

RANDOMISED CONTROLLED CLINICAL TRIAL TO COMPARE THE EFFICACY OF SHEPHALI PATRA KWATHA AND TRAYODASHANGA GUGGULU IN MANAGEMENT OF GRUDHRASI**Dr. Priya Bapurao Jadhavar^{*1} and Dr. Sadanand V. Deshpande²**¹PG Scholar, Department of Kaychikitsa, TAMV Pune.²HOD Kaychikitsa, TAMV Pune.Article Received on
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Kaychikitsa, TAMV Pune.**ABSTRACT**

Ayurveda is an ancient system of medicine. Ayurvedic science describes what is essential and what is harmful for long lasting healthy and prosperous life. Ayurveda having aim, that is protection of health and prevention from disease which is possible due to the identification of disease And removal of the root Cause of the disease. Today medical science becomes advanced with the invention of newer and finest technology. Due to the easily available medical facilities, health awareness amongst people leads to increase in life span. In Grudhrasi piercing type of pain which restricts the movement of affected leg, make his walking pattern like bird vulture and put him in disgraceful condition. Grudhrasi is routine disturbing disease due to pain, chankramankashtata. In modern limited medical science limited

temporary treatment option available like analgesic, NSIDS or steroids. In Ayurveda plenty of drugs and their many kalpanas are effective on Grudhrasi (sciatica). Present study on Shephalipatra Kwath and Trayodashang Guggulu by oral administration. To revalidate its efficacy in management of Grudhrasi (sciatica), this topic has been selected.

KEYWORDS: Grudhrasi, Sciatica, Chankramankashtata, Shephalipatra Kwatha, Trayodashanga guggulu, Allopathy.

INTRODUCTION

In this extremely growing competitive era various activities like travelling, tremendous work load, consumption of unhealthy food leads to various types of diseases. The aim of ayurveda is to Maintain health and then to cure disease.^[1]

The causes for the disease related to both mind and body are Atiyog (excessive utilisation), Heena yog (less utilisation) and mithya yoga (wrong utilisation) of kala (time), Buddhi, Indriya (objects of sense organs).

The disease Grudhrasi is described in classical texts by its name and included under 80 types of Vatavyadhi. It is pain dominant disease and reduces human activity considerably in terms of personal as well as social and professional life. The condition resembles disease Grudhrasi mentioned in ayurveda under the umbrella of Vatavyadhi and here piercing type of pain which restricts the movement of affected leg, make his walking pattern like bird vulture and put him in disgraceful condition. In this modern era change in lifestyle is major cause of sciatica (Grudhrasi) with prevalence rate of 5% in general population according to a Research Article.^[2]

In Shephali Patra Kwatha, shephali (Nirgundi) is the only one content which is katu, tikta rasatmaka and its virya is Ushna and having Katu vipaka. Gunas of shephali are laghu and ruksha and doshaghata is kaphavatahamaka.

In Trayodashanga guggulu most of dravyas have madhur and katu, tikta rasatmaka properties and vatakapashamak and tridoshashamaka properties.

Ayurveda classics have given a detailed description about the treatment of vata vyadhi but detailed description about treatment of grudhrasi is mentioned by few experts only. Also in Grudhrasi there is a severe type of pain which restricts the movement of affected leg, make his walking pattern like bird vulture and put him in disgraceful condition. Therefore the present study has been planned to evaluate the effect of Shephali Patra Kwatha and Trayodashanga Guggulu in the management of Grudhrasi.

AIM AND OBJECTIVES

Aim

To compare the efficacy of Shephalipatra Kwatha and Trayodashanga Guggulu in management of grudhrasi.

OBJECTIVES

1. To assess the efficacy of Shephalipatra Kwatha in the management of Grudhrasi.
2. To assess the efficacy of Trayodashang Guggulu in the management of Grudhrasi.

3. To compare the effect of Shephalipatra Kwatha and Trayodashanga Guggulu in the management of Grudhrasi (Sciatica).

OTHER OBJECTIVES

1. To study in detail about Grudhrasi (Sciatica) according to ayurvedic classics.
2. To Observe Change in SLR Test.
3. To Observe Any Adverse Effect.

