## Department of DRAVYAGUNA

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AMRITA SCHOOL OF AYURVEDA

AMRITA VISWAVIDYAPEETHAM
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

FOR

AYURVEDA VACHASPATI (M.D) IN DRAVyAGUNA

“OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE CHOLESTEROL LOWERING ACTIVITY OF KaidaRYA (Murraya koenigii Linn.) IN NON-DIABETIC PATIENTS”

BY
Dr. Aisha Shabna Kamal
(1st YEAR P.G. SCHOLAR)

GUIDE: Dr. Vimala K.S MD (Ay)
READER

CO-GUIDE: Dr. Priyalatha MD (Ay)
LECTURER

DEPT. OF P.G STUDIES IN DRAVyAGUNA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O.

KOLLAM

SESSION: 2013-2014
1. BRIEF RESUME OF THE INTENDED WORK:

1.1 NEED FOR THE STUDY.

Way of life is the cause for health as well as illness. Our life style has changed entirely from that of olden times. Cravings for fast food, junk food and lack of exercises are some of the main causes for the life style disorders. Hypercholesterolemia is one such problem arised due to the altered life style of people and is progressing day by day. People are forced to take the allopathic medicine and are thus victims of its side effects. Thus an effective management for hypercholesterolemia is mandatory. Since a large population is the victim, the drug of choice must be such that it is abundantly available, cheap and if possible can be cultivated. Hence the drug Kaidarya (Murraya koenigii Linn.) a traditionally unavoidable household plant (used in food) is selected for the study. The drug available in market is contaminated with pesticides, so it is decided to collect the drug from near by villages.

Kaidarya is mentioned under gudoochyadi varga in Nighantu. Charaka Acharya mentioned it in kandya and samnjastrapana gana. It has katu, tiktha rasa and seeta veerya. Some studies have been done on kaidarya. Animal study done was found effective in lowering blood sugar but it showed negligible effect on blood cholesterol. A clinical study done on diabetic patients also did not show any significant result on blood cholesterol. The probable reason may be its small dose (10gms). Thus I have taken up this study to evaluate the effect of kaidarya on hypercholesterolemia of non-diabetic patients by increasing the dose and adding an anupana. If the study showed good results, this shall form a cost effective remedy for common man as the drug is readily available and economic. The pharmacognostic, analytical and clinical evaluation of drug kaidarya to reduce the increased cholesterol level will be studied.

1.2 REVIEW OF LITERATURE:

- Susrutha samhita mentions kaidarya in pippalyadi gana
- Ashtanga Hridaya in sakavarga
- Raja Nighantu in Guloochyadi varga
- Bhavaprakasa Nighantu in gudoochyadivarga
- Charaka Samhita in kandya and samnjastrapana dasemani
- Dhawanthara Nighantu in gudoochyadi varga
1.3 Previous research works.


b) Dr. Ansary P.Y – An experimental study on the effect of musta (Cyprus rotundus) in Hypercholesterolemia – Govt. Ayurveda Medical college, Kerala University, Tvm (1994).


d) Dr. Akhil T. – Pharmacological evaluation of Asana (Pterocarpus marsupium) in Hypercholesterolemia. Rajiv Gandhi University.

e) Dr. Vimala – Anti-helminthic and antacid property of kaidarya – Govt. Ayurvedic Medical College, Kerala University, Tvm.


1.4. AIM AND OBJECTIVE OF THE STUDY.

AIM: To study the effect of Kaidarya with takra as anupana in hypercholesterolemia.

OBJECTIVE: a) To study the effect of kaidarya + takra in T.C, SGOT, SGPT, HDL and LDL.

b) To provide a cost effective medicine for hypercholesterolemia.
2. MATERIALS & METHODS:

2.1. SOURCE OF DATA:

- Literary data is collected from the relevant classical texts (A.H, Cha.Sam, Ra.Ni, Dha.Ni etc)
- Modern books
- Other available sources of information. (internet etc)

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2 (i) METHODS OF COLLECTION OF DATA:

A. SAMPLE:

- Patients will be selected from the camp conducted as well as O.P.D according to inclusion criteria.
- This is a before and after trial hence, there will not be any $\beta$ error.
  So the sample size can be fixed to 30 patients.\(^8\)

B. INCLUSION CRITERIA:

- Non- diabetic patients of age group (30 – 70) yrs
  Showing serum cholesterol level >200 are selected.
- Both males and females are included.

