A comparative Clinical Study to Evaluate the Efficacy of Anuvasan Basti with Brahatchaglyadi Ghritam and Guggulutiktam Ghritam in the management of Gridhrasi (Sciatica): A Study Protocol

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Authors’ contributions

This work was carried out in collaboration among all authors. Author AKG designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author SP designed the study, managed the analyses of the study managed the literature searches, reviewed and final drafting of the of the manuscript. Authors TG and MN managed the analyses of the study. All authors read and approved the final manuscript.

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ABSTRACT

Background: Gridhrasi is such a Ruja Pradhaana Vatavyadhi. In Gridhrasi intense shooting pain characteristically radiates from Sphika (gluteal region) to Pada (foot). Based on symptoms of Gridhrasi, it can be equated with the disease sciatica in modern science. The lifetime incidence of

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low back pain is 50-70%, with Sciatica more than 40%. Charaka has considered Basti therapy as half of the disease's treatment, while some authors consider it as the complete remedy for all the ailments. Basti is one of the unique procedures explained for the management of Vatavyadhi (Neurological Disorder) where Gridhrasi (Sciatica) is being the predominant of Vata dosha, Basti is being used widely for the management of Gridhrasi (Sciatica). Therefore we have taken the Basti modality for the treatment of Gridhrasi (Sciatica). Hence the study is carried to evaluate the effect of Anuvasanbasti with Brihachagalyadi Ghritam & Guggulutiktaka Ghritam in the management of Gridhrasi (Sciatica).

### Aims and Objectives:
Evaluate Anuvasan Basti's efficacy with Brihachagalyadi Ghritam & Guggulutiktaka Ghritam in the control of Gridhrasi (Sciatica) and to compare the effectiveness of Brihachagalyady Ghritam & Guggulutiktak Ghritam Anuvasan Basti in the direction of Gridhrasi.

### Methodology:
Procedure: This study, a total of 66 patients, will be separated haphazardly divided into 2 groups (33 in each). In Group A (Interventional Group)- will Treat with Brihachagalyady Ghritam as an Anuvasan Basti in increasing dose pattern for nine days and Group B (Control Group) –patients will Treat with Guggulutiktaka Ghritam as an Anuvasanbasti in increasing dose pattern for nine days. The evaluation will be recorded on 0 and 9th day.

### Conclusion:
It may be more beneficial and more effective in pain as well as other subjective and objective parameters.

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**Keywords:** AnuvasanBasti; brihatchagalyadi ghritam; guggulutiktaka ghritam; gridhrasi (Sciatica).

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### 1. INTRODUCTION

The Chief cause is visiting the doctor is a pain in most patients. It is known as Ruja, which is one of the synonyms of disease. It disturbs the physical and mental status of a patient. Pain is a cardinal symptom in most of the Vatavyadhis.

The altering lifestyle of human existence has created several resentments in the biological system. As the encroachment of tiring, professional and social life, inappropriate sitting posture, overexertion, jerky movements – all these factors produce gratuitous pressure to the spinal cord and play an essential role in building Gridhrasi (Sciatica).

**Gridhrasi** is a disease with neurological symptoms of sciatic nerve [1]. It is a crippling disease involving sira and Kandara of katipradesha, characterized by the radiating type of pain from the low back through the lower part of a buttock, thigh, and calf muscles foot [2].

The most common musculoskeletal disorder affecting the movement of the leg is low back pain. Among the affected patients, 40% have radicular pain, and these cases can be classified under the umbrella term of sciatic syndrome. Low back pain is extraordinarily common, second only to the common cold. About 50% of working adults experience a back injury each year [3].

**Gridhrasi**, an entity enumerated by Shula Pradhana, is among the 80 types of Nanatmaja Vata Vyadhi. According to Charaka, Stambha, Ruka, Toda, and Spandana are the signs and symptoms of Vataja Gridhrasi. Aruchi, Tandra, and Gaurav are additional symptoms of Vata-Kaphaja Gridhrasi [4].

In definitions of Sciatica, pain generally radiating to the leg, generally below the knee and into the foot and toes. As with low back pain, Sciatica is a symptom rather than a specific diagnosis, but lumbar disk herniation and lumbar canal or foraminal stenosis are the typical pathologies that may cause sciatic pain [5,6].

Spondylosis is identified with the pressure of the vascular and neural structures. It brought about by a misfortune in the plate tallness and impinging osteophytes. It add to the deadness, stun like sensations, pain, interminable motor and tangible effects, which if not revised may prompt lasting incapacities [7].

**Basti** is the most important among Panchakarma due to its multiple effects. **Basti** is best for Vata disorders and equally effective in correcting the morbid Pitta, Kapha and Rakta [8]. Charaka has considered **Basti** therapy as half of the disease's treatment, while some authors consider it as the complete remedy for all the ailments [9]. **Basti** is one of the unique procedures explained for the management of Vatavyadhi,

In the *chikitsa sutra* of Vatavyadhi, many Acharyas advised **Basti**, and Acharya Charaka has mentioned **Basti** as a *brumhana sneha* [10] where **Gridhrasi** is the predominant of Vata.
dosha, Basti is being used widely for the management of Gridhrasi. We are using Brihatchagalyadi Ghritam & Guggulutiktaka Ghritam as a basti, and it is the best formulation in Gridhrasi disease due to having excellent Vatashamaka property.

