COMPARATIVE CLINICAL TRIAL ON EFFICACY OF PATHYADI GUGGUL AND ERANDMULADI BASTI IN THE MANAGEMENT OF GRIDHRASI W.R.T LUMBAGO SCIATICA SYNDROME  

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INTRODUCTION  

The most common disorder which affects the movement of the leg particularly in most productive period of life is low back pain, out of which 40% of person will have radicular pain and this comes under the sciatic-syndrome.1 such presentation were common in olden period too and ancient science of life named it as Gridhrasi. It is consider as a shoolpradhana vata vyadhi.2 Many research conducted on this disease, still the complete cure of this is a mirage. Gridhrasi as the term meaning goes indicates the typical gait that resemble of a Gridhra or Vulture which is often seen in Gridhrasi.3 The symptoms seen in Gridhrasi can be well corrected with sciatica in modern terminology. Sciatica is a very painful condition in which pain pain begins in lum-
bar region and radiates along the posterolateral aspect of thigh and leg. Hence, movement of the affected leg is restricted and patient is not able to walk properly. This problem which evidently has a favorable natural history even then it can be remarkably disabling, has challenged health care providers. So efforts should be directed to re-establish the measures indicated for Gridhrasi in the classic texts of Ayurveda by proving its efficacy on the parameters established by recent medical science. Here one group was given pathyadi guggulla for shaman therapy whereas the other group was given Basti treatment that comes under shodhan therapy. The samanyachikista siddhan of Gridhrasi includes siravedha, bastikarma and agnikarma for its management. Basti karma is very effective on adhomarga especially pakvashaya. pakvashaya is most important sthan of vata. Gridhashi is a vattavyadhi and Basti is said to be best treatment for vatadosha and diseases cause due to it. So, here we study the effect of Basti in the management of the Gridhrasi. This Basti comprises 1) Erandamuladi nirooh basti and 2) Prasarni oil anuvasan basti.

AIM: To study the comparative efficacy of Pathyadi guggul and Erandmooladi basti in management of Gridhrasi.

OBJECTIVES:
1. To study Gridhrasi clinically in the literature of Ayurveda and modern science.
2. To study the effect of Pathyadi guggul in the management of Gridhrasi.
3. To study the efficacy of Erandmooladinirooh basti and Prasarni oil anuvasanbasti in management of Gridhrasi.

MATERIALS AND METHODS:

Study Design: Type of study: Open Randomized Comparative study. The study was exclusively based on clinical trials. A well detailed case record from was prepared to study the patient as well as the disease. The patients attending the O.P.D. and I.P.D. of Department of Kayachikitsa at Smt. K.G. MittalP. AyurvedHospital and Research institute were selected irrespective of their age, sex etc. The selected patient of Gridhrasi were subjected to clinical examination. Thus the assessment of Gridhrasi was done by Clinical and classical features of Gridhisa and similarly the follow up assessment.

Ethical Clearance: The study was approved by Ethics Committee for Human Research of PG section, Smt. K.G.P. Ayurvedic College & Hospital, Mumbai. Patient confidentiality was ensured at all times during the study. Patients were treated under two groups.

Group-A]: 20 patients were administered the treatment of Pathyadi guggul, 250 mg twice a day with warm water as anupana before food for 4 weeks (32days); whereas in Group-B]: 20 patients were administered Erandmooladi nirooh basti and Prasarani oil anuvasan basti alternate day for 4 weeks (32days) with Snehan and Swedan as a purvakarma. The protocol of this clinical study includes the Study Design, Inclusion-Exclusion Criteria & Criteria for Clinical Assessment, as follows.

A) Inclusive criteria:
1. Patients of age limit between 20 - 70 years, irrespective of sex and socio-economic status.
2. Patients with classical symptoms of Gridhrasi and diagnosed cases of Gridhrasi were included.
3. Patient with positive SLR test.
4. Patient willing to give informed written consent.

B) Exclusive criteria:
1. Patients with age below 20yrs. and above 70yrs.
2. Bone tumors, carcinoma of spine, tuberculosis of the vertebral column, fibrosis of sacral ligaments.
3. Patient suffering from infectious diseases, pregnant women.
4. Patients contraindicated for basti treatment as per classical texts of Ayurveda.

Consent: Patients fulfilling criteria for selection were included under study after receiving their written consents.

Withdrawal from the Study:
- Discontinuation of treatment during trial.
- Development of any complication at any point of time when treatment is continuing.

Period of Study - 4 weeks (32 days),
Follow Up - Weekly follow up.

Statistical Analysis: Statistical analysis was done on all details obtained from case record form. Statistical test as per requirement statistical test was applied. Level of significance at 5% level. A special proforma was designed which included all the important and relevant data related to Gridhrasi. The following sign and symptoms of Gridhrasi (Sciatica) were assessed before and after treatment in both the groups.8,9

Kati Rukka (Low backradiating pain), Stambha (Stiffness), Toda (pricking sensation), Tandra (Lethargy), Arochak (Tastelessness), Janusandhisphuran (Twitching Sensation in knee joint), Agnimandya (Diminished Appetite), SLR (Straight Leg Raising), La- segue’s Sign. Following grading pattern were adopted for the subjective as well as objective parameters for the assessment of clinical condition of patients before treatment (BT) and after treatment (AT).

