

TITLE

**EFFICACY OF SNEHIK NASYA (CHARAKOKTA PANCHAGAVYA GHRIT) IN
VATAJ SHIROROG**

RESEARCH QUESTION:

Does the *Snehik Nasya Panchagavya Ghrith* is effective in *Vataj Shirorog* ?

HYPOTHESIS

Panchagavya Ghrith Nasya is effective in *Vataj Shirorog*.

NULL HYPOTHESIS

H_0

Panchagavya Ghrith Nasya is not effective in *Vataj Shirorog*.

ALTERNATE HYPOTHESIS

H_1

Panchagavya Ghrith Nasya is effective in *Vataj Shirorog*.

INTRODUCTION:

In this competitive world, due to stressfull life style every individual is facing the problem of headache. Headache can occur as a result of many conditions whether serious or not. Frequent headache can affect relationship and employment . There is also an increased risk of depression in those with severe attacks.

Due to increasing stress the prevalence of headache is also increasing day by day. Mostly women are more prone to headache than men. Now a days maximum type of headache may be easily correlated in *Ayurveda* with *Vataj Shirorog*. Hence *Vataj Shirorog* is a broad spectrum which is explained in *Charak Samhita* , *Sushrut Samhita* and *Vagbhat Samhita*.

As it has been stated in *Charak Samhita (Cha Su 17)*^[1] that, the place where all the vital organs are situated and where the life of the person is depend is called as *Uttamang* i.e head. Hence head is given special importance in *Ayurveda*.

In *Ayurveda* , *Acharya Charak* has mentioned (*Cha Chi 26*)^[2] that, *Snehan*, *Swedan* and *Nasya* is the best treatment for *Vataj Shirorog*. Also *Acharya Vagbhat* stated, ***Nasa Hi Shiraso Dwaaram*** (*AH Su 20*)^[3] as *Nasa* is the doorway to brain and *Nasya* is the nearest way to administer the drug. In all four types of *Sneha*, *Ghrit* is considered as best remedy or component in *Ayurvedic* treatment among all.

Panchagavya are the five organic products obtained from cow that enhance the immunity as well as growth. Hence the combination of five products obtained from cow is beneficial in different ways as medicine, food supplements and many more. Owing to its very natural properties the five essentials obtained from cow come to many uses.

In *Ayurveda* according to *Acharya Charak* , *Panchagavya ghrita* is the miracle drug in many neurological diseases as it is very well known and effective medicine in *Apasmaar*.

1) STUDY RATIONALE:

The episodes of headache are increasing day by day due to increasing stress in day to day lifestyle. Many times the etiology of headache is not known hence the management of such type of headache according to modern medicine is mostly the use of analgesics.

The effect of analgesics persists with its use but the withdrawal from treatment the symptoms reoccur. The effect of these modern medicine is not permanent also the constant use of analgesics leads to constipation, gastritis, drowsiness, skin itching or rash. So there is a need of alternate safe and effective treatment on headache.

In *Vagbhat Samhita* , *Snigdha Nasya* is suggested in the treatment for *Vataj Shirorog* ^[4] which has proven highly effective and the incidence of reoccurrence of symptoms is very less or negligible.

2) NASYA

1. *Acharya Vagbhat* has stated in *Sutra Sthaan* that, *Nasya* is the best treatment for all diseases in head region. ^[5]
2. Drug administered through the nasal cavity may rapidly traverse through cribriform plate into the CNS by Olfactory neurons.
3. Nasal mucosa absorb lipid soluble drugs much more rapidly, so *Sneha Pradhan Dravya* gets absorbed and reduced *Vata Dosha*.