2. AIM AND OBJECTIVES

Aim: To compare the efficacy of Brahatchagalyadi Ghritam & Guggulutiktaka Ghritam Anuvasan Basti in the management of Gridhrasi.

Objectives:

- To evaluate the efficacy of Anuvasan Basti with Brihatchagalyadi Ghritam in the management of Gridhrasi (Sciatica).
- To evaluate the efficacy of Anuvasan Basti with Guggulutiktaka Ghritam in the management of Gridhrasi (Sciatica).
- To compare Anuvasan Basti's efficacy with Brihatchagalyadi Ghritam & Guggulutiktaka Ghritam in the management of Gridhrasi (Sciatica).

Case Definition:

1. Patients with cardinal features of the disease, such as dull or piercing pain, twitching and stiffness in back, lumbar region, buttock, thigh, back of the knee, calf, and feet area order.
2. Positive SLR test in the affected leg

Research Question: Whether Anuvasan Basti with Brahatchagalyadi Ghritam is more efficacious than Guggulutiktaka Ghritam Anuvasan basti in the Management of Gridhrasi (Sciatica)?

Research Hypothesis: Anuvasa Basti with Brahatchagalyadi Ghritam is more efficacious than Guggulutiktaka Ghritam Anuvasa basti in the Management of Gridhrasi (Sciatica).

Null Hypothesis: There is no difference between Anuvasa Basti with Brahatchagalyadi Ghritam & Guggulutiktaka Ghritam in the Management of Gridhrasi (Sciatica).

Trial Design – Randomized, Reference, standard control double-blind Clinical trial.

3. METHODOLOGY

Study setting- The patients of Gridhrasi will be selected randomly, from OPD/IPD, Mahatma Gandhi Ayurved College, Hospital and Research Institute, Salod (H) Wardha M.H. India.

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Registration Number- registered for CTRI, no awaited.

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Drugs Authentication & procurement: All Raw drugs will be verified and authenticated from the Dravyagun department of Mahatma Gandhi Ayurved College, Hospital and Research Institute, Salod(H) Wardha M.H. India. Drugs will procurement by GMP certified Ayurveda Pharmacy.

1. Age group 20-45yrs of either gender
2. Limitation of SLR test angle 30°-70° due to pain,
3. Unilateral or bilateral radiation of pain in the sciatica nerve distribution,
4. Patient is fit for Basti treatment
5. Patient assigns Inform consent form

3.2 Exclusion Criteria:

1. History of spinal surgery and vertebral fracture,
2. Evidence of Ischemic Heart Disease, tuberculosis,
3. A clinical condition such as hypersensitive skin, cardiac pacemaker, pregnancy,
4. Established tumours/malignancy,
5. Motor weakness such as stroke, diabetic neuropathy
6. Patients having back pain due to non-spinal illness will exclude, e.g. UTI, gastrointestinal diseases, and uterine diseases
7. Lumber disc prolapsed & Osteoporosis

Criteria for discontinuing or modifying allocated interventions- The subject will be withdrawn from the study if any untoward incidence, features of drug sensitivity, or any other diseases or problem arises, the subject will be offered free treatment till the pain subsides.

Follow up – 0 – 9th day – 18th day

Primary Outcome- We will see the effect of Brahatchagalyadi Ghritam and Guggulutiktaka Ghritam on Pain, radiating pain on both left or right and both legs, restricted movements before and after treatment. Data will be expressed as the standard error of the mean at 5 % level of significance.
Composition of trail drugs-

*Brihachaglyadi Ghritam* (Trial Drugs) [11]