C. EXCLUSION CRITERIA:

- Patients <30 yrs and >70 yrs are not selected
- Patients suffering from known cases of HIV, Tuberculosis, diabetics, malignancy, hypothyroidism, nephrotic syndrome are excluded.
2.2.(ii) PROCEDURE AND DESIGN OF THE STUDY.

1. MATERIALS AND METHODS.
   Materials – Drug KAIDARYA
   Instruments for phytochemical study
   Methods - analytical study
   Clinical study

2. DESIGN OF THE STUDY.
   A. Drug study
      (i) Pharmacognostical Study
         a. Macroscopic study
         b. Microscopic study
      (ii) Analytical study
         a. Organoleptic study
         b. Physio-chemical study
            • Foreign matter
            • Total ash
            • Water soluble ash
            • Chromatography study (TLC)
   B. Clinical study
      Effect of drug kaidarya + takra will be assessed by administering it to patients.

3. GROUPING AND TREATMENT /PROCEDURE, etc.
   • It is an open labelled single armed uncontrolled study.
   • 30 Non-diabetic patients of age group (30-70) yrs with serum cholesterol >200 will be taken for study.
   • Drug kaidarya in the form of choorna (dried under shade) is administered to these patients 10gms before food, thrice daily with takra as anupana.
   • Blood sample before, during and after medicament is tested for total cholesterol
   • T.C, SGOT, SGPT, Serum amylase, HDL and LDL before and after medicament will be compared.
(3.) **ASSESSMENT CRITERIA.**

Criteria for assessment of blood cholesterol includes laboratory investigations of blood samples before and after medicament:

a) Total cholesterol – normal < 200mg/dl
b) HDL – male(45 -70)mg/dl
   females(50 – 90)mg/dl
c) LDL - normal <130mg/dl
d) SGPT – male(10 -55) units/liter
   female(7-30) IU/L
e) SGOT – normal(10 – 34)IU/L
f) serum amylase – (23 – 85)U/L

Objective parameters of pre and post medicament of 30 patients are to be analyzed statistically.

(4) **STATISTICAL METHOD:**

The data will be collected and analysed statistically using paired ‘ t ’ test.

(5) **Does the study requires any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:**

Yes, the study requires laboratory investigations of blood samples of patients before and after treatment for :

a) Total cholesterol
b) HDL
c) LDL
d) SGPT
e) SGOT
f) serum amylase
(6) Has ethical clearance been obtained from your institution in case (3)?

YES

(7) LIST OF REFERENCES.


(4) www.pubmed.com


(6) Pandit Narahari, Raaja Nighantu edited with Dravyagunaprakaasika commentary by Dr. Indradeo Tripathi., Chowkhamba Krishnadas Academy, Varanasi.


(9) Dr.L. Mahadevan’s Guide to Ayurvedic Clinical Practice published by Dr. Y. Mahadevan Iyer’s, Sri Sarada Ayurvedic Hospital, 4th edition -2013, page 370,378 & 385.
AMRITA SCHOOL OF AYURVEDA
AMRITA VISWAVIDYAPEETHAM
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI (M.D) IN DRAVYAGUNA

“HARIDRA (Curcuma longa Linn.) AS A SUBSTITUTE FOR KUMKUMA
(Crocus sativus Linn.); AN ANALYTICAL STUDY”

BY
DR. ANU SREEDEVI
(PRELIMINARY P.G. SCHOLAR)

GUIDE
DR. PRIYA S., M.D (Ay)
PROFESSOR AND HOD

CO-GUIDE:
DR. RAIBY PAUL, M.D (Ay)
LECTURER

DEPT. OF P.G STUDIES IN DRAVYAGUNA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014
FROM,

DR. ANU SREEDEVI
Preliminary M.D (Ay) Scholar,
Department of Post Graduate Studies in Dravyaguna,
Amrita School of Ayurveda,
Vallikavu, Kollam 690525.

TO,

The Registrar,
Amrita Viswavidyapeetham,
Ettimadai Post, Coimbatore-641105

THROUGH,

The Principal and
Head of the Dept. of Dravyaguna
Amrita School of Ayurveda, Vallikkavu, Kollam 690525.

