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A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF MULAKADI TAILA MATRABASTI IN GRIDHRASI VIS-À-VIS SCIATICA

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ABSTRACT

Background and Objectives: Low backache is one of the most common clinical symptoms experienced by a substantial portion of the population. *Gridhrasi* is defined as *Vata vyadhi*[2] characterized by radiating pain from the lumbosacral region (*Spik kati purva*) through the thigh, knee, calf, and foot (Uru, *Janu, Jangha, Pada*). The disease *Gridhrasi* described in *Ayurveda* and Sciatica described in western medical textbooks has absolute similarity in their manifestation. It can be conveniently concluded that these two represent the same disease. Considering all these the present study was undertaken to evaluate the efficacy of *Mulakadi taila matra basti in Gridhrasi.*
Objective: To clinically evaluate the efficacy of *Mulakadi taila Matrabasti* in *Gridhrasi* vis-à-vis sciatica.
Methods: Study Design: A controlled clinical study with pre and post-test design.
Intervention: The interventions were as follows. Group A – Control Group. *Katibasti* with *Ksheerabala taila* for eight consecutive days for 45 minutes was carried out. Group B – Test Group. *Katibasti* with *Ksheerabala taila* for eight consecutive days for 45 minutes along with *Mulakadi taila Matrabasti* was carried out. The data was collected on 0day, after the intervention i.e., on the 8th day, and after the completion of the follow-up period i.e., on the 16th day. The results were analyzed statistically by using Descriptive statistics, „t" test- independent and paired samples, Repeated measure ANOVA, and Contingency co-efficient test analysis using Service product for statistical solution (SPSS) for Windows software. **Results:** In the study, it was observed that the trial Group

(Group B) showed clinically and statistically highly significant results, improvement in SLR, reduction of the pain, stiffness, and *Spandana* with p-value of 0.000. And showed highly significant results in a reduction of Bragards sign with p-value of 0.002. The control group (Group A) showed clinically and statistically highly significant results, improvement in SLR, reduction of the pain, and stiffness with p-value of 0.000. And showed the non-significant result in the reduction of *Spandana* (p-value of 0.141) and Bragards sign (p-value of 0.343).
The overall result in Group B, 7 patients (35%) got complete relief, 12 patients (60%) got marked improvement and 1 patient (5%) got moderate improvement. In Group A, 3 patients (15%) got complete relief, 13 patients (65%) got marked improvement and 4 patients (20%) got moderate relief.

Keyword: *Gridhrasi*, Sciatica, *Mulakadi Taila*.

INTRODUCTION

Low backache is one of the most common clinical symptoms experienced by a substantial portion of the population. Despite the multitude of possible causes in the vast majority of cases, low backache is caused due to sciatica. Sciatica is defined as pain radiating from the lumbosacral route to the leg[1].

Gridhrasi is defined as *Vata vyadhi*[2] characterized by radiating pain from the lumbosacral region (*Spik Kati purva*) through the thigh, knee, calf, and foot (Uru, *Janu, Jangha, Pada*). It is also characterized by stiffness (*Stambha*), pricking sensation *(Toda), Spandana* (throbbing pain)[3].

The disease *Gridhrasi* described in *Ayurveda* and Sciatica described in western medical textbooks has absolute similarity in their manifestation. It can be conveniently concluded that these two represent the same disease.

Management of sciatica through the western system of medicine includes the usage of NSAIDs, muscle relaxants, and opioids. Symptomatic relief is obtained in 85% of adults with above palliative management. Even though they are highly useful in acute pain conditions long-term usage of the above medicines may have many adverse effects such as APD, renal and hepatic impairment. Surgery is reserved for a small portion of the patients where conservative treatment fails[4].In the above situation to explore time hold, traditional methods of *Ayurvedic* therapy are an important area of research. Early effective intervention may not only provide symptomatic relief of pain but also may reduce the need for surgical intervention. The treatment modalities described in Ayurveda for *Gridhrasi* include both the *Upakramas* mentioned in *Vata vaydi*, and specific modalities mentioned in *Gridhrasi*. Basti chikitsa is one of the most important treatment modalities employed in all *Vata vyadis* in general and *Gridhras*i in particular. Among the different varieties of *Basti, Matra basti* is considered as safest and economical variety. It is helpful in various conditions of *Vata dosha* were in *Bruhmana* effect is specifically required.