MATERIALS AND METHODS

Grudhrasi

Nidan^[3]

Causative factor having ability to produce disease is Nidan. Hetusevan is primary process of vyadhi utpatti. Grudhrasi is counted fewer than 80 types of Nanatmaja Vatavyadhi. Cause of Grudhrasi is considered as Vitiating of Vata dosha. Vitiating of Vata dosha is happened due to following 2 components:

1. Dhatukshayajanya Vataprakop.
2. Margavarodhjanya Vataprakopa.

These Nidanas (hetus) are considered under 5 groups

- 1) Aharaj- Rukshaya Anna, Sheet Anna, Alpa (Parimit) Anna, Laghu Anna, Langhana, Anashana (Abhojana), Katu, Tikta, Kashaya Rasa atisevan, Shusha Shak, Shushka Mansa.
- 2) Viharaj-Ativyaya, Ativyayam, Aticheshta, Dukkha Shayya, Abhighata, Marmabhighata, Balwat, Vighraha, Prapatan, Ati Adhyayana, Prahar/Prapidan, Bhara Vahan, Vega Vidharan, Uchchaye Bhashanam, Padaaticharya
- 3) Kalaj- Chinta, Krodha, Bhaya, Shoka, Tamoguna pradhyana
- 4) Manasik- Pravata, Grishmante, Jeernante, Ahoratri, Shishir Rutu, Varsha Rutu, Pradoshe, Sheet Kala, Abhira kala, Prabhat kala, Aparahna
- 5) Miscellaneous

Purvaroop^[4]

Charakaacharya mentioned that, in Vatavyadhi, purvarupas are "Avyakta". Chakrapani cleared it in tika that, few mild symptoms can be considered as purvaroop.

Purvaroopas divided into two types.

1. Samanya purvaroop
2. Vishesh purvaroop

Roop^[5]

स्फिकपूर्वा कटिपृष्ठोरूजानुजंघापदम क्रमात् ।

गृध्रसी स्तंभरुक्तोदै गृहणाती स्पंदते मुहुः॥

वाताद वातकफात तन्द्रागौरवारोचकान्विता ॥

च.चि. २८/७६-७७.

Samprapti^[6]

“देहे स्रोतांसि रिक्तानि पुरयित्वानिलो बली ।

करोति विविधान् व्याधिन् सर्वाङ्गैकान्गस्त्रितान् ॥”

(च. चि. २८/१८)

Nidana	<i>Hetusevan (Vataprakopa), Dhatukshayajanya Margavarodhak)</i>
Dosha	<i>Vata , Vata- Kapha</i>
Dushya	<i>Rasa, Rakta, Mansa, Meda , Asthi ,Kandara and Snayu.</i>
Agni	<i>Jatharagni and Dhatvagni</i>
Udbhavsthana	<i>Pakvashaya for Vata, Aamashaya for VataKapha.</i>
Strotas	<i>Rasavaha, Mansavaha, Medovaha, Asthivaha.</i>
Strotodushti	<i>Sanga and Vimargagamana.</i>
Bheda	<i>Vataj and vatkaphaj</i>
Swabhava	<i>Chirkari</i>

Study Design – Randomized controlled clinical trial.

Study Setting- In OPD & IPD of Kayachikista department of concerned Medical institute. Cases will be divided in 2 groups i.e. Group A & Group B Respectively. Both the group will comprise same no. of cases according to gender equally.

Group A- Was received Shephalipatra Kwatha.

शेफालिकादलवकाथो मूढग्निपरिसाधितः ।

दुर्वारं गृध्रसीरोगं पीतमात्रं समुद्धरेत् ॥४७॥

(भैषज्यरत्नावली २६/४७)

Group B- Was received Trayodashang Guggulu.

