WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 11, Issue 11, 1572-1583. Research Article ISSN 2277– 7105

CLINICAL STUDY TO EVALUATE THE EFFICACY OF '*DASHMOOLADI KASHAYA*' IN THE MANAGEMENT OF *GRIDHRASI* (SCIATICA)

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Article Received on
20 June. 2022,

Revised on 10 July 2022,
Accepted on 31 July 2022

DOI: 10.20959/wjpr202211-25188

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ABSTRACT

Ayurveda is the traditional, ancient system of health science. According to *Ayurveda*, Tridosha are the factors which are responsible for health (*Doshasamyata*) or cause of disease (*Doshavaishamyata*). Among *Tridosha*, Vata is an essential constituent and responsible for maximum diseases and *'Gridhrasi Roga'* is one of them. It can be correlated with Sciatica in modern medical science through its clinical presentation. Modernization and rapid living are the order of the day. Everyone is preoccupied and leads a hectic life. The modern human being's changing lifestyle has resulted in a number of biological inconsistencies. Overexertion, incorrect sitting posture in the office or prolonged work in one posture as a result of a busy professional and social life. Lifting large weights, jerking motions when travelling, and other factors place unnecessary pressure and stress on the spine, contributing to diseases such as sciatica.

KEYWORDS: *Ayurveda, Doshasamyata, Gridhrasi,* Sciatica.

INTRODUCTION

The lifetime incidence of sciatica is estimated to be between 13% and 40%. The prevalence of sciatic symptoms reported in the literature varies considerably ranging from 1.6% in the general population to 43% in a selected working population. The lifetime prevalence of true sciatica has been reported at 5.3% in men and 3.7% in women. In sciatica there is spinal nerve irritation producing pain in the area of distribution of sciatic nerve which is often associated with lumbago. The symptoms of sciatica can be correlated to the disease called Gridhrasi, mentioned in Ayurvedic text under Vata Vyadhi, having symptoms like Ruk (pain). Toda (pricking Sensation), Stambha(stiffness), Spandana (twitching), Sigtuna (numbness) and Rick (pain) radiating from Kat-Pradesha (lumbosacral region) to Padangull (foot). In modem medicine, the management of sciatica includes analgesics, epidural steroid injections, peri-radicular infiltration and surgical treatment at the cost of their own limitations and complications. While in barved there are therapies like Bheshaja, Shehana, Svedana, Siravedha, Agnikarma and vasti karma which are simple, safe and cost effective.

The cardinal clinical features of 'Gridhrusi Roga' are:-

- **Stambha** (Stiffness)
- **Ruk** (Pain)
- **Toda** (Pricking Sensation)
- **Spandana** (Twitching sensation) in the*Sphik- Katiprishtha - Uru – Janu- Jangha-Pada in order.*
- In *Kaphanubandha Gridhrusi* ***Tandra, Gaurava*** and ***Arochaka*** are also present.

Indeed, patients at high risk for becoming disabled, often receive more diagnostic tests and less focus in medical management, leading to chronic condition. Moreover, the modern treatment of Sciatica is not very satisfactory and includes use of Analgesics, Corticosteroids and few surgical Procedures, which is often associated with many adverse effects. Because of such problems, it affects not only the social and economical position of the individual and his family, but also leads to draining of national resource due to working hours lost, resulting into diminished production.

The incidence and prevalence of back pain and sciatica in world is underscored by the following:-

- Back Pain is the most common cause of disability in patients in which 40% radicular pain.

