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A RANDOMIZED OPEN-LABEL CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *SHEPHALIKA PATRA KASHYAM* IN THE MANAGEMENT OF *GRIDHRASI* WITH SPECIAL REFERENCE TO SCIATICA

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Abstract:
Context: Ayurveda is a practical science of living whose principles are relevant to daily life, addressing harmony and longevity. **Gridhrasi** is a debilitating disease mentioned in Ayurvedic classics that hampers the ambulatory function of patients. It is corelated with **Sciatica** in modern medicine.
Objective: To evaluate and compare the efficacy of **Shephalika Patra Kashyam** (trial drug) and **Sahacharadi Kashyam** (controlled drug) in the management of *Gridhrasi* w.s.r. to Sciatica.
Methodology: A randomized, open-label, parallel-group clinical study was conducted with 30 subjects (15 per group) for a trial period of 45 days. Group A received oral *Shephalika Patra Kashyam* and Group B received oral *Sahacharadi Kashyam*.
Results: Both interventions showed highly significant relief. Group A showed a **72%** overall improvement, while Group B showed a **59%** improvement. *Shephalika Patra Kashyam* showed higher efficacy in reducing cardinal symptoms like *Ruk* (pain), *Stambha* (stiffness), and improving SLR test results.
Conclusion: *Shephalika Patra Kashyam* is a potent, safe, and cost-effective Ayurvedic therapy for the management of *Gridhrasi* (Sciatica).

INTRODUCTION

Ayurveda addresses all aspects of human life, providing wisdom perfected over many years. Health is considered the supreme foundation for a happy life. In the present era, locomotor disorders are increasing due to changing lifestyles, poor posture, and overexertion, leading to low back pain and Sciatica.
Gridhrasi is described as a severe debilitating disease where the patient's gait resembles that of a vulture (*Gridhra*) due to extreme pain. It is a *Shoola Pradhana Vatavyadhi* and considered a *Mahagada* by Acharya Charaka. Sciatica is defined by pain in the distribution of the sciatic nerve, often caused by spinal nerve irritation or disc prolapse. As modern treatments often involve analgesics with adverse effects or costly surgeries, Ayurvedic principles offer a holistic alternative.

DRUG REVIEW

Group A: *Shephalika Patra Kashyam* (Trial Drug)

- **Ingredients:** *Shephalika Patra* (*Vitex negundo*).
- **Properties:** *Katu-Tikta Rasa, Laghu-Ruksha-Tikshna Guna, Ushna Veerya,* and *Katu Vipaka*.
- **Action:** Acts as *Vata-Kaphahara, Vedanasthapana* (analgesic), and *Shothahara* (anti-inflammatory).

Group B: *Sahacharadi Kashyam* (Controlled Drug)

- **Ingredients:** *Sahachara, Devdaru,* and *Nagar/Shunthi*.
- **Properties:** Predominantly *Tikta-Katu Rasa, Ushna Veerya,* and *Katu Vipaka*.

- **Action:** Acts as *Vata-Kapha Shamaka, Dipana, Pachana,* and *Anilahara*.

MATERIALS AND METHODS

- **Source of Data:** 30 patients were selected from the OPD and IPD of Jammu Institute of Ayurveda and Research.
- **Study Design:** Randomized, open-label, parallel-group, pre- and post-test clinical study.
- **Sample Size:** 30 subjects (15 per group).
- **Randomization:** Done using chits.
- **Trial Duration:** 45 days.
- **Posology:** 50 ml BD (before meals) for both groups.

A. INCLUSION CRITERIA

Patients between the age group of 25 – 60 years.

1. Patient representing signs and symptoms of *Gridhrasi* who were willing to participate in study.
2. Subjects willing to participate with written informed consent, which is conveyed in the language which the subject can understand.
3. Both males and female was selected

B. EXCLUSION CRITERIA

1. Age below 25 years and above 60 years.
2. Patients suffering from Cardiac Diseases.
3. Uncontrolled Diabetes Mellitus, Hypertension.
4. Cancer of Lumbo-Sacral spine
5. Tuberculosis of vertebral column.
6. Pregnant and lactating women.
7. Patient suffering from Ankylosing spondylitis, sacroiliac arthritis, herpes simplex infection causing radiating pain, disc prolapse, degenerative changes, bony osteophytic growth.
8. Any trauma related to Lumbo-sacral spine