REVIEW OF LITERATURE:

1. *Lakshan of Vataj Shirorog from Ayurved Samhitas.*
2. *Concept of Nasya from Bhrihat-trayee.*
3. *Preparation of drug from Charak Samhita.*
4. *Related references from media, internet, research journals and articles.*

PREVIOUS WORK DONE

- 1) A randomized controlled trial of the efficacy of *Panchagavya Ghrit* in the management of Obsessive Compulsive Disorder. 2014
Shihabudden E M, Jithesh M. Pune .
- 2) A clinical study of on the role of *Nasya Karma* and *Ghritkalpana* in the management of *Ardhambhedak* vis-à-vis Migranous headache.
Shrikant, Chopra, Jaya Prakash Narayan.
- 3) *Panchagavya Ghrita- A promising drug in Ayurvedic Psychiatry.*
-Asian journal of Pharmaceutical Research and Development.
May 2013.
- 4) Explorative study on efficacy of *Ayurvedic* therapy and *Ayurvedic* compound preparation in the management of epilepsy

.Chittarangana CN, Suhas K Shetty, Karnataka 2014.
- 5) *Dashmool tail Abhyanga* in the prevention of *Vataj Shirashool* with special refrence to episodic tension type of headache.
Vd. Kumbhar Jayesh Laxman 2015.
- 6) Comparative study of *Goghrit Nasya* and *Godugdha Nasya* on *Pittaj Shirashool..*
Vd. Bhoir Akshay Janardan 2015.

- 7) A comparative study of *Vachadi Tail Nasya* and *Shigruvadi Tail Nasya* *Ardhavbhedaka* w.r.t to Migrane.
Vd Bargal Rohan Shivaji 2015.
- 8) A randomized control trial to evaluate the efficacy of *Baladi Tailam* in the management Migrane. 2011
- 9) Clinical evaluation of *Nasya* with *Nirgundyadi Ghrit* on *Ardhavbhedak*. 2011

OBJECTIVES

PRIMARY OBJECTIVE:

To study the efficacy of *Panchagavya Ghrit* in *Vataj Shirorog*.

SECONDARY OBJECTIVES:

1. To form the conceptual platform of *Vataj Shirorog* and the mode of action of *Panchagavya Ghrit Nasya* in the same.
2. To assess the efficacy of *Snehik Pratimarsha Nasya* in *Vataj Shirorog*.

METHODOLOGY

STUDY DESIGN: – CLINICAL STUDY

40 patients will be selected and *Panchagavya Ghrith Snehik Pratimarsha Nasya* for 1 month will be done.

Initial assessment



Treatment will be given for 1 month



Assessment on 15th day and 30th day



Follow up on 45th day and 60th day



Observation



Data collection



Statistical analysis



Discussion



Conclusion

DURATION OF WORK:

Duration of work will be 18 months.

PLACE OF WORK:

OPD and IPD of hospital attached with institute.

METHOD OF SELECTION OF STUDY SUBJECTS:**ELIGIBILITY CRITERIA-****Inclusion criteria:-**

1. Patients presenting with clinical feature of *Vataj Shirarog* according to *Ayurved aspect* will be selected.
2. Patients of both sex will be selected.
3. Patients of age group 20 – 60 years will be selected.

Exclusion criteria:-

1. Patients with Space Occupying Lesion
2. Patients with head injury.

OPERATIONAL DEFINATIONS:-

Nasya :- Administration of drug through nasal cavity is called *Nasya*.

STANDARD OPERATING PROCEDURE OF NASYA ^[6]:

Patients will be asked to lie down on *Nasya* table in supine position with slightly chin lifted and head lying behind.

As per the *Maatra* of *Pratimarsha Nasya*, **2 Bindu** will be introduced in both nostril alternately.

Patient will be asked to stay in the same position until the drug reaches his/her throat.

Then patient will be asked to spit off all the impurities and the *Nasya* drug that reaches his/her mouth.

MATERIALS

Nasya-

- 1) *Panchagavya Ghrit*
- 2) Dropper
- 3) Container for heating the Ghrit

DRUG REVIEW

Panchagavya Ghrit procedure ^[7]:

1. *Gomaya Rasa*- 1 part
2. *Godadhi* - 1 part
3. *Godugdha*- 1 part
4. *Gomutra* -1 part
5. *Goghrit* -1 part

All the five contents will be taken in same quantity and boiled until no water is left in it.