- Sciatica is a relatively common condition with a lifetime incidence varying from13% to 40%. The annual incidence of a sciatica recurrence typically varies from 1% to 6%.
- The lifetime prevalence of true sciatica has been reported at 5.3% in men and3.7% in women. It is generally accepted that 90% of acute episodes of low backpain settle, allowing return to work within 6 weeks.
- The prevalence of sciatic symptoms has been documented in the literature to range from 1.6 percent in the general population to 43 percent in a specific working population.
- Risk factors include male gender, age, heavy weight lifting or twisting, increasing height, stressful occupation, walking, jogging (if a previous history of sciatica),
  lower income and cigarette smoking.
- Sciatica is most common in men and develops one to three times more frequently in men than in women in their third to sixth decades of life.
- Many herbal formulations (*Churna, Vati, Guggulu, Kwatha and Taila*) for the management of '*Gridhrasi Roga*', are described in *Ayurvedic* literature and their therapeutic effect is yet to be explored. On the quest of such an effective management of '*Gridhrasi Roga*', we came across some very effective drugs, which have been individually proven successfully such as '*Dashmooladi Kashaya'.*
- These drugs having effective properties to manage *Vatavyadhies* and given good results in various researches on clinical trials. For a better and stable result, a combination of these drugs was selected for trial.

AIMS AND OBJECTIVES

✓ To study aetiopathogenesis, symptomatology and progress of 'Gridhrasi (Sciatica).

✓ Clinical evaluation of Dashmooladi Kashaya in the management of Gridhrasi.

✓ To evaluate adverse drug reaction of trial drug.

MATERIALS AND METHODS

Following material and method will be adopted for conducting the present research study.

- Selection of patients Well diagnosed and confirmed 40 patients of Sciatica will be selected randomly from OPD & IPD of P. G. Deptt. Of Kayachikitsa, Hospital of University college of Ayurved, Jodhpur.

SELECTION CRITERIA

Inclusion criteria

- The Patients between the age group of 20 to 60 years in either sex presenting with clinical features of Sciatica.
- Well diagnosed & confirmed patient of Sciatica on the basis of Modern texts.
- Patients with presence of Ruk, Toda, Stambha and Spandana in the Sphik, Kati, Uru, Janu, Jangha and Pada
- Patient with tenderness along the course of Sciatic nerve.
- S.L.R. test in affected leg as objective measure for diagnosis as well as for improvement of the treatment. 6) Popliteal Compression Test.
- Foot Flexion Test.
- Knee-Jerks and Ankle-Jerks.

Exclusion Criteria

The patients suffering from following conditions will be excluded from the study.

- Cancer of spine
- Tumour of Cauda Equina and Lumbosacral Plexus
- Uncontrolled Diabetes Mellitus
- Cardiovascular Disease
- Pregnancy
- Tuberculosis of Vertebral Column

MODE OF ADMINISTRATION

40 well diagnosed and clinically confirmed patients of Gridhrasi (Sciatica) will be administered Dashmooladi Kashaya in the dose of 20 ml twice a day with lukewarm water for 45 days.

FOLLOW UP

1. Patients will be followed up on every 7 days.
2. Improvement and other effect will be noted.
3. Laboratorial investigations repeated for the assessment.

TRIAL DRUG

1. Dashmooladi Kashaya

दशमुलाबलारास्नागुडुचीविश्वभेषजम

ग्रधसीखंञपंगुषु ।। (Chakradutta-Vatavyadhi Chikitsa / 40)

CRITERIA FOR ASSESSMENT

The improvement in the patient will be assessed mainly on the basis of relief in the cardinal signs and symptoms of the disease. According to Acharya Charaka the sign & symptoms of Gridhrasi are as follows-

स्फिक्पूर्वा कटिपृष्ठोरुजानुजंघाद ं क्रमात्।

गृध्रसी स्तम्भरुकोदैर्गृह्यति स्पन्दते मुहुः।। (च. चि. **28 / 56**)

To assess the effect of therapy objectively, all the sign and symptoms will be scored depending upon their Grade as described below.