C. DIAGNOSTIC CRITERIA

1. Subjective Parameters.
2. Objective Parameters.

CRITERIA FOR ASSESSMENT

Assessment will be done before and after the treatment adopting the following parameters:-

SUBJECTIVE CRITERIA

1) RUK (Pain)

Table no. 1

Lakshana	**Grade**
No pain	0
Occasional Pain	1
Mild Pain (No Difficulty in Walking)	2
Moderate Pain (Slight Difficulty in Walking)	3
Severe Pain (Severe Difficulty in Walking)	4

2) *TODA* (Pricking Sensation):

Lakshna	***Grade***
No Pricking sensation	0
Occasional Pricking Sensation	1
Mild Pricking Sensation (once a day)	2
Moderate Pricking Sensation (frequently in a day)	3
Severe Pricking Sensation (persistence)	4

3) *STAMBHA* (STIFFNESS)

Lakshna	***Grade***
No stiffness	0
Stiffness for few minutes after sitting for long duration but relieved by mild movements	1
Stiffness more than 1 hour or more than once in a day but routine works are not disturbed	2
Stiffness lasting for more than 1 hour or many times a day mildly affecting the daily routine.	3
Episodes of stiffness lasting for 2-6 hours. \ Daily routines are hampered severely	4

***4)* *SPANDANA* (FASICULATION)**

Lakshana	**Grade**
No Spandana	0
Sometimes for 5 to 10 minutes	1
Daily for 10 to 30 minutes	2
Daily for 30 – 60 minutes	3
Daily >1 hour	4

***5)* *GAURAVA* (HEAVINESS)**

Lakshana	**Grade**
No feeling of heaviness	0
Occasional feeling of heaviness not affecting the normal movements	1
Frequent feeling of heaviness affecting the normal movements	2
Feeling of heaviness throughout the day severely affecting the normal movements	3
Feeling of heaviness throughout the day totally Hampering normal movements	4

OBJECTIVE CRETERIA:

1) X-RAY SPINE:-

2) VAS SCORE: - A visual Analogue Scale is a measurement instrument that tries to measures a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms.

3) Straight leg raising test (S.L.R.)

S.L.R.	**GRADE**
Negative	0
60 degree and above	1
In between 30 degree and 60 degree	2
Less than 30 degree	3

4) Bragard"s Test :-

Bragard"s Test	**Grade**
Absent	0
Mildly Positive	1
Moderately Positive	2
Highly Positive	3

TABLE NO.2 Paried sample Statistics for Group A

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Ruk	Pre	3.20	15	.775	.200
	Post	.73	15	.594	.153
*Toda_*	Pre	3.13	15	.743	.192
	Post	.60	15	.632	.163
Stambha	Pre	3.00	15	.756	.195
	Post	.67	15	.617	.159
Spandana	Pre	2.13	15	.516	.133
	Post	.20	15	.414	.107

Gaurava	Pre	3.00	15	.756	.195
	Post	.60	15	.632	.163
X-Ray Spine	Pre	3.40	15	.632	.163
	Post	.67	15	.617	.159
VAS	Pre	2.93	15	.704	.182
	Post	.47	15	.640	.165
SLR_	Pre	2.27	15	.594	.153
	Post	.67	15	.724	.187
Bragarad	Pre	2.27	15	.594	.153
	Post	.33	15	.488	.126

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Ruk	Pre - Post	-2.467	.640	.165	2.112	2.821	14.929	14	.000
Toda	Pre - Post	-2.533	.516	.133	2.247	2.819	19.000	14	.000
Stambha	Pre - Post	-2.333	.816	.211	1.881	2.785	11.068	14	.000
Spandana	Pre - Post	-1.933	.704	.182	1.544	2.323	10.640	14	.000
Gaurava	Pre - Post	-2.400	.632	.163	2.050	2.750	14.697	14	.000
X-ray Spine	Pre - Post	-2.733	.458	.118	2.480	2.987	23.127	14	.000

VAS	Pre Post	-2.467	.516	.133	2.181	2.753	18.500	14	.000
SLR	Pre Post	-1.600	.828	.214	1.141	2.059	7.483	14	.000
Bragarad	Pre Post	-1.933	.704	.182	1.544	2.323	10.640	14	.000

