus, Hypertension, cardiac and renal disorders were excluded.
- Individuals who are suffering from psychological disorders.

3. **Inclusion criteria:**
   - Patients in the age group 25-60 irrespective of sex.
   - Individuals who are using computers for more than 1 year.
   - Minimum 3hr/day exposure to any type of video display terminals (VDT) like desktop, laptop and similar devices.
   - Computer users complaining of eye strain, dry eyes, blurred vision, redness, burning eyes, excessive tears, double vision, and headache. Patients having minimum three symptoms of CVS.

ii. **PROCEDURE AND DESIGN OF THE STUDY**

1. **Materials and methods**
   - Computer vision patients.
   - Go ghrita manda

2. **Design of the study:**
Comparative clinical study:
The study is an open randomized comparative study in which 30 patients will be selected on the basis of simple random sampling (SRS) procedure & will be divided in 2 equal groups,

**G1-trial group1:** 15 patients of this group were treated with Tarpana using ghritamanda.
   - Vicharana snehapana for 5 days with Go ghrita manda-15 gms (each day)
   - Virechanam with sukumareranda taila
   - Pratimarsha nasyam with anutailam for 3 days.
Application of ghritamanda tarpana for five days once in 15 days follow up for the period of 1 month.
After treatment, the patients will be regularly observed. The progress is noted in the specially prepared case sheet.

**G2-Trial group 2:** 15 patients of this group were treated with Ascyotana using ghritamanda.
   - Vicharana snehapana for 5 days with Go ghrita manda-15 gms (each day)
- Virechanam with sukumareranda taila
- Pratimarsha nasyam with anutailam for 3 days in the morning.
- Ascyotana with ghrita manda 10 drops evening for 1 month.

1 month follow up and after treatment, the patients will be regularly observed. The progress is noted in the specially prepared case sheet.

3. **Grouping and treatment procedure**

**SAMPLE SIZE:** 30 patients will be selected and randomly categorized into two Groups as Group A (trial group 1) and Group B (trial group 2)

**Group A:**
- Sample size: 15 Patients
- Drug: Ghrita manda
- Procedure:
  - Snehana with Go ghrita manda + virechana and Pratimarsha nasya
  - Application of Ghritamanda tarpana for five days and 1 month follow up.

**Group B:**
- Sample size: 15 patients.
- Drug: Ghrita manda
- Procedure: Ascyotana-15 days-Ghrita manda
- Dosage: 10 drops morning and evening for 1 month
- Duration: 1 month follow up

**Duration of Follow up**: Follow-up will be done fortnightly to assess the changes and withdrawal effects.

3. **Assessment criteria**

Assessment will be done on subjective and objective parameters before and after the treatment. It will be on the basis of self formulated scoring scale.
Subjective parameters:
1. Eye strain
2. Dry eyes
3. Eye irritation
4. Blurred vision
5. Headaches
6. Watering of eyes
7. Redness
8. Double vision

Objective parameters:
- Schirmer’s Test\(^{12}\)
- Tear film break up test
- Visual acuity

Follow up study:
- After completion of the treatment the patients will be followed at regular intervals of every 15 days for a period of 1 month.

5. Statistical methods
The data obtained will be tabulated and statistically analyzed using paired Student T Test

3. Does the study require any investigations or interventions to be conducted on patients, Healthy volunteers, cadaver or animals? If so please describe briefly:

Yes, Study will be conducted on the Healthy volunteers of computer vision syndrome patients only. No animal experiments will be conducted.

4. Has ethical clearance been obtained from your institution in case of (3)?
(Human /Animal) –

Yes
5. LIST OF REFERENCES

Name of the researcher : Sumitha Prakash C

Name and designation of the guide : Dr. K.V. Subhadra Anthejanam
   Professor and HOD
   Department of Shalakya tantra
   Amrita School of Ayurveda

Name and designation of the co-guide : Dr. K. Sivabalaji
   Assistant professor
   Department of Shalakya tantra
   Amrita school of Ayurveda

Name and designation of Head of Department : Dr. K.V. Subhadra Anthejanam
   Professor and HOD
   Department of Shalakya tantra
   Amrita school of Ayurveda

