

OPEN IDEALISTIC CLINICAL TRIAL EVALUATING THE EFFECT OF LASHUNA RASAYANA IN GRIDHRASI / SCIATICA

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ABSTRACT

Spine is an important part of the human being responsible for locomotion. *Gridhrasi*, one among the 80 *vataja nanatmaja vyadhi*, equated to sciatica is the most common illness of the spine. In the present study, *lashuna rasayana* an effective safe treatment modality in *ayurveda* was planned. In the present study, 23 patients of *gridhrasi* / Sciatica were selected from IPD of S.D.M. College of Ayurveda & Hospital, Udupi. It was an open single group study with pre-test, post test design. The patients were subjected to *virechana karma* followed by *lashuna rasayana*. The assessment of therapy was done by suitable scoring methods which were critically analyzed. The results thus obtained were subject to statistical analysis by paired 't' test. The end results which were obtained were interpreted and graded according various grades. The study showed *rasayana* treatment as highly effective in the management of *gridhrasi*.

Keywords: *Gridhrasi, Virechana, Lashuna Rasayana*

INTRODUCTION

For daily activities throughout life Spinal column has a major role in locomotion. It is impossible to imagine a human being without a healthy mobile spine. In present day competitive era, especially the wear and tear of this particular part of the body get damaged because of improper sitting posture, strenuous activities etc. The various actions lead to undue pressure on the spine and cause the most common radicular pain called the Sciatica syndrome.

Gridhrasi is a *Vata Vyadhi* characterized by stiffness, pain, pinprick sensation and frequent fasciculation. The discomfort initially begins at the buttock as well as back of the pelvis and then radiates to the back of the thigh, knee, leg and foot respectively¹. These manifestations of the *Gridhrasi* match with the clinical presentation of Sciatica of conventional medicine. A syndrome characterized by very painful radiating pain beginning from the back into the buttock, lower extremity all along its postero-lateral

part, and mainly caused by protuberance of lower lumbar disc². The straight leg raising test which confirms Sciatica is described as 'Sakthikshepanigraha' meaning restriction of leg flexion³.

The treatment in the modern parlance for Sciatica is unsatisfactory and includes use of analgesics and complicated surgical procedures which are often associated with many secondary complications. It is well known that chronic lingering disease that may show recurrence is best treated by Rasayana treatment. Hence in the present study, the Lashuna which is indicated in Vatavyadhi in general and Sciatica in particular is adopted here as Lashuna Rasayana⁴.

Aim and Objective:

To evaluate the therapeutic effect of Lashuna Rasayana in Gridhrasi/ Sciatica

Materials and methods:

It is an open group clinical study where in 23 patients of gridhrasi with classical symptoms were randomly selected from OPD & IPD of SDM College of Ayurveda, Udupi.

Plan of the study:

The selected patients were subjected to Virechana Karma as pre-requisite for Rasayana, which was followed by administration of Lashuna Rasayana.

Virechana Karma

The following procedures are sequentially carried out as part of Virechana Karma

- Deepana Pachana with- Chitrakadi Vati⁸ 250mg TID for 3 days.
- Snehapana with- Dasamuladhya Gritha⁹, 50 - 150mL for next 5 days
- Abhyanga with Mahanarayana Taila¹⁰ followed by Snigdha Sarvanga Sveda was carried out for 30 minutes with Dashamula Kvatha for consecutive 4 days following Snehapana.
- On the 4th day of Abhyanga and Sveda, Virechana is done by administering with Trivrut Leha¹¹ in a dose of 40gm to achieve Madhyama Shodhana.
- From the day of Virechana, Peyadi Samsarjana Krama is followed for 5 days.

Lashuna Rasayana

The capsules of Lashuna containing 500mg of dry powder of Lashuna were obtained from SDM Ayurveda Pharmacy Udyavara; the same is administered as Lashuna Rasayana in the following dosage schedule:

- Orally 12 capsules of Lashuna was administered every day from Day 1 to Day 4 following Samsarjana Krama,
- Orally 24 capsules of Lashuna was administered every day from Day 5 to Day 8,
- Orally 36 capsules of Lashuna was administered every day from Day 9 to Day 12,
- Orally 48 capsules of Lashuna was administered every day from Day 13 to Day 16,

Anupana – Ksheera¹² 200mL

To complete the Rasayana Vidhi, Trivrut Leha is orally administered in a dose of 8gm to induce Rechana¹³ on Day 17.

