



## **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 manuscript. Authors TG and MN managed the analyses of the study. All authors read and approved the final manuscript.*

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**Study Protocol**

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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 *Brihatchagalyadi Ghritam* & *Guggulutiktaka Ghritam* in the control of *Gridhrasi* (Sciatica) and to compare the effectiveness of *Brihachagalyadi Ghritam* & *Guggulutiktaka 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 *Brihachagalyadi 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 9<sup>th</sup> day.

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

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

## 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 *Brihachagalyadi 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 *Brihatchagalyadi Ghritam* & *Guggulutiktak Ghritam Anuvasan Basti* in the management of *Gridhrasi*.

### Objectives:

- To evaluate the efficacy of *AnuvasanBasti* with *Brihatchagalyadi Ghritam* in the management of *Gridhrasi* (Sciatica).
- To evaluate the efficacy of *Anuvasan Basti* with *Guggulutiktak Ghritamin*, the management of *Gridhrasi* (Sciatica).
- To compare *Anuvasan Basti*'s efficacy with *Brihatchagalyadi Ghritam* & *Guggulutiktak 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 *Brihatchagalyadi Ghritam* is more efficacious than *Guggulutiktaka Ghritam Anuvasana basti* in the Management of *Gridhrasi* (Sciatica)?

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

**Null Hypothesis:** There is no difference between *Anuvasana Basti* with *Brihatchagalyadi 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.

**Registration Number-** registered for CTRI, no awaited.

**IEC-** MGACHRC/IEC/December-2020-165

**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  $30^{\circ}$ - $70^{\circ}$  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 – 9thday – 18<sup>th</sup> day**

**Primary Outcome-** We will see the effect of *Brihachagalyadi 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 trial 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 Snigdha	Sheet	Madhur	Vata- Piitta Shamak	
2.	Satavari	<i>Asparagus racemosus</i>	Madhur Tikta	Guru Snigdha	Sheet	Madhur	Vata- Piitta Shamak Balya, Vaya sthapana	Saponin
3.	Kshira	Milk	Madhur	Laghu Snigdh	Sheet	Madhur	Vata- Piitta Shamak Balya, Vaya sthapana, Jeevniya, Rasayan	
4.	Chagamamsa	Meat of Goat	Madhur	Laghu Snigdh	Sheet	Madhur	Trodoshasa-mak, Peenasasn-am, Brahaniya, Veeryavardhanam	
5.	Kasmari	<i>Gamelia Arboria</i>	Tikta Kasaya Madhur	Guru	Ushna	Katu	Sothahara	Butiric & Terteric acid
6.	Vilva	<i>Aegle marmelos</i>	Kasaya Tikta	Laghu Ruksha	Ushna	Katu	Sothahara, Arshoghna Aasthapano-paga, Anovasanop-agha	Sarkara, Tanin, Tikta satva
7.	Patala	<i>Steriospermum colais</i>	Tikta Kasaya	Laghu Ruksha	Ushna	Katu	Sothahara	Tanin, Stable oil
8.	Syonak	<i>Oroxylum indicum</i>	Madhur Tikta Kasaya	Laghu Ruksha	Ushna	Katu	Sothahara, Sheetprasa-man Anovasanop-agha	Oroxylin A, Baicalein, Chrysin
9.	Agnimanth	<i>Premnacorymbosa</i>	Tikta, Katu, Kasaya, Madhur	Laghu Ruksha	Ushna	Katu	Sothahara, Sheetprasa-man Anovasanop-agha	Saponin, Tanin, Glycosidase
10.	Salparni	<i>Pseudarthriaviscida</i>	Madhur Tikta	Guru & Snigdha	Ushna	Madhur	Sothahara, Balya, Snehopaga	Rol, Oil, Alkaloid