Matra basti in *Gridhrasi* is carried out by various *Tailas* that are described in the textbooks. However, *Mulakadi taila*[5] explained in the context of *Gridhrasi chikitsa* in Bhaishajya Rathnavali is one formulation that has not been evaluated very frequently. Most of the ingredients of *Mulakadi taila* are *Ushna veerya, Vedana sthapaka, asti poshaka,* and *Vata Kapha hara*.

From this perspective, the current study was undertaken to evaluate the efficacy of *Mulakadi taila Matrabasti* in *Gidhrasi*. *Katibasti* which is a variety of *Bahya snehana* with *Swedana* was adopted as a control. *Ksheerabala taila* was used for *Katibasti*. The present study was a controlled clinical study with pre and post-test design. The patients fulfilling the diagnostic criteria of *Gridhrasi* were assigned into two groups viz., Group A (Control group) and Group B (Test group). Each group consisted of 20 patients.

In Group A (Control Group*): Katibasti with Khseerabala taila* for about 45 minutes for 8 days was given.

For Group B (Test Group): *Katibasti* with *Ksheerabala taila* for about 45 minutes followed by *Matra*

basti with *Mulakadi taila* in a dose of 70ml for 8 days was given.

The assessment was done based on the following parameters. Measurement of SLR and Bragards sign was taken as an objective parameter. Improvement in symptomatology such as *RUK, STAMBHA*, and *SPANDANA* was taken as subjective parameters for assessment. The study consists of three assessments i.e, 0-day, 8th day and, 16th day.

In the present control clinical trial, the effect of *Matra basti in Gridhrasi* was observed and analyzed that the efficacy of *Matra basti*, when compared with *Katibasti*, was highly statistically significant in the following components i.e, SLR with p-value 0.000, Bragards sign with a p-value of 0.002 and *Spandana* with a p-value of 0.000. And other components like *RUK* and *STAMBHA* have shown better results with high contingency coefficient values with a p-value of 0.000. The above result suggests that *Mulakadi taila Matra basti* has a possible significant role in the management of *Gridharsi* vis-à-vis sciatica.

METHODOLOGY

MATERIALS AND METHODS MATERIALS:

The materials used in the study were *Ksheerabala taila, Mulakadi taila*

Source of Drugs and Method of preparation:

The ingredients of *Ksheerabala Taila* are as follows.

1) *Bala mula*

2) Ksheera

3) Tila taila

Ksheerabala taila manufactured from Govt. Central Pharmacy, Bengaluru supplied to Govt. *Ayurveda* Medical College Hospital, Mysore and was procured for study.

The ingredients of *Mulakadi Taila* were procured from Abdul Ravoof Pansari shop, Mysore. Identification of drugs was confirmed by the experts of the department of *Dravya Guna*. Milk and Curd available in the brand name of Nandini were purchased from KMF, Mysore.

Mulakadi taila was Prepared as per classical method in the pharmacy of Govt. Ayurveda Medical College, Mysore. Sixteen liters of *Mulakadi taila* were prepared by the classical method in required quantities.

The ingredients for *Mulakadi taila* are *Mulaka swarasa, Tila taila, Kanji*, Milk, and Curd *Kalka Dravya* they are as follows.

