

“Randomized open controlled clinical study of therapeutic effect of oral administration of *Shiva Guggul* with comparison to *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* with special reference to Sciatica in age group from 22 to 60 years.”

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ABSTRACT:

INTRODUCTION- *Ayurveda* is a science of life. This holistic ancient science has two objectives- 1) To maintain the health of healthy person, 2) To treat the sick person. The common symptoms of *Vatkaphaj Grudhrasi* are pain which start from *sphik* and then radiate up to *Kati*, *Prushta*, *Uru*, *Janu*, *Jangha*, *Pada*, along with *Stambha*, *Toda*, *Spandana*, *Tandra*, *Gourava*, *Aruchi*. *Grudhrasi* comes under 80 types of *Nanatmaja Vatvyadhi*. It explained by various Acharya's under *Vatvyadhi* chapter. Sciatica is a disease with neurological symptoms pertains to sciatic nerve. Modern science describe sciatica as a benign syndrome characterized especially by shooting pain starting in the lumber region and spreading down the back of the one lower limb, to the ankle and sometimes foot or any region like thigh, knee joint, calf region or foot. The pain in sciatica is mostly neuralgic type of pain referred to the muscle supplied by sciatic nerve.

In modern medicine, analgesic & steroid therapy is described for treatment

of sciatica. If not responding to conservative treatment, surgery may have to be advised or if progressive neurological deficit develops.

AIM & OBJECTIVES- To compare the effect of *Shiva Guggul* and *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* with special reference to Sciatica in age group from 22 to 60 years.

MATERIALS & METHODS- Total 60 patients of *Vatkaphaj Grudhrasi* selected randomly, which is then divided into two equal group i.e. 30 patients in each group. Giving intervention by *Shiva Guggul* in group A and *Rasna Guggul* in group B for 45 days treatment and followed up taken for therapy 45 days. Analysis of all patients were done and that result and conclusion were drawn.

RESULT & CONCLUSION- *Shiva Guggul* and *Rasna Guggul* both are effective in reducing subjective and objective parameters of *Vatkaphaj Grudhrasi*. *Shiva Guggul* is more effective in reducing *Vedana*, *Stambha*, *Toda*, *Tandra*, *Gourav*, *Aruchi*, *SNDT* & *SLRT*.

Rasna Guggul is more effective in reducing Tandra of *Vatkaphaj Grudhrasi*.

KEYWORDS- *Shiva Guggul, Rasna Guggul, Vatkaphaj Grudhrasi, Kati, Shawat.*

INTRODUCTION:

Ayurveda is a science of life. This holistic ancient science has two objectives- 1) To maintain the health of healthy person, 2) To treat the sick person.

“प्रयोजनं चास्य स्वस्थस्य स्वास्थ्यरक्षणमातुरस्य ववकारप्रशमनं च ॥२६॥” (च.सु.३०/२६)

This unique feature of *Ayurveda* makes it different from other system of medicine. *Ayurveda* is called ‘*Shaswat*’ because it is still relevant in the era of modern medicine. The objective of *Ayurveda* is to provide physical, mental, social, & spiritual wellbeing of mankind as well as treat the diseases with its various approach².

Today’s lifestyle and nature of work are putting added tension on the usual health. The factors such as over exertion, sedentary occupation, jerky movements during travelling and lifting weights create stress leads to backache. On account of our busy lives unknowingly our muscles and bones are put under strains. This strains can mount up incrementally and result in a serious impaction on the body such as sudden fall or a misalignment of the Spine resulting into lower back pain, leg pain, calf and foot pain etc. Although low back pain is a common condition & it affects 80-90 percent of persons during their lifetime, but true Sciatica occurs in about 5 percent of cases.

The common symptoms of *Vatkaphaj Grudhrasi* are pain which start from *sphik* and then radiate up to *Kati, Prushta, Uru, Janu, Jangha, Pada*, along with *Stambha, Toda, Spandana, Tandra,*

Gourava, Aruchi. Grudhrasi comes under 80 types of *Nanatmaja Vatvyadhi*. It explained by various Acharya’s under *Vatvyadhi* chapter. Sciatica is a disease with neurological symptoms pertains to sciatic nerve. Modern science describe sciatica as a benign syndrome characterized especially by shooting pain starting in the lumber region and spreading down the back of the one lower limb, to the ankle and sometimes foot or any region like thigh, knee joint, calf region or foot. The pain in sciatica is mostly neuralgic type of pain referred to the muscle supplied by sciatic nerve.