Table 1. Ingredients of *Brihachaglyadi Ghritam*

| Sr.No | Drugs   | Botanical name       | Rasa   | Guna     | Veerya | Vipaka | Karma                  | Chemical composition                      |
|-------|---------|----------------------|--------|----------|--------|--------|-------------------------|-------------------------------------------|
| 1.    | Ghritam | Ghee                 | Madhur | Guru     | Sheet  | Madhur | Vata-Pitta Shamak       |                                           |
| 2.    | Satavari| *Asparagus racemosus*| Madhur | Tikta    | Sheet  | Madhur | Vata-Pitta Shamak       | Balya, Vaya sthapana                      |
| 3.    | Kshira  | *Milk*               | Madhur | Laghu    | Sheet  | Madhur | Vata-Pitta Shamak       | Balya, Vaya sthapana, Jeevniya, Rasayan   |
| 4.    | Chagamamsa | *Meat of Goat*       | Madhur | Laghu    | Sheet  | Madhur | Trodoshasa-mak, Peenasnas-am, Brahatniya, Veeryividhanam |                                           |
| 5.    | Kasmari | *GameliaArboria*     | Tikta Kasaya Madhur | Guru | Ushna | Katu    | Sothahara              | Butiric & Terteric acid, Sarkara, Tanin, Tikta satva |
| 6.    | Vilva   | *Aeglemarmelos*      | Tikta Kasaya Tikta | Laghu Ruksha | Ushna | Katu    | Sothahara, Arshoghna Aasthanopaga, Anovasanop-aga |                                           |
| 7.    | Patala  | *Steriospermum colais* | Tikta Kasaya Madhur | Laghu Ruksha | Ushna | Katu    | Sothahara              | Tanin, Stable oil, Oroxylin A, Baicalein, Chrysin |
| 8.    | Syonak  | *Oroxylum indicum*   | Tikta Kasaya Madhur | Laghu Ruksha | Ushna | Katu    | Sothahara, Sheetprasa-man Anovasanop-aga |                                           |
| 9.    | Agnimanth| *Premnacorymbosa*    | Tikta, Katu, Kasaya, Madhur | Laghu Ruksha | Ushna | Katu    | Sothahara, Sheetprasa-man Anovasanop-aga |                                           |
| 10.   | Salparni| *Pseudarthriavis cida* | Madhur Tikta | Guru & Snigdha | Ushna | Madhur | Sothahara, Balya, Snehopaga |                                           |
| Sr.No | Drugs          | Botanical name           | Rasa       | Guna       | Veerya | Vipaka | Karma                          | Chemical composition                   |
|-------|----------------|--------------------------|------------|------------|--------|--------|--------------------------------|----------------------------------------|
| 11.   | Prishnaparni   | *Desmodium gangeticum*   | Madhur     | Laghu & Snigdha | Ushna  | Madhur | Sothahara, Angamarda-prashman, Sandhaniya | Tanin, Glycosidase                      |
| 12.   | Brihti         | *Solanum manguivii*      | Katu Tikta | Laghu, Ruksha, Teeksha | Ushna  | Katu   | Sothahara, Angamarda-prashman, Kanthya, Hikkanigra-han | Solanine, Solandine, Solasonine        |
| 13.   | Nidigdhika     | *Solanum virginianum*    | Tikta Katu | Laghu, Ruksha, Teeksha | Ushna  | Katu   | Sothahara, Angamarda-prashman, Kanthya, Hikkanigra-han | Diogenin, Potassium Carbonate, Sulphate, and Nitrate, Solesonin Alkaloid, Stable oil, Sugandhita oil, Glycosides, Harman & Harmine Cuseohygrine, Anahygrine, Tropine & Anaferine Alkaloid, Ephedrine |
| 14.   | Gokshura       | *Tribulus terrestris*    | Madhur     | Guru Snigdha | Sheet  | Madhur | Sothahara, Anovasanop-aga, Kramighna, Mutravirechaniya | Vajikarana |
| 15.   | Ashwagandha    | *Withania somnifera*     | Tikta, Katu, Madhur | Laghu Snigdha | Ushna  | Madhur | Balya, Brahana                  | Albuminoid, Starch, Alkaloid           |
| 16.   | Bala           | *Sidacordifolia*         | Madhur     | Laghu Snigdha Picchila | Sheet  | Madhur | Balya, Brahana Prajasthapa-na   | Ephedrine                              |
| 17.   | Masha          | *Vigna mungo*            | Madhur     | Guru Snigdha | Ushna  | Madhur | Vajikarana                      | Alkaloid, Albuminoid, Starch, Alkaloid |
| Sr.No | Drugs        | Botanical name       | Rasa      | Guna          | Veerya | Vipaka  | Karma     | Chemical composition                      |
|-------|--------------|----------------------|-----------|---------------|--------|---------|-----------|-------------------------------------------|
| 18    | Jivanti      | Leptodeniarettulata  | Madhur    | Laghu Snigdha | Sheet  | Madhur  | Jeevniya  | Sterol                                    |
|       |              | Glycyrrhizaalabra    |           | Guru Snigdha  |        |         |           | Glycyrrizinsoliquiritin, Liquiritin,      |
|       |              |                      |           |               |        |         |           | Aspagarine, Starch, Glucose               |
| 19    | Madhuka      |                      | Madhur    | Laghu Snigdha | Sheet  | Madhur  | Jeevniya, Kanthya, Sandhaniya, Varna,     |
|       |              |                      |           | Guru Snigdha  |        |         |           | Kandughna, MutaviranjaniySonitasthapan,   |
|       |              |                      |           |               |        |         |           | Chardingrahana, Snehopaga, Vannopag      |
| 20    | Draksha      | Vitisvinifera        | Madhur    | Guru Snigdha  | Sheet  | Madhur  | Sneehopaga, Virechnopaga, Kasahara, Jwarhara |
|       |              |                      |           | Mradu         |        |         |           |                                             |
| 21    | Dvikakoli    | Withaniasomnifera    | Tikta, Katu, Madhur | Laghu Snigdha | Ushna  | Madhur  | Balya, Brahana |                                             |
|       | (Sub)        | (Sub.)               |           |               |        |         |           | Cuseohygrine, Anahygrine, Tropine &      |