Inclusion Criteria:

1. Patients of gridhrasi/sciatica between the ages of 16 to 70 years.
2. Patients with/without radiological evidence of lumbar spondylosis.
3. Patients of with/without radiological evidence of disc prolapse.

Exclusion Criteria:

1. Sciatica with Congenital deformities of spine
2. Trauma to the spine leading to sciatica.
3. Neoplastic conditions of the spine with radicular pain.
4. Infections of the spine with sciatica.
5. Patients with any other systemic illness associating sciatica.

Duration of study: 35 days

Diagnostic criteria:

1. Presence of symptoms of Gridhrasi that include stiffness, pain, pricking sensation, twitching, in waist, buttocks & then radiating to back of the thigh, leg, ankle, foot suggestive of vataja gridhrasi. The additional symptoms like heavi-

ness in the legs, drowsiness and tastelessness may be present.

2. Presence of radicular pain of Sciatica that includes sudden/gradual onset of low back ache, radiating to buttock, thigh, calf and foot.

Assessment Criteria:

Subjective Parameters:

1. Parameters like *Sthambha* (stiffness), *Ruk* (Pain), *Toda* (Pricking Sensation), *Spandana* (Twitching), *Aruchi* (Anorexia), *Tandra* (Drowsiness), *Gaurava* (Heaviness) were assessed according to severity and graded accordingly.
2. Assessment of Pain - Was done by *Greenough and Fraser scoring method*, based on various parameters like frequency of taking pain killers consultation with doctor, work status, effect on activity, dressing, sleeping, travelling, sex life. The higher the score, the better the performance status.
3. Functional ability- Was assessed by Sugar baker & Barofsky Clinical Mobility Scale⁵ based on various mobility parameters like posture, walking, gait, sitting, stair climbing, and dependency on various supports. The higher the score, the better the performance.
4. Functional disability- Was assessed by Oswestry disability Assessment Questionnaire⁶. The Questionnaire description as follows 10 sections describing the pain and its impact with each section scored from 0-5, with higher values indicating more severe impact.
5. Individual functional abilities-
 - a. Walking for 30 feet- For this purpose patient was asked to walk 25 feet distance in a straight

way in full speed and time taken was recorded by the help of a stopwatch in seconds. The walking time was noted before and after the treatment.

- b. Floor hand distance- for this purpose, the patient was asked to bend forward to touch the floor. The distance between tips of middle finger and floor was measured in centimeters before and after treatment
- c. Climbing 10 steps- For this purpose patient was asked to climb 10 steps in full speed and speed and time taken was recorded by the help of a stopwatch in seconds. The time was noted before and after the treatment.
- d. 10 sit ups- For this purpose patient was asked to do 10 sit-ups in full speed and speed and time taken was recorded by the help of a stopwatch in seconds. The time was noted before and after the treatment.

Objective Parameters:

1. Restricted limb movement/SLR- An SLR above 45 degrees was scored 1, below 45 scored 0
2. Lasegue's -Positive was scored 1, negative scored 0
3. Schober's test- While the patient is in a standing position the examiner makes a mark approximately at the level of L5 (fifth lumbar vertebra). Two points are marked: 5 cm below and 10 cm above this point (for a total of 15 cm distance). Then the patient is asked to touch his/her toes while keeping the knees straight. If the distance of the two points do not increase by at least 5 cm (with the total distance greater than 20 cm) its marked 1, if it is more than 20cm its is scored 0
4. Neurological deficit- Herron & Turners Rating⁷

Parameter	Finding	Points
Neurological signs	Normal	0
	reflex asymmetry, age > 50 or previous surgery	0
	reflex asymmetry, age <= 50 years of age	5
	motor weakness	10
	sensory deficit	10
	motor and sensory deficits	25
Root tension signs	list-flexed knee stance	10

femoral nerve stretch positive	10
unilateral straight leg raising > 75°	0
unilateral straight leg raising 60-75°	10
unilateral straight leg raising < 60°	20
crossed straight-leg response	20

Statistical analysis – done by paired student ‘t’ test
CRITERIA FOR ASSESSING THE TOTAL EFFECT

Considering the overall improvement had shown by the patient in sign and symptoms, the total effect of the therapy has been assessed as below.