TABLE NO. 3 :- Comperative analysis of Group A and Group B

Paired Samples Statistics					
		Mean	N	Std. Deviation	Std. Error Mean
Ruk	Group A	.73	15	.594	.153
	Group B	1.73	15	.704	.182
Toda	Group A	.60	15	.632	.163
	Group B	1.27	15	.961	.248
Stambha	Group A	.67	15	.617	.159
	Group B	1.40	15	1.242	.321
Spandana	Group A	.20	15	.414	.107
	Group B	.60	15	.828	.214
Gaurava	Group A	.60	15	.632	.163
	Group B	1.00	15	.845	.218
X-Ray Spine	Group A	.67	15	.617	.159
	Group B	1.60	15	.507	.131
VAS	Group A	.47	15	.640	.165
	Group B	1.60	15	.828	.214
SLR	Group A	.67	15	.724	.187
	Group B	1.00	15	.756	.195
Bragarad	Group A	.33	15	.488	.126
	Group B	.47	15	.640	.165

Paired Samples Test				
	Paired Differences	t	df	Sig. (2-

		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				tailed)
					Lower	Upper			
Ruk	Group A - Group B	-1.000	.926	.239	-1.513	-.487	-4.183	14	.001
Toda	Group A - Group B	-.667	1.113	.287	-1.283	-.050	-2.320	14	.036
Stambha	Group A - Group B	-.733	1.534	.396	-1.583	.116	-1.852	14	.085
Spandana	Group A - Group B	-.400	.986	.254	-.946	.146	-1.572	14	.138
Gaurava	Group A - Group B	-.400	1.056	.273	-.985	.185	-1.468	14	.164
X-Ray spine	Group A - Group B	-.933	.884	.228	-1.423	-.444	-4.090	14	.001
VAS	Group A - Group B	-1.133	1.125	.291	-1.757	-.510	-3.900	14	.002
SLR	Group A - Group B	-.333	1.175	.303	-.984	.317	-1.099	14	.290
Bragarad	Group A - Group B	-.133	.834	.215	-.595	.328	-.619	14	.546

COMPARATIVE ANALYSIS OF OVERALL EFFECT OF THERAPY BETWEEN GROUP A AND GROUP B

Overall Assessmentof Therapy was assessed based upon Significance Of Paired T-Test values in Subjective Parameters And Objective Parameters.

Table No. 4: - Comperative Analysis Of Overall Effect Of therapy Between Group A and Group B

GROUP	MEAN%
A	72%
B	59%

DISCUSSION:

SHEPHALIKA PATRA KASHYAM:-

This formulation beneficial in Gridhrasi as *Vata- Kapha Shamaka oushdi*, because it is the main causative factor, formulation helps to improve Vata- *Kaphahara, Caksusya,Kesya, Krmi, Vranopana, Vishahara*, Digestive, Stomachic, anti- inflammatory, diuretic, expectorant, Carminative properties.

This formulation is dominant of *Katu Rasa pradhana, Laghu, Snigdha*, and *Tikshna guna, Ushna Veerya* and *Katu Vipaka.* This formulation balances Kapha and Vata. Pharmacologically this does *Vedanasthapana, Shothahara, Hrudya, Anulomana, Rasayana.* This formulation is beneficial on *Gridhrasi* (Sciatica) to reduce the pain. As a *Katurasa* and *Tikshna Guna Pradhana Yoga* helps in *Pachana of Ama*(ROS, free radicals), does *Anulomana* of *Vata.*

Their *Ushna, Teekshna*, help to clear micro- channels and counters inflammatory biomarkers, contributing to its therapeutic efficacy in managing Sciatica and can be in early stage of *Gridhrasi* where pain and stiffness and Tenderness.*The karmas that helps in breaking the pathogenesis of the disease include Jawraghna (febrifuge), Vishaghna (antidotes), deepana (appetizers), Pachana (metabolizers), bhedhana (laxative), Shophahara (anti- inflammatory), Shulajit (analgesic), dahaprada (pyrogenic), balya, lekhana (lipolytics), swedala (hidrotics), sara (laxatives), Chedhana (drugs that cause excision), rochana (appetizers), mutrala (diuretics), amaghana (antioxidents), Rasayana, Shoshana (Absorbant), Rukshana (Reduces excessive secreations), Medohara.* are dominant symptoms.

