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Research article

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Open randomized controlled clinical trial of *Simhnaad Guggulu* in the management of *Janu Sandhigatavata* w.s.r. to Osteoarthritis

Deepti Kaushik*, Narendra Singh, Suryanshu Dutt Sharma, Sriram Chandra Mishra, Vandana Gupta

Department of Kaya Chikitsa, V.Y.D.S. Ayurved Mahavidyalaya, Khurja, Bulandshahar, U.P., India.

*Corresponding Author: Deepti Kaushik

ABSTRACT

Sandhivata or Sandhigatavata, a type of Vatavyadhi, is a degenerative disorder of the joints. It especially affects weight bearing joints like knee joint; hip joint etc. results in painful and restricted movement of the affected joint. The clinical presentation of Sandhivata closely mimics with the disorder called Osteoarthritis which is the second most common rheumatologic problem. A comparative clinical study was conducted at V.Y.D.S Ayurved Mahavidyalaya, Khurja to compare the efficacy of Simhnaad Guggulu with the well-established control drug Yograj Guggulu in the management of Janu sandhigatavata w.s.r. to Osteoarthritis. Defining to the benefits assessed both the drugs were found capable to enforce relief, but based on % of improvement and clinical assessment of result, it can be concluded that Control drug (Yograj Guggulu) was more effective than trial drug (Simhnaad Guggulu) in most of the sign and symptom of the disease at extremely significant level.

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Keywords: Sandhivata, Osteoarthritis, Simhnaad Guggulu, Yograj Guggulu

INTRODUCTION

Sandhivata or Sandhigatavata, a type of Vatavyadhi, is a degenerative disorder of the joints. It has been explained under the name of Sandhigata Anila¹, Gulphavata², Khuddavata³, Vata Kantaka⁴ by different Acharyas. Sandhivata is a type of Vatavyadhi which most commonly occurs in old age (Vridhavastha) due to Dhatukshaya. The clinical presentation of Sandhivata closely mimics with the disorder called Osteoarthritis which is the second mostcommon rheumatologic problem. Most commonly affected joints are Knee & Hip. Symptoms of *Sandhigatavata* ⁵⁻⁷ are *Sandhishula* (Pain in joints), *Sandhishotha* (Swelling in joints), *Akunchana prasarana janya vedana* (painful joint movement), *Vatapura drutisparsha* (palpations of joints felt like a bag filled with air), *Sandhisphutana atopa* (Crepitus sound), *Sandhi-graha/stambha* (Stiffness in joints). It is characterized by progressive disintegration of articular cartilage (hanti sandhi gata sandhin), formation of new bone in the floor of the cartilage lesions (eburnation) and at the joint margins (osteophytes) and leads to chronic disability at older ages⁸. The diseases produced by morbid *vatadosha* are more common in Jaravastha (old age). The vitiated vata combines with other vitiated dosha, rakta, ama, etc. and gets located in the joint to produce the disease ⁹. Being related to madhyamarogamarga, а disease Sandhigatavata is either Kastasadhya or Asadhya¹⁰. Snehana, Svedana, Upanaha, Agnikarma, Bandhana, Unmardana, Basti and Mridu Virechana etc. are specially elaborated for management of Sandhigatavata. Vatakapha shamaka, agni dipana, ama pachana and srotoshodhaka dravya are generally advised for the management of Sandhigatavata.11-13

Here in this study, *Simhnaad Guggulu (Bhaishajya Ratnavali Amavatachikitsa Prakarana)* is considered for clinical trial which possesses anti-inflammatory and analgesic actions. It prevents degenerative changes in bones and joints. It reduces inflammation, pain, and stiffness of joints. The well-known drug Yograj Guggulu (Bhaishajya Ratnavali Amavatachikitsa Prakarana) has been selected as a control drug.

This study was undertaken with the following aims and objectives:

- To assess the effect of *Simhnaad Guggulu* in the management of *Sandhigatavata* (Osteoarthiritis).
- To study of literature related to the disease "*Sandhigatavata*" from Ayurveda as well as "Osteoarthritis "from modern point of view.
- To compare the clinical efficacy of *Simhnaad Guggulu* with controlled group *Yograj Guggulu* in the management of *Sandhigatavata* (Osteoarthritis).