- Cured 100% relief in sign and symptoms
- Marked Relief More than 75% relief in sign and symptoms.
- Moderate Relief 50% - 75% relief in sign and symptoms.
- Mild Relief 25% - 50% relief in signs and symptoms.

- Unchanged Up to 25% relief in sign and symptoms.

Results

Effect of Lashuna Rasayana on the Patients of Gridhrasi:

After *Virechana Karma* depending on amount of *Vaigiki Shuddhi*, *Samsarjana* was planned accordingly. After *Samsarjana*, *Lashuna Rasayana* in the prescribed dosage was administered for a period of 16 days and was ended with *Virechana* with *Trivrut Leha* 8gms. After the completion of the course the patients were evaluated for various subjective and objective parameters. The detail account has been explained below:

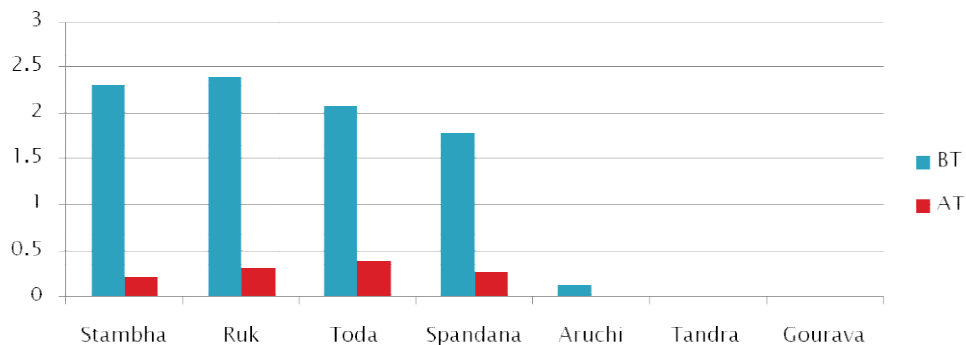
Effect of Lashuna Rasayana on the symptoms of Gridhrasi:

The effect of *lashuna rasayana* on symptoms of *gridhrasi* like *stambha*, *ruk*, *toda*, *muhurspandana* have been mentioned below.

SI No	Symptom of Gridhrasi	Table/Graph
1	<i>Stambha</i>	(Table No 01& Graph No 1)
2	<i>Ruk</i>	(Table No 01& Graph No 1)
3	<i>Toda</i>	(Table No 01& Graph No 1)
4	<i>Spandana</i>	(Table No 01& Graph No 1)
5	<i>Aruchi</i>	(Table No 01& Graph No 1)

The symptoms *tandra* and *gaurava* were not observed in any of the patients.

Graph 01 - Effect of Lashuna Rasayana on various symptoms of gridhrasi

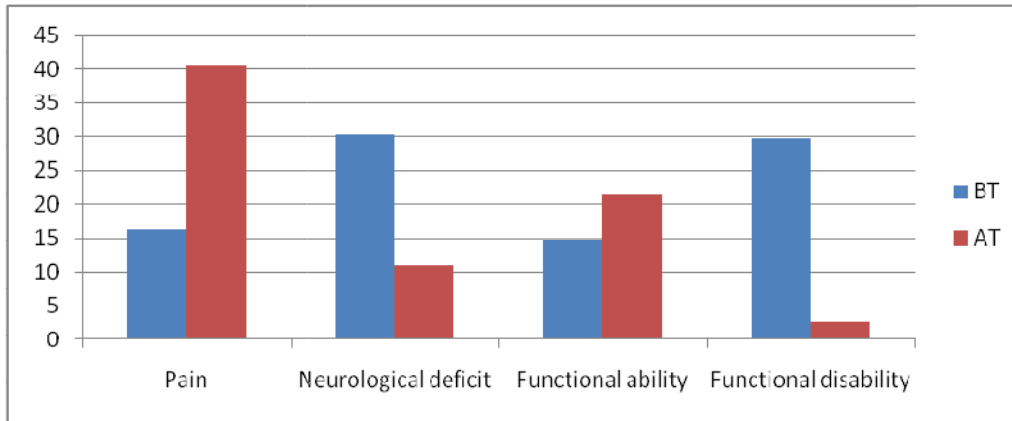


Effect of *Lashuna rasayana* on various outcome measures:

The effect of *Lashuna rasayana* on various outcome measures like pain, neurological deficit, functional ability, functional disability have been mentioned below