Sr.No	Drugs	Botanical name	Rasa	..Guna	Veerya	Vipaka	Karma	Chemical composition
11.	Prishnaparni	<i>Desmodiumgangeticum</i>	Madhur Tikta	Laghu & Snigdha	Ushna	Madhur	Sothahara, Angamarda-prashman, Sandhaniya	Tanin, Glycosidase
12.	Brihti	<i>Solanumanguivi</i>	Katu Tikta	Laghu, Ruksha, Teekshna	Ushna	Katu	Sothahara, Angamarda-prashman, Kanthya, Hikanigra-han	Solanine, Solanidine, Solasonine
13.	Nidigdhika	<i>SolanumVirginiatum</i>	Tikta Katu	Laghu, Ruksha, Teekshna	Ushna	Katu	Sothahara, Angamarda-prashman, Kanthya, Hikanigra-han	Diogenin, Potassium Carbonate, Sulphate, and Nitrate, Solesonin
14.	Gokshura	<i>Tribulusterrestri</i> s	Madhur	Guru Snigdha	Sheet	Madhur	Sothahara, Anovasanop-aga, Kramighna, Mutravirechaniya	Alkaloid, Stable oil, Sugandhita oil, Glycosides, Harman & Harmine
15.	Ashwagandha	<i>Withaniasomnifera</i>	Tikta, Katu, Madhur	Laghu Snigdha	Ushna	Madhur	Balya, Brahana	Cuseohygrine, Anahygrine, Tropine & Anaferine
16.	Bala	<i>Sidacordifolia</i>	Madhur	Laghu Snigdha Picchila	Sheet	Madhur	Balya, Brahana Prajasthapa-na	Alkaloid, Ephedrine
17.	Masha	<i>VignaMungo</i>	Madhur	Guru Snigdha	Ushna	Madhur	Vajikarana	Albuminoid, Starch, Alkaloid

Sr.No	Drugs	Botanical name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
18.	Jivanti	<i>Leptodenia reticulata</i>	Madhur	Laghu Snigdha	Sheet	Madhur	Jeevniya	Sterol
19.	Madhuka	<i>Glycyrrhiza glabra</i>	Madhur	Guru Snigdha	Sheet	Madhur	Jeevniya, Kanthya, Sandhaniya, Varna, Kandughna, Mutravirjanjiy, Sonita sthapa na, Chardinigrahana, Snehopaga, Vamnopaga	Glycyrnizinsol, Liquiritin, Aspagarine, Starch, Glucose
20.	Draksha	<i>Vitis vinifera</i>	Madhur	Guru Snigdha Mradu	Sheet	Madhur	Snehopaga, Virechnopaga, Kasahara, Jwarhara	Glucose, Tertaric, Cytric, Rasemic Kcl, Nacl, K2So <sub>4</sub> , Mg
21.	Dvikakoli (Sub) Ashwagandha	<i>Withania somnifera</i> (Sub.)	Tikta, Katu, Madhur	Laghu Snigdha	Ushna	Madhur	Balya, Brahana	Cuseohygrine, Anahygrine, Tropine & Anaferine
22.	Nilamulpala	<i>Monochoria vaginalis</i>	Madhur	Guru Snigdha	Sheet	Madhur	Antioxident, Antiinflamatory	Flavanoids,
23.	Musta	<i>Cyperus rotundus</i>	Tikta, Katu, Kasaya	Laghu Ruksha	Sheeta	Katu	Jwarghna, Stholyahara, Sothahara	Flavanoids, B-sistosterol, Ascorbic acid
24.	Chandana	<i>Santalum album</i>	Tikta Madhur	Laghu Ruksha	Sheeta	Katu	Vishagna, Daurgandhyahar Kramighna, Varnya, Hradya	Sesquiterpine, Alcohol, Volatile oil
25.	Rasna	<i>Alpinia galanga</i>	Tikta	Guru	Ushna	Katu	Kramighna, Deepana, Pachana, Anulomana Aampachana	Alkaloids, Saponin, Glycosides
26.	Mashparni	<i>Dyslobium pilosum</i>	Madhur Tikta	Laghu Snigdha	Sheet	Madhur	Jeevniya, Shukrajanan	-
27.	Mudgaparni	<i>Vigna radiata</i>	Madhur	Laghu Ruksha	Sheet	Madhur	Jeevniya, Shukrajanan	-