MATERIAL AND METHODS

STUDY TYPE

Randomized Clinical trial. Label: Open Blinding/Masking: None Randomization: Simple

SAMPLE SIZE

30

PLACE OF STUDY

Clinical study was conducted on patients in OPD/IPD of Kayachikitsa, V.Y.D.S. Ayurveda Mahavidyalaya, Khurja.

SELECTION OF PATIENTS

Diagnosed cases of *Sandhigatavata* (Osteoarthritis) of knee joint were randomly selected keeping the followings in consideration

- Fulfillment of inclusion criteria.
- Agreed for giving consent after making aware of the merits/demerits of the trial.
- Agreed for investigations before inclusion into the trial and after completion of trial.
- Follow up of the patients for assessment and clinical evaluation.

DIAGNOSIS CRITERIA

The patients were diagnosed according to the signs and symptoms of *Sandhigatavata* in Knee region vis-avis Osteoarthritis of Knee Joint i.e. *sandhishula* (Pain in joints), *sandhishotha* (Swelling in joints), *akunchana prasarana janya vedana* (painful joint movement), *vatapura drutisparsha* (palpations of joints felt like a bag filled with air), *sandhisphutana/ atopa* (Crepitus sound), *sandhi-graha/stambha* (Stiffness in joints) with presence of Osteoarthritic changes in Knee X-ray findings.

STUDY DESIGN

The selected patients were divided into two groups Group-A (Trial Group) - 15 patients were given Simhnaad Guggulu.

Group-B (Control Drug) - 15 patients were given Yograj Guggulu.

INCLUSION CRITERIA

Patients of both sex, between age group of 30 to 65 years suffering from disease for less than 3 years, who fulfill the diagnosis criteria i.e., presence of Clinical features of Knee Osteoarthritis (Kellgren-Lawrence / KL grades 0-3). Also, who agreed for giving consent after making aware of the merits/demerits of the trial.

EXCLUSION CRITERIA

Patient below 30 years and above 65 years of age, suffering from Osteoarthritis of other joints, presence of Kellgren-Lawrence / KL grades 4 and who not agreed for giving consent / investigations / follow up. Also, patient suffering from disease like *Madhumeha*, *Arbuda*, *Kushta* rog, *Vata*-Rakta, *Aamvata*, *Phiranga* roga, *Gridhrasi*, *Rajyakshma* and Polymyalgia Rheumatica, Poliomyelitis, Transverse Myelitis, Fibromyalgia, Congenital Anomalies of joints, Motor neuron diseases that interfere with the course of treatment will be excluded from the study. Lactation and Pregnant women will be excluded. Patient with any Anatomical deformity or *Sandhigatavata* due to any *Abhighata* (Trauma). Patients undergoing other modalities of treatment for *Sandhigatavata*. Patients who are incapacitated, bedridden and confined to wheelchair.

LABORATORY INVESTIGATIONS

X-Ray of Knee joint (Findings: Narrowing of Joint space and Osteophytes formulation). Blood investigations such as Complete Blood Count (CBC), Erythrocyte Sedimentation Rate (ESR), C - reactive protein (CRP), Rheumatoid Factor (RA Factor) etc. were done to rule out other conditions.

DRUG INTERVENTION

Trial Drug: *Simhnaad Guggulu*¹⁴ (*Bhaisajyaratnavali* 29/176-184)

Ingredients – *Guggulu* (Su) (Exd.), *Katutaila* (*Sarsapa* oil) - Each 768 ml, *Sunthi* (Rz). *Pippali* (Fr), *Marica* (Fr), *Haritaki* (P), *Bibhitaki* (P), *Amalaki* (P), *Mustaka* (Rz), *Vidanga* (Fr), *Devadaru* (Ht. Wd) *Guduci* (St), *Citraka* (Rt), *Tibrit* (Rt), *Danti* (Rt), *Cavya* (St), *Surankanda* (Rz), *Manakanda* (Rz), *Parada* (Su), *Gandhak* (Su) – each 48 gm, *Jayapala* (Su) (Enm) - 120 gm.

Dosage: 1.5 gm twice daily (3 gm/day)¹⁵

Route of administration: Oral

Frequency of administration: Twice per day.

Anupana: Lukewarm water.