1] Kati Rukka (Low backradiating pain):
0- No pain
1- Mild pain complained by patient when asked
2- Patient frequently complained of pain and has painful look
3- Excruсitation pain associated with painful cries and agonizing look

2] Stambha (Stiffness):
0- SLR 90°
1- SLR 61°-80°
2- SLR 31°-60°
3- SLR 0°-30°

3] Toda (pricking sensation):
0- No pricking sensation
1- Mild pricking sensation sometimes
2- Frequent pricking sensation
3- Severe pricking sensation all the time

4] Tandra (Lethargy):
0- Notandra
1- Mild tandra
2- Moderate tandra
3- Severe tandra

5] Arochak (Tastelessness):
0- No complains
1- 1-2 times weekly complains of no desire to eat anything
2- 3-4 times weekly complains of no desire to eat anything
3- Always complains of no desire to eat anything

0- No twitching
1- Sometimes for 5-10 minutes
2- Daily for 10-30 minutes
3- Daily for 30-60 minutes

7] Agnimandya(Diminished Apetite):
0- No complains
1- 1-2 times weekly complains of anorexia
2- 3-4 times weekly complains of anorexia
3- Always complains of anorexia
8] SLR (Straight Leg Rising)
0- SLR 90°
1- SLR 61°-80°
2- SLR 31°-60°
3- SLR 0°-30°

9] Lasegue’s Sign:
0- No pain when ankle is dorsiflexed in supine position with hips flexed
1- Mild pain when ankle is dorsiflexed in supine position with hips flexed.
2- Moderate pain when ankle is dorsiflexed in supine position with hips flexed
3- Sever pain when ankle is dorsiflexed in supine position with hips flexed

OBSERVATIONS AND RESULTS:
Criteria for selection of test:
Though the data collected in this study was ‘Rating Scale’ data; both parametric as well as nonparametric tests could be applicable. But after treating this data by Statistical Software, it was found that Distribution of Data was not according to Normal Distribution [Gaussian distribution]. That is why “t” test was not applicable [as for application of “t” test requires data to be have normal distribution]. After taking expert advice of Statistician, data was treated with first Wilcoxon Match Paired Test for every symptom of each group to check whether given treatment makes any changed in disease or not.

The Score magnitude where treated as sign & rank given accordingly.
Where,
S.D.: Standard Deviation
S.E.: Standard Error
E.S.: Extremely significant
V.S.: Very Significant
N.S.: Not Significant
S.: Significant

Data when treated with Wilcoxon assuming

| Table no. 1] Application of Wilcoxon matched pairs sign rank test for each symptom of Group-A: |
|-----------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Symptoms  | Mean (BT) | S.D. (BT) | Mean (AT) | S.D. (AT) | Wilcoxon two-tailed ‘p’ value | Significance | Spearman’s co-efficient ‘r’ |
| KatiRukka (Low back radiating pain) | 2.350 | 0.7500 | 0.4894 | 0.4443 | <0.0001 | ES | 0.1816 |
| Stambha (Stiffness) | 2.000 | 1.500 | 0.4588 | 0.8272 | 0.0078 | VS | 0.5579 |
| Toda (pricking sensation) | 2.250 | 0.7500 | 0.4443 | 0.4443 | <0.0001 | ES | 0.3333 |
| Tandra (Lethargy) | 1.950 | 1.050 | 0.9987 | 0.6863 | <0.0001 | ES | 0.7515 |
| Arochak (Tastelessness) | 1.250 | 0.6500 | 0.7684 | 0.4894 | 0.0020 | VS | 0.5038 |
| Janusandhisphuran (Twitching in knee joint) | 1.000 | 0.9000 | 0.7255 | 0.7881 | 0.5000 | NS | 0.9152 |
| Agnimandya (Diminished Apetite) | 1.200 | 0.5000 | 0.7678 | 0.5130 | 0.0002 | ES | 0.6708 |
| SLR (Straight Leg Rising) | 2.000 | 0.6500 | 0.4588 | 0.4894 | <0.0001 | ES | 0.4688 |
| Lasegue’s Sign | 2.050 | 0.8500 | 0.5140 | 0.4894 | <0.0001 | ES | 0.2282 |

| Table no. 2] Application of Wilcoxon matched pairs sign rank test for each symptom of Group-B: |
|-----------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Symptoms  | Mean (BT) | S.D. (BT) | Mean (AT) | S.D. (AT) | Wilcoxon two-tailed ‘p’ value | Significance | Spearman’s co-efficient ‘r’ |
| Arochak (Tastelessness) | 1.250 | 0.6500 | 0.7684 | 0.4894 | 0.0020 | VS | 0.5038 |
| Janusandhisphuran (Twitching in knee joint) | 1.000 | 0.9000 | 0.7255 | 0.7881 | 0.5000 | NS | 0.9152 |
The two-tailed P value is < 0.0001, for many symptoms, in both the groups. This concludes that difference between values Before & After treatment is considered to be extremely significant. But in some symptoms like Stambha (Stiffness) and Arochak (Tastelessness) of Group- A it is very significant whereas in symptoms Janusandhisphuran (Twitching in knee joint) of Group-A it is not significant.