PROPERTIES OF PANCHAGAVYA

| <i>Contents</i> | <i>Rasa</i> | <i>Veerya</i> | <i>Vipaka</i> | <i>Guna</i> | <i>Dosha Karma</i> |
|--------------------|------------------------|---------------|----------------|-------------------------------|---|
| <i>Gomaya Rasa</i> | <i>Kashaaya, Tikta</i> | <i>Sheeta</i> | <i>Katu</i> | <i>Laghu, Ruksha</i> | ----- |
| <i>Godadhi</i> | <i>Amla</i> | <i>Ushna</i> | <i>Amla</i> | <i>Guru</i> | <i>Vata Shaman, Kapha Pitta Vardhak</i> |
| <i>Godugdha</i> | <i>Madhura</i> | <i>Sheeta</i> | <i>Madhura</i> | <i>Snigdha, Guru</i> | <i>Vata Pitta Shaman, Kapha Vardhak</i> |
| <i>Gomutra</i> | <i>Katu, Lavana</i> | <i>Ushna</i> | <i>Katu</i> | <i>Laghu, Ruksha, Tikshna</i> | <i>Kapha Vata Shaman, Pitta Vardhak</i> |
| <i>Goghrit</i> | <i>Madhur</i> | <i>Sheeta</i> | <i>Madhura</i> | <i>Snigdha</i> | <i>Vata Pitta Shaman</i> |

MATRA OF NASYA:

In *Sharangdhar Samhita* (U. 8) *Matra* of *Pratimarsha Nasya* is 2 *Bindu* ^[8].

According to *Achaarya Sharangdhar* ^[9],

8 *Bindu*- 1 *Shan*

1 *Shan*-1/4 *Tola*

1/4 *Tola*- 2.5 ml

Hence, 1 *Bindu*- 0.312 ml

2 *Bindu*- 0.624 ml ~ 0.6 ml in each nostril.

METHOD OF ADMINISTRATION

| | |
|-------------------------|--------------------------|
| NO OF PATIENTS | 40 |
| THERAPY | <i>NASYA</i> |
| <i>KALA</i> | MORNING AND EVENING |
| ROUTE OF ADMINISTRATION | INTERNALLY THROUGH NOSE |
| DRUG | <i>PANCHAGAVYA GHRIT</i> |
| DOSE | <i>2 BINDU</i> |
| DURATION | 1 MONTH |

RESEARCH METHODOLOGY SPECIFIED AND EXPLAINED FOR DATA COLLECTION

Sample size:-

$$n = \frac{Z^2 p(1 - p)}{D^2}$$

Z= 1.96 = Standard Normal Variable.

P= 0.03 = Prevalence

D= 0.05 = error term

$$= \frac{(1.96)^2 \times 0.03 \times (1 - 0.03)}{(0.05)^2}$$

n=40

Sampling Technique-

1. Screening of patients will be done by using a Purposive Sampling Method which meet the inclusion criteria.
2. 40 patients of *Vataj Shirorog* will be purposively selected in OPD and IPD basis irrespective of gender, economic status, religion, occupation.

METHOD FOR DATA COLLECTION RELEVANT TO OBJECTIVES-

The patients will be assessed on the basis of subjective parameter.