Control Drug: *Yograj Guggulu* ¹⁶ (*Bhaisajyaratnavali* 29/152-157)

Ingredients: Chitrak (Rt.), Pippalimula (Rt.), Yamani (Sd.), Krishna Jiraka (Fr.), Vidanga (Fr.), Ajamoda (Fr.), Jiraka (Fr.), Suradaru (Ht.Wd), Cavya (St.), Ela (Sd.), Saidhava Lavana, Kustha (Rt.), Rasna (Rt./Lf.), Gokshura (Fr.), Dhanvaka (Fr.), Haritaki (P.), Bibhitaki (P.), Amalaki (P.), Mustaka (Rz.), Sunthi (Rz.), Maricha (Fr.), Pippali (Fr.), Tvak (St. Bk.), Ushira (Rt.), Yavakshara (Pl.), Talisha Patra (Lf.), Tejapatra (Lf.), Guggulu (Exd.), Goghrita - each 1 part **Dosage:** 1.5 gm twice daily (3 gm/day)¹⁷ Route of administration: Oral Frequency of administration: Twice per day. Anupana: Lukewarm water. **Duration of treatment** – 30 days Follow up: Every 10th day during trial period and once after 15 days of completion of trial.

OBSERVATIONS

Various demographic parameters viz Age, Sex etc. were analysed in the present trial. The assessment was done on subjective and objective parameters. The obtained results were analyzed with the use of Wilcoxon signed rank method to check the significance of subjective parameters and Paired 't' test for objective parameters. Comparison of efficacy was done using Mann-whitney test in subjective parameters and Unpaired t- text in objective parameters. Statistical analysis on the percentage of improvement in each parameter will evaluate by the formula: Average BT – Average AT * 100/ Average BT.

| Assessment criteria for Subjective parameters | | | | | | | |
|---|----------------|--|--|--|--|--|--|
| | G_0 | No Pain (Scale - 0) | | | | | |
| Shula (Pain in joints) | G_1 | Mild Pain (Scale - Up to 3 mark) | | | | | |
| (The Numeric Pain Scale) | G ₂ | Moderate Pain (Scale - 4 to 6 mark) | | | | | |
| | G ₃ | Severe Pain (Scale - 7 to 10 mark) | | | | | |
| <i>Sotha</i> (Swelling in joints) | G_0 | No Swelling | | | | | |
| | G_1 | Slight Swelling | | | | | |
| | G_2 | Moderate Swelling | | | | | |
| | G ₃ | Severe Swelling | | | | | |
| Alumoniama | G_0 | Freely movable No pain | | | | | |
| Akuncanjanya- Drasaranajanya Vodana | G_1 | Movable with mild pain (no winching on face while movement) | | | | | |
| (poinful movement) | G ₂ | Movable with moderate pain (winching on face while movement) | | | | | |
| (paintui niovement) | G ₃ | Movable with severe pain (shouts & doesn't allow movements) | | | | | |
| Vata poornadriti sparsha | G_0 | No Effusion | | | | | |
| (resembles | G_1 | Minimum Effusion | | | | | |

Table 1: Scoring Pattern Adopted for Assessment

| a bag filled with air) | G ₂ | Moderate Effusion | | | | | |
|--|-----------------------|--|--|--|--|--|--|
| | G ₃ | Excessive effusion | | | | | |
| | G_0 | No crepitus | | | | | |
| Sandhisphutna | G_1 | Mild Audible crepitus | | | | | |
| (Crepitus) | G_2 | Moderate Audible and Palpable crepitus | | | | | |
| | G ₃ | Severe Audible crepitus | | | | | |
| | G_0 | No Stiffness | | | | | |
| Sandhi-graha | G_1 | Stiffness lasts for $5 - 15$ minutes | | | | | |
| (Stiffness in joints) | G_2 | Stiffness lasts for 30 minutes | | | | | |
| | G3 | Stiffness lasts for more than 30 minutes | | | | | |
| Assessment criteria for Objective parameters | | | | | | | |
| | | Sandhihanti (↓Range of motion) | | | | | |
| | G_0 | Range between $> 135^{\circ}$ | | | | | |
| Flexion | G_1 | Range between >90-135° | | | | | |
| (Knee Joint) | G_2 | Range between $>45 - 90^{\circ}$ | | | | | |
| | G ₃ | Range between ≤45° | | | | | |
| | G_0 | Range between ≤45° | | | | | |
| Extension | G_1 | Range between $>45 - 90^{\circ}$ | | | | | |
| (Knee Joint) | G ₂ | Range between >90-135° | | | | | |
| | G ₃ | Range between $> 135^{\circ}$ | | | | | |