Si. No	Outcome measures	Table/Graph
1	Pain	Table No 02 and Graph No 02
2	Neurological deficit	Table No 03 and Graph No 02
3	Functional ability	Table No 04 and Graph No 02
4	Functional disability	Table No 05 and Graph No 02

Graph 02: Overall Effect of *Lashuna Rasayana* on various outcome measures:

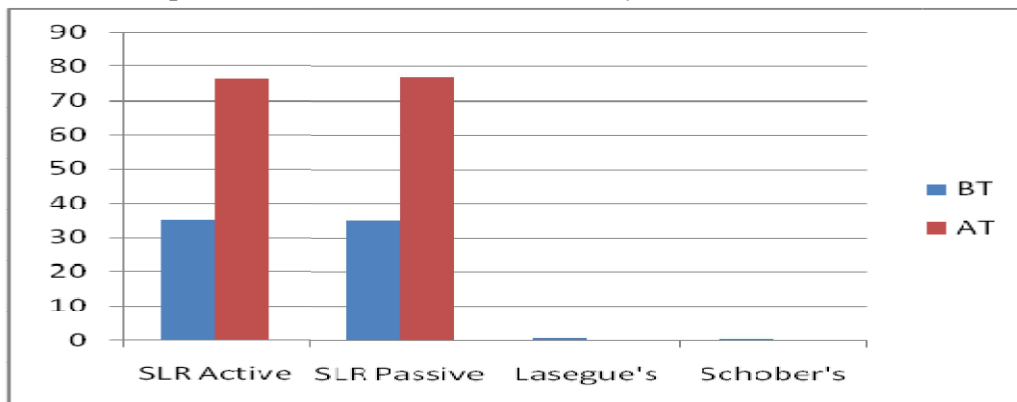


Effect of *Lashuna Rasayana* on various tests for Sciatica:

Effect of *lashuna rasayana* on various tests of sciatica like SLR active and passive, lasegue’s sign, bregard’s test, bowstring’s test, schober’s test have been mentioned below.

SI No	Outcome measures	Table/Graph
1	SLR test Active	Table No 06 and Graph No 03
2	SLR Passive	Table No 06 and Graph No 03
3	Lasegue’s test	Table No 07 and Graph No 03
4	Schober’s test	Table No 08 and Graph No 03

Graph 03: Overall Effect of *Lashuna Rasayana* on tests of sciatica:

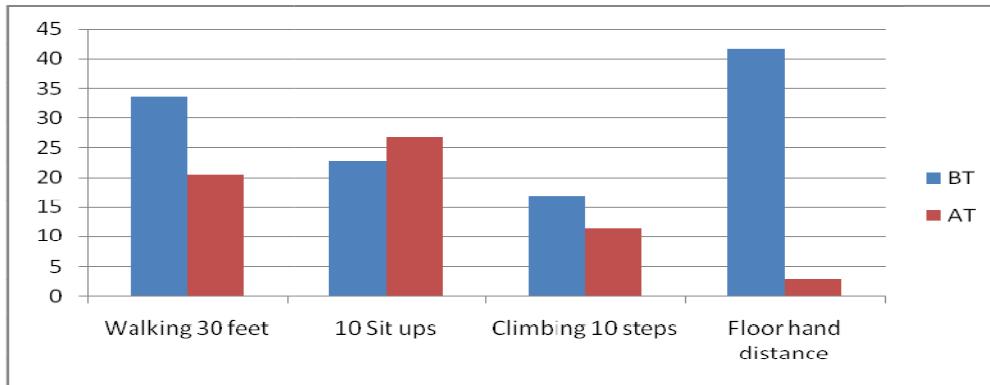


Effect of *Lashuna Rasayana* on individual functional abilities:

Effect of *lashuna rasayana* on individual functional abilities like walking for 30 feet, 10 sit ups, climbing 10 steps, floor hand distance have been mentioned below

Sl No	Outcome measures	Table/Graph
1	Walking for 30 Feet	Table No 09 and Graph No 04
2	10 Sit Ups	Table No. 10 and Graph No 04
3	Climbing 10 Steps	Table No. 11 and Graph No 04
4	Floor Hand Distance	Table No. 12 and Graph No 04

Graph 04: Overall Effect of *Lashuna Rasayana* on individual functional abilities:

