

## A CLINICAL STUDY TO EVALUATE THE THERAPEUTIC EFFICACY OF RASNADI GHRITA ON JANU SANDHIGATA VATA W.S.R. TO OSTEOARTHRITIS

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## ABSTRACT

**Objectives:** The objective of the study includes answers to the research questions or the hypothesis that is set. The present study was conducted to evaluate the therapeutic effect of Rasnadi ghritha in Janu sandhigata Vata/ Osteoarthritis—**method: Interventional** non-randomized open labelled single group study with pre-test and post test design. Twenty patients diagnosed with Janu sandhigata Vata/osteoarthritis satisfying inclusion and exclusion criteria were selected from OPD/IPD of S.D.M. Ayurveda Hospital, Udupi. The selected patients were administered Rasnadi Ghritha 24 ml on an empty stomach with lukewarm water at 8 A.M. once daily for the duration of 14 days. Statistical analysis was done using students paired 't'-tests and Wilcoxon signed rank test. **Result.** The overall effect of the treatment in this study showed that 0% of the patients fell into minor and no improvement, 90% into moderate improvement, and 10% into the marked improvement category. **Conclusion:** Rasnadi ghruta has shown significant improvement in Janusandhigata Vata/osteoarthritis. The efficacy of the medication has been proved with the statistical analysis of the parameters.

**Key words:** Rasnadi Ghritha, Janu sandhigatavata, Osteoarthritis.

## INTRODUCTION

In the present era, every people suffer from any kind of disease and disease that produces uncomforted feeling and pain. Many people experience aches and pain in muscles and joints at some point in their lives. There may be various factors that cause pain. Osteoarthritis (O.A.) is the most common cause of joint pain and mostly affects middle-aged and older people. O.A. is also found in ancient animals, fish, amphibians, reptiles (dinosaurs), birds, mammoths, and cave bears. It affects almost all vertebrates, saying that it appeared with the evolutionary arrival of the bony skeleton.<sup>1</sup>Osteoarthritis also known as wear and tear arthritis, mostly affects the weight-bearing joints, including the knees, hips, cervical lumbosacral spine, and ankle. Among the elderly, knee O.A. is the major cause of chronic disability in developed countries; some 100,000 people in the United States are unable to walk independently due to osteoarthritis of the knee and hip. In those less than 55 years, joint involvement in men and women is similar. But radiographic evidence suggestive of knee O.A., and especially of symptomatic knee O.A., is more common in women than in men. In a radiographic survey, women are more prone to this disease than men, and for those greater than 65 years, it was 68%.<sup>2</sup>Knee O.A. is one of the most common forms of degenerative joint disease, and is associated with pain, swelling, tenderness, functional impairment, and a high economic cost.<sup>3</sup>Vata Dosha is responsible for all types of movements in our body and almost all the diseases. Sandhigatavata is explained under vatavyadhi adhyaya in classical texts. The affliction of sandhi by vitiated Vata is the main phenomenon in the samprapti of Sandhigatavata. It is a kashtasadhya vyadhi because it is situated in marmasthisandhi and mainly occurs due to the various etiological factors, which are classified as dhatukshayajanya and Margavaranajanya. The main symptoms are pain, stiffness, swelling, crepitus, and restricted movements of the joints. The treatment modalities which are explained in contemporary science include non-pharmacological and pharmacological measures mainly. Exercises, lifestyle chang-

es, and proper administration of medication play an important role in reducing the symptoms. In advanced cases, where other treatments modalities have not been helpful, surgery to repair, strengthen or replace damaged joints may also be considered. If it is not treated properly, it will lead to further complications such as bowing of the leg, etc. Although it provides symptomatic relief, there will be less response and more side-effects. According to Ayurveda's point of view, the increased morbidity of the disease is treated by many treatment principles, i.e., Samshodhna and Samshamana chikitsa. Samsodhana and Samshamana Chikitsa include Antapari-marjana and Bahipari-marjana chikitsa. The basic treatment has been described by Acharya Charaka, and later other authors described the specific treatment of the disease. Snehana, svedana, mardana, upanaha, agnikarma, and bandhana, are the specific line of treatments. There are many shamanoushadhis mentioned in the literature. Rasayana dravyasare is also used, which helps to nourish the dhatus. Sandhishoola, Sandhishopha, and Prasaranaakunjanayopravriti are the pradhana lakshnas of Sandhigata vata which are explained in the classics. In this study, Rasnadi Ghrita consists of dravyas which are shoolahara, shothahara, and Tridoshashamaka, especially vatahara. So, to analyse the efficacy of these shamanoushadhis in the morbid condition, the present work entitled "A CLINICALSTUDY TO EVALUATE THE THERAPEUTIC EFFICACY OF RASNADI GHRITA ON JANU SANDHIGATA VATA w.s.r. TO OSTEOARTHRITIS" was planned.