Table 2: Overall Assessment of the Therapy

| Overall assessment of the therapy | Grade | | | | | |
|---|-------|--|--|--|--|--|
| Complete remission (100%): Free from all cardinal signs & symptoms associated with | 0 | | | | | |
| Sandhigata vata (O.A.) with a normal range of movement. | | | | | | |
| Marked improvement (75 - <100%): More than 75% relief in the signs & symptoms with major | | | | | | |
| improvement in range of movement. | | | | | | |
| Moderate improvement (50 - < 75%): 50-75% results in the cardinal signs & symptoms with | | | | | | |
| moderate improvement in range of movement. | | | | | | |
| Mild improvement (25 - < 50%): 25-50% results in the signs & symptoms with mild improvement | 3 | | | | | |
| in range of movement. | | | | | | |
| Unimproved (<25%): No notable changes with or without undiminished signs & symptoms of | 4 | | | | | |
| Janu Sandhigatavata (O.A.) | | | | | | |

OBSERVATIONS ON DEMOGRAPHIC DATA



















OBSERVATION ON STATISTICAL DATA

| | | N | Mean Score | | Maa | % | | | | | |
|---|----|------|-------------------|-----|------------|-----------|-----------|-----------|-------------|--------------|-----------------------|
| Sign & Symptoms | N | B.T. | A.] | Γ. | n diff. | of Imp | ± S.D. | ± S.E. | w– Value | p - Value | Signi-ficance |
| Shulo | | 2.4 | A.T.1 | 2.2 | 0.2 | 8.3 | 0.4 | 0.1 | 6 | 0.25 | not significant |
| (Pain in joints) | 15 | 2.4 | A.T.2 | 1.7 | 0.7 | 30.6 | 0.7 | 0.2 | 45 | 0.0039 | very significant |
| (1 am m joints) | | 2.4 | A.T.3 | 1.5 | 0.9 | 38.9 | 0.8 | 0.2 | 55 | 0.002 | very significant |
| Shotha | Q | 2.5 | A.T.1 | 2.4 | 0.1 | 5.0 | 0.4 | 0.1 | 1 | > 0.9999 | not significant |
| (Sweining III | 0 | 2.5 | A.T.2 | 1.6 | 0.9 | 35.0 | 0.6 | 0.2 | 21 | 0.0313 | significant |
| joints) | | 2.5 | A.T.3 | 1.1 | 1.4 | 55.0 | 0.5 | 0.2 | 36 | 0.0078 | very significant |
| Akuncanjanya | | 1.5 | A.T.1 | 1.3 | 0.3 | 17.4 | 0.5 | 0.1 | 10 | 0.125 | not significant |
| – Prasarana | | 1.5 | A.T.2 | 0.9 | 0.7 | 43.5 | 0.5 | 0.1 | 55 | 0.002 | very significant |
| janya Vedana (painfull movement) | 15 | 1.5 | A.T.3 | 0.7 | 0.9 | 56.5 | 0.6 | 0.2 | 66 | 0.001 | extremely significant |
| | 12 | 2.0 | A.T.1 | 1.8 | 0.3 | 12.5 | 0.5 | 0.1 | 6 | 0.25 | not significant |