1. *Bala mula churna*
2. *Chitraka mula churna*
3. *Saindhava lavana churna*
4. *Pippali churna*
5. *Ativisha churna*
6. *Rasna churna*
7. *Pushkara mula churna*
8. *Agaru kanda churna*
9. *Bhallataka beeja churna*
10. *Vacha churna*
11. *Kushta churna*
12. *Shunti churna*
13. *Shati churna*
14. *Bilva phala churna*
15. *Shatavari churna*
16. *Devadaru churna*
17. *Shigru beeja churna*
18. *Shvadamshtra beeja churna*
19. *Tagara churna*
20. *Chavika churna*

METHODS

Source of data: Patients of all Gender diagnosed to be suffering from *Gridhrasi* were selected from the OPD, IPD of Government Ayurveda Medical College Hospital, Mysore. Sample size and Sampling method: Irrespective of gender, socio-economic status, and religion, 47 patients having the signs and symptoms of *Gridhrasi* fulfilling the inclusion criteria were registered for the study with the help of a proforma prepared for study after taking consent from the patient. Incidental selection and Random sampling techniques were employed. Out of 47 patients registered, there were 5 dropouts in Group A and 2 dropouts in Group B, and the study was completed in 40 patients with 20 patients in each Group.

Inclusion Criteria

Selection of the patients for the study was done with the following criteria

• Patients of all gender between the age group of 20-60years were selected.

• Patients with signs and symptoms of *Gridhrasi*/Sciatica were included.
• Patients with a co-morbidity of Controlled DM were also included in the study.
• Both fresh and treated cases were included in the study.

The definition of fresh and treated cases includes,

1. Freshly detected and untreated cases of *Gridhrasi*.
2. Already diagnosed and treated cases of *Gridhrasi*, who had voluntarily discontinued the treatment for at least one week before the cases were taken for the study.
3. Established and treated cases of *Gridhrasi*, who are continuing the medicines.

In the first two categories, an intervention was started from the same day. In the last category, the medicines were stopped, and a flush-out period of 7 days was given before starting the intervention.

Exclusion Criteria

Following were the criteria to exclude the patients from the study.

• Patients with neoplastic conditions of the lumbar spine were excluded.
• Patients with a history of recent fracture (< 6months) of the lumbar spine were excluded.
• Pregnant and lactating women were excluded.
• Patients suffering from any other co-morbidity of systemic disorders such as uncontrolled DM (RBS>300mg/dl), renal disorders, endocrine disorders which interfere with the intervention were excluded.
• Patients with infective conditions of the lumbar spine were excluded.
• Those patients who were considered ineligible for *Basti karma* were excluded.

Diagnostic Criteria:

Diagnosis of the cases was made in the present study according to the signs and symptoms of *Gridhrasi*/ sciatica are as follows.

• SLR test positive (up to 600) in the affected leg as objective measures for diagnosis.
• Positive Bragards sign.
• Presence of radiating pain, *Toda, Stambha*, and *Spandana* in the *Spik, Kati, Uru, Janu, Jangha*, and *Pada.*

Assessment

Parameters of assessment: Assessment parameters included the clinical grading of signs and symptoms of the disease *Gridhrasi*/ Sciatica. The assessment was done based on the following parameters.

Objective parameters

Straight leg raising test
• <20 degrees - severe
• 20-40 degrees - moderate
• 40-60 degrees - mild Bragards sign- Positive/Negative

Subjective parameters

Ruk
• No pain – R0
• Mild pain – R1
• Moderate pain – R2
• Severe pain – R3

Stambha
• No stiffness -ST0
• Mild Stiffness -ST1
• Moderate Stiffness -ST2
• Severe stiffness -ST3

Spandana
• No Throbbing pain – T0
• Mild Throbbing pain – T1
• Moderate Throbbing pain – T2
• Severe Throbbing pain – T3

Assessment schedules:

In this trial, a total of three assessments of the patients were made. Before starting the Intervention i.e., pre-test assessment was done on 0 days. Mid-test assessment was done on the 8th day i.e., after completion of the intervention and post-test assessment was done on 16th i.e., on the day of the follow-up period.

Statistical methods

The data was collected on 0day, after the intervention i.e., on the 8th day, and after the completion of the follow-up period i.e., on the 16th day. The result was analyzed statistically by using Descriptive statistics, _t' test- independent and paired samples, Repeated measure ANOVA, and Contingency co-efficient test

analysis using Service product for statistical solution (SPSS) for Windows software.