SUBJECTIVE PARAMETER-

A. Pain : Headache

a) Sites of pain- Shankha, Lalat, Manya, Karna^[10]

- Grade 4- All 4 sites involved
- Grade 3- Any 3 sites involved
- Grade 2- Any 2 sites involved
- Grade 1- Any 1 sites involved
- Grade 0- No sites involved

b) Type of pain-

- Grade 4- Unbearable
- Grade 3- Distressing
- Grade 2- Tolerable
- Grade 1- Mild
- Grade 0- No pain

c) Duration of pain-

- Grade 4- 18 – 24 hour
- Grade 3- 12-18 hour
- Grade 2- 6-12 hour
- Grade 1- 15min- 6 hour
- Grade 0- No pain

d) Frequency of pain-

- Grade 4- 1-2 episodes/ week
- Grade 3- 1-2 episodes/ month
- Grade 2- 1-2 episodes/ 3 month
- Grade 1- 1-2 episodes/ 6 month
- Grade 0- No pain

B. Bhrama(vertigo)-

- Grade 3- Unbearable
- Grade 2- Disturbance in work
- Grade 1- Tolerable
- Grade 0- Absent

C. Associated symptoms^[10]:-

1. *Karnaswana* (tinnitus)-
Present- 1
Absent- 0
2. *Seerasphuran*-
Present- 1
Absent- 0
3. *Hanugraha* (va)^[11]-
Present- 1
Absent- 0
4. *Akshikarshan*-
Present- 1
Absent- 0
5. *Manyastambha*(neck stiffness)-
Present- 1
Absent- 0
6. *Prakash Akshamta*^[11](photophobia)-
Present- 1
Absent- 0
7. *Ghranastraav*^[11](coryza)-
Present- 1
Absent- 0

Total score of symptoms = 26

Interpretation of scores are as follows:-

0-6 = No significant headache

7-12 = Mild headache

13-18 = Headache with moderate severity

19-26 = Severe headache

OBSERVATIONS:-

Observations will be drawn from the outcome of the treatment.

STATISTICAL ANALYSIS:-

Analysis will be done on the basis of data collected using **Z test**. Also other applicable tests will be applied.

DISCUSSION:-

On the basis of available data and statistical analysis, discussion will be done.

CONCLUSION:-

From the available data conclusion will be drawn.

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10. निस्तुद्येते भृशं शंखौ घाटा सम्भिद्यते तथा|
भ्रुवौर्मध्यं ललाटं च तपतिवातिवेदनम् ||१९||
वध्यते स्वनतः श्रोत्रे निष्कृष्येते इवाक्षिणि|
घूर्णतिव शिरः सर्वं सन्धिभ्य इवमुच्यते ||२०||
स्फुरति अतिसिराजालं स्तभ्यते च शिरोधरा|

स्निग्धोष्णमुपशेते च शिरोरोगे अनिलात्मके ||२१|| च.सु १७/१९-२१

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भ्रुवौर्मध्यं ललाटं च पततिवातिवेदनम् ||४||
बाध्यते स्वनतः श्रोत्रे निष्कृष्येते इवाक्षिणि|
घूर्णतिव शिरः सर्वं सन्धिभ्य इवमुच्यते ||५||
स्फुरति अतिसिराजालं कन्धराहनुसंग्रह|

प्रकाश अक्षमता घ्राणस्त्रावो अकस्माद्द्वयाथाशमौ ||६||

मार्दवं मर्दनस्नेहस्वेदबन्धैश्च जायते ||अ.ह.उ.२३/४-६

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ANNEXURE 1
MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

CASE RECORD FORM

“EFFICACY OF SNEHIK NASYA (CHARAKOKTA PANCHAGAVYA GHRIT) IN VATAJ SHIROROG”

| | |
|------------------------------|----------------------------|
| Guide: | P.G. Scholar: |
| Sr no: | Date: |
| Patient's name: | Age: |
| Address: | Sex: |
| Phone no.: | OPD No.: |
| Occupation: | IPD No.: |
| Date of commencement of T/t: | Date of Completion of T/t: |

1) Marital status: Married , Unmarried

2) Eco. Status: Higher/ Middle/ Lower

3) Educational Status: Literate/ Illiterate

4) Religion: Hindu/ Muslim/Buddha/Other

5) Occupation:

6) Present complaints with duration:

7) H/O present illness :

8) H/O past illness HTN/DM/MI :

9) DIET: Veg./ Non Veg./Mixed/Oily

10) Sleep: Day:.....Hr Sound/ Disturbed.