Table 3: Statistical analysis showing the effectiveness of Trial drug

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| Vata | | 2.0 | A.T.2 | 1.3 | 0.8 | 37.5 | 0.5 | 0.1 | 45 | 0.0039 | very significant |
|--|----|-----------|-------|-----------|------|------|------|-----|--------------|-------------|-----------------------|
| poornadriti sparsha (resembles a bag filled with air) | | 2.0 | A.T.3 | 1.1 | 0.9 | 45.8 | 0.7 | 0.2 | 45 | 0.0039 | very significant |
| Sandhisphutna | 10 | 2.1 | A.T.1 | 2.0 | 0.1 | 4.8 | 0.3 | 0.1 | 1 | > 0.9999 | not significant |
| (Crepitus) | 10 | 2.1 | A.T.2 | 1.7 | 0.4 | 19.0 | 0.5 | 0.2 | 10 | 0.125 | not significant |
| | | 2.1 | A.T.3 | 1.3 | 0.8 | 38.1 | 0.6 | 0.2 | 28 | 0.0156 | Significant |
| | | 2.5 | A.T.1 | 2.1 | 0.4 | 16.2 | 0.5 | 0.1 | 21 | 0.0313 | Significant |
| Sandhi-graha (Stiffness in joints) | 15 | 2.5 | A.T.2 | 1.6 | 0.9 | 35.1 | 0.4 | 0.1 | 91 | 0.0002 | extremely significant |
| | | 2.5 | A.T.3 | 1.0 | 1.5 | 59.5 | 0.5 | 0.1 | 120 | < 0.0001 | extremely significant |
| | | 73.0 | A.T.1 | 76.3 | 3.3 | 4.6 | 9.6 | 2.5 | t = 1.348 | 0.1989 | not significant |
| Flexion (Knee Joint) | 15 | 73.0 | A.T.2 | 102. 0 | 29.0 | 39.7 | 16.2 | 4.2 | t = 6.947 | < 0.0001 | extremely significant |
| | | 73.0 | A.T.3 | 107. 3 | 34.3 | 47.0 | 15.1 | 3.9 | t = 8.804 | < 0.0001 | extremely significant |
| | | 107. 3 | A.T.1 | 102. 0 | 5.3 | 5.0 | 9.2 | 2.4 | t = 2.256 | 0.0406 | Significant |
| Extension (Knee Joint) | 15 | 107. 3 | A.T.2 | 76.3 | 31.0 | 28.9 | 15.8 | 4.1 | t = 7.583 | < 0.0001 | extremely significant |
| | | 107. 3 | A.T.3 | 73.0 | 34.3 | 32.0 | 15.1 | 3.9 | t = 8.804 | < 0.0001 | extremely significant |
| | | | | | | | | | | | |

Table 4: Statistical analysis showing the effectiveness of Control drug

| Sign & n Symptoms | | Ν | Iean Scoi | e | Mea | % + | + | + | | n - | |
|---|----|------|-----------|-----|------------|------------|------|------|-------------|--------------|-----------------------|
| | | B.T. | A.T. | | n diff. | of Imp. | s.D. | s.e. | w– Value | p - Value | Signi-ficance |
| | | 2.2 | A.T.1 | 1.9 | 0.3 | 12.1 | 0.5 | 0.1 | 10 | 0.125 | not significant |
| Shula (Pain in joints) | 15 | 2.2 | A.T.2 | 1.5 | 0.7 | 33.3 | 0.5 | 0.1 | 66 | 0.001 | extremely significant |
| | | 2.2 | A.T.3 | 0.9 | 1.3 | 60.6 | 0.6 | 0.2 | 105 | 0.001 | extremely significant |
| Shotha (Swelling in 11 joints) | | 2.4 | A.T.1 | 2.2 | 0.2 | 7.7 | 0.4 | 0.1 | 3 | 0.5 | not significant |
| | 11 | 2.4 | A.T.2 | 1.3 | 1.1 | 46.2 | 0.5 | 0.2 | 55 | 0.002 | very significant |
| | 11 | 2.4 | A.T.3 | 0.7 | 1.6 | 69.2 | 0.5 | 0.2 | 66 | 0.001 | extremely significant |
| Akuncanjany | | 1.9 | A.T.1 | 1.6 | 0.3 | 17.2 | 0.5 | 0.1 | 15 | 0.0625 | not quite significant |
| a – Prasarana janya Vedana (painfull movement) | 15 | 1.9 | A.T.2 | 1.2 | 0.7 | 37.9 | 0.5 | 0.1 | 66 | 0.001 | extremely significant |
| | | 1.9 | A.T.3 | 0.8 | 1.1 | 58.6 | 0.7 | 0.2 | 78 | 0.0005 | extremely significant |
| Vata poornadriti | 10 | 1.6 | A.T.1 | 1.5 | 0.1 | 6.3 | 0.3 | 0.1 | 1 | > 0.9999 | not significant |