1. *Stambha* (Stiffness)

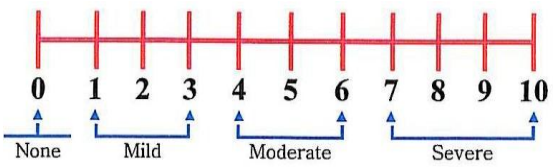
1.	No stiffness	0
2.	Some time for less than 30 min.	1
3.	Daily for 30 min. to 1 hour	2
4.	Daily for 1-2 hour	3
5.	Whole the day	4

2. *Ruka (*Pain*)*

All the patients registered for present trial will be looked for any changes in their growing feeling ofwellbeing, pre and post assessment.

To assess feeling of wellness or worsen in pain we will use, "Pain Intensity Instruments" developedby National Institutes of Health – Warren Grant Magnuson Clinical Center. July 2003. Archived from the original (PDF) on 2019-03-24. This scale will be used and analyse on all the registered patient on every follow up. The scoring/rating of this scale as described below –

Numeric Rating Scale



SN	Pain Level	Rating
1	No Pain	0
2	Mild Pain (nagging, annoying, interfering little with activitiesof daily living)	1–3

3	Moderate Pain (interferes significantly with activities of dailyliving)	4–6
4	Severe Pain (disabling; unable to perform activities of dailyliving)	7–10

3. *Radiation of Pain*

1.	No Radiating Pain	0
2.	Pain Radiating to hip and back of thigh	1
3.	Pain Radiating to Popleteal fossa	2
4.	Pain Radiating upto foot	3

4. *Supti* (Numbness)

1.	No Numbness	0
2.	Mild Numbness (Once/day)	1
3.	Moderate Numbness (2-3/day)	2
4.	Continuous Numbness	3

5. *Toda (*Pricking Sensation*)*

1.	No pricking sensation	0
2.	Occasional pricking sensation	1
3.	Mild pricking sensation	2
4.	Moderate pricking sensation	3
5.	Severe pricking sensation	4

6. *Spandana (*Twitching*)*

1.	No twitching	0
2.	Some times for less than 30 min.	1
3.	Daily for 30 min. -1 Hour	2
4.	Daily for 1-2 Hour	3
5.	Whole the day	4

7. *Tandra* (Torpor)

1.	No Tandra	0
2.	Mild Tandra	1
3.	Moderate Tandra	2
4.	Severe Tandra	3

***8. Gaurava* (Heaviness)**

1.	No heaviness	0
2.	Mild heaviness	1
3.	Moderate heaviness	2
4.	Severe heaviness	3

6) Straight leg raise [S.L.R.] test

1.	More than 90°	0
2.	71°-90°	1
3.	51°-70°	2
4.	31°-50°	3
5.	up to 30°	4

7). Diagnostic study

Following pathological and biochemical investigations will be carried out to exclude the possibility ofany other disease as well as to know the present condition and diagnosis of the patients.

1) Haematological analysis – T.L.C., D.L.C., E.S.R., Hb%,
2) Routine and microscopic examination of urine
3) X-ray of Lumbosacral region (Anterior Posterior & Lateral View)
4) MRI (Optional).

Assessment of Progress

Once the therapy start, patient will be assessed till the therapy course will completed and there afterpatients will examined for vital signs and symptoms and for the general body condition. The cases will be subjected to clinical observation as designed earlier throughout the course of treatment to assess the efficacyof the drug from time to time. Clinical & subjective progress up to 45 days will be recorded in case recordform on every follow-up for final assessment of the efficacy of the therapy.

All the Results are calculated by using Software: **In Stat Graph Pad 3.**

- For Nonparametric Data **Wilcoxon matched-pairs signed ranks test** is used while for Parametric Data **Paired‘t’ Test** is used and results Calculated in 40 patients.

Table No. 1: Showing effect of therapy on subjective parameters in 40 patients. (Wilcoxon matched pairs single ranked test).