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita University, as partial fulfillment of M.D. (Ayurveda) in Dravyaguna.

THE TITLE OF DISSERTATION

“HARIDRA (Curcuma longa Linn.) AS A SUBSTITUTE FOR KUMKUMA (Crocus sativus Linn.); AN ANALYTICAL STUDY”

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

Thanking you,

Yours faithfully,

Place: Vallikkavu
Date: 

DR. ANU SREEDEVI
1. BRIEF RESUME OF THE INTENDED WORK:

1.i. NEED FOR THE STUDY.

Natural sources of medicinal plants are often unable to meet the demand for popular herbal products. Population of many species have limited distribution in their natural habitats, requiring conservation strategies for protection. Unavailability of such medicinal plants has led to arbitrary substitutes in the raw drug market.

Pratinidhi dravyas are substitute drugs utilized for the drugs which are not easily available. It mainly deals with rational substitution of crude drugs required for medicinal purpose. i.e., they are an alternate to rare/extinct/difficult to procure original drugs. Also the drugs which are much expensive can be substituted with cheaper drugs having the same qualities. The main requirement for an appropriate pratinidhi dravya is to possess similar gunas to that of original drugs. It can overcome the depletion of rare drugs that lend a support in conservation and sustainability of medicinal plants and provide a quality herbal formulation with economic feasibility.

Concept of substitution prevailed ages back. In Ayurveda we can find this in Bhavaprakasha Nighantu, Bhaishajya Ratnavali, Yoga Ratnakara. Almost 46 pairs of substitutes have been identified from these books. Out of these kumkuma-haridra have been selected for the study purpose because of its great importance in therapeutic and economic use. Kumkuma (Crocus sativus) otherwise known as saffron is a bulbous perennial growing in Kashmir at 1,600 m altitude. As it has got great economic value, it is adulterated with various other drugs which is of lesser quality. In our classical text book, Bhaishajya Ratnavali, it is stated that kumkuma can be substituted with haridra (Curcuma longa). The study will be much beneficial if it is proved that haridra can be substituted instead of kumkuma.

1.ii. REVIEW OF LITERATURE

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

Post 16th century, Ayurvedic texts and lexicons gave specific examples of possible substitutes. The concept of substitute use is mentioned as early as Bhavaprakasha Nighantu, Bhaishajya Ratnavali and Yoga Ratnakara name different plant pairs.
As per the Ayurvedic Pharmacopoeia of India, the properties and action of kumkuma and haridra is as follows:

Kumkuma
Rasa – katu, tikta
Guna – snigdha
Veerya – ushna
Vipaka – katu
Karma – varnya, sleshmahara, vatahara, rasayana, vishaghna, jantuhara

Haridra
Rasa – tikta, katu
Guna – rooksha
Veeya – ushna
Vipaka – katu
Karma – varnya, kaphapittahara, vishaghna, kushtaghna, krimighna, pramehanaashak

1.ii. Previous Research Works.

1. B. Anirudhan, A. Thenmozhi, P. Priyadharshini- Evaluation of preliminary phytochemicals and antioxidant efficacy of Crocus sativus Linn. P.G. Department of biochemistry, SRM Arts and Science College, Kattankulathur-603, 2014


3. Dr. A. Sikha, Phytochemical analysis of haridra(Curcuma longa Linn.) cultivated and collected in different ritu(seasons) by, Dept. of PG studies in dravyaguna, SDM College of Ayurveda, Hassan, Rajiv Gandhi University of Health Sciences, 2012-2013

1.iii. AIM AND OBJECTIVE OF THE STUDY.

1. To find out whether haridra can be used as a substitute for kumkuma.
2. To analyze the drugs kumkuma and haridra using histological and physicochemical parameters.
3. To compare the data and to find out whether there is any similarity in the analytical profile.

2. MATERIALS & METHODS:

2.1. SOURCE OF DATA:

Samhitas, Nighantus, modern books on pharmacognosy, various journals, magazine and other published works.
Data collected from various seminars, conferences.
Various websites.