आभाऽश्वगन्धा हपुषा गुडूची शतावरी गोक्षुरकं च रास्ना।

श्यामा शटी घोषवती यवानी सनागरा चेति समं विचूर्ण्य ॥१॥

सर्वैः समं गुग्गुलुमत्र दत्त्वा कुर्यात्ततोऽधः प्रणिधाय सर्पिः।

अर्धाक्षमात्रा गुटिकास्ततोऽस्य कार्याः पुरस्याथ दिनाननेऽद्यात् ॥२॥

एकां ससर्पिर्मधुना यथा न स्पर्शो भवेदन्ततः कथञ्चित् ।

ततः कवोष्ण सलिलं सुरं वा गव्यं पयो वाऽप्यथ मुद्गयूषम् ॥३॥

किं वा रसैर्मासभर्वैर्निपीय तवङ्गमेकं बढने निदध्यात् ।

कटिग्रहे गृध्रसिबाहुष्पृष्ठे हनुग्रहे जानुपदग्रहे च ॥४॥

सन्धिस्थिते वास्थिगते समरि मज्जाश्रिते स्नायुगतेऽतिदुष्टे ।

शूलद्रव्ये पार्श्वशिरोरुजायां मन्याग्रहे कण्ठहृदोर्ग्रहे हे वा ॥५॥

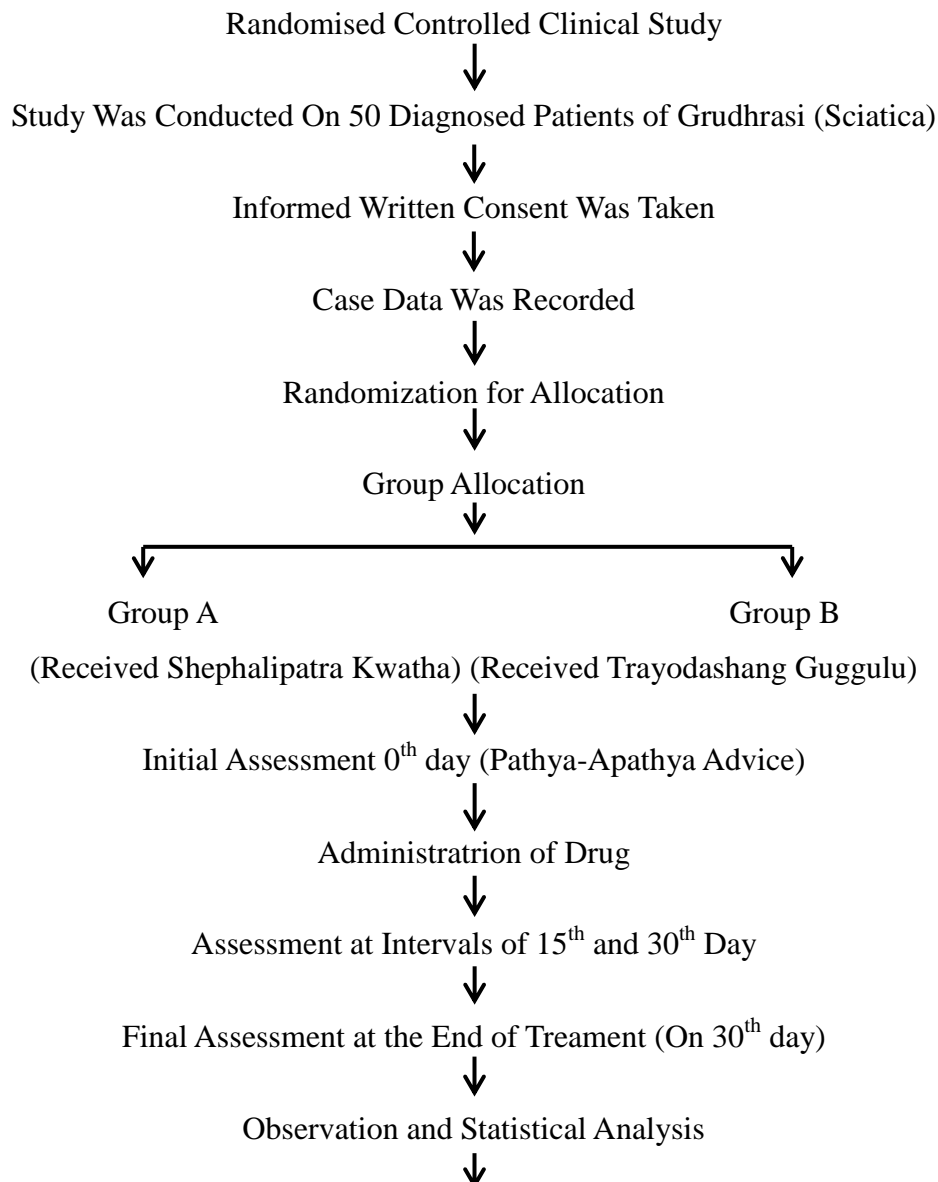
त्रयोदशाङ्गोऽयमतिप्रशस्तो जयेद् गहान् वातकफप्रभूतान् ॥६॥

(योगरत्नकर १-६)

Duration of Study- 30 days

Place of Work

OPD and IPD of kayachikitsa, Male and Female ward of concerned hospital.