Physiological, biochemical, and radiological study: The diagnosis and the assessment did not include any biochemical investigations. However, all the patients were evaluated for their physiological status in terms of pulse, respiration, body temperature, and pallor. Whenever it was necessary, patients were subjected to the following investigations to exclude other systemic diseases, fracture of lumbar spine and indications for surgery: -

• X-ray of lumbosacral region Lateral and AP view.
• MRI in required patients to exclude surgical conditions of *Gridhrasi*.
• Blood for Hb%, TC, DC, ESR, RBS.
• Urine for sugar, albumin, micro, was done whenever it was considered necessary.

Research design: A controlled clinical trial with Pre and post-test design.

Intervention: The interventions were as follows.

Group A – Control Group: *Katibasti* with *Ksheerabala taila* for eight consecutive days for 45 minutes was carried out.

Group B – Test Group: *Katibasti* with *Ksheerabala taila* for eight consecutive days for 45 minutes along with *Mulakadi taila Matrabasti* was carried out.

RESULTS: In this study, it was hypothesized that Group B (Test Group) intervention will be more effective than Group A (Control Group) intervention in the management of *Gridhrasi*. The efficacy of both the Groups in *Gridhrasi* was evaluated keeping various parameters for intervention. The data were collected from the subjects based on SLR, Bragards sign, and the scoring given to each of the symptoms as mentioned in the assessment criteria. It was collected on the 0th day (Pretest), the 8th day (Mid test), and the 16th day (Posttest). The results were analyzed statistically and assessed.

The statistical analysis of the results was done using the chi-square test, contingency coefficient test, student paired t' test, and repeated measure ANOVA.

Table 1: Showing total scores of Paired tests of SLR

	Group	Mean	Std. Deviation	N
SLR_BT	Group A	33.25000	9.072080	20
	Group B	29.75000	9.101041	20
	Total	31.50000	9.142743	40
SLR_AT	Group A	50.0000	6.88247	20
	Group B	60.7500	14.44363	20
	Total	55.3750	12.42348	40
SLR_FT	Group A	51.2500	8.71704	20
	Group B	62.2500	14.09320	20
	Total	56.7500	12.83774	40

In both, groups a significant increase was observed in posttest assessment in mean SLR. F value (F=150.842). This increase was found to be highly significant with a p-value of 0.000. From the mean values, it is evident that a mean of 31.500degree was observed before, which was increased to 55.3700 degrees in the mid-test assessment. In the post-test assessment, the mean total SLR was slightly increased to 56.7500 degrees.

However, SLR assessment in between the Groups was a statistically highly significant result with a p-value of 0.000 (F= 12.889), with the trial indicating that group B showed better effect compared to group A. For group A the increase was found to be 18 degrees (pre-33.2500; post 51.25000) and for group B the increase was found to be 32.5 degrees (pre-29.7500; post 62.25000), the mean difference between the groups was 14.5 degrees, which shows Group B showed better result than group A.

Table 2: Showing total scores of Paired tests of Bragards sign.

GROUP				BRAGARDS		Total
				Negative	Positive	
Group A	SESSION	BT	Count	0	20	20
			% Of SESSION	.0%	100.0%	100.0%
		AT	Count	2	18	20
			% Of SESSION	10.0%	90.0%	100.0%
		FU	Count	2	18	20
			% Of SESSION	10.0%	90.0%	100.0%
	Total		Count	4	56	60
			% Of SESSION	6.7%	93.3%	100.0%
Group B	SESSION	BT	Count	0	20	20
			% Of SESSION	.0%	100.0%	100.0%
		AT	Count	8	12	20
			% Of SESSION	40.0%	60.0%	100.0%
		FU	Count	9	11	20
			% Of SESSION	45.0%	55.0%	100.0%
	Total		Count	17	43	60
			% Of SESSION	28.3%	71.7%	100.0%

The results obtained regarding Bragards sign showed highly significant results in Group B with a p-value of 0.002 and a non-significant result in Group A with a p-value of 0.343.