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2.i. METHODS OF COLLECTION OF DATA:

D. SAMPLE:

The samples of Kumkuma will be collected from different GMP certified distributors and also from natural habitat (Kashmir). Sample of haridra collected from Wayanad will be taken and compared with the authenticated sample of kumkuma.
2.2. ii. PROCEDURE AND DESIGN OF THE STUDY:

1. MATERIALS AND METHODS
The samples of both the drugs will be procured from major drug dealers and from their natural habitats. The analytical facilities of Amrita School of Ayurveda will be utilized for the study purpose.

2. DESIGN OF THE STUDY
The study will be carried out in 4 phases.

a) LITERATURE REVIEW
Related literature will be compiled from relevant Ayurveda and contemporary science treatise, journals and related sources.

b) COLLECTION AND IDENTIFICATION OF DRUGS
Market samples of kumkuma collected from major drug dealers is compared with the kumkuma collected from natural habitat. The authenticated sample of kumkuma will be compared with the haridra collected from Wayanad.

c) EVALUATION OF THE DRUGS
   - macroscopic evaluation
   - microscopic evaluation
   - organoleptic study
   - loss on drying
   - ash value
   - Water soluble extract
   - alcohol soluble extract
   - TLC
d) **ASSESSMENT OF THE DATA**

After the phytochemical evaluation of samples of both the drugs, the data will be compared to identify any similarity in their value.

**4. STATISTICAL METHODS.**

The data will be collected and analyzed by using student “t” test & chi-square test.

**5. Does the study require any investigations or interventions to be conducted on patients or other human or animal? If so please describe briefly…**

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

   Yes.

6. **LIST OF REFERENCES**


4. The Ayurvedic Pharmacopoeia of India, Government of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, (AYUSH), New Delhi, part 1, volume 1, 1st edition, page no. 45

5. The Ayurvedic Pharmacopoeia of India, Government of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, (AYUSH), New Delhi, part 1, volume 4, 1st edition, page no. 52-54


1. NAME OF THE RESEARCHER/ SCHOLAR: ANU SREEDEVI

SIGNATURES

2. NAME AND DESIGNATION OF THE GUIDE: DR. PRIYA.S, MD(Ay)

REMARKS OF THE GUIDE:

SIGNATURES WITH OFFICIAL SEAL

3. NAME AND DESIGNATION OF THE CO-GUIDE:

SIGNATURES WITH OFFICIAL SEAL

4. NAME AND DESIGNATION OF HEAD OF THE DEPARTMENT:

SIGNATURES WITH OFFICIAL SEAL

5. NAME AND DESIGNATION OF HEAD OF THE INSTITUTION:

SIGNATURES WITH OFFICIAL SEAL

___________________________________________________________________
AMRITA SCHOOL OF AYURVEDA
AMRITA VISWAVIDYAPEETHAM
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

FOR

AYURVEDA VACHASPATI (M.D.) IN DRAVYAGUNA

“IN-VITRO STUDY TO EVALUATE THE ANTIMICROBIAL ACTIVITY OF
Emilia sonchifolia(Linn)DC IN BETA HAEMOLYTIC STREPTOCOCCUS”

BY

DR.D.DIVYA RAJ
(PRELIMINARY P.G. SCHOLAR)

GUIDE

DR.PRIYA. S, M.D(Ay)
PROFESSOR AND HOD

CO-GUIDE

DR.PRIYALATHA, M.D(Ay)
LECTURER

DEPT.OF P.G.STUDIES IN DRAVYAGUNA

AMRITA SCHOOL OF AYURVEDA,VALLIKAVU,CLAPPANA POST,KOLLAM
SESSION:2013-2014

TOP
FROM,

DR.D.DIVYA RAJ
Preliminary M.D (Ay) Scholar,
Department of Post Graduate Studies in Dravyaguna,
Amrita School of Ayurveda,
Vallikkavu, Kollam 690525.

TO,

THE REGISTRAR,
AMRITA VISWAVIDHYAPEETHAM,
ETTIMADAI POST, COIMBATORE-641105

THROUGH,
The Principal and
Head of the Dept. of Dravyaguna
Amrita School of Ayurveda, Vallikkavu, Kollam 690525.

Subject: Submission of Completed Performa for Registration of Synopsis of Dissertation

Respected sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita University, for partial fulfillment of M.D. (Ayurveda) in Dravyaguna.