In modern medicine, analgesic & steroid therapy is described for treatment of sciatica. If not responding to conservative treatment, surgery may have to be advised or if progressive neurological deficit develops.

In *Ayurveda* this disease mentioned in very clear aspect and offers options in the management of disease like *Shaman chikitsa, shodhan chikitsa* like *Katibasti, Snehana, Swedana* etc.

AIM AND OBJECTIVES:

AIM:

To compare the effect of *Shiva Guggul* and *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* with special reference to Sciatica in age group from 22 to 60 years.

PRIMARY OBJECTIVE:

- To compare the effectiveness of *Shiva Guggul* and *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* with special reference to Sciatica in age group from 22 to 60 years.
- To access effect on *Kati-Sphik-Prushta-Uru-Janu-Jangha-Pada Vedana, Stambha, Toda, Tandra, Gourava, Aruchi.*

- To access effect on Straight Leg Raising (SLR) Test.
- To access effect on Sciatic Nerve Deep Tenderness Test (SNDT).

SECONDARY OBJECTIVE:

- To study detail etiopathogenesis of *Vatkaphaj Grudhrasi*.
- To access side effects of *Shiva Guggul* if any.

MATERIALS AND METHOD:

Study Design: Prospective, randomized, Controlled, open labelled clinical study.

Place– PG Department of kayachiktsa, Laxmanrao Kalasapurakar Ayurved Rugnalaya, Yavatmal, affiliated with D.M.M, Ayurved College, Yavatmal.

Duration: 45 days drug intervention and after that 45 days follow up.

SELECTION OF PATIENTS:

A. Inclusion Criteria:

- Age group – 22 to 60 years.
- Both sex-Male and Female.
- Patient irrespective of caste and religion.
- Patient with *Pratyatma lakshna of Vatkaphaj Grudhrasi i. e. kati-sphik-Prusht-uru-Janu-jangha-pad vedana, stambh, tod, tandra, gaurav, aruchi*.

- S.L.R. Test positive – Above 30° (Active SLRT)

- Sciatic notch tenderness.
- Patient belonging to any socio-economic class.

B. Exclusive Criteria:

- Patient with history of any direct or indirect trauma to spine.
- Patient having severe lumbar canal stenosis, 3rd and 4th degree disc Prolapse.
- Pregnancy and children.
- Patient with other systemic disorders like, CA Spine, Bone cancer, Fracture.
- Patient not willing to participate in trial.
- Severe alcoholic patient.
- Age group below 22 years and above 60 years.

C. Withdrawal Criteria:

- If the patient refused to continue treatment.
- If patient develops any adverse effect then.
- If patient is not responding to treatment and symptoms worsens then.
- If patient is not regular at OPD or no regular follow up.
- Death of patient occur due to any cause.
- Non cooperative behavior of patient.

TREATMENT DETAILS: Table no.1- Treatment details-

Group	Group A	Group B
No. of patients	30	30
Treatment	<i>Shiva Guggul</i>	<i>Rasna Guggul</i>
Dose	500 mg	500 mg

Kalpana	<i>Vati (tablet)</i>	<i>Vati (tablet)</i>
Anupana	<i>Koshnjal</i>	<i>Koshnjal</i>
Duration	Treatment 45 days Follow up 45 days	Treatment 45 days Follow up 45 days
Time of Administration	<i>Pragbhakt</i>	<i>Pragbhakt</i>
Route	Oral	Oral

Contents of Shiva Guggul- *Haritaki, Bibhitak, Amalaki, Erand oil, Gandhak, Rasna, Vidang, Marich, Pippali, Danti, Jatamansi, Shunthi, Devdar, Guggul.*