Night:.....hr Regular/ Irregular

- 11) Habits/ Addiction :.....
- 12) Exercise: Mild/ Moderate/ Severe Regular/Irregular
- 13) Daily Work: sitting/ Standing/Wandering/Labour/.....
- 14) Defecation:.....times Micturation:.....times
- 15) Average Working hr.:.....
- 16) Average Resting hr.:.....
- 17) Family history: DM/ HT/ T.B./Asthama/ Cardiac problems/ Ano Rectal
Disease
- 18) General examination :
- Ashtavidha Pariksha-
- | | |
|----------------|-----------------|
| <i>Nadi :</i> | <i>Shabda:</i> |
| <i>Mala ::</i> | <i>Sparsha:</i> |
| <i>Mutra :</i> | <i>Druka:</i> |
| <i>Jivha :</i> | <i>Akruti:</i> |
- 19) Systemic examination:-
- RS-
- CVS-
- CNS-
- B.P.:-
- P:-
- 20) Prakrutivinishchaya;- V / P / K / VP /PK /VK /VPK
- 21) Dushta Strotas Parikshan:-
-
-

22) Assessment criteria (before treatment)

Dt- (----/----/-----)

Pain sites:- *Shanka, Lalat, Manya, Karna*

| GRADE | 4 | 3 | 2 | 1 | 0 |
|-------------------|----------------------|----------------------|-----------------------|-----------------------|-----------|
| Sites of pain | All 4 sites involved | Any 3 sites involved | Any 2 sites involved | Any 1sites involved | No sites |
| Type of pain | Unbearable | Distressing | Tolerable | Mild | No pain |
| Duration of pain | 18 – 24 hour | 12-18 hour | 6-12 hour | 15min- 6 hour | No pain |
| Frequency of pain | 1-2 episodes/ week | 1-2 episodes/ month | 1-2 episodes/ 3 month | 1-2 episodes/ 6 month | No pain |
| Bhrama | ----- | Unbearable | Disturbance in work | Tolerable | No Bhrama |

ASSOCIATED SYMPTOMS:-

| GRADE | 1- PRESENT | 0- ABSENT |
|-------------------------|-------------------|------------------|
| <i>Karnaswana</i> | | |
| <i>Seerasphuran-</i> | | |
| <i>Hanugraha</i> | | |
| Akshikarshan | | |
| <i>Manyastambha</i> | | |
| <i>Prakash Akshamta</i> | | |
| <i>Ghranastraav</i> | | |

23) *Samprapti Vidnyan:-*

Hetu:-

Dosha:-

Dushya:-

Strotas:-

Adhishthana:-

24) Total score of symptoms = ____ / 26

25) Interpretation of scores are as follows:

0-6 = No significant headache

7-12 = Mild headache

13-18 = Headache with moderate severity

19-26 = Severe headache

26) Diagnosis:- _____

27) Treatment: - *Panchagavya Ghrit Pratimarsha Nasya*

28) Assessment of symptoms:-

15th day:- _____

30th day:- _____

29) Assessment criteria (after treatment)

Dt- (----/----/-----)

Pain sites:- *Shanka, Lalat, Manya, Karna*

| GRADE | 4 | 3 | 2 | 1 | 0 |
|-------------------|----------------------|----------------------|-----------------------|-----------------------|-----------|
| Sites of pain | All 4 sites involved | Any 3 sites involved | Any 2 sites involved | Any 1 sites involved | No sites |
| Type of pain | Unbearable | Distressing | Tolerable | Mild | No pain |
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| Bhrama | ----- | Unbearable | Disturbance in work | Tolerable | No Bhrama |