Variable	N=40	Mean		MeanDiff.	% Relief	SD±	SE±	p value	R
		BT	AT						
Stambha (Stiffness)	N=40	0.71	0.46	0.25	56.00	0.44	0.07	**0.0137**	**S**
Ruka (Pain)	N=40	0.69	0.40	0.29	61.67	0.52	0.09	**0.0039**	**VS**
Radiation of pain	N=40	0.97	0.69	0.28	59.41	0.52	0.09	**0.0039**	**VS**
Supti (Numbnes)	N=40	0.46	0.37	0.09	38.75	0.17	0.03	**0.0625**	**NS**
Toda (Pricking sensation)	N=40	0.46	0.29	0.17	57.50	0.41	0.07	**0.0313**	**S**
Spandana (Twitching)	N=40	0.49	0.34	0.15	29.41	0.36	0.06	**0.0625**	**NS**

Aruchi (Anorexia)	N=40	1.00	0.71	0.29	58.57	0.46	0.08	**0.0020**	**VS**
Gaurava (Heaviness)	N=40	0.66	0.43	0.23	64.78	0.41	0.07	**0.0039**	**VS**
S.L.R Test	N=40	0.60	0.37	0.23	68.10	0.43	0.07	**0.0078**	**VS**

(VS: Very Significant, S: Significant, NS: Non Significant)

Effect of Therapy on *Stambha (Stiffness)*

★ The mean Score before treatment was 0.71 which lowered down to 0.46 after treatment, with SD± 0.44 giving a relief of 56.00% which was statistically **significant. ((p < 0.05))**

Effect of Therapy on *Ruka (Pain)* score

★ The mean Score before treatment was 0.69 which lowered down to 0.40 after treatment, with SD±0.52 giving a relief of 61.67 % which was statistically **Very significant. ((p < 0.01))**

Effect of Therapy on Radiation of pain score

★ The mean Score before treatment was 0.97 which lowered down to 0.69 after treatment, with SD± 0.52 giving a relief of 59.41% which was statistically **Very significant. ((p < 0.01)).**

Effect of Therapy on *Supti (Numbnes)* score

★ The mean Score before treatment was 0.46 which lowered down to 0.37 after treatment, with SD± 0.17 giving a relief of 38.75% which was statistically **significant. ((p < 0.05))**

Effect of Therapy on *Toda* (Pricking sensation) score

★ The mean Score before treatment was 0.46 which lowered down to 0.29 after treatment, with SD± 0.41 giving a relief of 57.50 % which was statistically **very significant. (p < 0.01)**

Effect of Therapy on *Spandana* (Twitching) score

★ The mean Score before treatment was 0.49 which lowered down to 0.34 after treatment, with SD± 0.36 giving a relief of 29.41% which was statistically **Non significant. (p > 0.05)**

Effect of Therapy on *Aruchi* (Anorexia)

★ The mean Score before treatment was 1.00 which lowered down to 0.71 after treatment, with SD± 0.46 giving a relief of 58.57% which was statistically **very significant. (p < 0.01)**

Effect of Therapy on Gaurava (Haeviness)

★ The mean Score before treatment was 0.66 which lowered down to 0.43 after treatment, with SD± 0.41 giving a relief of 64.78 % which was statistically **very significant. (p < 0.01).**

Effect of Therapy on S.L.R Test

★ The mean Score before treatment was 0.60 which lowered down to 0.37 after treatment, with SD± 0.43 giving a relief of 68.10 % which was statistically **very significant. (p < 0.01).**

Table No. 2: Showing Effect of Therapy on Laboratory Parameters (Objective Parameters) in 40 patients: (PAIRED 'T' TEST).