In Group A, 20 (100%) patients had Bragards sign positive in pre-test assessment. In mid-test 18 (90.00%) patients remained positive for Bragards sign and only 2 patients (10.0%) showed Bragards sign negative. In post-test assessment same result was observed as that of mid-test assessment.

In Group B, 20 (100%) patients had Bragards sign positive. In mid-test assessment, 12 (60.00%) patients remained positive for Bragards sign, and 8 patients (40.0%) showed Bragards sign negative. In post-test assessment 11 (55.00%) patients remained positive for Bragards sign and 9 patients (45.0%) showed Bragards sign negative.

Table 3: Showing total results on *RUK.*

GROUP			**RUK**				**Total**
			No pain	**Mild pain**	**Moderate pain**	**Severe pain**	
Group A	**SESSION**	**BT**	0	0	4	16	20
			.0%	.0%	20.0%	80.0%	100.0%
		AT	1	16	3	0	20
			5.0%	80.0%	15.0%	.0%	100.0%
		FU	3	14	3	0	20
			15.0%	70.0%	15.0%	.0%	100.0%
	Total		4	30	10	16	60
			6.7%	50.0%	16.7%	26.7%	100.0%
		BT	0	0	2	18	20
			.0%	.0%	10.0%	90.0%	100.0%
		AT	7	13	0	0	20

			35.0%	65.0%	.0%	.0%	100.0%
Group B	**SESSION**	**FU**	7	13	0	0	20
			35.0%	65.0%	.0%	.0%	100.0%
	Total		14	26	2	18	60
			23.3%	43.3%	3.3%	30.0%	100.0%

The results obtained regarding the reduction in *RUK* showed a highly significant result in both the groups with a p-value of 0.000.

In Group A among 20 patients, the pain was severe in 16 patients (80.0%) and moderate pain in 4 patients (20.0%) in pre-test assessment. In mid-test assessment, 16 (80.00%) patients had mild pain, 3 patients (15.0%) had moderate pain and 1 patient (5.0%) had completely relieved from pain. In post-test assessment 14 (70.00%) patients had mild pain, 3 patients (15.0%) had moderate pain and 3 patients (5.0%) had completely relieved from pain.

In Group B among 20 patients 18 patients (90.0%) reported severe pain and 2 patients (10.0%) had moderate pain in pre-test assessment. In mid-test assessment, 13 (65.00%) patients reported mild pain and 7 patients (35.0%) had completely relieved from pain.

In post-test assessment 13 (65.00%) patients reported mild pain and 7 patients (35.0%) had completely relieved from pain.

The study also showed better results in Group B than Group A for a reduction in pain with a high contingency coefficient value.

Table 4: Showing total results on *STAMBA*

GROUP			***STAMBA***				**Total**
			No Stiffness	**Mild Stiffness**	**Moderate Stiffness**	**Severe Stiffness**	
Group A	**SESSION**	**BT**	0	3	14	3	20
			.0%	15.0%	70.0%	15.0%	100.0%
		AT	5	14	1	0	20
			25.0%	70.0%	5.0%	.0%	100.0%
		FU	5	14	1	0	20
			25.0%	70.0%	5.0%	.0%	100.0%
	Total		10	31	16	3	60
			16.7%	51.7%	26.7%	5.0%	100.0%
Group B	**SESSION**	**BT**	0	1	11	8	20
			.0%	5.0%	55.0%	40.0%	100.0%
		AT	9	11	0	0	20
			45.0%	55.0%	.0%	.0%	100.0%
		FU	9	11	0	0	20
			45.0%	55.0%	.0%	.0%	100.0%
	Total		18	23	11	8	60
			30.0%	38.3%	18.3%	13.3%	100.0%

The results obtained regarding reduction in *STAMBA* showed a highly significant result in both the groups with a p-value of 0.000.