Contents of Rasna Guggul- *Rasna, Guggul.*

ASSESSMENT CRITERIA: Table no. 2: Assesment criteria-

A) SUBJECTIVE PARAMETERS -

Score	Vedana (Pain)	Stambha (Stiffness)	Toda (Pricking Sensation)	Tandra (Drowsiness)	Gourav (Heaviness)	Aruchi (Anorexia)	SNDT
0	No pain	No stiffness	No pricking sensation	No drowsiness	No heaviness in affected limb/region	No complaint	No tenderness
1	Mild pain	Stiffness for sometime and relieves after some movement	Mild pricking sensation sometime	Mild drowsiness not affecting routine work	Mild heaviness in affected limb/region not affecting work	1-2 times weekly c/o no desire to eat anything	Mild tenderness with no Facial wincing
2	Considerable amount of pain which is bearable	Moderate stiffness not relieved by movement	Moderate pricking sensation	Moderate drowsiness affecting routine work	Moderate heaviness in affected limb/region affecting work	3-4 times weekly	Face wincing due to pain

3	Severe unbearable pain	Stiffness for all time and affects activities	Severe pricking sensation all the time	Severe drowsiness with no work at all	Severe heaviness in affected limb/region with no work at all	No desire to eat anything at all	Withdrawal of affected limb
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B) OBJECTIVE PARAMETERS –

Sr. No.	SLRT
1	SLR more than 90°
2	SLR 71° to 90°
3	SLR 51° to 70°
4	SLR 30° to 50°

OBSERVATION AND RESULTS:

Table no. 3: Comparative Statistical analysis of Vedana

Symptom	<i>Kati-spik-prusht-uru-janu-jangha-pada vedana (pain)</i>
Mean difference score, Group A	1.20
Mean difference score, Group B	0.933
S.D. (+) of Group A	0.406
S.D. (+) of Group B	0.253
S.E. (+) of Group A	0.074
S.E. (+) of Group B	0.046
U	336
U'	564
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level $\alpha = 0.05$, we should reject the null hypothesis H_0 and accept the alternate

hypothesis H_a , i. e. *Shiva Guggul* (Group A) is significant than *Rasna Guggul* (Group B) for *Kati-spik-prusht-uru-janu-jangha-pada vedana (pain)*.

Table no. 4: Comparative Statistical analysis of Stambha-

Symptom	<i>Stambh (stiffness)</i>
Mean difference score, Group A	1.00
Mean difference score, Group B	0.567
S.D. (+) of Group A	0.742
S.D. (+) of Group B	0.504
S.E. (+), of Group A	0.135
S.E. (+), of Group B	0.092
U	307
U'	593
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level $\alpha = 0.05$, we should reject the null

hypothesis H_0 and accept the alternate hypothesis H_a , i. e. *Shiva Guggul* (Group A) is significant than *Rasna Guggul* (Group B) for *Stambh* (stiffness).

Table no. 5: Comparative Statistical analysis of Toda-

Symptom	Toda (pricking sensation)
Mean difference score, Group A	0.867
Mean difference score, Group B	0.50
S.D. (+) of Group A	0.571
S.D. (+) of Group B	0.572
S.E. (+), of Group A	0.104
S.E. (+), of Group B	0.10
U	305.5
U ‘	594.5
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level $\alpha = 0.05$, we should reject the null

hypothesis H_0 and accept the alternate hypothesis H_a , i.e. *Shiva Guggul* (Group A) is significant than *Rasna guggul* (Group B) for *Toda* (pricking Sensation).

Table no. 6: Comparative Statistical analysis of Gourav-

Symptom	Gourav (heaviness)
Mean difference score, Group A	0.90
Mean difference score, Group B	0.467
S.D. (+) of Group A	0.758
S.D. (+) of Group B	0.571
S.E. (+), of Group A	0.138
S.E. (+), of Group B	0.104
U	309.5
U ‘	590.5
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level $\alpha = 0.05$, we should reject the null

hypothesis H_0 and accept the alternate hypothesis H_a , i.e. *Shiva Guggul* (Group A) is significant than *Rasna guggul* (Group B) for *Gourav* (heaviness).