### MATERIALS AND METHODS

**AIM:** This study entitled 'A clinical study to evaluate the therapeutic efficacy of Rasnadi ghrita on Janu Sandhigata vata w.s.r. osteoarthritis' was aimed to fulfill the following criteria.

### OBJECTIVES OF STUDY:

1. To evaluate the therapeutic efficacy of Rasnadi Ghrita in patients suffering from Janu sandhigatavata (Osteoarthritis).

2. To improve the functional ability of patients of Janu Sandhigata vata.

#### **MATERIAL AND METHOD:**

**1. Source of data:** A minimum of 20 diagnosed patients of Janu Sandhigata vata irrespective of sex and caste was selected from OPD and IPD of S.D.M. Ayurvedic hospital, Udupi.

**Drugs** - Rasnadi Ghrita was manufactured at SDM Ayurveda pharmacy, Udupi.

**2. Method of collection:** A minimum of 20 diagnosed patients of Janu Sandhigata vata were selected irrespective of their gender, caste, or creed. A special proforma was prepared with all points of history taking, physical signs and symptoms mentioned in the disease, and laboratory investigations, and the patient's data was recorded. The parameter, including signs, symptoms, and investigations, was scored on the basis of standard proforma.

**Study design:** It is an open clinical study with pre-test and post-test design.

**Intervention:** All 20 patients were treated with Rasnadi Ghrita 24 ml<sup>172</sup> on an empty stomach with hot water at 8 A.M. once daily for the duration of 14 days.

**Follow Up:** All the patients were reviewed once in two weeks for the duration of 30 days.

**Total duration of study:** 14 days treatment and 30 days follow up.

#### **Diagnostic criteria:**

- Symptoms of Janu Sandhigata vata (Sandhi Shula, Sandhi Shopha and prasarana akunchana vedana)
- Patients fulfilling the diagnostic criteria according to A.C.R. diagnostic guidelines of Osteoarthritis of the knee.<sup>173</sup>

#### **Inclusion criteria:**

- Patients fulfilling the diagnostic criteria of Janu sandhigata vata.
- Patients between the age group of 30 years to 70 years were selected for the study.

#### **Exclusion criteria:**

- Patients suffering from diseases like Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, and Gouty Arthritis.

- Patients with complications of O.A., Pseudogout, Spontaneous osteonecrosis of the knee, Ruptured Baker cyst, Bursitis, Anserine bursitis.
- Patients suffering from Diabetes mellitus, De-ranged liver disease, renal disease, and other illnesses which will interfere with the disease and treatment.

**Assessment criteria:** Patients with Signs and Symptoms of Janu sandhigata vata (Osteoarthritis Knee) were scored and assessed before, during, and after treatment, i.e., on 0, 14<sup>th</sup> and again on the 44<sup>th</sup> day during the follow-up. Subjective and objective parameters were scored before and after treatment and analyzed statistically using paired 't'-tests to compare the effect within the group.

**Statistical analysis:** The effect of the therapy was analyzed statistically by calculating the mean, standard deviation, standard error, 't,' and 'p' values by using paired test.

#### **Subjective Parameters:**

- Knee Joint pain
- Swelling
- Stiffness.

#### **Objective Parameters:**

- Pain-Visual Analogue Scale (VAS)<sup>174</sup>
- The swelling girth of the joint is measured with tape.
- Movement of joints-measurement is done with Goniometer.
- WOMAC- Index for Osteoarthritis.<sup>175</sup>
- Functional ability:
  - Walking - time required to cover 30 meters in seconds.
  - 10 sit-ups time required in seconds.
  - Time is taken to climb 10 steps.

#### **Investigations:**

##### ***Haematological investigations:***

- Haemoglobin %
- T.C., DC
- Erythrocyte Sedimentation Rate, Random blood sugar.

##### ***Urological investigations:***

- Sugar, Albumin & Microscopic.

**Radiological investigations:**

- X-ray: A.P. & Lateral view of the knee.