In Group A among 20 patients' stiffness was severe in 3 patients (15.0%), moderate in 14 patients (70.0%) and mild in 3 patients (15.0%). In mid-test assessment 14

(70.00%) patients had mild stiffness, 1 patient (5.0%) had moderate Stiffness and 5 patients (25.0%) had completely relieved from stiffness. In post-test as-

sessment same score was observed as that of mid-test assessment.

In Group B among 20 patients Stiffness was severe in 8 patients (40.0%), moderate in 11 patients (55.0%) and mild in 1 patient (5.0%). In mid-test assessment, 11 (55.00%) patients had mild stiffness and 9 patients (45.0%) had completely relieved from stiffness. In post-test, the same results were observed as that of mid-test assessment.

The study also showed better results in Group B than Group A for a reduction in *Stamba* with a high contingency coefficient value.

Table 5: Showing total results on *SPANDANA*

GROUP			*SPANDANA*				Total
			No Throbbing pain	Mild Throbbing pain	Moderate Throbbing pain	Severe Throbbing pain	
Group A	SESSION	BT	6	11	3		20
			30.0%	55.0%	15.0%		100.0%
		AT	12	8	0		20
			60.0%	40.0%	.0%		100.0%
		FU	12	7	1		20
			60.0%	35.0%	5.0%		100.0%
	Total		30	26	4		60
			50.0%	43.3%	6.7%		100.0%
Group B	SESSION	BT	2	4	12	2	20
			10.0%	20.0%	60.0%	10.0%	100.0%
		AT	10	8	2	0	20
			50.0%	40.0%	10.0%	.0%	100.0%
		FU	12	8	0	0	20
			60.0%	40.0%	.0%	.0%	100.0%
	Total		24	20	14	2	60
			40.0%	33.3%	23.3%	3.3%	100.0%

The results obtained regarding reduction *SPANDANA* showed the highly significant result in Group B with a p-value of 0.000 and non-significant in Group A with a p-value of 0.141.

In Group A among 20 patients throbbing pain was moderate in 3 patients (15.0%), mild in 11 patients (55.0%), and no throbbing pain in 6 patients (30.0%) in pre-test assessment. In mid-test assessment 8 (40.00%) patients had mild throbbing pain, and 12 patients (60.0%) had completely relieved from throbbing pain. In post-test assessment 7 (35.00%) patients had mild throbbing pain, 1 patient (5.0%) had moderate throbbing pain and 12 patients (60.0%) had completely relieved from throbbing pain.

In Group B among 20 patients throbbing pain was severe in 2 patients (10.0%), moderate in 12 patients (60.0%), and 4 patients (20.0%) who had a mild throbbing pain in pre-test assessment. In mid-test assessment, 8 (55.00%) patients had mild throbbing pain, 2(10.00%) patients had moderate throbbing pain and 10 patients (50.0%) had completely relieved from throbbing pain. In post-test assessment 8 (35.00%) patients had mild throbbing pain, and 12 patients (60.0%) had completely relieved from throbbing pain.

The study also showed a highly significant result in Group B than Group A for the reduction in throbbing pain with a high contingency coefficient value.

Overall assessment

The assessment was graded in the following manner:

Complete relief: Complete reduction in all the signs and symptoms in subjects. Marked improvement:

Reduction in all the signs and symptoms except any-one sign or symptom in subjects.
Moderate improvement: Reduction in all the signs and symptoms except any two signs or symptoms in subjects
Mild improvement- Reduction in any one sign or symptom in subjects. Insignificant improvement- No Reduction in any signs and symptoms in subjects.

Table 6: Showing total results on an overall assessment

	Group A	Group B	Total
Complete relief	3 (15%)	7 (35%)	10 (25%)
Marked improvement	13 (65%)	12 (60%)	25 (62.5%)
Moderate improvement	4 (20%)	1 (5%)	5 (12.5%)
Mild improvement	0	0	0
No improvement	0	0	0

After completion of the study, the overall result in Group A, 3 patients (15%) got complete relief, 13 patients (65%) got marked improvement and 4 patients (20%) got moderate relief.
In Group B, 7 patients (35%) got complete relief, 12 patients (60%) got marked improvement and 1 patient (5%) got moderate improvement.