Table no. 7: Comparative Statistical analysis of Aruchi-

Symptom	Aruchi
Mean difference score, Group A	1.00
Mean difference score, Group B	0.533
S.D. (+) of Group A	0.83
S.D. (+) of Group B	0.628
S.E. (+), of Group A	0.151

S.E. (+), of Group B	0.114
U	310
U ‘	590
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level alpha = 0.05, we should reject the null

hypothesis H₀ and accept the alternate hypothesis H_a, i. e. *Shiva Guggul* (Group A) is significant than *Rasna Guggul* (Group B) for *Aruchi*.

Table no. 8: Comparative Statistical analysis of Tandra-

Symptom	Tandra
Mean Score, B.T.	0.567
Mean Score, A.T.	0.033
S.D. (+), B.T.	0.817
S.D. (+), A.T.	0.182
S.E. (+), B.T.	0.149
S.E. (+), A.T.	0.033
W	55
Z	-2.80
P	<0.05
Result	Significant

Mean difference of Group A is less than mean difference of Group B and P value is greater than the significance level alpha = 0.05, we should accept the null

hypothesis H₀ and reject the alternate hypothesis H_a, i. e. *Shiva Guggul* (Group A) is not significant than *Rasna guggul* (Group B) for *Tandra*.

Table no. 9: Comparative Statistical analysis of SNTD-

Sign	Sciatic Notch Deep Tenderness (SNTD)
Mean difference score, Group A	0.867
Mean difference score, Group B	0.33
S.D. (+) of Group A	0.507
S.D. (+) of Group B	0.479
S.E. (+) of Group A	0.092
S.E. (+) of Group B	0.087
U	230
U ‘	670
P	<0.05

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level alpha = 0.05, we should reject the null hypothesis H₀ and accept the alternate

hypothesis H_a, i.e. *Shiva Guggul* (Group A) is significant than *Rasna Guggul* (Group B) for *Sciatic Notch Deep Tenderness (SNTD)*.

Table no. 10: Comparative Statistical analysis of SLRT-

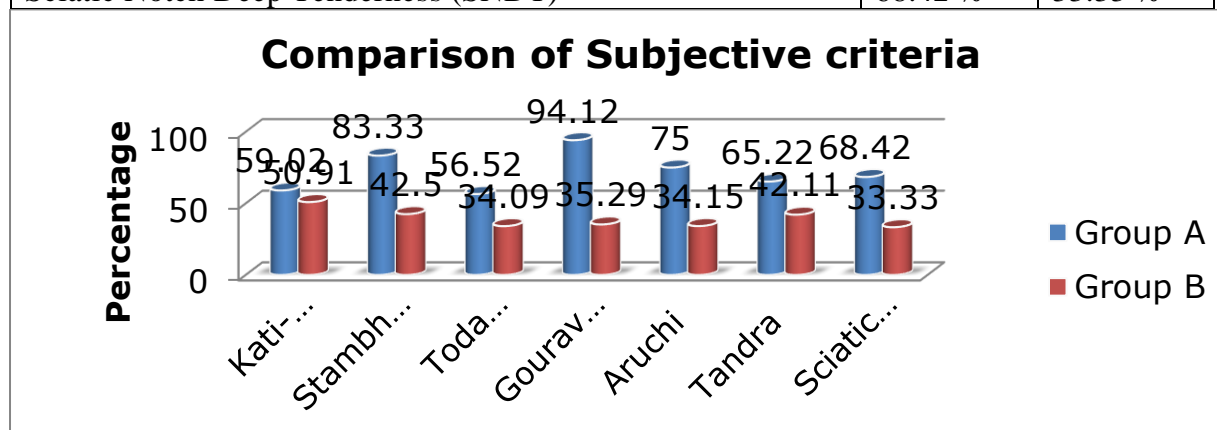
Symptom	Straight Leg Raise Test (SLRT)
Mean Difference Score, Group A	-22.33
Mean Difference Score, Group B	-9.50
Combined S.D. (+)	7.77
S.E. (+)	2.00
Unpaired t	6.39
P	<0.05

As the t value calculated is greater than the t tabulated value at $p=0.05$, Where $df = 5$, we should reject the null hypothesis and accept the alternate hypothesis i. e. **According to % relief in symptoms-**

Shiva Guggul (Group A) is significant than *Rasna Guggul* (Group B) for Straight Leg Raise Test.