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|-----------------------------------|------|---------------------|-------|------------|----------|----------------|------|---------|----|
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| sparsha (resembles | | 1.6 | A.T.2 | 1.1 | 0.5 | 31.3 | 0.5 | 0.2 | 15 | 0.0625 | not quite significant |
|---------------------------|-----|-----------|-------|-----------|------|------|------|-----|--------------|--------------------------|--------------------------|
| a bag filled with air) | | 1.6 | A.T.3 | 0.5 | 1.1 | 68.8 | 0.3 | 0.1 | 55 | 0.002 | very significant |
| Sandhianhutn | | 2.3 | A.T.1 | 2.0 | 0.3 | 14.3 | 0.5 | 0.1 | 10 | 0.125 | not significant |
| Sanumsphutn | 12 | 2.3 | A.T.2 | 1.7 | 0.7 | 28.6 | 0.5 | 0.1 | 36 | 0.0078 | very significant |
| (Crepitus) | 12 | 2.3 | A.T.3 | 1.1 | 1.3 | 53.6 | 0.6 | 0.2 | 66 | 0.001 | extremely significant |
| Sou dhi cuche | 2.1 | A.T.1 | 1.7 | 0.3 | 16.1 | 0.5 | 0.1 | 15 | 0.0625 | not quite significant | |
| (Stiffness in | 15 | 2.1 | A.T.2 | 1.3 | 0.7 | 35.5 | 0.5 | 0.1 | 66 | 0.001 | extremely significant |
| joints) | | 2.1 | A.T.3 | 0.9 | 1.1 | 54.8 | 0.7 | 0.2 | 78 | 0.0005 | extremely significant |
| | | 70.0 | A.T.1 | 76.0 | 6.0 | 8.6 | 9.5 | 2.4 | t = 2.449 | 0.0281 | significant |
| Flexion (Knee Joint) | 15 | 70.0 | A.T.2 | 99.3 | 29.3 | 41.9 | 14.1 | 3.6 | t = 8.043 | < 0.0001 | extremely significant |
| | | 70.0 | A.T.3 | 103. 3 | 33.3 | 47.6 | 15.2 | 3.9 | t = 8.495 | < 0.0001 | extremely significant |
| | | 104. 7 | A.T.1 | 102. 0 | 2.7 | 2.5 | 7.0 | 1.8 | t = 1.468 | 0.1643 | not significant |
| Extension (Knee Joint) | 15 | 104. 7 | A.T.2 | 76.3 | 28.3 | 27.1 | 13.8 | 3.6 | t = 7.926 | < 0.0001 | extremely significant |
| (| - | 104. 7 | A.T.3 | 73.0 | 31.7 | 30.3 | 13.7 | 3.5 | t = 8.943 | < 0.0001 | extremely significant |

| Table 5: Showing the incidence of | f patients according to | the % of improvement | t after treatment in | both group |
|-----------------------------------|-------------------------|---------------------------------------|----------------------|------------|
| | 1 | · · · · · · · · · · · · · · · · · · · | | |

| Cardinal features | TG | CG |
|--|-------|-------|
| Shula (Pain in joints) | 38.89 | 60.59 |
| Sotha (Swelling in joints) | 55.00 | 69.20 |
| Akuncanjanya - Prasaranajanya Vedana (Painful movement) | 56.54 | 58.61 |
| Vata poornadriti sparsha (resembles a bag filled with air) | 45.84 | 68.75 |
| Sandhisphutna (Crepitus) | 38.10 | 53.58 |
| Sandhi-graha (Stiffness in joints) | 59.46 | 54.81 |
| Flexion (Knee Joint) abnormality | 47.03 | 47.62 |
| Extension (Knee Joint) abnormality | 31.99 | 30.25 |

Table 6: Comparison of effects on different parameters of both drugs

| Symptoms | Group | No Of Patients | Mean | U Value | P-Value | Remark | |
|--------------------------|-------|----------------|---------|---------|---------|-----------------|--|
| Shula (Pain in joints) | TG | 15 | 0.9333 | 80.5 | 0 1575 | not significant | |
| Shuta (1 ani in joints) | CG | 15 | 1.333 | 80.5 | 0.1375 | not significant | |
| Sotha | TG | 8 | 1.375 | 22.5 | 0 2042 | not significant | |
| (Swelling in joints) | CG | 11 | 1.636 | 52.5 | 0.2945 | | |
| Akuncanjanya- | TG | 15 | 0.8667 | | | not significant | |
| Prasaranajanya Vedana | CG | 15 | 1 1 3 3 | 89.5 | 0.3039 | | |
| (painfull movement) | 0 | 15 | 1.155 | | | | |
| Vata noornadriti snarsha | TG | 10 | 1.1 | 50.5 | 0.448 | not significant | |
| vata poornadriti sparsna | CG | 12 | 0.9167 | 50.5 | 0.440 | not significant | |