DISCUSSION ON RESULTS

Effect on SLR: In between the Groups, improvement was verified, and a significant difference was observed. Change in between the Groups showed statistically highly significant results with a p-value of 0.000 (F= 12.889), indicating that group B showed marked improvement compared to group A. For group A the improvement was found to be 18 degrees (pre-33.2500; post 51.25000) and for group B the improvement was found to be 32.5 degrees (pre-29.7500; post 62.25000). The mean difference between the groups was 14.5, which shows Group B showed marked improvement over group A.
However, it was observed that in both groups mean of 31.500 degrees was observed in the pre-test, which was increased to 55.3700 degrees in the mid-test. In post-test, the mean total SLR was slightly increased to 56.7500 degrees.
A significant increase was observed from pre-test to post-test in mean SLR in both groups. F value (F=150.842) for this increase was found to be significant with a p-value of 0.000.

Effect on Bragards sign:
The results obtained regarding Bragards sign showed a highly significant result in Group B with a p-value of 0.002 and a non-significant result in Group A with a p value of 0.343.
When the percentage of improvement in Bragards sign in post-test was observed, group B showed the highly significant result in improvement in Bragards sign i.e, 45%, whereas group A showed a non-significant result in improvement in Bragards sign i.e, 10%.
It was observed that In Group B, 20 (100%) patients had Bragards sign positive. In mid-test assessment, 12 patients (60.00%) remained with positive bragards signs. 8 patients (40.0%) showed Bragards sign negative. In post-test assessment 11 (55.00%) patients remained positive for Bragards sign and 9 patients (45.0%) showed Bragards sign negative.
Whereas in Group A, 20 (100%) patients had Bragards sign positive. In mid-test 18 (90.00%) patients remained positive for Bragards sign and only 2 patients (10.0%) showed Bragards sign negative. In post-test assessment, the same results were observed as that of mid-test assessment.

Effect on *RUK*
The observations revealed that group B shows better results in a reduction of pain than group A statistically with a high contingency coefficient value.
It was observed that in pretest, In Group B among 20, 18 (90.0%) patients reported severe pain and 2 pa-

tients (10.0%) reported moderate pain. In mid-test assessment, 13 (65.00%) patients reported mild pain and 7 patients (35.0%) had completely relieved from pain. In post-test assessment 13 (65.00%) patients reported mild pain and 7 patients (35.0%) had completely relieved from pain.

Whereas in Group A among 20 patients 16 (80.0%) patients reported severe pain, 4 (20.0%) patients reported moderate pain. In mid-test 16 (80.00%) patients reported mild pain, 3 (15.0%) patients reported moderate pain, and 1(5.0%) patient completely relieved from pain. In post-test 14 (70.00%) patients reported mild pain, 3 patients (15.0%) reported moderate pain and 3 (15.0%) patients reported being completely relieved from pain.

The results obtained regarding the reduction of pain showed a highly significant result in both the groups with a p-value of 0.000.

Effect on *STAMBA*

The study showed better results in Group B than Group A statistically for reduction of stiffness with a high contingency coefficient value.

It was observed that In Group B among 20 patients in pre-test Stiffness was severe in 8 (40.0%) patients, moderate in 11 patients (55.0%), and mild in 1patient (5.0%). In mid-test 11 (55.00%) patients had mild stiffness and 9 patients (45.0%) had completely relieved from stiffness. In the post-test same results were observed as that of the mid-test assessment.

Whereas In Group A among 20 patients' stiffness was severe in 3 patients (15.0%), moderate in 14 patients (70.0%), and mild in 3 patients (15.0%). In mid-test 14(70.00%) patients had mild stiffness, 1 patient (5.0%) had moderate Stiffness and 5 patients (25.0%) had completely relieved from stiffness. In post-test same results were observed as that of mid-test assessment. The results obtained regarding the reduction of stiffness showed highly significant results in both groups with a p-value of 0.000.