Table no. 11: symptoms wise percentile relief-

Symptoms	Percentage Relief	
	Group A	Group B
<i>Kati-spik-prusht-uru-janu-jangha-pada vedana (pain)</i>	59.02 %	50.91 %
<i>Stambh (stiffness)</i>	83.33 %	42.50 %
<i>Toda (pricking sensation)</i>	56.52 %	34.09 %
<i>Gourav (heaviness)</i>	94.12 %	35.29 %
<i>Aruchi</i>	75.00 %	34.15 %
<i>Tandra</i>	65.22 %	42.11 %
Sciatic Notch Deep Tenderness (SNDT)	68.42 %	33.33 %

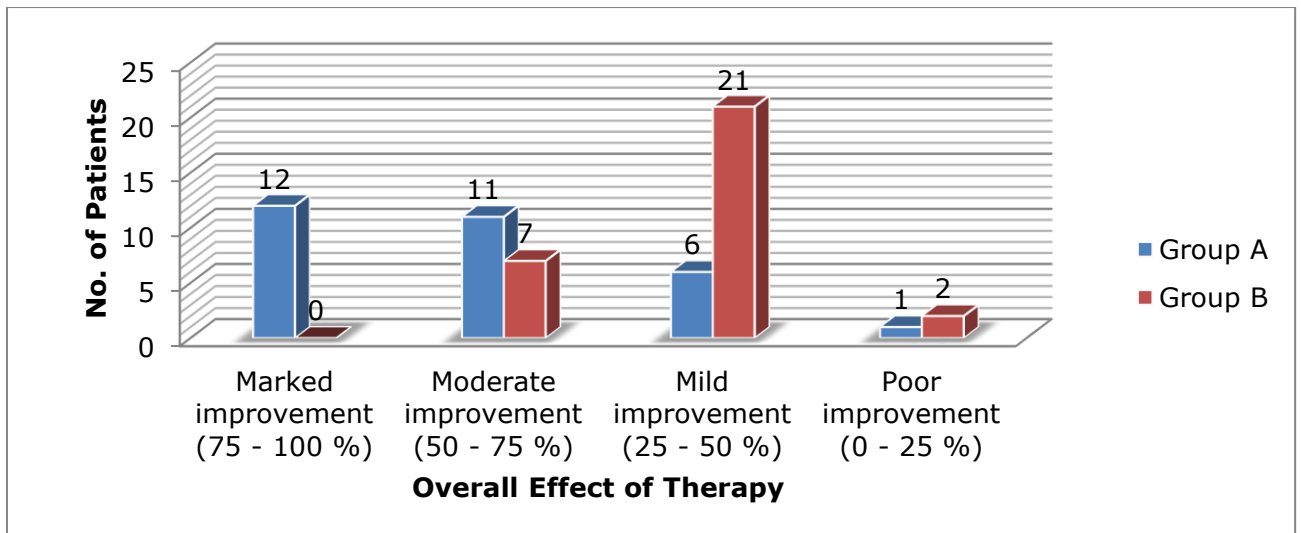
**Table no. 12: S.L.R.T. Improvement Before Treatment & After Treatment -**

Sr. No.	Group A SLRT (In Degrees)		Group B SLRT (In Degrees)	
	B. T.	A. T.	B. T.	A. T.
1.	45°	80°	50°	60°
2.	40°	60°	50°	60°
3.	45°	60°	40°	60°
4.	30°	60°	40°	60°
5.	35°	60°	30°	50°