Variable		Mean		Mean Diff.	% Relief	SD±	SE±	T	P value	R
		BT	AT							
HB	N=40	10.61	10.58	0.03	0.25	0.46	0.08	0.6500	0.5195	NS
TLC	N=40	7583.14	7583.71	0.57	0.01	1144.96	7583.14	0.1957	0.8458	NS
ESR	N=40	17.80	12.09	5.71	32.10	6.39	1.08	2.092	0.430	S

(Hb - Haemoglobin**; TLC-**Total Leucocytes Count; **ESR-**Erythrocyte Sedimentation Rate)

Effect of Therapy on HB Score

★ The mean Score before treatment was 10.61 which lowered to 10.58after treatment, with SD±0.46giving an improvement of 0.25% which was statistically **non significant (P>0.05).**

Effect of Therapy on TLC Score

★ The mean Score before treatment was 7583.14which lowered to 7583.71after treatment, with SD± 1144.46giving an improvement of 0.01% which was statistically **non significant (P>0.05).**

Effect of Therapy on ESR Score

★ The mean Score before treatment was 17.80 which lowered to 12.09 after treatment, with SD±6.39 giving an improvement of 32.10% which was statistically **significant (P<.05).**

Table No -3: Showing the % relief in in Subjective Parameters in 40 patients.

S.N	Subjective Parameters	% Relief
1.	*Stambha (Stiffness)*	56.0
2.	*Ruka (Pain)*	61.67%
3.	Radiation of pain	59.41%

4.	*Supti (Numbnes)*	38.75%
5.	Toda (Pricking sensation)	57.50%
6.	Spandana (Twitching)	29.41%
7.	Aruchi (Anorexia)	58.57%
8.	Gaurava (Haeviness)	64.78%
9.	S.L.R Test	58.10%
TOTAL		54.68 %

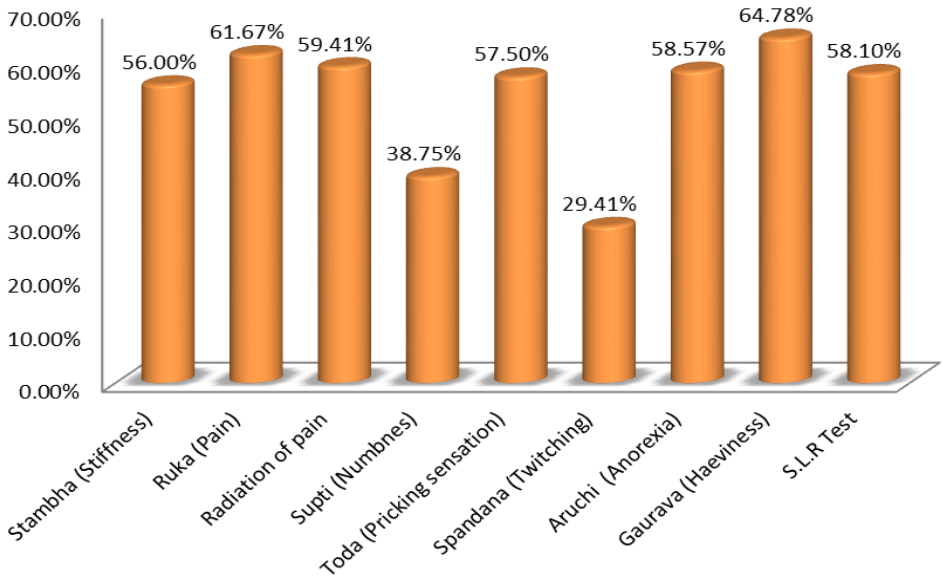
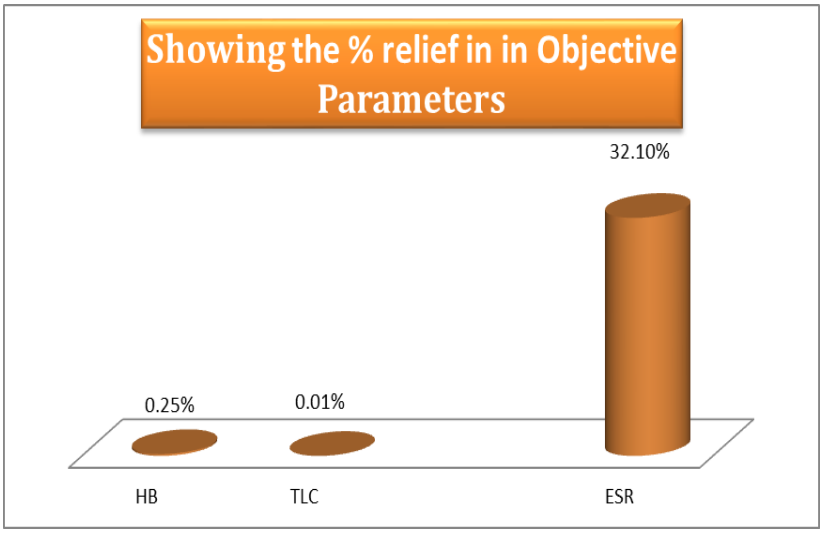