Name and designation of Head of Institution : Dr. M. R. Vasudevan Namboothiry
   Principal,
   Amrita school of Ayurveda

TOP
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI [M.D]/[MS] IN SHALAKYA

“A CLINICAL STUDY TO EVALUATE THE CAUSATIVE ROLE OF PACHAKA
PITTA IN THE PRODUCTION OF OCULAR TEAR FILM (QUALITATIVE &
QUANTITATIVE) W.S.R. TO AGNI DUSHTI”

BY
SUSHMA N.S
1ST YEAR P.G SCHOLAR
DEPARTMENT OF P.G. STUDIES IN SHALAKYA TANTRA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O.
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Vd. GOPINATHAN G
ASSOCIATE PROFESSOR
DEPARTMENT OF SHALAKYA TANTRA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O.
KOLLAM

SESSION-2013-14
From
Sushma N.S
Preliminary M.S. (Ayu) Scholar,
Department of Shalakya Tantra,
Amrita school of ayurveda,
Vallikkavu P.O
Kollam.

To
The Registrar,
Amrita Vishvavidya Peetham Deemed University,
Coimbathore.

Through,
The Principal and Head of the Department of Shalakya Tantra,
Amrita school of ayurveda,
Vallikkavu P.O
Kollam.
Respected Sir,

Sub: Submission of completed Proforma for Registration of Subject for dissertation
I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita Vishwavidya Peetham Deemed University, Coimbathore. For partial fulfillment of M.S. (Ayurveda).

Title of the Dissertation:
“A CLINICAL STUDY TO EVALUATE THE CAUSATIVE ROLE OF PACHAKA PITTA IN THE PRODUCTION OF OCULAR TEAR FILM (QUALITATIVE & QUANTITATIVE) W.S.R. TO AGNI DUSHTI”

Herewith I am enclosing a completed proforma of synopsis for registration of subject for dissertation.

Thanking you,

Place: Vallikkavu
Date: 20-05-2014
Your’s faithfully,

Sushma
Amrita Vishwavidya Peetham Deemed University,
Coimbathore

Completed Proforma for Registration of Subject for Dissertation

1. NAME OF THE CANDIDATE : SUSHMA N.S
   AND ADDRESS : PRELIMINARY M.S. (AYU) SCHOLAR.
   (IN BLOCK LETTERS) : DEPT. OF SHALAKYA TANTRA,
   AMRITA SCHOOL OF AYURVEDA,
   VALLIKAVU P.O
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2. PERMANENT ADDRESS : MATA AMRITANANDAMAYI MATH
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3. NAME OF THE INSTITUTION : AMRITA SCHOOL OF AYURVEDA,
   VALLIKAVU P.O
   KOLLAM

4. COURSE OF THE STUDY AND : M.S. (AYURVEDA) – SHALAKYA
   SUBJECT

5. DATE OF ADMISSION TO THE COURSE : 18TH NOV 2013

6. TITLE OF THE TOPIC :

“A CLINICAL STUDY TO EVALUATE THE CAUSATIVE ROLE OF
PACHAKA PITTA IN THE PRODUCTION OF OCULAR TEAR FILM
(QUALITATIVE & QUANTITATIVE) W.S.R. TO AGNI DUSHTI”
1. BRIEF RESUME OF THE INTENDED WORK

I. Need for the Study
As long as life in man, every organ, tissue, cell has to undergo process of constant changes to meet survival, need and ambition in the world. This constant process of change either for yielding energy (catabolic) or synthesize (anabolic) the tissue, an inherent factor exists termed as Agni. Agni is prime and also ultimate factor in the process of maintenance of life. Where the concept of Agni in the form of pitta is physiological approach, the concept of Aama is a pathological one which is mainly due to Agni dusthi i.e ahara rasa resulted due to dysfunctioning of agni hampers the functions of Rasadi dhatus. Production of Samyak Rasa dhatu is having direct role in the production of Ocular tear film (integral part of Rasadhatu). Proper functioning of Pachaka Agni will result in proper ahara rasa formation which will definitely supports the function of netrasritha dhatwagni (rasa & rakta) leading to proper Ashru formation i.e qualitative & quantitative. By keeping this concept in mind, the following study has been planned to asses subjectively as well as objectively the role of Pachaka pitta in the production of Ocular tears film.