- The comparative drug under consideration, which contains *Sahacharadi Kashayam*, contains *sahachara, Devdaru, Nagar/ Shunthi* has been taken from *Ashtanghridayam.*
- The majority of *Dravyas* contain *Tikta* (bitter) and *Katu* (pungent) *Rasa*, which serve as *Agni Deepena* (digestive stimulant) and *Ama Pachna* and *Vata Shamaka. Kashaya* (astringent) *Rasa* helps on *Shoshanan* (desiccant) of *Kapha.*
- *Tikta, Katu*, and *Kashaya Rasa* act as *Kapha Shamaka*. *Madhura* (sweet) rasa could act as *Vata Shamaka* and can be used as *Rasayana*. *Laghu, Ruksha* (dry), *Ushna* (hot), and *Tiksha Guna* work as *Kapha Shamaka*. On the other hand, *Tikshana Guna* and *Ushna Veerya* help pacify *Vata*. *Ushna Veerya* helps as both *Kapha* and *Vata Shamaka*.

DISCUSSION ON OBSERVATION:

AGE:

In the present study the maximum number of patients was seen in 26- 40 years were (67%) which supports the incidence rate of sciatica between 26 to 40 years of age, 41-55 years (27%) & 56-70 years (7%). So it supports the fact that incidence of *Gridhrasi* was found to be maximum in this age group i.e. 3th decade then 4th decade. Spine including the intervertebral discs shows degenerative changes with the advancing age. The degree of hydration of the intervertebral discs decreases with age that leads to the

cycle of degeneration resulting in disc problems. Progressive disc resorption and disruption can cause disc herniation as complications which leads to sciatica by compressing the nerve roots. The young adults and middle aged people are more exposed to strong biomechanical forces and heavy work, which may also create this condition. Hence the prevalence rate is high in middle aged people, which is supported by the findings of the present study.
In group B the number of patients is seen in age group 26-40 years (20%) and 41-55 years and 56-70 years shares the equal percentage i.e.40%.

SEX:
In present study, maximum number of patients were female i.e. 60% followed by male (40%). Highest incidence was observed in females because females are tending to more physical work like lifting, bending, sitting and sustained postures predispose to Sciatica. Similarly, in male who are at hard physical jobs and in particular frequent lifting and postural stress are known to increase the risk of sciatica.
In Group B, maximum number of patients were male i.e. 53% followed by female (47%).

OCCUPATION:
Majority of the patient i.e. 40% were householders, 20% were serviceman, 13% were businessman and farmers, 7% were driver and shopkeeper. It is because of the more incidences of the female patients. They have to lift many and varied weights and have to stand or work in unusual postures for long periods. Various surveys suggest that physical workers or laborers have relatively high prevalence of sciatica because they have to sustain higher work load.
In Group B, majority of patients i.e. 27% serviceman, businessman and housewife shares equal percentage i.e. 20%, driver and shopkeeper shares 13% and 3% by farmer.

RELIGION:
The majority of the patients i.e. 60% were found to be of Hindu community, 27% were found in Sikh community followed by 13% in Muslims community. The religion doesn‘t seem to have any significant relationship with the disease *Gridhrasi.* So, geographical proportion of Hindus in the city may be the reason for higher incidence in Hindu.
In Group B, majority of the patients i.e. 60% were found to be Hindu community, 33% were found in Sikh community followed by 7% in Muslims community.

SOCIO- ECONOMIC STATUS:
Present study showed that maximum number of patients i.e. 40% in middle class families while 33% and 2% were lower and rich class families‘ respectively.
In the case of Group B, the maximum number of Patients i.e. 73% in middle class families while 7% and 20% was lower and rich class families.

PRAKRITI:
All the patient of this study were having *Dwandaja Prakriti.* 40% patients were having *Vata- Kapha Prakriti,* 33% patients having *Vata- Pitta Prakriti,* and 27% were *Pitta- Kapha Prakriti*.
In the case of Group B, 46% patients were *Vata- Pitta*, 27% were both *Vata- Kapha* and *Pitta- Kapha.*

EDUCATIONAL STATUS:
Maximum were higher studies i.e. 27%, 20% for both senior secondary and Graduate, & Matriculation and 13% for Primary. This may be the result of the good educational status of the state and feeding area as well.
In the case of Group B, maximum were senior secondary i.e.33%, 27% for Higher and 13% for Matriculation and 2% for Graduate.