**Table no. 3** Showing comparison between total score in both Groups:

<table>
<thead>
<tr>
<th>symptom</th>
<th>Group-A</th>
<th>Group-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>10.05</td>
<td>12.000</td>
</tr>
<tr>
<td>SD</td>
<td>3.576</td>
<td>2.772</td>
</tr>
<tr>
<td>SEM</td>
<td>0.7996</td>
<td>0.6198</td>
</tr>
<tr>
<td>Min.</td>
<td>5.000</td>
<td>7.000</td>
</tr>
<tr>
<td>Max.</td>
<td>18.000</td>
<td>17.000</td>
</tr>
<tr>
<td>Passed normality</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Mann-Whitney U statistic=127.50, One tailed ‘p’ value = 0.02495, considered Significant

**Result:** The Results were obtained by considering the difference in total score for before and after treatment between two groups, the value for U is 127.50 with One tailed ‘p’ value = 0.02495, which indicates significant difference between two groups.

**Table no. 4** Showing difference between total score of two Groups symptomatically:

<table>
<thead>
<tr>
<th>symptom</th>
<th>Group-A</th>
<th>Group-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>17.091</td>
<td>21.909</td>
</tr>
<tr>
<td>SD</td>
<td>10.084</td>
<td>8.154</td>
</tr>
<tr>
<td>SEM</td>
<td>3.040</td>
<td>2.459</td>
</tr>
<tr>
<td>Min.</td>
<td>2.00</td>
<td>12.000</td>
</tr>
<tr>
<td>Max.</td>
<td>32.000</td>
<td>33.000</td>
</tr>
<tr>
<td>Passed normality</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Test applied unpaired ‘t’ test, Two tailed ‘p’ value = 0.2329, considered NotSignificant

**Result:** The Results were obtained by considering the difference in symptoms of total score for the two groups; the p value is 0.2329 which indicates not significant difference between two groups.

**DISCUSSION**
Gridrasi is apparently minor neuro-muscular disorder is posing a serious threat to the quality of life of the most productive group of population in today’s India. The chances of occurrence is expected to be increasing through the coming years due to the increasing tendency for computerization and also because of hectic routines resulting in postural abnormalities, increasing body weight, mental stress, unwholesome diet etc., all of which leads to a fertile condition for the occurrence of Gridrasi,

Gridrasi is a painful condition in which the person can’t sit and walk properly that hampers normal activity. Almost of all signs and symptoms of Gridrasi resemble with the condition of Sciatica described by modern text.Group- A showed statistically significant results in subjective parameters, however, there is no significant result in Janusandhisphurana (Twitching in knee joint). Group- B showed extremely significant results in all subjective parameters Thus Group- B are better than Group- A, in all parameters. Difference between both groups, makes it clear that clinical efficacy of Group-B [Erandmooladi nirooh basti and Prasarani oil anuvasa basti] were better than that of Group-A [Pathyadi guggul].

**Mode of action of Pathyadi guggul:**
Pathyadi guggul due to its katu, tiktarasa and ushnaveerya causes panchan of sam-pittaandagnideepan, thus curing the vikruti of pachakpitta and samanvayu respectively. Also due to its laghuguna it act as strostoshodhi and kapheshamak which cures the symptoms like: shotha stambha(stiffness) gaurav etc.
Pathyadi guggul due to its madhur veepaka and ushna veerya will cause vatamuloman, bruhan and poshan of Gridrasi nadi, as a result of which the symptoms like: veda(Pain), stambha(Stiffness) etc. subside.10

**Mode of action of Erandmooladi nirooh and Prasarani oil anuvasan basti:**
Erandmooladi nirooh basti acts mostly on vyan, apan and samanvayu, pachak pitta, kledak bodhak and shleshak kapha. Erandmooladi nirooh basti enters the pakvashaya via anal canal, pakvashaya is the main site of vata. This basti having tikta rasa causes amapachan, agnideepan and rochan. Thus in Gridrasi Erandmooladi nirooh basti will work on sign and symptoms mentioned in Ayurved text. Prasarani oil due to its snigdha guna reduces the dhatu kshayajanya vata prakopa and causes bruhan and poshan Gridrasi nadi.11,12

**CONCLUSION**

Gridrasi can be equated with Sciatica or Lumbago Sciatica Syndrome in modern parlance. Pathyadi guggul and Erandmooladi nirooh basti and Prasarani oil anuvasan basti have both shown encouraging results in management of Gridrasi. Gridrasi can be effectively managed by giving Pathyadi guggul and Erandmooladi nirooh basti and Prasarani oil anuvasan basti. On comparison it was found that patients given Erandmooladi nirooh basti and Prasarani oil anuvasan basti showed better result than those given Pathyadiguggul. Pathyadiguggul if given to patients for a longer period of time might show better results, nevertheless, it can be concluded that both these treatment plans improve the life style of Gridrasi patients by giving them very good relief.

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REFERENCES


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