6.	50°	75°	50°	50°
7.	50°	80°	45°	45°
8.	40°	60°	45°	50°
9.	45°	60°	50°	60°
10.	50°	70°	40°	50°
11.	60°	70°	45°	60°
12.	30°	60°	50°	50°
13.	40°	60°	45°	50°
14.	45°	60°	45°	50°
15.	30°	60°	40°	50°
16.	40°	55°	50°	60°
17.	40°	60°	40°	50°
18.	40°	60°	35°	60°
19.	30°	60°	35°	45°
20.	45°	60°	50°	60°
21.	40°	50°	60°	60°
22.	45°	60°	50°	50°
23.	45°	60°	55°	45°
24.	45°	60°	45°	60°
25.	35°	60°	45°	40°
26.	45°	60°	40°	45°
27.	40°	60°	50°	60°
28.	40°	60°	40°	45°
29.	40°	60°	40°	30°
30.	50°	80°	45°	50°

Table no. 13 – Overall effect of therapy according to subjective criteria on 60 patients of Vatkaphaj Grudhrasi w. s. r. to Sciatica:

Result	Group A		Group B	
	Number of patients	%	Number of patients	%
Marked improvement (75 - 100 %)	12	40.00%	0	0.00%
Moderate improvement (50 – 75 %)	11	36.67%	7	23.33%
Mild improvement (25 – 50 %)	6	20.00%	21	70.00%
Poor improvement (0 to 25 %)	1	3.33%	2	6.67%



DISCUSSION ON STATISTICAL ANALYSIS:

Statistical Analysis: In Trial Group and in Control Group (By Wilcoxon Signed Ranks Test for subjective & Paired t Test for objective criteria) Wilcoxon Signed Ranks test and Paired t test were applied to Subjective and objective criteria respectively to both groups separately to observe whether the difference between Before Treatment and After Treatment score is significant or not.

Group A-

In case of Symptoms *Kati-Sphik-Prushta-Uru-Janu-Jangha-Pada Vedana, Stambha, Toda, Tandra, Gourav, Aruchi*, SLRT, SNDT the tests have show's significant difference between B.T. and A.T. Scores. It is hence concluded that *Shiva Guggul* as oral administration has significantly reduced *Kati-Sphik-Prushta-Uru-Janu-Jangha-Pada Vedana, Stambha, Toda, Tandra, Gourav, Aruchi*, Sciatic Notch Deep Tenderness (SNDT) & increases S.L.R. angle.

Group B-

In case of Symptoms *Kati-Sphik-Prushta-Uru-Janu-Jangha-Pada Vedana, Stambha, Toda, Tandra, Gourav, Aruchi*,

SLRT, SNDT the tests have show's Significant difference between B.T. and A.T. Scores. It is hence concluded that *Rasna Guggul* as oral administration has significantly reduced *Kati-Sphik-Prushta-Uru-Janu-Jangha-Pada Vedana, Stambha, Toda, Tandra, Gourav, Aruchi*, SLR & Sciatic Notch Deep Tenderness (SNDT) & increases S.L.R. angle.

Statistical Analysis: Comparison of Group A and Group B (By Mann Whitney's U Test for subjective criteria & Unpaired t Test for objective criteria):

Mean difference of Group A is more than mean difference of Group B and p value is lower than the significance level $\alpha = 0.05$, we should reject the null hypothesis H_0 and accept the alternate hypothesis H_a , i. e. *Shiva Guggul* (Group A) is significant than *Rasna guggul* (Group B) for *Kati-Sphik-prusht-uru-janu-jangha-pada vedana* (Pain), *Stambha* (Stiffness), *Toda* (Pricking Sensation), *Gourav* (Heaviness), *Aruchi* (Anorexia), SNDT & SLRT.

Mean difference of Group A is less than mean difference of Group B and p value is greater than the significance level

alpha = 0.05, we should accept the null hypothesis H₀ and reject the alternate hypothesis H_a, i. e. *Shiva Guggul* (Group A) is not significant than *Rasna guggul* (Group B) for *Tandra*.

Overall Effect of Therapy:

Effect of Therapy according % Relief

% Relief in Patients-

- In Group A of *Shiva Guggul* out of 30 patients, Marked Improvement (75 To 100 % relief) was noted in 12 patients i. e. 40 %, Moderate Improvement (50 to 75 % relief) was noted in 11 patients i. e. 36.67 %, Mild Improvement (25 to 50 % relief) was noted in 6 patients i. e. 20 %, and Poor Improvement (0 to 25 % relief) was noted in 1 patient i. e. 3.33 %.