II. REVIEW OF LITERATURE:

“Sarveabhi roga Mandaagnau”
Agni mandhya (dysfunctioning of agni) is the prime cause for all the diseases¹. Meanwhile maintenance of proper health is also due to samyak agni Pravrutti². Acharya Chakrapani opines that proper functioning of Agni is responsible for proper Drushti (physiology of vision)³. This shows the inevitable role of ocular tear film in the physiological process of vision⁴. Clinical manifestations like Netradaha⁵, Netra vaivarna, Avila darshana⁶, Sushkaakshi⁷ and Akshikuta sotha⁸ are evident in Agni dusthi which shows the definite role of Agni in the Netra roga Samprapthi and vice versa. Schirmers test⁹, Rosebengal test¹⁰ and Tear film break¹¹ up time will help to asses the quality and quantity of the tear production. Meanwhile medications like Eranda brishta haritaki for kostha shuddhi and Guda sunthi¹² will help in the correction of Agni dushti.
PREVIOUS WORKS DONE:
No study had been carried out till today, to assess the role of Pachaka pitta in the production of Ocular tear film.

III. AIM AND OBJECTIVE OF THE STUDY

1. To evaluate the role of Pachaka pitta in the production of tears of the eye (qualitative & quantitative).

2. To establish an ophthalmic objective parameter for Agni dushti.

2. MATERIALS AND METHODS

I. Source of data
Patients: The patients with signs and symptoms of Agni dushti attending the OPD and IPD of Shalakya Tantra in Amrita school of Ayurveda & Hospital.

Trial drug: Guda Sunthi and Haritaki Churna

II. Materials required for the study
i. Method of collection of data

1. Sample:
Patients attending the hospital will be surveyed for the symptoms of Agni dushti and tears of the eye will be assessed (qualitative & quantitative) with special performa. Later the patient fulfilling the criteria of the study protocol will be registered for the trial.

Sample size: 40 patients

2. Inclusion criteria:
1. Patients in the age group 25-55 yrs irrespective of sex
2. Patients with signs & symptoms of Agni dushti with chronicity of one year.
3. Patients with ocular symptoms like blurring of vision, Sushkaakshi, Netra daha and Vaivarnya.
3. Exclusion criteria:
1. Any clinical condition containing ocular pathology leading to tear film instability will be excluded.
2. Other systemic disorders like Diabetes Mellitus, Hypertension, and Menopausal syndrome, cardiac and renal disorders will be excluded.

ii. PROCEDURE AND DESIGN OF THE STUDY

1. Materials and methods
Patients: The patients with signs and symptoms of Agni dushti attending the OPD and IPD of Shalakya Tantra in Amrita school of Ayurveda & Hospital.

2. Design of the study
Survey followed by Open randomized clinical trial

3. Grouping and treatment procedure
Selected 40 patients will be given Haritaki Churna for Kostha Shodhana.
Once the kostha shuddhi is attained Guda sunthi will be given for Agni dusthi.

- Form: Gutika
- Dose: 2 tab BD before food
- Period: 15 days to one month
- Follow up: One month with 15 days interval

4. Assessment criteria
Subjective parameters:
1. Signs & symptoms of Agni dushti
2. Ocular symptoms like blurring of vision, Sushkaakshi, Netra daha and Vaivarnya will be assessed with Ocular surface disease index Questionnaire.

Objective parameters:
- Schirmers test\(^9\)
- Tear film break\(^11\) up time
- Rosebengal test\(^10\)
- Visual Acuity
- Tear Meniscal height
5. Statistical methods

Student T Test

3. Does the study require any investigations or interventions to be conducted on patients, Healthy volunteers, cadaver or animals? If so please describe briefly

Yes, patients

4. Has ethical clearance been obtained from your institution in case of (3)?

(Human /Animal)

Yet to be obtained

LIST OF REFERENCES:

Name of the researcher : Sushma N.S

Name and designation of the guide : Dr. K.V. Subhadra Antherjanam
                        Professor and HOD
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Name and designation of Head of Institution : Dr. M. R. Vasudevan Namboothiry
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