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| Sandhisphutna | TG | 10 | 0.8 | 20.5 | 0.1164 | · · · · · · · · · · · · · · · · · · · |
|-----------------------|----|----|--------|-------------|--------|---------------------------------------|
| (Crepitus) | CG | 12 | 1.25 | - 38.5 | 0.1164 | not significant |
| Sandhi-graha | TG | 15 | 1.467 | 104 | 0.7160 | not significant |
| (Stiffness in joints) | CG | 15 | 1.333 | 104 | 0.7109 | |
| Flexion | TG | 15 | 34.333 | t = 0.1808 | 0 8570 | |
| (Knee Joint) | CG | 15 | 33.333 | -1 = 0.1808 | 0.6379 | not significant |
| Extension | TG | 15 | 34.333 | t = 0.5063 | 0.6166 | not significant |
| (Knee Joint) | CG | 15 | 31.667 | -1 = 0.3003 | 0.0100 | |

Table 6; Overall clinical effects of therapy

| | Overall Effect of therapy | | | |
|----------------------------|---------------------------|--------|----|--------|
| Clinical effect of therapy | TG | | CG | |
| | f | % | f | % |
| Complete remission | 0 | 0 | 0 | 0 |
| Marked improvement | 0 | 0 | 0 | 0 |
| Moderate improvement | 1 | 6.67% | 2 | 13.33% |
| Mild improvement | 13 | 86.67% | 12 | 80% |
| Unsatisfactory | 1 | 6.67% | 1 | 6.67% |

DISCUSSION

In this present study, *Simhnaad Guggulu* (*Bhaishajya Ratnavali Amavatachikitsa Prakarana*) is considered for clinical trial. The well-known drug *Yograj Guggulu* (*Bhaishajya Ratnavali Amavatachikitsa Prakarana*) has been selected as a control drug.

The compositions in both the drugs are approachable lieu of principles of treatment of *Sandhigatavata*. The main ingredient of both drug *Simhnaad Guggulu* and *Yograj Guggulu* is *Guggulu*. Guggulsterone present in *Guggulu* is reported to inhibit significantly lipopolysaccharide-induced up regulation of tumor necrosis factor-alpha expression and cyclooxygenase-2 production for which it acts as anti-inflammatory drug.

The drug Simhnaad Guggulu carries an indication against Sandhigatavata. It is a powerful purgative (Tivrit, Danti, Javpala) and the ingredients in it are scanned to be propagative. Sandhigatavata specially occurs in vriddhavastha due to dhatukshya. Rasayan drugs nourish Dhatus and overcome dhatukshya. So rasayana & balya drugs should be in for the treatment of Sandhigatavata. Triphala, Guduchi, Shudh Gandhak, Shudh Parada and Guggulu come under it. These drugs increase the overall vitality of body thus making dhatuposhana proper and help to hamper degenerative disease process in Janusandhi or helps in rebuilding of damaged cartilage. Guduchi has rasayana and Shudh immunomodulatory properties. Guggulu, Sarsapa, Shunthi, Maricha, Pippali etc. drugs are kown as vedanasthapan, vatashamaka, sulaprashamana, hence these drugs mainly helps to alleviate sandhisula, sandhisotha, sandhigraha etc. by their particular action on joints due to their specific guna and karma. Shunthi, Maricha, Pippali, Chitrak etc. drugs are amapachana, rochana, deepana and are helpful in maintaining digestive mechanism, which helps in assimilation of Ama dosha in the body. This Ama formation is the major cause for disease according to Avurveda. Sandhigatavata requires reduction in the states of meda (Obesity), ama & kapha, which is considered to be possible with the trial drug, innervated with katu, tikta and kashaya guna. Katurasa by virtue of its chhedana & lekhana properties helps to cure the dosasamurchhana & srotabhisanga. Devadaru has amapachaka and shothahara Prabhava.