Sr.No	Drugs	Botanical name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
28.	Sweta Sariba	<i>Hemidesmusindicus</i>	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	<i>Ichnocarpusfrutescens</i>	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.	Dvimedra	<i>Puerariatuberosa</i> (Sub.)	Madhur	Guru Snigdha	Sheet	Madhur	Balya, Brahana, Varnya, Kantha, Snehopaga	Carbohydrate & Protein
31.	Kushtha	<i>Saussurealappa</i>	Tikta, Katu, Madhur	Laghu Ruksha Teeksha-na	Ushna	Katu	Sukrasodha-na, Lekhniya, Aasthapano-paga	Saussurine Alkaloid, Tanin, Inulin- 18 %
32.	Dvijivaka Sub( Vidari )	<i>Puerariatuberosa</i> (Sub.)	Madhur	Guru Snigdha	Sheet	Madhur	Balya, Brahana, Varnya, Kantha, Snehopaga	Carbohydrate & Protein
33.	Sati	<i>Hedychiumspicatum</i>	Tikta, Katu, Kasaya	Laghu Teeksha-na	Ushna	Katu	Shwashara, Hikanigra-hana	Starch (52%), Organic acid, Glycoside
34.	Priyangu	<i>Callicarpamacrophylla</i>	Tikta, Kasaya, Madhur	Guru, Ruksh	Sheet Katu		Mutraviranjnee, Pureeshsamgrahniya	Hydrocynic acid
35.	Darvi	<i>Barberisaristata</i>	Tikta	Ruksha	Ushna	Katu	Pachana, Stanyadosh-ahara	-
36.	Abhaya	<i>Terminaliacheb</i>	Pancharasa	Laghu	Ushna	Madhur	Prajasthapana, Jwarghna,	Chebulagic

Sr.No	Drugs	Botanical name	Rasa	..Guna	Veerya	Vipaka	Karma	Chemical composition
		ula	(Lavan Absent) Kasaya Pradhan	Ruksha			Kushtaghna, Arshoghna, Kasaghna	acid, chebulinic acid, coriligin
37.	Amalaki	<i>Phyllanthusemblica</i>	Pancharasa (Lavan Absent) Amla Pradhan	Guru, Ruksha sheet	Sheet	Madhur	Vayasthapana, Virechnopaga	Vit-C, Galic acid, Tanic acid, Albumin, Cellulose, Protein ,Vasa, Minerals
38.	Vibhitaka	<i>Terminaliabellirica</i>	Kasaya	Ruksha Laghu	Ushna	Madhur	Virechnopaga, Jwarahara	Tanin (21.4%), B-Systosterol, Galic acid, Elegika acid, Ethyl galate, Chebulegic acid, Manitol, Glucose, Galactose
39.	Nata	<i>Valerianawalliehii</i>	Tikta Katu kasaya	Laghu	Ushna	Katu	Vishaghna, Raktadoshahara, Manasdoshahar	Sesquiterpenoids, Alkaloides, Glucosides, Resins, terpineol, flavonoids
40.	Talisa	<i>Abiesspectabilis</i>	Tikta Madhur	Laghu Teekshna	Ushna	Katu	Shirovirechna	Volatile oil
41.	Padmaka	<i>Prunusceracoides</i>	Kasaya Tikta	Laghu	Sheet	Katu	Vedanasthapana, Varnya	Scuratanin, Jaquanin, Prunetin, Padmakasthin, Sukranin,

Sr.No	Drugs	Botanical name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
42.	Ela	<i>Eletarriacardanomum</i>	Katu Madhur	Laghu	Sheet	Madhur	Hridya, Mutral, Deepan, Anuloman	Taxifolin Volatile oil
43.	Tejapatra	<i>Cinnamonomumtamaala</i>	Katu Madhur	Laghu Picchila Teekshna	Ushna	Katu	Rucya, Arshoghna	Methyl eugenol, trans cinnamyl, Beta caryophyllene Saponin
44.	Vari	<i>Asparagusracemosus</i>	Madhur Tikta	Guru Snigdha	Sheeta	Madhur	Balya, Vayasthapana	
45.	Nagakeshar	<i>Mesuaferrea</i>	Tikta katu kasaya	Laghu Ruksha	Ushna	Katu	Varnya, Urdhwajatrugatavikara nasaka	Lipid, Carbohydrate, protein, oleorasin
46.	Jatikusuma	<i>Jasminumgrandiflorum</i>	Tikta kasaya	Laghu Snigdh Mradu	Ushna	Katu	Kushtaghna	Salycyclic acid, Jasminine
47.	Dhanyaka	<i>Coriandrumssativum</i>	Kasaya Madhur tikta Katu	Laghu Snigdha	Ushna	Madhur	Trashnanigrahana, Sheetprasamana	Carbohydrate, Vitamin, Fat, Minerals, Coriandrol
48.	Manjistha	<i>Rubiacordifolia</i>	Kasaya Madhur tikta	Guru	Ushna	Katu	Aartavjanan, Prameyaghna	Anthroquinone s, Glycosides, Saponin, Resin
49.	Dadima	<i>Punicagranatum</i>	Madhur Kasaya Amla	Laghu Snigdha	Anushna	Madhur Species- Madhur Amla Species- Amla	Hradya, Chardinigrahana	Carbohydrate, Vitamin, Fat, Minerals, Fe, Manitol, Vit-C
50.	Daru	<i>Cedrusdeodara</i>	Tikta	Laghu Snigdha	Ushna	Katu	Dustavranasodhaka, Pramehaghna	Alcaloids, Glycosides, Flavonoids