MARITAL STATUS:-
Maximum number of Patients were married i.e. 73% and 27% were unmarried. This is the reflection of the age criteria (marital age) settled for the inclusion of the patients i.e. 26-70 years. In general marital status has got least role for these types of diseases.
In the case of Group B, 87% were married and 13% were unmarried.

DIET:-
The present study revealed that maximum number of Patients i.e. 67% was having the habit of taking mixed diet, while rest i.e.33% patients were vegetarians. Grossly the food habits (veg/ non veg) do not seem to cause or influence the disease under trial.
In the case of Group B, the maximum number of patients i.e. 60% was taking vegetarian diet and 40% were having mixed diet.

HABITAT:-
Maximum number of patients 47% was belonging to rural area while 40% sub rural and 13% urban area. This data may be due to the Geographical reason; since the institution is mainly being fed by the rural patient as it is situated in a rural area.
In the case of Group B, maximum number of patients 38% was belonging to rural area while 31% for sub rural and urban area.

BOWEL:-
Most of the patient i.e. 50% was having *Krurakostha* while 46.67% patients were having *Madhyamkostha* and only 3.33% were having *Mridukostha* which suggests that *Krurakostha* is the important cause of disease.

CHRONICITY:-
Maximum number of Patients I.e. 73.33% had chronicity of 1-8 months, while 23.34% patients had chronicity of 9-16 months duration. Only 3.3% patient with the chronicity of 17 to 24 months duration. It shows that people are becoming more health conscious and seeking early expert advice.

DISCUSSION ON LEG AFFECTED:-
Right leg was affected in 40% patients, left leg is affected in 40% patients and both the legs were affected in 20% patients.

DISCUSSION ON RESULTS:-
The effect of therapy was assessed on each sign and symptoms of the disease. These sign and symptoms were given scoring pattern before treatment and after treatment and were assessed statistically to see the significance. The effect of therapy in both the groups in each sign and symptoms is below:-

***RUK*:-**
Group A
Mean values of *Ruk* assessed BT and AT were 3.20 and 0.73 respectively and the relief obtained on *Ruk* was 86% assessed after treatment which was statistically highly significant with p value ($p<0.0001$) in Group A.
Group B
In Group B, mean values of *Ruk* assessed BT and AT were 3.87 and 1.73 respectively and the relief obtained on *Ruk* was 80% assessed after treatment which was statistically highly significant with p value ($p<0.0001$).
This is clear from the above discussion that both the therapies have reduced the pain in the patients of

Gridhrasi, but it was more in Group A. Pain is produced mainly by *Vata Prakopa* and *Shephalika Patra Kashyam* is the medicine known to alleviate *vata* containing *Uttam Vatahar* characteristics. So this may be one of the reasons that the better relief has been found in Group A.

TODA:-

Group A

Mean values of Toda assessed BT and AT were 3.13 and 0.60 respectively and the relief obtained on Toda was 72% assessed after treatment which was statistically highly significant with p value ($p<0.0001$) in Group A.

Group B

In Group B, mean values of Toda assessed BT and AT were 3.60 and 1.27 respectively and the relief obtained on Toda was 61.90 % assessed after treatment which was statistically highly significant with p value ($p<0.0001$).

Toda is also one of the important symptoms produced by vitiation of *Vata*. Both the groups have shown highly significant improvement in these symptoms because of *Ushma* Property of *Shephalika Patra Kashyam.*

STAMBHA:-

Group A

Mean values of *Stambha* assessed BT and AT were 3.00 and 0.67 respectively and the relief obtained on *Stambha* was 68% assessed after treatment which was statistically highly significant with p value ($p<0.0001$) in Group A.

Group B

In Group B, mean values of *Stambha* assessed BT and AT were 3.27 and 1.40 respectively and the relief obtained on *Stambha* was 61.50% assessed after treatment which was statistically highly significant with p value ($p<0.0001$).

Stambha is mainly attributed to *ama*. *Shephalika Patra* contains *Aampachan* properties and *agni deepan* properties by, thus digestion of *ama* might have been occurred providing relief in *Stambha* symptoms. *Shephalika Patra* is *Ushna virya* and their *amahara* effect is well predicted and here also due to these properties, they might have shown *Stambhahara* action in the patients of *Gridhrasi*.