Effect on *SPANDANA*

The results obtained regarding the reduction of throbbing pain showed highly significant results in Group B with a p-value of 0.000 and non-significant in Group A with a p-value of 0.141.

The study showed statistically highly significant results in Group B than Group A for a reduction in throbbing pain with a high contingency coefficient value.

It was observed that in Group B among 20 patients throbbing pain was severe in 2 (10.0%) patients, moderate in 12 (60.0%) patients, and mild in 4 patients (20.0%). In mid-test 8 (55.00%) patients had mild throbbing pain, 2 (10.00%) patients had moderate throbbing pain and 10 patients (50.0%) had completely relieved from throbbing pain. In post-test assessment 8 (35.00%) patients had mild throbbing pain and 12 patients (60.0%) had completely relieved from throbbing pain.

Whereas In Group A among 20 patients throbbing pain was moderate in 3 (15.0%) patients, mild in 11 (55.0%) patients, and no throbbing pain in 6 (30.0%) patients. In mid-test 8 (40.00%) patients had mild throbbing pain, and 12(60.0%) patients had completely relived from throbbing pain. In post-test 7 (35.00%) patients had mild throbbing pain, 1 (5.0%) patient had moderate throbbing pain and 12 (60.0%) patients had completely relived from throbbing pain.

GENERAL OBSERVATIONS:

There were some general observations made in the clinical trial. They are discussed below.

Reduction of pain: Though the individual in both the groups have shown clinically and statistically significant improvement in reduction of pain. It was observed that the reduction of pain was faster in a trial group when compared to the control group. While most of the patients reported a reduction of pain on the 3rd or 4th day in the trial group. It was on the 6th or 7th day in the control group.

Reoccurrence of pain: It was also observed that the reduction of pain was sustained for a longer period in a trial group when compared to the control group. The reoccurrence of pain in follow-up done on patients who reported periodically after intervention also suggested that reoccurrence was relatively high in the control group.

It was also observed that the patient who had normal or slightly raised ESR showed better results than those who had highly raised ESR.

CONCLUSION

Based on concepts, analysis, and clinical observations made in this study, the following conclusions were drawn.

Gridhrasi is a *Vata Nanatmaja vyadhi*. The *Dushyas* such as *Asthi, Mamsa, Sira and Snayu, Srothas* such as *Vatavaha, Astivaha, Mamsavaha* and *Majjavaha* play an important role in the pathology of the disease *Gridhrasi.*

Mulakadi taila explained in Bhaishyaja Ratnavali is a formulation advised for the management of *Gridhrasi*. Also, the *Rasa, Guna, Veerya, Vipaka*, and *Doshaghnata* of individual ingredients and the formulation as a whole were analyzed and hypotheses that it is having *Vedana Stapaka, Asthi poshaka, Vata dosha*, and *Kapha dosha hara* property which is mainly required in the *Samprapti vighatana* of the disease *Gridhrasi*. So, this formulation was selected as a trial in the present study, *Katibasti* was taken as a control.

This is a controlled clinical study, conducted on 40 patients with 20 patients in each group. In the study, it was observed that the trial Group (Group B) showed clinically and statistically highly significant results, improvement in SLR, reduction of the pain, stiffness and *Spandana* with a p-value of 0.000. And showed highly significant results in a reduction of Bragards sign with a p-value of 0.002.

The control group (Group A) showed clinically and statistically highly significant results, improvement in SLR, reduction of the pain, and stiffness with a p-value of 0.000. And showed the non-significant result in a reduction of spandana (p-value 0.141) and bragards sign (p-value 0.343).

On comparing the overall effect of the study, a trial group (Group B) showed better results than the control group (Group A). Hence, *Mulakadi taila Matra basti* has a significant role in the management of *Gridhrasi*

No adverse or side effects were observed during the study period.

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