Sr.No	Drugs	Botanical name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
51.	Renuka	<i>Piper cubeba</i>	Katu Tikta	Laghu Ruksha Teekshna	Ushna	Katu	Hradya, Aartavjanan	Cubebin, Cubebol
52.	Elavaluka	<i>Prunusavium</i>	Kasaya	Laghu	Sheet	Katu	Kandughna, Kushtaghna, Trashnahara	-
53.	Vidanga	<i>Embeliaribes</i>	Katu Tikta	Laghu Ruksha Teekshna	Ushna	Katu	Kramighna, Deepan Pachana	Alkaloids, Glycosides, Flavanoides, Tarpenoides,
54.	Jeerak	<i>Cuminumcyminum</i>	Katu	Laghu Ruksha	Ushna	Katu	Shulaprasamana, Shirovirechana	VitA, Vit-C, protein, carbohydrates, Minerals
55.	Sarkara	<i>Saccharumofficinarum</i>	Madhur	Guru Snigdha	Sheet	Madhur	Vrasya, Stanyajanaana	Sugar, Fat, Albumin, Guanine, Ca-Oxalate

**Guggulutiktak Ghritam [12]****Table 2. Ingredients of Guggulutiktak Ghritam**

Sr.Nu	Drugs	Botanical Name	Rasa	..Guna	Veerya	Vipaka	Karma	Chemical composition
1	Ghritam	Ghee	Madhur	Guru Snigdha Laghu	Sheet	Madhur	Vata- Piitta Shamak Kandughna	
2	Nimba	<i>Azardirachta indic a</i>	Tikta Kasaya	Laghu	Sheet	Katu		Nimbinin, Nimbidin, Nimbosterol, Volatile oil Tannin
3.	Amrita	<i>Tinospora cardifoli a</i>	Tikta Kasaya	Laghu	Ushna	Madhur	Rasayan, Deepan, Pachana, Jwaraghna Raktasodhana	G- Glycosides Sesquiterpinoid Starch Polysacharide Protein, Calcium Phosphorus
4.	Vrisha	<i>Adatodavasaca</i>	Tikta Kasaya	Laghu	Sheet	Katu	Hradya, Raktasamgrahi, Kasaghna	Anthraquinones, Saponin, Alkaloids, Flavanoids, Terpendois
5.	Patol	<i>Trichosanthes di oca</i>	Tikta	Laghu Ruksha	Ushna	Katu	Traptighna, Trashnanigrahan	Protein, Fat, Carbohydrate, Minerals, Greenish oil
6.	Nidigdhi ka	<i>Solanum virginian um</i>	Tikta Katu	Laghu, Ruksha, Teekshna	Ushna	Katu	Sothahara, Angamarda- prashman, Kanthya, Hikkanigra-han	Diogenin, Potassium Carbonate, Sulphate, and Nitrate, Solesonin
7.	Patha	<i>Cycleapeltata</i>	Tikta	Laghu Teekshna	Ushna	Katu	Stanyasodhana, Jwarahara, Sandhaniya	Pelosine, Bebeerine, Saponin, Cycline Alkaloid
8.	Vidanga	<i>Embeliaribes</i>	Tikta Katu	Laghu, Ruksha, Teekshna	Ushna	Katu	Deepana, Pachana, Anuloman Kramighna Vishaghna	Embelin, Christembine, Vilangin,
9.	Suradar u	<i>Cedr darus deodar a</i>	Tikta	Laghu Snigdha	Ushna	Katu	Dustavranasodhak a, Pramehaghna	Alcaloids, Glycosides, Flavonoids