Discussion



Conclusion

Study Population

Patients of age group 25-60 years of any cast, any occupation, any religion, and socioeconomic status in IPD & OPD.

Detailed Research Plan

The proposed study was done primarily in three levels.

Level 1- Conceptual review of the subject.

Level 2- Generation of data on Standardization of drugs used for study.

Level 3- Comparative clinical trial.

Sampling Technique

Patients fulfilling inclusion criteria will be selected from institute's OPD & IPD and were grouped into Group A & Group B with 25 patients in each group.

Procedure

1. Permission for conduction of trial and no objection certificate from Institutional Ethics committee was taken.
2. Written informed consent was taken from every patient.
3. Proper case history was taken and special case record was prepared.
4. Clinical findings were recorded as per case record form.

Method of Selection of Study Subjects

All patients attending kayachikitsa O.P.D. and I.P.D. of our hospital were selected irrespective of religion, economic status, education, occupation etc. also having clinical symptoms of Grudhrasi with Objective Like SLRT, Oxford Pain Chart, Visual Analog Scale, Walking Time.

Inclusion Criteria

- Age Group 25- 60 years
- Patient Having Signs and Symptoms of Grudhrasi (Sciatica) ie Shool, Stambha, Toda, Graha, Kaphaj Lakshanas - Tandra, Gaurava, Vanhimardava, Bhaktadwesh.
- Patient in Which One Leg Is Affected.

Exclusion Criteria

- Age Group <25 and >60 years.
- Patient having spinal deformities, severe traumatic injury to spinal cord, Spinal tumors were excluded.
- Patient having nerve root compression was excluded.
- Patient having major illness since long time and Systemic pathogenesis Eg. Cardiac, Renal, Diabetics, Autoimmune Diseases Etc.
- Pregnancy and PNC patients were excluded.
- Complicated cases like Pott's spine, Vertebral fracture, acute vertebral disc prolapse, vertebral fusion, vertebral herniation, vertebral sacralisation, and Bamboo spine were excluded.
- HIV, HBsAg positive. Patient affected with both legs were excluded.

Withdrawal Criteria

- Occurrence of Serious Adverse Effect.
- Patient has become non co-operative.

Treatment Permitted

In emergency cases lifesaving drugs, antibiotics, IV Fluids were permitted if two experts agree on their necessity.

Treatment Not Permitted

- During the trial- Analgesics, Corticosteroids, Local application of steroid and analgesics.
- Self-Medication.

Criteria For Assessment

- Special case paper was prepared incorporating all Sign and symptoms of gudhrasi (Sciatica) were recorded according to severity.
- Oxford pain chart was prepared and assessed before, during and after treatment.
- Darshan, sparshan, prashnapariksha.
- Investigations like X-Ray L.S. spine with preparation was done as per necessity.
- Subjective parameters.

A) Subjective Criteria

1. Shoola (Pain)

2. Toda (Pricking Sensation)
3. Stambha (Stiffness)
4. Graha
5. Bhaktadwesh (loss of appetite)
6. Tandra (Drowsiness)
7. Gaurav (Feeling Of Heaviness)
8. Vanhimardav

Grading and scoring:

1) Shool

0	No Pain
1	Occasional Pain
2	Mild Pain
3	Moderate Pain
4	Severe Pain

2) Toda

0	No Pricking Sensation
1	Occasional Pricking Sensation
2	Mild Pricking Sensation
3	Moderate Pricking Sensation
4	Severe Pricking Sensation

3) Stambha

0	No Pricking Sensation
1	Occasional Pricking Sensation
2	Mild Pricking Sensation
3	Moderate Pricking Sensation
4	Severe Pricking Sensation

4) Graha

0	No Twitching
1	Sometime for 5-10 min
2	Daily for 10-30 min
3	Daily for 30-60 min
4	Daily more than 60 min

5) Bhaktadwesh

0	Absent
1	Mild
2	Moderate
3	Severe

6) Tandra

0	Absent
1	Mild
2	Moderate
3	Severe

7) Gaurav

0	Absent
1	Mild
2	Moderate
3	Severe

8) Vanhimardav

0	Absent
1	Mild
2	Moderate
3	Severe

Objective parameters

1. SLR Test
2. Oxford Pain Chart
3. Visual Analogue Scale
4. Walking Time

1) SLR Test

G0	80-90
G1	51-80
G2	31-50
G3	<30

2) Oxford pain chart

Sr.No	Grading	Condition	Score
1	0	No Pain	0
2	+	Mild Pain Precipitating Time To Time With Heavy Movement	1
3	++	Moderate Pain, Continuous During Movement	2
4	+++	Severe Pain, Patient Unable To Do Any Movement	3

3) Visual Analogue Scale

There will be a 10cm horizontal line on each follow up, for pain assessment. There is an O marking on left hand side end and marking of 10 on right hand side end. All symptoms were

assessed by using this scale. For example-pain 0 indicates absolutely no pain. 10 indicate severe most pain.