|       | Ashwagandha  |                      |           |               |        |         |           | Anaferine Flavanoids,                     |
| 22    | Nalamulpala  | Monochoraviginaulis | Madhur    | Guru Snigdha  | Sheet  | Madhur  | Antioxidant, Antiinflammatory             |                                             |
| 23    | Musta        | Cyperusrotundus      | Tikta, Katu, Kasaya | Laghu Ruksha | Sheeta | Katu   | Jwarghna, Sthothyahara, Sothahara        |                                             |
|       |              |                      |           |               |        |         |           | Flavanoids, Bisistosterol, Ascorbic acid  |
|       |              |                      |           |               |        |         |           | Sesquterpene, Alcohol, Volatile oil       |
|       |              |                      |           |               |        |         |           | Alkaloids, Saponin, Glycosides            |
| 24    | Chandana     | Santalum album       | Tikta Madhur | Laghu Ruksha | Sheeta | Katu   | Vishagna, Daurgandhyahar Kramighna, Varnya, Hradya |
|       |              |                      |           |               |        |         |           |                                             |
| 25    | Rasna        | Alpiniaagalanga      | Tikta     | Guru          | Ushna  | Katu   | Kramighna, Deepana, Pachana, Anulomana    |                                             |
|       |              |                      |           |               |        |         |           | Aampachana, Jeevniya, Shukrajanan         |                                             |
| 26    | Mashparni    | Dysolobiumpilosum    | Madhur Tikta | Laghu Snigdha | Sheet  | Madhur  | Jeevniya, Shukrajanan                      |                                             |
| 27    | Mudgaparni   | Vignaradiata         | Madhur    | Laghu Ruksha  | Sheet  | Madhur  | Jeevniya, Shukrajanan                      |                                             |
| Sr.No | Drugs              | Botanical name  | Rasa            | Guna       | Veerya | Vipaka       | Karma                          | Chemical composition                                      |
|-------|--------------------|-----------------|-----------------|------------|--------|--------------|--------------------------------|----------------------------------------------------------|
| 28.   | Sweta Sariba       | *Hemidesmus indicus* | Madhur Tikta    | Guru Snigdha | Sheet   | Madhur Stanyasodh- ana, Purishsamgrahniya, Jwarahara, Dahaprsam-ana | P- Methoxy salicylic aldehyde, B-sitosterol, B-amyrins, lupeool, tetracyclic triterpene alcohols |
| 29.   | Krishna Sariba     | *Ichnocarpusfrutescens* | Madhur Tikta    | Guru Snigdha | Sheet   | Madhur Stanyasodh- ana, Purishsamgrahniya, Jwarahara, Dahaprsam-ana | P- Methoxy salicylic aldehyde, B-sitosterol, B-amyrins, lupeool, tetracyclic triterpene alcohols |
| 30.   | Dvimeda            | *Pueraria tuberosa* (Sub.) | Madhur       | Guru Snigdha | Sheet   | Madhur Balya, Brahana, Varnya, Kantha, Snehopaga | Carbohydrate & Protein |
| 31.   | Kushtha            | *Saussurea* (Sub.) | Tikta, Katu, Madhur | Laghu Ruksha Teeksha-na | Ushna   | Katu Sukrasodha-na, Lekhniya, Aasthapano-paga | Saussurine Alkaloid, Tanin, Inulin- 18 % |
| 32.   | Dvijvaka Sub (Vidari) | *Pueraria* (Sub.) | Madhur       | Guru Snigdha | Sheet   | Madhur Balya, Brahana, Varnya, Kantha, Snehopaga | Carbohydrate & Protein |
| 33.   | Sati               | *Hedychium* | Tikta, Katu, Kasaya | Laghu Teeksha-na | Ushna   | Katu Shwashara, Hikkanigra-hana | Starch (52%), Organic acid, Glycoside |
| 34.   | Priyangu           | *Callicarpas* | Tikta, Kasaya, Madhur | Guru Ruksh | Sheet   | Katu Mutraviranjnee, Pureshamsangrahiya | Hydrocynic acid |
| 35.   | Darvi              | *Barberisaristata* | Tikta Panchara, Madhur | Ruksha Panchara | Ushna   | Katu Pachana, Stanyadosh-ahara | Chebulagic |
| 36.   | Abhaya             | *Terminalia* | Tikta Panchara, Madhur | Laghu Ushna | Ushna   | Madhur Prajasthapana, Jwarghna | Chebulagic |
| Sr.No | Drugs      | Botanical name       | Rasa                      | Guna | Veerya | Vipaka | Karma                          | Chemical composition                                                      |
|-------|------------|----------------------|---------------------------|------|--------|--------|-------------------------------|--------------------------------------------------------------------------|
| 37.   | Amalaki    | *Phyllanthus semblica* | (Lavan Absent) Kasaya     | Ruksha |        |        | Kasaghna, Arshoghna, Kasaghna | acid, chebulinic acid, coriligin                                        |
|       |            |                      | Pradhan Pancharasa (Lavan |        |        |        |                               |                                                                          |
|       |            |                      | Absent) Amla Pradhan      |        |        |        |                               |                                                                          |
| 38.   | Vibhitaka  | *Terminalia bellirica* | Kasaya                    | Ruksha | Sheet  |        | Vayasthapana, Virechnopaga    | Vit-C, Galic acid, Tanic acid, Albumin, Cellulose, Protein, Vasa, Minerals |
|       |            |                      | Laghu                      | Ushna |        |        |                               |                                                                          |