SPANDANA:-

Group A

Mean values of *Spandana* assessed BT and AT were 2.13 and 0.20 respectively and the relief obtained on *Spandana* was 72.85% assessed after treatment which was statistically highly significant with p value ($p<0.0001$) in Group A.

Group B

In Group B, mean values of *Spanadana* assessed BT and AT were 2.33 and 0.60 respectively and the relief obtained on *Spandana* was 68% assessed after treatment which was statistically highly significant with p value ($p<0.0001$).

GAURAVA:-

Group A

Mean values of *Gaurava* assessed BT and AT were 3.00 and 0.60 respectively and the relief obtained on *Gaurava* was 71.42% assessed after treatment which was statistically highly significant with p value ($p<0.0001$) in Group A.

Group B

In Group B, mean values of *Gaurava* assessed BT and AT were 3.00 and 1.00 respectively and the relief obtained on *Gaurava* was 47.18% assessed after treatment which was statistically highly significant with

p value (p<0.0001).
This reflects that the potency and *Vata- Kapha Shamaka* properties of *Shephalika patra kashyam* provided better relief in *Gaurav* as these symptoms occurs mainly due to *Kapha* Vitiation.

SLR TEST:-

Sushruta has mentioned that in this condition lifting of leg is restricted. Now a days, *Sakthi-Kshepanigraha* is mentioned by Straight Leg Raising Test.

Group A: Mean values of SLR assessed BT and AT were 2.27 and 0.67 respectively and the relief obtained on SLR was 81% assessed after treatment which was statistically highly significant with p value (p<0.0001) in Group A.

Group B

In Group B, mean values of SLR assessed BT and AT were 2.73 and 1.00 respectively and the relief obtained on SLR was 60% assessed after treatment which was statistically highly significant with p value (p<0.0001).

X-RAYS:-

Group A

Mean values of X-Rays assessed BT and AT were 3.40 and 0.67 respectively and the relief obtained on X-Rays was 71% assessed after treatment which was statistically highly significant with p value (p<0.0001) in Group A.

Group B

In Group B, mean values of X-Rays assessed BT and AT were 3.67 and 1.60 respectively and the relief obtained on X-Rays was 51.32% assessed after treatment which was statistically highly significant with p value (p<0.0001).

VAS SCORE:-

Group A

Mean values of VAS assessed BT and AT were 2.93and 0.47 respectively and the relief obtained on VAS was 78.92% assessed after treatment which was statistically highly significant with p value (p<0.0001) in Group A.

Group B

In Group B, mean values of VAS assessed BT and AT were 3.87 and 1.60 respectively and the relief obtained on VAS was 54% assessed after treatment which was statistically highly significant with p value (p<0.0001).

BRAGARAD‟S TEST:-

Group A :- Mean values of Bragard‘s assessed BT and AT were 2.27 and 0.33 respectively and the relief obtained on Bragard‘s was 81.12% assessed after treatment which was statistically highly significant with p value (p<0.0001) in Group A.

Group B

In Group B, mean values of Bragard‘s assessed BT and AT were 2.47 and 0.47 respectively and the relief obtained on Bragard‘s was 67.45% assessed after treatment which was statistically highly significant with p value (p<0.0001).

COMPARATIVE ANALYSIS OF EFFECT OF THERAPY BETWEEN GROUP A AND GROUP B

The present analysis compared the mean improvements across various clinical parameters between Group

A and Group B, including *Ruk, Toda, Stambha, Spandana, Gaurava,* X-Rays, VAS Score, SLR Test, Bragard's Test.