Yograj Guggulu is a famous and versatile Ayurvedic medicine is ladened with rejuvenating properties and is widely used for ages to treat musculoskeletal disorders. Rasayana & Balya drugs like Haritaki, Vibhitaki, Amalaki, Mustaka, Sunthi, Maricha, Pippali, Guggulu, Go-ghrita helps in rebuilding of damaged cartilage. Rasna has shula and shothahara. Shunthi has amapachaka and rasayana, Guduchi has rasayana and immunomodulatory properties, Gokshura is liver protective and shothahara properties.

The demographic data in this study reveals that Maximum numbers of patients i.e. 15 (46.87%) were observed between the age group of >50 -65 years, Maximum numbers of patients i.e. 18 (56.25%) were females, Highest number of patients i.e. 12 (37.50%) had business occupation, Most of the patients i.e. 18 (56.25%) were in 2 yr - 3 yrs of chronicity status, Most of the Patients i.e. 11 (34.38%) were in Sannipataja prakriti group. X-Ray shows in Right Knee joint, Joint space narrowing & Osteophytes formation in all patients i.e. 100%, whereas Subchondral sclerosis in 80% and Tibia lateral subluxation found in 73.33% patients. In left Knee joint, Joint space narrowing & Osteophytes formation found in all patients i.e. 100%, whereas Subchondral sclerosis in 60.71% and Tibia lateral subluxation found in 39.29% patients. According to KL Gradation of osteoarthritis, Right knee osteoarthritis shows 46.67% were in Grade 1 & Grade 2, 6.67% were in Grade 3. Left knee osteoarthritis shows 32.14% were in Grade 1, 53.57% were in Grade 2 and 6.67% were in Grade 3. After treatment, in both groups there are no changes found in the X-Ray findings.

The clinical data in this study reveals that all patients belonging to TG & CG were got relief, which has been critically assessed in the language of percentage. So far the improvement of cardinal sign symptoms in the present study, the percentage being 38.89% & 60.59% in *Shula* (Pain in joints), 55% & 69.20% in *Sotha* (Swelling in joints), 56.54% & 58.61% in *Akuncanjanya - Prasaranajanya Vedana* (Painful movement), 45.84% & 68.75% in *Vata poornadriti sparsha* (resembles a bag filled with air), 38.10% & 53.58% in *Sandhisphutna* (Crepitus), 59.46% & 54.81% in *Sandhi-graha* (Stiffness in joints) among Trial group (TG) & Control Group (CG) respectively. This shows, the cases achieved more benefit by Control Group (*Yograj Guggulu*) than trial drug (*simhnaad guggulu*).

Considering the vital objective parameters, the study reveals all patients attained improvement, which was evaluated in various percentage against different objectives. The percentage being 47.03% & 47.62% in Flexion (Knee Joint) abnormality, 31.99% & 30.25% in Extension (Knee Joint) abnormality among Trial group (TG) & Control Group (CG) respectively. This shows, the cases achieved more benefit by Control Group (*Yograj Guggulu*) than trial drug (*Simhnaad Guggulu*).

The statistical adjudication with suitable parameters shows that both drugs (*Simhnaad Guggulu & Yograj Guggulu*) were extremely/very significant on subjective & objective parameters among both groups.

OVERALL CLINICAL ASSESSMENT OF RESULTS

In *Simhnaad Guggulu* group overall clinical effect was assessed as 1 (6.67%) patients were get Moderate improvement, 13(86.67%) patients were get Mild improvement and 1(6.67%) patients were get unsatisfactory improvement.

In *Yograj Guggulu* group, overall clinical effect was assessed as 2 (13.33%) patients were get Moderate improvement, 12(80%) patients were get Mild improvement and 1(6.67%) patients were get unsatisfactory improvement.

None of the patient was completely cured (100%) observed in both the groups.



CONCLUSION

Results of this study indicate that, the efficacy of all the trial drugs found capable to enforce relief as a statistically significance response was obtained after the therapy in maximum symptoms and at the end of the study none of the case remained unchanged, but the cases achieved more benefit by Control Group (*Yograj* *Guggulu*) than trial drug (*Simhnaad Guggulu*). The trial drug (*Simhnaad Guggulu*) cannot be discarded inferior to control drug (*Yograj Guggulu*) as both the drugs were found capable to enforce relief and the comparison of

effect of trial drug on various symptoms in TG and CG shows not significant that means the relief provided by both group was not so much differ.

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