| 39.   | Nata       | *Valerianawallic*     | Tikta Katu kasaya         | Laghu | Ushna  |        | Vishaghna, Raktadosahara,     | Sesquiterpenoids, Alkaloides, Glucosides, Resins, terpineol, flavonoids |
|       |            | hii                   |                            |       |        |        | Manasdoshahar                  |                                                                          |
| 40.   | Talisa     | *Abiespectabilis*     | Tikta Madhur Teekshna     | Laghu | Ushna  |        | Shirovirechna                 | Volatile oil                                                            |
|       |            | Prunusceracoidius     |                            |       |        |        |                               |                                                                          |
| 41.   | Padminaka  | *Prunusceracoidius*   | Kasaya Tikta              | Laghu | Sheet  |        | Vedanasthapan, Varnya         | Scuratanin, Jaquanin, Pruatin, Padmakasthin, Sukranin,                  |
| Sr.No | Drugs         | Botanical name                | Rasa      | Guna   | Veerya | Vipaka   | Karma                                | Chemical composition                                      |
|-------|---------------|-------------------------------|-----------|--------|--------|----------|--------------------------------------|----------------------------------------------------------|
| 42.   | Ela           | *Eletarriacardanomum*         | Katu Madhur | Laghu  | Sheet  | Madhur   | Hridya, Mutral, Deepan, Anuloman     | Taxifolin Volatile oil                                     |
| 43.   | Tejaputra     | *Cinnamomonumtumala*          | Katu Madhur | Laghu Picchila Teekshna | Ushna | Katu     | Rucya, Arshoghna                     | Methyl eugenol, trans cinnamyl, Beta caryophyllene        |
| 44.   | Vari          | *Asparagus racemosus*         | Madhur Tikta Kasaya | Guru Snigdha | Sheeta | Madhur   | Balya, Vayasthapana                  | Saponin                                                  |
| 45.   | Nagakeshar    | *Mesuaferrea*                 | Tikta katu Kasaya | Laghu Ruksa | Ushna  | Katu     | Varnya, Urdhwa jatragatavikara nasaka | Lipid, Carbohydrate, protein, oleorasin                   |
| 46.   | Jatikusuma    | *Jasminumgrandiforum*         | Tikta kasaya | Laghu Snigdha Mradu | Ushna  | Katu     | Kushtaghna                           | Salycylic acid, Jasminine                                 |
| 47.   | Dhanyaka      | *Coriandrumsativum*           | Kasaya Madhur tikta Katu | Laghu Snigdha | Ushna  | Madhur   | Trashnanigrahana, Sheetprasamana     | Carbohydrate, Vitamin, Fat, Minerals, Coriandrol           |
| 48.   | Manjistha     | *Rubiacordifolia*             | Kasaya Madhur tikta | Guru   | Ushna  | Katu     | Aartavjanan, Prameyaghna             | Anthroquinones, Glycosides, Saponin, Resin                |
| 49.   | Dadima        | *Punicagranatum*              | Madhur Kasaya Amla | Laghu Snigdha | Anushna | Madhur | Hradya, Chardinigrahana             | Carbohydrate, Vitamin, Fat, Minerals, Fe, Manitol, Vit-C   |
| 50.   | Daru          | *Cedrusdeodara*               | Tikta     | Laghu Snigdha | Ushna  |         | Dustavranasodhaka, Pramehaghna       | Alcaloids, Glycosides, Flavonoids                         |
| Sr.No | Drugs  | Botanical name       | Rasa       | Guna     | Veerya | Vipaka | Karma                        | Chemical composition                      |
|-------|--------|----------------------|------------|----------|--------|--------|------------------------------|-------------------------------------------|
| 51.   | Renuka | *Piper cubeba*       | Katu Tikta| Laghu    | Ushna  | Katu   | Hradya, Aartavjanan          | Cubebin, Cubebol                          |
|       |        |                      |            | Ruksa    |         |        |                              |                                           |
|       |        |                      |            | Teekshna |         |        |                              |                                           |
| 52.   | Elavaluka | *Prunus avium*     | Kasaya    | Laghu    | Sheet  | Katu   | Kandughna, Kushtaghna,      | -                                         |
|       |        |                      |            |          |        |        | Trashnahara                  |                                           |
| 53.   | Vidanga | *Embeliaribes*       | Katu Tikta| Laghu    | Ushna  | Katu   | Kramighna, Deepan            | Alkaloids, Glycosides, Flavanoides,       |
|       |        |                      |            | Ruksa    |         |        | Pachana                      | Tarpenoides, VitA, Vit-C, protein,        |
|       |        |                      |            | Teekshna |         |        |                              | carbohydrates, Minerals                    |
| 54.   | Jeerak | *Cuminum cyminum*    | Katu       | Laghu    | Ushna  | Katu   | Shulaprasamana, Shirovirecha| Sugar, Fat, Albumin, Guanine, Ca-Oxalate  |
|       |        |                      |            | Ruksa    |         |        |                              |                                           |
| 55.   | Sarkara | *Saccharum officinarum* | Madhur    | Guru     | Sheet  | Madhur | Vrasya, Stanyajanana        |                                           |
|       |        |                      |            | Snigdha  |        |        |                              |                                           |
### Table 2. Ingredients of Guggulutiktak Ghritam