- In Group B of *Rasna Guggul* out of 30 patients, Moderate Improvement (50 to 75 % relief) was noted in 7 patients i. e. 23.33 %, Mild Improvement (25 to 50 % relief) was noted in 21 patients i. e. 70 % Poor Improvement (0 to 25 % relief) was noted in 2 patients i.e. 6.67 % and no one was noted in Marked improvement (75 to 100 % relief) in this study.

Hence according to statistical analysis,

- Oral administration of *Shiva Guggul* is effective than oral administration of *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* in reducing *Kati-Spik-prusht-uru-janu-jangha-pada Vedana, Stambha, Toda, Gourav, Aruchi, SLRT & SNTD*.

- Oral administration of *Shiva Guggul* is not effective than oral administration of *Rasna Guggul* in the management of *Vatkaphaj Grudhrasi* in reducing *Tandra*.

PROBABLE MODE OF ACTION OF DRUGS:

A) Effect on *Dosha*: *Shiva Guggul* most of contains are *Ushna Virya, Vat-Kaphshamak & tridoshghna* properties. In *Vatkaphaj Grudhrasi Vata & Kapha prakopa* occurs, so it results in reduction in these vitiated *Dosha's*.

B) Effect on *Dhatu's*: In *Vatkaphaj Gridhrasi* involvement of *Ashti, Majja, Ras, Rakt dhatu* is present. The contains of *Shiva guggul* are *Amapachak* so results in *Rasshuddi*, Some contents are *Raktshodhak*, results in *Raktshuddhi* and as *Sira, Kandara, & Snayu* are *updhtu's* of *Rakt Dhatu* results in improvement of *Grudhrasi nadi*.

C) Effect on *Dushya*: In *Gridhrasi Shoth of Sira, Kandara, & Gridhrasi Nadi* is there, the *Shiva Guggul* contents are *Raktshodhak & Rasayan* properties, as *Sira & Kandar's* are *Updhatu's of Rakt*, and maximum contents are *Shothaghna* so reduced *Shoth of Grudhrasi Nadi*, and Provides power to *Sira & Kandara* at *katipradesha* by there *Rasayan* property.

D) Effect on *Strotasa's*: In *Vatkaphaj Grudhrasi* involvement of *Rasavaha, Raktvaha, Asthivaha, Majjavaha & Manovaha Strotasa's* are there.

- Some contents of *Shiva Guggul* have *Amapacahak* and *Agnivardhak* Properties, so results in *Amapachana & Rasshodhana*.

- As Most contents of *Shiva Guggul* are *Raktshodhak*, so results in *Raktashodhana* and improves *Rakt-dhatwagni*, and as *sira, kandara*, are *Updatu's of Rakta*, results in there improvement.

- As *Asthidhra kala & Purishdhara kala* i. e. *pakwashaya* has relationship, so most of contents of *Shiva Guggul* are *Vatanulomaka, Vatashamak* properties

Results in *Vatnulomana* hence improves *Purishdhara kala* and indirectly impact On *Asthivaha strotas*.

- Most of contents of *Siva Guggul* are *Rasayan, Naddiuttejak, & Balvardhak* properties, so acts on *Majjavaha strotas*.
- Some contents like *Jatamansi, Devdaru*, have antianxiety properties so helpful in reliving anxiety and acts on *Manovaha strotas*.

CONCLUSION:

Shiva Guggul and *Rasna Guggul* both are effective in the management of *Vatkaphaj Grudhrasi* to reduce Subjective and objective parameters.

The oral administration of *Shiva Guggul* is more effective than *Rasna Guggul* in reducing *Kati-spik-prusht-uru-janu-jangha-pada vedana* (pain), *Stambh* (stiffness), *Toda* (pricking sensation), *Gourav* (heaviness), *Aruchi* and Sciatic Notch Deep Tenderness (SNDT) of *Vatkaphaj Grudhrasi* w. s. r. to Sciatica.

The effect of *Shiva Guggul* is less effective than *Rasna guggul* in reducing *Tandra* of *Vatkaphaj Grudhrasi* w. s. r. to Sciatica.

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