Each centimetre indicates digits from 0 to 10. Patient was asked to grade their pain and define according in numbers.

4) Walking Time

Walking time of patient for distance to 30 meters recorded on 0th day, 15th day and 30th day.

Medication and Treatment given

Group	Group A	Group B
No.of Patients	25	25
Treatment	Shephali Patra Kwatha	Trayodashang Guggulu
Dose	80ml/day (40 ml BD)	5gm/day (2.5 gm BD)
Route	Oral	Oral
Anupan		Madhu/Ghrita
Kalpana	Kwatha	Vati
Kal	Vyanodan kal	Vyanodan kal
Duration	30 days	30 days
Follow up	At 15 th , 30 th day	At 15 th , 30 th day

RESULT

1) In the present study, in Group A, received Shephalipatra Kwatha had got relief in symptoms Shool by 62.92%, Toda by 68.24%, Stambha by 50.82%, Graha by 58.93%, Bhaktadwasha by 56.76%, Tandra by 57.89%, Gaurav by 58.06%, Vanhimardav by 65.31%, SLRT by 25.81%, Oxford pain chart by 50.00%, Visual analogue scale by 50.00% and Walking time by 54.17%.

2) Whereas, effect of Trayodashanga Guggulu with anupan madhu/ ghrita in symptoms Shool by 57.30%, Toda by 58.82%, Stambha by 45.65%, Graha by 48.48%, Bhaktadwasha by 54.17%, Tandra by 47.62%, Gaurav by 50.00%, Vanhimardav by 41.67%, SLRT by 24.62%, Oxford pain chart by 38.46%, Visual analogue scale by 45.55% and Walking time by 43.08%.

DISCUSSION

- In this clinical study Group A with Shephalipatra Kwatha was given to the patients of Grudhrasi.
- The reduction in objective and subjective parameters was observed after 15th and 30th days of treatment.

- Similarly Group B with Trayodashanga Guggulu was given to patients with anupan madhu/ ghrita.
- It was found that there was more effect of Group A with Shephalipatra Kwatha as the overall percentage of effectiveness was 54.91% as compared to Group B with Trayodashanga Guggulu which was 46.28%

From the above information it may be possible to say, that Shephalipatra Kwatha provided significant and better relief in qualitative and quantitative parameters. This may be due to action of Shephalipatra Kwatha is more strong. Also Shephalipatra Kwatha has Deepana and Pachana properties and Shephalipatra Kwatha is a drug of choice in Grudhrasi as per Ayurvedic text. As per Ayurvedic text if we improve the Agni of patients the disease will be easy to cure. Though the Group B obtains less result it can be given for more duration which is useful for replenishing the dhatus in kshaya avastha.

Hence it can be stated that Shephalipatra Kwatha works more effectively than Trayodashanga Guggulu.

CONCLUSION

- After observing and analyzing the raw data we have come to the conclusion that both drugs are effective as a treatment in Grudhrasi but Shephalipatra Kwatha is more effective than Trayodashanga Guggulu.
- Incidence is more in females compared to males. Maximum prevalence is in the elderly age group.
- Classical Ayurvedic text cited that the Grudhrasi Chikitsa is chiefly “Lekhana and Kledashoshana” Chikitsa, which play an important role in Sampraptibhanga. Here Shephalipatra Kwatha is more effective than Trayodashanga Guggulu with these properties.
- The quantitative parameter (Oxford Pain Chart and Visual Analogue Scale) showed significant difference in the patient of Group A as compared to Group B.
- The qualitative parameters (Shool, Toda, Stambha, Graha, Tandra and Vanhimardav) showed significant difference in the patient of Group A as compared to Group B.
- Group A had a higher mean of overall percentage relief when both qualitative and quantitative parameters were considered.

- In the present study, Shephalipatra Kwatha establishes notable improvement in subjective as well as objective parameters.
- There is evidence to state that Shephalipatra Kwatha is significantly effective in Grudhrasi.

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