| Sr.Nu | Drugs | Botanical Name | Rasa | Guna    | Veerya | Vipaka | Karma          | Chemical composition                                                                 |
|-------|-------|----------------|------|---------|--------|--------|----------------|---------------------------------------------------------------------------------------|
| 1     | Ghritam | Ghee         | Madhur | Guru    | Sheet  | Madhur | Vata- Pitta Shamak |                                                                        |
| 2     | Nimba  | Azadirachta indica | Tikta Kasaya | Laghu | Sheet  | Katu   | Kandughna                 | Nimbinin, Nimbidin, Nimbosterol, Volatile oil Tanin G- Glycosides Sesquiterpinoid Starch Polysacharide Protein, Calsium Phosphorus Anthraquinones, Saponin, Alkaloids, Flavanoids, Terpendois |
| 3     | Amrita | Tinospora cardifolia | Tikta Kasaya | Laghu | Ushna  | Madhur | Rasayan, Deepan, Pachana, Jwaraghna Raktasodhana Hrdya, Raktasamgrahi, Kasagha | Sothahara, Angamarda-prashman, Kanthya, Hikkanigrahan Diogenin, Potasium Carbonate, Sulphate, and Nitrate, Solesonin |
| 4     | Vrisha | Adatodava saca | Tikta Kasaya | Laghu | Sheet  | Katu   |                                                                       |
| 5     | Patol  | Trichosanthes disc a Solanum virginianum | Tikta | Laghu, Ruksa | Ushna  | Katu   |                                                                       |
| 6     | Nidgdi ka | Tikta Katu | Laghu, Ruksa, Teeksha | Ushna | Katu   |                                                                       |
| 7     | Patha  | Cycleapeltata | Tikta | Laghu, Teeksha | Ushna  | Katu   |                                                                       |
| 8     | Vidanga | Embellari tes | Tikta Katu | Laghu, Ruksa, Teeksha | Ushna  | Katu   |                                                                       |
| 9     | Suradar u | Cedr dum deodor a | Tikta | Laghu, Snidga | Ushna  | Katu   |                                                                       |
| Sr. No | Drugs | Botanical Name | Rasa | Guna | Veerya | Vipaka | Karma | Chemical composition |
|--------|-------|----------------|------|------|--------|--------|-------|----------------------|
| 10.    | Gajopakulya | Scindapsus officinalis | Katu | Teeksha | Ushna | Katu | Shwasahara, Kantharogahara, Kramighna, Atisarghna | Raal, Alkaloid |
| 11.    | Yavakshara | Carobanate of potash | Katu | Laghu Snigdha | Ushna | Katu | Shwasahara, Kantharogahara, Aamvatalara, Deepan, Pachana | Carbonate of potash |
| 12.    | Sauvarchala | Sodicarbonimus pura | Lavana | Snigdha, Visada | Ushna | Madhur | Vibandhahara, Shulahara, Aanahara, Deepan, Pachana, Rochana | NaCl-97.8%, Sodium sulphite-0.918%, Iron-0.030%, Insoluble matter-0.07% |
| 13.    | Nagara | Zinger officinale | Katu | Laghu Snigdha | Ushna | Madhur | Aamdoshahara, Pachaka, Graahi Vishaghna, Kashthagha, Sothahara, Varnya, Kramighna, Pramehagha | Gingerols, shogaols, volatile oil, sequiterpine Curcumin-70-76%, Dimethoxycurcumin-16%, Dimethoxycurcumin-16%, bisdimethoxycurcumin-8%, Alkaloids, Cardiac glycosides, terpenes, Resin |
| 14.    | Nisha | Curcuma longa | Tikta | Ruksha | Ushna | Katu | Vishaghna, Kashthagha, Sothahara, Varnya, Kramighna, Pramehagha | |
| 15.    | Mishi | Anethum graveolens | Tikta | Katu | Ushna | Katu | Asthapanopaga | Sugandhita Taila |
| 16.    | Chavya | Piper chebula | Katu | Laghu Ruksha, Teeksha | Ushna | Katu | Traptighna, Arshoghna, Deepniya, Shulapraraman Sukrasodha-naa, Lakhaniiya, Aasthapana-paga | Piperine, Palitorin, Volatile oil, Starch |
| 17.    | Kushtha | Saassurealappa | Tikta, Katu, Madhur | Laghu Ruksha, Teeksha-na | Ushna | Katu | Sukrasodha-naa, Lakhaniiya, Aasthapana-paga | Saussurine Alkaloid, Tanin, Inulin-18% |
| 18.    | Tejovati | Celastruspaniculatus | Tikta, Katu, | Laghu Ruksha | Ushna | Katu | Shirovirechana, Arshaghna | Berberine, Dictamnine, Magnufluorine, Xanthoplamine, |
| Sr. Nu | Drugs | Botanical Name | Rasa | Guna | Veerya | Vipaka | Karma | Chemical composition |
|-------|-------|---------------|------|------|--------|--------|-------|---------------------|
| 19.   | Maricha | *Piper Nigrum* | Tikta, Katu, | Laghu | Ushna  | Katu   | Kasaghna | Skimmianine, Volatile Oil 1-2.5% volatile oil, 5-9% Alkaloids |
| 20.   | Dipyaka | *Tachyspermum mmi* | Katu, Tikta | Laghu | Ushna  | Katu   | Chedaniya, Ruchya, Pachaniya, Medahara, Kramihara Sheetprasaman |
| 21.   | Vatsaka | *Holarrhenapubes cens* | Katu, Tikta | Laghu | Sheet  | Katu   | Deepniya, Samgrahi | Ajowan oil- 2-4%, Thymol- 35-60%, Carvacrol, Thymine, Protein, Vasa, Carbohydrate, Minerals, Sodium, Potassium, Phosphorus, Calcium, Thimine, Riboflavin, Nicotinic Acid |
| 22.   | Agni   | *Plumbagozeylanica* | Katu, Tikta | Laghu | Ushna  | Katu   | Deepan, Pachana, Grahi, Shulagha, Sothahara | Alkaloid, Carbohydrate, Sugar, Oil Alkaloid Napthoquinones, Binapthoquinones, Coumarins, Diphenyl sulphone, carboxlic acid, Merotarpenes, Triterpenoid, Amino acids, Anthroquinones Picorhizin, Kutkin, D- Manitol, Banilika acid Kutkiol |
| 23.   | Rohini | *Picrorhyczuruha* | Tikta | Laghu | Sheet  | Katu   | Bhedaniya, Lekhniya, Stanyasodhana | Vranakaka taila, Bhlawanol, Semecarpol |
| 24.   | Arushkar a | *Semicarpusanac ardeum* | Katu, Tikta, Kasaya | Laghu | Ushna  | Madhur | Kustaghna, Deepniya, Mutrasamgrahiniya | Asaryl aldehyde, A-Asorone, B-Asorone, Acorin, Eugenol, Caffein |
| 25.   | Vacha  | *Acoruscalamus* | Katu | Laghu | Ushna  | Katu   | Virechnopaga, Lekhniya, Arshoghna, Traptighna, Aastahanopaga, Sheetprasaman |
| Sr.Nu | Drugs      | Botanical Name                  | Rasa       | Guna  | Veerya | Vipaka       | Karma                                      | Chemical composition                                      |
|-------|------------|---------------------------------|------------|-------|--------|--------------|-------------------------------------------|----------------------------------------------------------|
| 26.   | Pippli mula| *Piper longum root*             | Katu Tikta| Snigdha, Laghu | Anushna | Madhur       | Sangyasthapana Deepniya, Grahi, Arshogna, Shulahara, Shothena Aartavjanan, Prameyagha | Volatile oil, Resin, Waxy alkaloids, Piperine, piperlongumine |
| 27.   | Manjistha  | *Rubia cardifolia*              | Kasaya Madhur tikta | Guru | Ushna | Katu | Aartavjanan, Prameyagha | Anthroquinones, Glycosides, Saponin, Resin |
| 28.   | Ativisha   | *Aconitum heterophyllum*        | Tikta Katu | Laghu Ruksha | Ushna | Katu | Arshogna, Lekhniya | Atisine, Hetratisine, Hetisin |
| 29.   | Visha      | *Aconitum ferox*                | Madhur     | Laghu Snigdha Teekshna Vyavayi Vikashi | Ushna | Madhur | Jwarhara | Aconitine, Pseudo aconitine, Picro aconine, Benzoil Aconin |
| 30.   | Yavani     | *Cumimum cyminum*               | Katu Tikta | Laghu Ruksha Teekshn | Ushna | Katu | Deepan, Pachana, Anuloman Shulahara Kramighna | Carbohydrate, Fat, Proteins, Fiber, Saponin, Flavno, Minerals |
| 31.   | Guggulu    | *Commiphoramukul*               | Tikta Katu | Old Guggulu-Laghu Ruksha Teekshn Visad sukshma Sara New Guggulu-Snigdha Picchil | Ushna | Katu | Medohara | Volatile oil, Raal |
Secondary Outcome- We will see the effect of Brihachagalyadi Ghritam and Guggulutiktaka Ghritam on goniometer parameters reading of all types of back movement, Extension, Right Lateral, Left Lateral, through goniometer device.