THE TITLE OF DISSERTATION:

IN-VITRO STUDY TO EVALUATE THE ANTI-MICROBIAL ACTIVITY OF Emilia sonchifolia (Linn)DC IN BETA HAEMOLYTIC STREPTOCOCCUS

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

Thanking you,

Yours faithfully,

Place: Vallikkavu

Date: DR.D.DIVYA RAJ
COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

1. NAME OF THE CANDIDATE : DR. D. DIVYA RAJ
   & ADDRESS
   PRELIMINARY M.D (Ay) SCHOLAR
   (IN BLOCK LETTERS)
   DEPT. OF POST GRADUATE STUDIES
   IN DRAVYAGUNA
   AMRITA SCHOOL OF AYURVEDA,
   VALLIKKAVU, KOLLAM- 690525

   PERMANENT ADDRESS : KARINGATTIL HOUSE
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                        CHENGANNUR 689121

2. NAME OF THE INSTITUTION : AMRITA SCHOOL OF AYURVEDA,
   VALLIKKAVU, KOLLAM-690525

3. COURSE OF STUDY & SUBJECT : M.D.(Ay) DRAVYAGUNA

4. DATE OF ADMISSION TO THE COURSE : 18/11/2013

5. TITLE OF THE TOPIC : IN-VITRO STUDY TO EVALUATE THE ANTI-
                        MICROBIAL ACTIVITY OF Emilia sonchifolia(Linn)DC
                        IN BETA HAEMOLYTIC STREPTOCOCCUS
1. BRIEF RESUME OF THE INTENDED WORK:

1.1. NEED FOR THE STUDY:

Tonsillitis is one of the most common diseases of upper respiratory tract, which commonly affects children\(^1\). The usage of antibiotics and surgical interventions are the most common remedies in modern system of medicine. To minimize the usage of antibiotics and to develop a natural new drug to control pathogenic microorganism, i.e., beta haemolytic streptococcus, the present study has been designed. The common organism for tonsillitis is beta haemolytic streptococcus. The signs and symptoms of tonsillitis can be closely related to Tundikeri in Ayurveda.

Sasasruti(*Emilia sonchifolia* (Linn)DC) is the drug which is easily available, cheaper, non-controversial and is found to be effective in tonsillitis\(^2\). The external application of sasasruti has been done previously and is found to be effective but the disease was found to be reccuring. Before clinically evaluating the drug internally, here an invitro study has been designed to evaluate the anti-microbial activity of *Emilia sonchifolia*(Linn)DC in beta haemolytic streptococcus.

1.2. REVIEW OF LITERATURE:

In classical Ayurvedic texts, the disease Tundikeri is described in different context. In *Ashtangahridaya*\(^3\), it is described as a “Kantaroga”. But in *Susrutasamhita*\(^4\), *Bhavaprakasha*\(^5\) and *Yogaratnakara*\(^6\) it is included under “Talugata” rogas. Tundikeri is a disease of kapha-pitta origin. The drug sasasruti is having katu, tikta, kashaya rasa, laghuguna, seta veerya, katuvipaka and is found to be kapha pitta samana\(^7\).

1.3. PREVIOUS DISSERTATION WORKS DONE:

1. Dr. Prasanth, A comparative in vitro evaluation of Kutaja(*Holarrhena antidysenterica* Roxb) twak, pushpa and beeja for krimighna activity w.s.r to Staphylococcus pyogens infection, Rajiv Gandhi University of Health Sciences, Bangalore, 2011.


4. Dr.Pandey U.J.-Role of Kalakachoorna in the management of Tundikeri to Tonsillitis.Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurveda University, Jamnagar, 1994.


6. Dr.P.K.Pratibha–Clinical study on the management of Tundikeri with Kanchanaraguggulu and kavaladharana with Vachadikwatha, Government Ayurvedic College, Bangalore, RGUHS, 1997

7. Dr.Beena-Clinical effect of sasasruti on Tundikeri, Government Ayurveda College, Trivandrum.

1.4. AIM AND OBJECTIVE OF THE STUDY:
An in-vitro study to evaluate the antimicrobial activity of *Emilia sonchifolia* (Linn) DC in beta haemolytic streptococcus.