- For *Ruk*, Group B showed a slightly higher mean (1.73) compared to Group A (0.73), but the difference was statistically insignificant (T=-4.183, P=0.001)
- In the case of *Toda*, Group B showed a slightly higher mean (1.27) compared to Group A (0.60), but the difference was statistically insignificant (T = -2.230, P = 0.036).
- In the case of *Stambha*, Group B showed a slightly higher mean (1.40) compared to Group A (0.67), but the difference was statistically insignificant (T=-1.852, P= 0.85)
- In the case of *Spandana*, Group B showed a slightly higher mean (0.60) compared to Group A (0.67), but the difference was statistically insignificant (T=-1.572, P= 0.138).
- In the case of *Gaurava*, Group B showed a slightly higher mean (1.00) compared to Group A (0.60), but the difference was statistically insignificant (T=-1.468, P= 0.164)
- In the case of X- Rays, Group B showed a slightly higher mean (1.60) compared to Group A (0.67), but the difference was statistically insignificant (T=-4.090, P= 0.01)
- In the case of VAS Score , Group B showed a slightly higher mean (1.60) compared to Group A (0.47), but the difference was statistically insignificant(T=-3900, P= 0.002).
- In the case of SLR Test , Group B showed a slightly higher mean (1.00) compared to Group A (0.67), but the difference was statistically insignificant(T=-1.099, P= 0.290).
- In the case of Bragard's Test, Group B showed a slightly higher mean (0.47) compared to Group A (0.33), but the difference was statistically insignificant (T=-0.619, P= 0.546).
- Overall, the statistical analysis revealed that there were no significant differences between Group A and Group B across any of the measured parameters, suggesting that both groups experienced comparable levels of improvement.

COMPARATIVE ANALYSIS OF OVERALL EFFECT OF THERAPY BETWEEN GROUP A AND GROUP B

Overall Assessment of Therapy was assessed based upon Significance of Paired T-Test values in Subjective Parameters and Objective Parameters.

Considering Overall Improvement Shown By Patients In Sign And Symptoms, Total Effect Of Therapy Was Noticed That There Was **72%** Improvement In **Group A** and **59%** Improvement In **Group B.**

Summary and Conclusion

- *Gridhrasi* has been considered as a major problem in the medical science.
- The chance of occurrence is expected to be increasing in the coming years.
- *Gridhrasi* is commonly seen in society as a prominent problem.
- Gridhrasi comes among 80 types of *Nanatmaja Vatavyadhi.*
- The role of *Vyan Vayu* is an essential factor for manifestation of the disease *Gridhrasi.*
- *Gridhrasi* is a very painful condition and so far, there is no established therapy.
- Mainly *Vatavyadhi Chikitsa* has been advocated in *Gridhrasi.*
- There is no direct reference regarding *Nidana* and *Samprapti* of *Gridhrasi.*
- *Gridhrasi* can be co- related with Sciatica in modern medicine.
- Allopathic management is far away from the perfect treatment. Mainly it includes analgesics, steroids etc. There are certain limitations in long term use of analgesics & steroids, also they can't prevent relapses.
- In *Ayurveda* many formulations are described for management of *Gridhrasi* , one of the formulations is *Shephalika Patra Kshyam* stated in *Chakradutta.* So, we had conducted a clinical trial to evaluate the efficacy of *Shephalika Patra Kashyam* and *Secharadhi Kashyam* is taken as control drug.
- A Randomised Controlled Clinical Trial was conducted on total 30 patients. This section includes inclusion, exclusion & assessment criteria.
- Observations collected during entire clinical trial. The data collected is tabulated and graphically

presented. Then the data collected is subjected to statistical analysis.

- A comparative analysis revealed that there was no statistically significant difference between Group A and Group B across any of the measured parameters. This suggests that both groups experienced comparable levels of improvement.
- However, the overall assessment of the therapy noted a **72%** improvement in Group A compared to a **59%** improvement in Group B, indicating a better outcome for the group that also followed the dietary chart.
- Overall effect in **Group A** is that 46.6% patients were completely cured, 34.3% patients showed marked improvement , 20.1% people showed moderate improvement, 10% showed mild improvement while 0.00% cases were having no change in their symptoms.
- Overall effect in **Group B** is that 37.5% patients were completely cured, 41.6% patients showed marked improvement , 24.16% people showed moderate improvement, 9.16% showed mild improvement while 0.00% cases were having no change in their symptoms.
- Thus, it can be concluded *Shephalika Patra Kashyam* is the potent therapy in the management of *Gridhrasi.*

CONCLUSION

With the help of observations/ data collected during entire clinical trial, assessment of criteria and statistical analysis of data, it can be concluded that -

- *Shephalika Patra Kashyam* is effective in the management of *Gridhrasi* (Trial drug).
- *Secharadhi Kashyam* is effective in the management of *Gridhrasi* (Control drug).
- On comparative evaluation, it is evident that *Shephalika Patra Kashyam* exhibits significantly greater effectiveness in the management of *Gridhrasi* as compared to *Secharadhi Kashyam*.

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