Table No. 4: Showing the % relief in Objective Parameters in 40 patients.

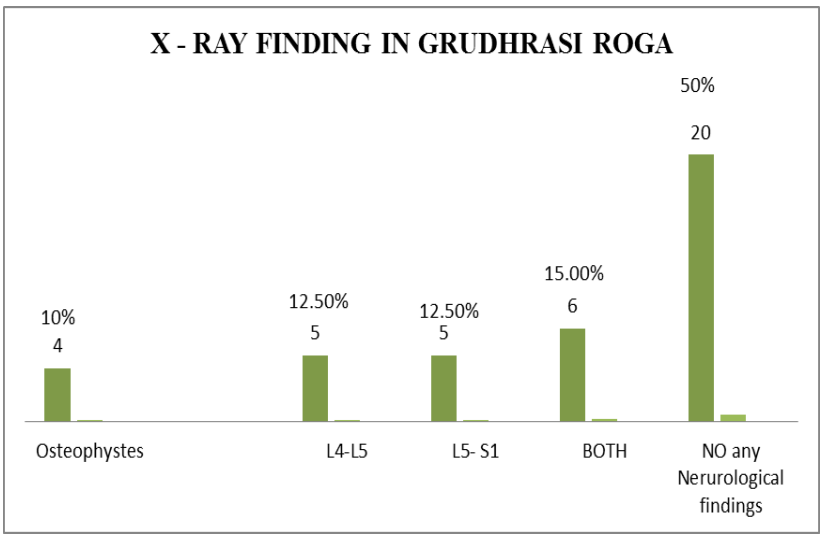
S.N	Objective Parameters	% Relief in Group A
1.	HB	0.25%
2.	TLC	0.01%
3.	ESR	32.10%



X-RAY FINDINGS

Table no 5: X - Ray Finding In Grudhrasi Roga.

s.n	x-ray findings	Number of patents	Percentage
1.	Osteophystes	04	10.00%
2.	Reduced spaces		
	L4-L5	05	12.50%
	L5- S1	05	12.50%
	BOTH	6	15.00%
3.	NO any Nerurological findings	20	50.00%



Follow-Up Study

Regular follow up during the trial & after 1 months of successful completion of trial was done. Regular follow up after trial was done after **7-7 days.**

Overall effect of Clinical trial

Table no – 6 Showing the criteria for the assessment of Overall effect (n=40).

S.n	Symptoms	Grading	Assessment
1.	Less than 25%	Mild	Non – Satisfactory
2.	25 to 50 %	Moderate	Good
3.	50 to 75%	Significant	Satisfactory
4.	75 to 100%	Complete relief	Excellent

Table no – 07: Assessment of Overall effect in the 40 patient (n-40).

S.n	Symptoms	Grading	No of patients
1.	Less than 25%	Mild	05
2.	25 to 50 %	Moderate	15
3.	50 to 75%	Significant	20
4.	75 to 100%	Complete relief	00

RESULT AND CONCLUSION

★ Overall effect of Clinical trial Showing the % relief in Subjective Parameters in 40 patients 54.68 % and Showing the % relief in Objective Parameters in 40 patients 10.68 %.