2. MATERIALS AND METHODS:

2.1. SOURCE OF DATA:
Samhitas, Nighantus, Modern books of medicine and pharmacology, Journals, Magazines and Websites.

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2.1. METHOD OF COLLECTION OF DATA:

A. SAMPLE
The powder extract of *Emilia sonchifolia* (Linn) DC and Beta haemolytic streptococcus bacteria will be cultured.

B. INCLUSION CRITERIA:
The causative organism of tonsillitis, Beta haemolytic streptococcus bacteria.

C. EXCLUSION CRITERIA:
Other bacteria and fungi are excluded.

3. PROCEDURE AND DESIGN OF THE STUDY:
Research work will be carried out in 3 phases:
1. Literary review:
   Data from Ayurvedic classics, nighantus, commentaries, data from contemporary sciences and other sources will be collected.

2. Drug study:
   Pharmacognosy studies: Microscopic and Macroscopic evaluation of the drug.
   Phytochemical studies: Moisture content, ash value, TLC$^8$

3. Anti-microbial study:
   The antimicrobial activity of *Emilia sonchifolia* (Linn) DC in beta haemolytic streptococcus.

   Culture media: As per the organism.
   - Anti-microbial assays by Disc Diffusion Method$^{9,10}$.
   - The test bacteria will be maintained in nutrient agar slants.
   - After incubation the bacteria grown in the culture will be swabbed uniformly across a culture plate.
   - Sterilized disc of whatman no.1 filterpaper impregnated with the extractof *Emilia sonchifolia* (Linn) DC will be then placed on the surface of the agar.
   - After incubation plates will be observed for any zones of inhibition surrounding the disc.
   - The size of the zone of inhibition is a measure of effectiveness. If the clear area around the disc is larger the extract preparation of *Emilia sonchifolia* (Linn) DC is more effective.

4. ASSESSMENT OF THE DATA:
   Assessment will be done according to the microbiological parameters. The obtained data will be analyzed at the end of the study.

5. STATISTICAL METHODS:
   The data will be collected and analyzed by using student ‘t’ test.

3. Does the study require any investigations or interventions to be conducted on patients or other human or animal? If so please describe briefly…

1. Has ethical clearance been obtained from your institution in case(3)?
   Yes.
6. LIST OF REFERENCES:

2. R.N.Chopra, Glossary of Indian medicinal plants, National institute of science communication and information resources page no:107.


6. Yogaratnakara, Yogaratnakara, Vidhyotinitihinditeeka edited by VaidyasriLakshmipatishastri, chaukambha publications, uttarardhagata


10. Antimicrobial activity of MachilusMacranthaNees(Lauraceae)stem bark extracts IJRAP, jan-feb.2014
1. Name Of The Researcher/Scholar : D. DIVYA RAJ

Signatures :

2. Name And Designation Of The Guide : DR.PRIYA. S, M.D. (Ay)

Remarks Of The Guide :

Signatures With Office Seal :

3. Name And Designation Of Head Of The Department : DR.PRIYA S M.D. (Ay)

Signatures With Office Seal :

4. Name And Designation Of The Co-Guide: DR.PRIYALATHAM.D. (Ay)

Signature With Office Seal :

5. Name And Designation Of The Head Of The Institution : DR.M.R.VASUDEVAN NAMPOOTHIRI M.D (Ay)

Signature With Office Seal :
PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR

AYURVEDA VACHASPATI (M.D) IN DRAVYAGUNA

“OPEN LABEL SINGLE ARM CLINICAL STUDY OF SUSHRUTOKTA BRUHATYAADI GANA IN CHRONIC URINARY TRACT INFECTION”

BY

DR. SREEJA. J

(PRELIMINARY P.G. SCHOLAR)

GUIDE

DR. VIMALA K.S, BAMS, MD(Ay)

READER

CO-GUIDE:

DR. RAIBY PAUL, BAMS, M.D (Ay)

LECTURER

DEPT. OF P.G STUDIES IN DRAVYAGUNA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014
FROM,

DR. SREEJA J
Preliminary M.D (Ay) Scholar,
Department of Post Graduate Studies in Dravyaguna,
Amrita School of Ayurveda,
Vallikkavu, Kollam 690525.