Sr.Nu	Drugs	Botanical Name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
10.	Gajopakulya	<i>Scindapsus officinalis</i>	Katu	Teekshna	Ushna	Katu	Shwasahara, Kantharogahara, Kramighna, Atisarghna	Raal, Alkaloid
11.	Yavakshara	<i>Carobanate of potash</i>	Katu	Laghu Snigdha	Ushna	Katu	Shwasahara, Kantharogahara, Aamvatahara, Deepan, Pachana	Carbonate of potash
12.	Sauvarchala	<i>Sodiicarbonusim pura</i>	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	<i>Zinger officinale</i>	Katu	Laghu Snigdha	Ushna	Madhur	Aamdosahara, Pachaka, Graahi	Gingerols, shogaols, volatile oil, sequiterpine
14.	Nisha	<i>Curcuma longa</i>	Tikta Katu	Ruksha	Ushna	Katu	Vishaghna, Kushtaghna, Sothahara, Varnya, Kramighna, Pramehaghna	Curcomin- 70-76%, Dimethoxycurcomin- 16%, Dimethoxycurcomin- 16%, bisdimethoxycurcomin- 8%, Alkaloids, Cardiac glycosides, terpenes, Resin
15.	Mishi	<i>Anethum graveolens</i>	Tikta Katu	Laghu, Ruksha, Teekshna	Ushna	Katu	Asthapanopaga	Sugandhita Taila
16.	Chavya	<i>Piper chebula</i>	Katu	Laghu Ruksha	Ushna	Katu	Traptighna, Arshoghna, Deepniya, Shulaprasaman	Piperine, Palitorin, Volatile oil, Starch
17.	Kushtha	<i>Saussurealappa</i>	Tikta, Katu, Madhur	Laghu Ruksha Teeksha-na	Ushna	Katu	Sukrasodha-na, Lekhniya, Aasthapano-paga	Saussurine Alkaloid, Tanin, Inulin- 18 %
18.	Tejovati	<i>Celastrus paniculatus</i>	Tikta, Katu,	Laghu Ruksha	Ushna	Katu	Shirovirechana, Arshaghna,	Berberine, Dictaminine, Magnufluorine, Xanthoplanine,

Sr.Nu	Drugs	Botanical Name	Rasa	Guna	Veerya	Vipaka	Karma	Chemical composition
19.	Maricha	<i>Piper Nigrum</i>	Tikta, Katu,	Laghu Ruksha Teeksha-na	Ushna	Katu	Chedaniya, Ruchya, Pachaniya, Medahara, Kramihara	Skimmaianine. Volatile Oil 1-2.5% volatile oil, 5-9% Alkaloids
20.	Dipyaka	<i>Tachyspermum ammi</i>	Katu, Tikta	Laghu Ruksha Teeksha-na	Ushna	Katu	Sheetprasaman	Ajowan oil- 2-4%, Thymol- 35- 60 %, Carvacrol, Thymine, Protein , Vasa, Carbohydrate, Minerals, Sodium, Potassium, Phosphorus, Calsium, Thimine, Riboflavin, Nicotinic Acid
21.	Vatsaka	<i>Holarrhenapubes cens</i>	Katu, Tikta	Laghu Ruksha	Sheet	Katu	Deepniya, Samgrahi	Alcaloid, Carbohydrate, Sugar, Oil Alkaloid
22.	Agni	<i>Plumbagozeylanica</i>	Katu,	Laghu Ruksha Teeksha-na	Ushna	Katu	Deepan, Pachana, Grahi, Shulaghna, Sothahara	Naphthoquinones, Binaphthoquinones, Coumarins, Diphenyl sulphone, carboxic acid, Merotarpenes, Triterpenoid, Amino acids, Anthroquinones
23.	Rohini	<i>Picrorhynchacuruha</i>	Tikta	Laghu Ruksha	Sheet	Katu	Bhedaniya, Lekhniya, Stanyasodhana	Picrorhizin, Kutkin, D- Manitol, Banilika acid Kutkiol
24.	Arushkara	<i>Semicarpusandreae</i>	Katu, Tikta Kasaya	Laghu Snigdha Teekshna	Ushna	Madhur	Kustaghna, Deepniya, Mutrasamgrahiniya	Vranakaraka taila, Bhlawanol, Semecarpol
25.	Vacha	<i>Acoruscalamus</i>	Katu	Laghu Teekshna	Ushna	Katu	Virechnopaga, Lekhniya, Arshoghna, Traptighna, Aasthapanopaga, Sheetprasaman,	Asaryl aldehyde, A-Asorone, B- Asorone, Acorin, Eugenol, Caffein