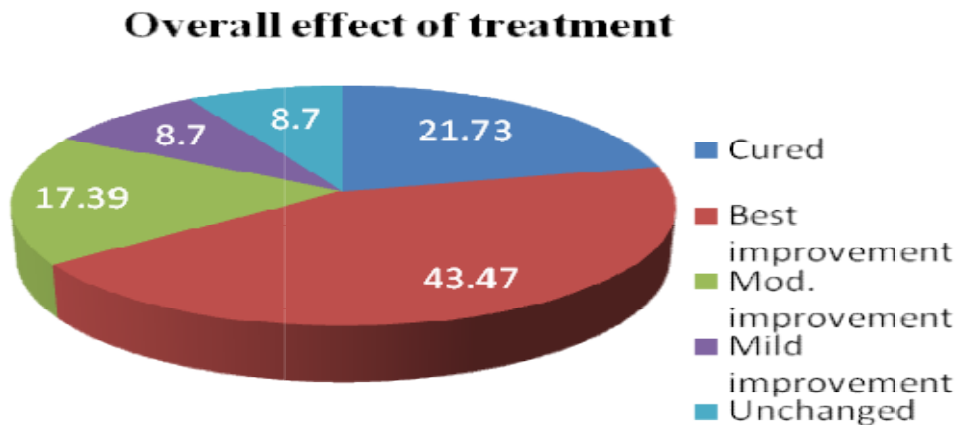


Overall Effect of Treatment in 23 Patients after *Lashuna Rasayana*

After the full course of *Virechana* and *lashuna rasayana* the patients were analysed for their symptoms. It was found that 21.73% of the patients got

complete cure, 43.47% of patients had best improvement, 17.39% had moderate improvement, 8.7% had mild improvement and equal number of patients it was unchanged. (Table No 13 and Diagram No. 01)

Diagram 01: Overall Effect of *Virechana* and *Lashuna Rasayana* of Treatment



DISCUSSION

Probable mode of action:

Lashuna Rasayana is a single drug medication. It contains only freeze dried powder of *Lashuna*. *Lashuna* has been told as an *Agreyra* for *Vatavyadhi*. Also use of the same in the *Rasayana* form has also been explained. All the properties of *Lashuna* are antagonistic to predominantly against *Vata* and secondarily *Kapha*. *Anupana* mentioned was *ksheera* which potentiates the action of *lashuna*.

During the whole course of the treatment all patients were extremely comfortable with no undesirable effects. *Chitrakadi Vati* was well tolerated during the course of *Deepana Pachana* without any dreadful symptoms.

For the *Snehapana*, *Dasamuladhya Gritha*, containing Drugs like *Dashamula*, *JeevaniyaGana* claimed as curative in *Vatavyadhi* like *Gridhrasi*. *Bashpa Sveda* was administered for a period of 4 days with the *Dashamula kvatha churna*. *Virechana karma* was administered on the 4th day of *Bashpa Sveda* with the *Trivrut leha* in the quantity of 40gms with milk as an adjuvant. All the patients had no any discomfort during the consumption of the medicine. After the *Virechana karma*, *Peyadi samsarjana Krama* was administered depending on *VaigikiShuddhi*. *Samsarjana Krama* 3-5 days was advised. *Lashuna Rasayana* was administered starting from the very next day of *Samsarjana krama*. The patients endured the whole course of *Rasayana* without any discomfort.

Gridhrasi is a disorder of sciatic nerve entrapment. Desiccation of the disc material is the major phenomenon that clears the impingement on the nerve route thereby clearing the entrapment. This may be a natural process over a period of time may occur in several months and once the entrapment is cleared compression of sciatic nerve is also cleared. Thus the patient becomes asymptomatic. Best response of medication in the course of 35 days coins towards the fact that desiccation of the disc is speeded up, thus the patient experiences complete relief from the pain, improving the functional ability of the patient.

Displacement of the disc impinging on the nerve root also initiates inflammation in the sciatic nerve. Reduction in the pain is only possible until the inflammation of the sciatic nerve is cleared. Remission of the sciatica/ *Gridhrasi* also indicates clearance of the sciatic neuritis by the medication of *Lashuna Rasayana*. Protruded disc causing the entrapment of sciatic nerve which initiates radicular pain leads to severe muscle spasm this in turn changes to deviated trunk position. Rectification of the gait with no scoliosis following treatment confirms the elimination of the muscle spasm that associate the sciatic nerve entrapment. In short, clearance of the nerve entrapment remission of the sciatic neuritis and absence of muscle spasm, all are the result of *Lashuna rasayana* leading to near complete relief from the symptoms of Sciatica / *Gridhrasi* by the 35 days of *Lashuna rasayana*.