TO,

THE REGISTRAR,
Amrita Viswavidyapeetham,
Ettimadai Post,
Coimbatore-641105

THROUGH,
The Principal and
Head of the Dept. of Dravyaguna
Amrita School of Ayurveda, Vallikkavu, Kollam 690525.

Subject: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita University, for partial fulfillment of M.D. (Ayurveda) in Dravyaguna.

THE TITLE OF DISSERTATION:
“OPEN LABEL SINGLE ARM CLINICAL STUDY OF SUSHRUTOKTA BRUHATYAADI GANA IN CHRONIC URINARY TRACT INFECTION”

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

Thanking you,

Yours faithfully,
I. BRIEF RESUME OF THE INTENDED WORK:

I. NEED FOR THE STUDY

Mootrakruchra\(^1\) is one of the elaborately explained rogas in Ayurvedic classics and is a bastimarmagata vikara. As basti is one among the trimarma, management of the disorders related to it has a greater therapeutic importance. In general 8 types of Mootrakruchra have been mentioned and can be co-related to signs and symptoms of urinary tract infection.

U.T.I ranks first among the bacterial diseases of adults. The majority of patients are women, as many as 20% of all women have an episode of U.T.I by the age of 30yrs.\(^2\) In Modern Science antibiotics have been used to compact urinary infections. Antibiotics have their own limitations like development of resistance to the microorganisms, re-infection and relapses etc. So to solve this problem it is highly relevant to search for an alternative treatment, which is both effective and economic.

BRUHATYAADIGANA\(^3\) explained by Sushruta Acharya is a combination of 5 medicinal plants and are Brihati, Kantakarika, kutajaphala, Patha & Madhuka. In the phalasruti Acharya explained as MUTRAKRICHRA RUJAPAHA-relieves pain & difficulty in urination which is considered as the primary symptom of U.T.I. In practice commonly used Kashaya for U.T.I. is Bruhatyaadi Kashaya explained by Vagbhata Acharya.\(^4\)

Thus an attempt to evaluate the efficacy of Bruhatyaadi gana explained by Sushruta Acharya in urinary tract infectious conditions is being taken.

II. REVIEW OF LITERATURE

Nidana, lakshana & samprapti of Mootrakruchra are explained in Charaka samhita chikitsa sthana 26\(^{th}\) chapter\(^5\), Susrutha samhita uttarasthana 59\(^{th}\) chapter\(^6\) and Ashtanga Hridaya nidanasthana 9\(^{th}\) chapter.

Sushrutha Acharya explained Bruhatyaadi gana in Dravyasamgrahaneeya adhyaya. Drugs mentioned here are Brihati –\textit{Solanum indicum} auct.non Linn, Kantakarika- \textit{Solanum xanthocarpum} Schrad & Wendl, kutajaphala (Indrayava) – \textit{Holarrhena antidysenterica} (Roxb.ex
Fleming) Wall.ex DC.,Patha–*Cyclea peltata* (Lam) Hook.f. & Tho and Madhuka – *Glycyrriza glabra* Linn. The therapeutic effects of this gana are tridoshahara, pachaneeya, arochakanasha, hridrogaahara, mutrakrichra and rujahara.

**Drug Review:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Rasa</th>
<th>Guna</th>
<th>Veerya</th>
<th>Vipaka</th>
<th>Karma</th>
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<tr>
<td>Bruhathi</td>
<td>Katu, thikta</td>
<td>Laghu</td>
<td>Ushna</td>
<td>Katu</td>
<td>Grahi,deepana, pachana</td>
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<tr>
<td>Kantakarika</td>
<td>Katu, thikta</td>
<td>Laghu, ruksha</td>
<td>Ushna</td>
<td>Katu</td>
<td>Deepana, pachana, aamadoshanashaka</td>
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<tr>
<td>Kutajaphala</td>
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<td>Laghu, ruksha</td>
<td>Sheetha</td>
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<td>Deepana, sangrahi</td>
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<tr>
<td>Patha</td>
<td>Kashaya</td>
<td>Guru, ruksha</td>
<td>Sheetha</td>
<td>Katu</td>
<td>Kledanashana, malabhedhi</td>
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<tr>
<td>Madhuka</td>
<td>Madhura</td>
<td>Guru, snigdha</td>
<td>Sheetha</td>
<td>Madhura</td>
<td>Vrishya, vishahara</td>
</tr>
</tbody>
</table>

**PREVIOUS RESEARCH DONE**

1. 2012, Pratik Bharat Wani, Uroflowmetric study of Brihatyadhiyogavasthi in the management of vatashteela (B.P.H), Rajiv Gandhi University of Health Sciences, Karnataka, Banglore.