Sr.Nu	Drugs	Botanical Name	Rasa	..Guna	Veerya	Vipaka	Karma	Chemical composition
26.	Pippli mula	<i>Piper longum</i> root	Katu Tikta	Snigdha, Laghu	Anushna	Madhur	Sangyasthapana Deepniya, Grahi, Arshoghna, Shulahara, Shothhara	Volatile oil, Resin, Waxy alkaloids, Piperine, piperlonguimine
27.	Manjistha	<i>Rubiocardifolia</i>	Kasaya Madhur tikta	Guru	Ushna	Katu	Aartavjanan, Prameyaghna	Anthroquinones, Glycosides, Saponin, Resin
28.	Ativisha	<i>Aconitum heterophyllum</i>	Tikta Katu	Laghu Ruksha	Ushna	Katu	Arshoghna, Lekhniya	Atisine, Hetratisine, Hetisin
29.	Visha	<i>Aconitum ferox</i>	Madhur	Laghu Snigdha Teekshna Vyavayi Vikashi	Ushna	Madhur	Jwarhara	Aconitine, Pseudo aconitine, Picro aconine, Benzoil Aconin
30.	Yavani	<i>Cumimumcymimum</i>	Katu Tikta	Laghu Ruksha Teekshn	Ushna	Katu	Deepan, Pachana, Anuloman Shulahara Kramighna	Carbohydrate, Fat, Proteins, Fiber, Saponin, Flavno, Minerals
31.	Guggulu	<i>Commiphoramukul</i>	Tikta Katu	Old Guggulu-Laghu Ruksha teekshn Visad sukshma Sara New Guggulu-Snidha Picchil	Ushna	Katu	Medohara	Volatile oil, Raal

**Secondary Outcome-** We will see the effect of *Brihachagalyadi Ghritam* and *Guggulutiktaka Ghritam* on goinometerparameters readingofall types ofback movementFlexion, 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** 18<sup>th</sup> days

**Follow up period-** 9<sup>th</sup> 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, raw 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

#### Intervention –

**Table-3 Intervention& Posology [13]**

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

- Sciatica Bothersomeness Index

#### Subjective Criteria:

- *Ruka*
- *Toda*
- *Stamba Spandana*
- *Aruchi Tandra*
- *Gourava*
- Modified Oswestry low back pain questionnaires
- Quebec disability scale
- VAS: A 10cm 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 vriddhi* (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.

## 5. DISCUSSION

Importance of *Basti Karma -Pakwashaya* 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 "Ardha 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 *Bheshaja*, *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 *Abhyantarasneha*, so it is beneficial in *Gridhrasi* (*Sciatica*) because *Snehadravya* 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 Dhatus* [18]

It also increases the *Dhatvagni* (metabolic stage), which helps in the proper nutrition of all

the *Dhatus*. Hence *Asthi Dhatus* and *Majja Dhatus* may get appropriate nourishment due to *Guggulutiktak 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 *Sneha 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 *Purishadhabha (asthidhara)* *Kala*, 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 *Sneha* 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*, *Kustha*, *Draksha*, *Devdaru* and *Rashna* subside the *Vata dosha* and nourishes the nerves. It is helpful to treat *Gridhrasi* (*Sciatica*).

*Brahatchagalyadi Ghritam* indicated in the treatment for *Gridhrasi*. *Brahatchagalyadi Ghritam* is made from Goat meat [23]. Goat meat is the best *dravya* 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 used 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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