Statistical Analysis- Data will be analyzed based on appropriate statistics paired with unpaired t-test, Chi-square, and ANOVA using SPSS software.

Time duration till following up 18th days

Follow up period- 9th days

Time schedule of enrolment, interventions- Subjects will be recruited for the study after clearance from the institutional Ethical Committee. Interventions will be Anuvasana basti with two different formulations with increasing dose.

Recruitment- 33 subjects in each group will be recruited by a single randomizing sampling method.

3.1 Inclusion Criteria:

4. METHODS

Literature review search, plan of work, blueprint in the form of flow chart, row materials collection, preparation of medicine, data collection, intervention, and effect will be observed and statistical analysis.

Data collection Methods- randomized sampling

Objective criteria-
- SLR test with Goniometry
- Range of motion in centimetres,
- Tenderness grading
- Sciatica Frequency Index
- Sciatica Bothersomeness Index

Subjective Criteria:
- Ruka
- Toda
- Stamba Spandana
- Aruchi Tandra
- Gourava
- Modified Oswestry low back pain questionnaires
- Quebec disability scale
- VAS: A 10 cm line will be used to assess the severity of pain.

Assessment of Basti:
1. Prasrushta Vitkata, mutra, samira (Passing urine, stool, flatus)
2. Laghavta (Lightness in the body)
3. Ruchi (appetite)
4. Agni vridhhi (Increased digestive power)
5. Asaya Laghuta (lightness of organs)

Investigations: If necessary, MRI Lumber region & X-Ray Lumber Region.

Data management- Data coding will be done by the principal investigator.

Statistical methods- Chi square test, Paired and Unpaired for objective criteria, nonparametric for subjective criteria, ANNOVA for comparing between two groups.