2. 2011, Dr.Priya Bhat, An observational clinical study on the effect of Gokshurachoorana, Pashanabhedadhi Kashaya & Swetaparpati in Mutrakruchchra VIS-VIS Lower urinary tract infection, Rajiv Gandhi University of Health Sciences, Karnataka.

3. 2009, Dr.Shivani. Role of an indigenous compound on urinary tract infections(UTI) in garbhini., Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore.

**III.AIM AND OBJECTIVE OF THE STUDY.**
1. To evaluate the therapeutic effect of Sushrutokta Bruhatyaadi gana in chronic Urinary tract infection.

2. To find out an easy and simple preparation for chronic Urinary tract infection.

2. MATERIALS & METHODS:

I. SOURCE OF DATA:


II. MATERIALS REQUIRED FOR THE STUDY:

a. METHOD OF COLLECTION OF DATA:

i. SAMPLE:
30 patients having symptoms of chronic U.T.I. will be selected randomly.

ii. INCLUSION CRITERIA:
1. Patients between the age group of 15-70yrs.
2. No discrimination of sex.
3. Patients having suggestive signs and symptoms of Mutrakrichra with positive urine microscopy (pus cell ≥ 5) and urine culture with growth of organism ≥1 lakh/ml.
4. Signs and symptoms of Moothrakrichra
   - Sadaha mootrapravarti (burning micturition)
   - Vankshanabastimedra soola (suprapubic pain)
   - Muhurmuhr mootrapravritti (increased frequency)

iii. EXCLUSION CRITERIA
1. Patients with complications of the diseases like upper urinary tract infection, sepsis, chronic renal failure will be excluded.
2. U.T.I in pregnancy will be excluded.
3. Patients of diabetes will be excluded.

b. PROCEDURE AND DESIGN OF THE STUDY.

i. MATERIALS AND METHODS.

a) 30 patients having symptoms of U.T.I. will be selected randomly from the camps conducted as well as O.P.D. of Amrita School of Ayurveda Hospital.
b) The Kashaya of Brihatyadhigana will be prepared and given.

ii. DESIGN OF THE STUDY

Research work will carried out in 3 phases.

1. Literary review
   Data from Ayurvedic classics, nighantus, and other literature includes commentaries, data from contemporary sciences & other sources will be collected.

2. Drug study
   Microscopic & macroscopic study.

3. Clinical study
   Evaluation of the effect of decoction of Bruhatyaadigana mentioned by Sushruta Acharya in chronic U.T. I.

iii) GROUPING AND TREATMENT/PROCEDURE etc.

Present study is an open label single arm clinical study. 30 patients will be selected by random sampling procedure. The selection of cases is on the basis of clinical presentation.

Dose of medicine - 30ml bd before meals.

Duration- 1 month
Pre and post evaluation will be done.

iv) ASSESSMENT CRITERIA

Assessment will be done based on the signs & symptoms of U.T.I. mentioned in the inclusion criteria.

Urine:

- Microscopy-done before and after treatment.
- Culture-done before treatment to know the infective organism and its growth.

5. STATISTICAL METHODS

The data will be collected and analyzed by 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. The study will be conducted on the patients of chronic U.T.I.

INVESTIGATIONS

Urine microscopy, urine culture, R.B.S

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

Yes.
5. LIST OF REFERENCES


2. Moselio Schaechter, Gerald Medoff, Barry. I. Eisenstein, Mechanisms of Microbial disease, 2nd edition, Published by Williams & Wilkins, chapter 59, Page no. 735


4. Vagbhata, Astangahridaya with Arunadatta’s Sarvanga Sundara commentary, edited by Pt Hari Sadasiva Sastri, Chaukamba Surbharati Prakashana, Varanasi, Chikitsa sthana, Chapter 11, Page no. 675