ASSOCIATED SYMPTOMS:-

| GRADE | 1-PRESENT | 0-ABSENT |
|-------------------------|------------------|-----------------|
| <i>Karnaswana</i> | | |
| <i>Seerasphuran-</i> | | |
| <i>Hanugraha</i> | | |
| Akshikarshan | | |
| <i>Manyastambha</i> | | |
| <i>Prakash Akshamta</i> | | |
| <i>Ghranastraav</i> | | |

30) Follow up:-

45th day:- _____

60th day:- _____

31) Upashaya :-

Marked relief:- Above 75% improvement

Moderate relief:- 50-75% improvement

Mild relief:- 25-50% improvement

No relief:- below 25% improvement

Signature of student

ANNEXURE 2

CONSENT FORM

TITLE:- “ EFFICACY OF SNEHIK NASYA (CHARAKOKTA PANCHAGAVYA GHRIT) IN VATAJ SHIROROG”

I Mr/Mrs.....given my consent to be included as subject in clinical trails of above study and may be treated with this drugs for above disorder. I have been fully explained the procedure of treatment given to me. I have been informed to my satisfaction by altering physician for the purpose of clinical trials and also the nature of drugs and follow up including various investigations to monitor and safeguard of my health.

I am also aware of my right to out of trials at any stage during the course of study without giving any reason.

Date:

Investigator's Signature:-

Signature of patient

मी श्री/श्रीमती _____

या चिकित्सा संशोधनाबद्दल सर्व माहिती जाणून व औषधाच्या चिकित्सिय परिक्षणाला सहमती देत अहोत. मी ज्या रोगाने पिडित आहे त्या रोगाची चिकित्सा या उपचाराने केली जाते हे मला माहित आहे. या उपचाराने होणारे लाभ व नुकसानाची मी वेळोवेळी चिकित्सकाला संपूर्ण माहिती देईल आणि आपल्या स्वास्थ रक्षणार्थ विभिन्न चिकित्सिय परिक्षणा करता मी सहाय्य करेल.

मला हे माहित आहे की मी हे चिकित्सिय परिक्षण स्वतःच्या जबाबदारीवर कधीही सोडु शकतो.

दि.

चिकित्सकाची स्वाक्षरी

रूग्णाची स्वाक्षरी

ANNEXURE 3 :

Abbreviations

- 1) च.सू.-चरक सूत्रस्थान
- 2) च.चि- चरक चिकित्सास्थान
- 3) अ.ह.सु- अष्टांग हृदय सुत्रस्थान
- 4) अ.ह.उ- अष्टांग हृदय उत्तरस्थान
- 6) शा.सं.उ- शारंगधर संहिता उत्तर खण्ड
- 7) SOP-Standard of Preparation
- 8) ml-milliliter

ANNEXURE 4

Pain sites:- *Shanka, Lalat, Manya, Karna*

| GRADE | 4 | 3 | 2 | 1 | 0 |
|-------------------|----------------------|----------------------|-----------------------|-----------------------|-----------|
| Sites of pain | All 4 sites involved | Any 3 sites involved | Any 2 sites involved | Any 1 sites involved | No sites |
| Type of pain | Unbearable | Distressing | Tolerable | Mild | No pain |
| Duration of pain | 18 – 24 hour | 12-18 hour | 6-12 hour | 15min- 6 hour | No pain |
| Frequency of pain | 1-2 episodes/ week | 1-2 episodes/ month | 1-2 episodes/ 3 month | 1-2 episodes/ 6 month | No pain |
| Bhrama | ----- | Unbearable | Disturbance in work | Tolerable | No Bhrama |

ASSOCIATED SYMPTOMS:-

| GRADE | 1-PRESENT | 0-ABSENT |
|-------------------------|-----------|----------|
| <i>Karnaswana</i> | | |
| <i>Seerasphuran-</i> | | |
| <i>Hanugraha</i> | | |
| Akshikarshan | | |
| <i>Manyastambha</i> | | |
| <i>Prakash Akshamta</i> | | |
| <i>Ghranastraav</i> | | |