Overall Effect of the Treatment:

Among the 23 patients taken for *Gridhrasi*, 21.73% were cured, 43.47% had best improvement, 17.39% patients had moderate improvement, 8.7 % patients had mild improvement and 8.7 % were unchanged.

CONCLUSION

- *Lashuna rasayana* is effective in the remission of the symptoms of *Gridhrasi* as evidenced by statistically significant reduction in the symptom score of *Stambha*, *Ruk*, *Toda*, *Muhurspandana*, and *Arochaka*
- *Lashuna Rasayana* is effective in reducing the neurological deficits manifested secondary to Sciatica.
- Quality of life is improved by the medication with *Lashuna Rasayana* as shown by improvement of functional ability, as well as reduction in the functional disability.
- The treatment is effective and equally safe.

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Table 01: Effect of *Lashuna Rasayana* on various symptoms of *gridhrasi*

	Mean		Difference In Means	% Relief	Paired 't' test			
	BT	AT			SD	SEM	t	P
<i>Stambha</i>	2.304	0.217	2.087	90.58	0.949	0.198	10.543	<0.001
<i>Ruk</i>	2.391	0.304	2.087	87.28	0.848	0.177	11.801	<0.001
<i>Toda</i>	2.087	0.391	1.696	85.36	1.185	0.247	6.865	<0.001
<i>Spandana</i>	1.783	0.261	1.522	85.36	0.994	0.207	7.342	<0.001
<i>Aruchi</i>	0.130	0.000	0.130	100	0.626	0.130	1.000	0.328

Table 02: Effect of *Lashuna Rasayana* on Pain

Mean		Difference In Means	% Improvement	Paired 't' test			
BT	AT			SD	SEM	T	P
16.304	40.391	24.087	40.35	10.574	2.205	10.925	<0.001

Table 03: Effect of *Lashuna Rasayana* on Neurological Deficit

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
30.217	11.087	19.130	63	16.213	3.381	5.659	<0.001

Table 04: Effect of *Lashuna Rasayana* on Functional Ability

Mean		Difference In Means	% Improvement	Paired 't' test			
BT	AT			SD	SEM	t	P
14.739	21.348	6.609	50	6.058	1.263	5.231	<0.001

Table 05: Effect of *Lashuna Rasayana* on Functional Disability:

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
29.783	9.348	20.435	68.61	9.115	1.901	10.752	<0.001

Table 06: Effect of *Lashuna Rasayana* on tests of sciatica

	Mean		Difference In Means	% Imp	Paired 't' test			
	BT	AT			SD	SEM	t	P
SLR Active	35.217	76.304	41.087	46.153	20.224	4.217	9.743	<0.001
SLR Passive	35.217	76.739	45.89	45.89	20.749	4.327	9.597	<0.001

Table 07: Effect of *Lashuna Rasayana* on Lasegue's Test

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
0.913	0.0870	0.826	90	0.388	0.0808	10.223	<0.001

Table 08: Effect of *Lashuna Rasayana* on Schober's Test

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
0.478	0.000	0.478	100	0.511	0.106	4.491	<0.001

Table 09: Effect of *Lashuna Rasayana* on Walking for 30 Feet:

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
33.609	20.565	13.043	38.81	13.927	2.904	4.492	<0.001

Table 10: Effect of *Lashuna Rasayana* on 10 Sit Ups

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
22.696	26.826	4.130	18	25.465	5.310	0.778	= 0.445

Table 11: Effect of *Lashuna Rasayana* on Climbing 10 Steps:

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
16.826	11.435	5.391	32	5.467	1.140	4.730	<0.001

Table 12: Effect of *Lashuna Rasayana* on Floor Hand Distance:

Mean		Difference In Means	% Relief	Paired 't' test			
BT	AT			SD	SEM	t	P
41.696	28.609	13.087	31.38	14.384	1.140	2.999	<0.001

Table 13: Overall Effect of *Virechana* and *Lashuna Rasayana* Treatment:

Effect	Cured	Best improvement	Moderate improvement	Mild improvement	Unchanged
No. of Patients	5	10	4	2	2
%	21.73	43.47	17.39	8.7	8.7

Source of Support: Nil

Conflict Of Interest: None Declared

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