Dissemination policy- The information will be discrete by paper distribution: creation qualification rules and any proposed expert scholars' application.

Informed consent materials- With all the data model assent structure and other related documentation will be given to members.

Intervention –

Table-3 Intervention & Posology [13]

| Groups | AnuvasanBasti Drugs | 1st Day | 2nd Day | 3rd Day | 4th Day | 5th Day | 6th Day | 7th Day | 8th Day | 9th Day |
|--------|---------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Group A: N=33 | Interventional Group BrihachagalyadiGhritam | 28.2 ml | 35.3 ml | 42.3 ml | 49.4ml | 56.4 ml | 63.5 ml | 70.5 ml | 77.6 ml | 84.7 ml |
| Group B: N=33 | Control group Guggulutiktaka Ghritam | 28.2 ml | 35.3 ml | 42.3 ml | 49.4ml | 56.4 ml | 63.5 ml | 70.5 ml | 77.6 ml | 84.7 ml |
5. DISCUSSION

Importance of Basti Karma -Pakhwashaya is the primary location of Vata Dosha. Vyana Vata is indeed vitiated in Gridhrasi. So, Basti is beneficial in pacifying Vata. Further, it is glorified that Basti Chikitsa as "Arda Chikitsa" of Vata [14] By these facts, Basti is the main Chikitsa in the Panchakarma for the treatment of Gridhrasi. No other therapy like Chikitsa, which was specifying and relating the force of Vata apart from Basti [15]

5.2 Limitation of Established Conventional Therapy of Sciatica

In the management of Sciatica, in modern medicine, only symptomatic treatment given like analgesic, non-steroidal anti-inflammatory drugs. Surgical procedures like laminectomy and discectomy are advised if nerve compression occurs, but these surgical procedures are expensive to the patient.

"In Ayurveda, Various methods used in the Treatment of Gridhrasi (Sciatica) are Bhesajaha, Snehana, Swedana, Siravedha, Agnikarma and Basti" [16]

Snehana and Basti are the best modalities to treat Vata-originated diseases like Gridhrasi (Sciatica) & Sandhivata (Osteoarthritis).

It proved that if we use different forms of herbs and herb extracts, the efficacy of that product increases when processed with ghee, compared to powder or tablet form. Therefore, Ghrita Preparation is effective in treating Gridhrasi (Sciatica) [17].

Anuvasana Basti is the type of Abhyantaraseshea, so it is beneficial in Gridhrasi (Sciatica) because Snehadrayya is having Snigdha property, which pacify the Vata dosha and nourish the nerves and tissues.

5.2 Why Guggulu Tiktaka Ghrita Anuvasanbasti As a Control

Guggulu Tiktaka Ghrita contains Tikta Rasa and Ushna Virya drugs predominantly. Being composed of Akasha and Vayu Mahabhuta, Tikta Rasa helps maintain the average health of Asthi Dhatu [18]

It also increases the Dhatvagni (metabolic stage), which helps in the proper nutrition of all the Dhatus. Hence Asthi Dhatu and Majja Dhatu may get appropriate nourishment due to Guggululiktak Ghritam. Owing to the Snigdha and Ushna Guna, Guggulu Tiktaka Ghrita helps in the pacification of aggravated Vata. Pharmacologically, Guggulu has anti-inflammatory, immunomodulatory, and antilipidemic properties [19].

Anuvasana Basti, is a type of Snehana Basti (oil enema) in Ayurveda. Moreover, Basti is best to pacify Vata and even for Asthi Gata diseases (Diseases related to bone). Asthi (bone) being the site of Vata and influences the Purishadhara (asthidhara) Kaal, i.e. Pakwashaya (Rectum). Asthi Vaha Srotas (locomotors system), the vitiated Vata, gets subsided when the asthi treated with Basti. As the primary site of Vata, the Basti acts better with its Snehana and Shamaka (pacification) properties [20,21].

Brahana Ksheera Basti with Guggulu Tiktaka Ghrita is an effective treatment method for reliable and successful management of Gridhrasi (Sciatica) induced by lumbar disc degeneration [22].

Brahatchagalyadi Ghritam made from 55 drugs; out of these drugs, Dashmool, Balamoola, Ashwagandha, Satavari, Kushta, Draksha, Devdaru and Rashna subside the Vata dosha and nourishes the nerves. It is helpful to treat Gridhrasi (Sciatica).

Brahatchagyadi Ghritam indicated in the treatment for Gridhrasi. Brahatchagalyadi Ghritam is made from Goat meat [23]. Goat meat is the best drug for Brahana Karma [24]. Therefore in this study, Brahatchagalyadi Ghritam Anuvasana Basti [25] taken in an interventional group. A number of related studies have been reported [26-28]. Some key studies with Ayurvedic remedies were reviewed [29-31].

Strengths- Positive outcome of this study may be use as an effective modality in the management of Gridhrasi (Sciatica).

6. CONCLUSION

Conclusion will be drawn after the deliberate analysis of data.

CONSENT

The made consent will be taken from the patient before beginning the assessment. During the
investigation, the classification of each patient will be kept up.

ETHICAL APPROVAL

Ethical approval from the research ethics committee has taken. Ref.No. MGACHR/IEC/December-2020/165

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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