**Score Grading**

**Table. No.1. Assessment of knee joint Tenderness**

| Tenderness   | Grade |
|--|-------|
| No Tenderness                                      | 0     |
| The patient says the joint is tender               | 1     |
| The patient winces                                 | 2     |
| The patient winces and withdraws the affected part | 3     |
| The patient will not allow the joint to be touched | 4     |

**Table. No.2. WOMAC Osteoarthritis Index**

|   |   |                 |                 |                     |                   |                    |
|---|---|-----------------|-----------------|---------------------|-------------------|--------------------|
| 1. <i>The following questions concern the amount of pain you are currently experiencing in your knees. For each situation, please enter the amount of pain you have experienced in the past 48 hours.</i>   |   |                 |                 |                     |                   |                    |
| <b>A.</b>   | Walking on a flat surface   | <b>None (0)</b> | <b>Mild (1)</b> | <b>Moderate (2)</b> | <b>Severe (3)</b> | <b>Extreme (4)</b> |
| <b>B.</b>   | Going up or down stairs   |                 |                 |                     |                   |                    |
| <b>C.</b>   | At night while in bed   |                 |                 |                     |                   |                    |
| <b>D.</b>   | Sitting or lying  |                 |                 |                     |                   |                    |
| <b>E.</b>   | Standing upright  |                 |                 |                     |                   |                    |
| 2. <i>Please describe the level of pain you have experienced in the past 48 hours for each one of your knees.</i>   |   |                 |                 |                     |                   |                    |
| <b>A.</b>   | Right knee  |                 |                 |                     |                   |                    |
| <b>B.</b>   | Left knee   |                 |                 |                     |                   |                    |
| 3.  | How severe is your stiffness after first awakening in the morning?              |                 |                 |                     |                   |                    |
| 4.  | How severe is your stiffness after sitting, lying, or resting later in the day? |                 |                 |                     |                   |                    |
| 5. <i>The following questions concern your physical function. By this, we mean your ability to move around and look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours in your knees. What degree of difficulty do you have with:</i> |   |                 |                 |                     |                   |                    |
| <b>A.</b>   | Descending (going down) stairs  |                 |                 |                     |                   |                    |
| <b>B.</b>   | Ascending (going up) stairs   |                 |                 |                     |                   |                    |
| <b>C.</b>   | Rising from sitting   |                 |                 |                     |                   |                    |
| <b>D.</b>   | Standing  |                 |                 |                     |                   |                    |
| <b>E.</b>   | Bending to floor  |                 |                 |                     |                   |                    |
| <b>F.</b>   | Walking on a flat surface   |                 |                 |                     |                   |                    |
| <b>G.</b>   | Getting in/out of the car   |                 |                 |                     |                   |                    |
| <b>H.</b>   | Going shopping  |                 |                 |                     |                   |                    |
| <b>I.</b>   | Putting on socks/stockings  |                 |                 |                     |                   |                    |
| <b>J.</b>   | Rising from bed   |                 |                 |                     |                   |                    |
| <b>K.</b>   | Taking off socks/stockings  |                 |                 |                     |                   |                    |
| <b>L.</b>   | Lying in bed  |                 |                 |                     |                   |                    |
| <b>M.</b>   | Climb up a high step.   |                 |                 |                     |                   |                    |
| <b>N.</b>   | Sitting   |                 |                 |                     |                   |                    |
| <b>O.</b>   | Getting on/off the toilet   |                 |                 |                     |                   |                    |

|    |           |   |              |  |  |  |                |
|----|-----------|---|--------------|--|--|--|----------------|
|    | <b>P.</b> | Heavy domestic duties (mowing the lawn, lifting heavy grocery bags) |              |  |  |  |                |
|    | <b>Q.</b> | Light domestic duties (such as tidying a room, dusting, cooking)    |              |  |  |  |                |
| 6. | <b>R.</b> |   | Minimum<br>0 |  |  |  | Maximum<br>104 |

**Table. No.3. WOMAC Score Grading**

| WOMAC Questions | WOMAC Score | Grade |
|-----------------|-------------|-------|
| None            | 0           | 0     |
| Mild            | 0-26        | 1     |
| Moderate        | 26-52       | 2     |
| Severe          | 52-78       | 3     |
| Extreme         | 78-104      | 4     |

## RESULTS

In this study on Osteoarthritis, patients were treated with Rasnadi Ghrita with lukewarm water as Anupana in a dose of 24 ml. The parameters like Pain, Morning stiffness, Swelling, Tenderness, Range of movement, and functional abilities like time required to walk 30 meters, time required to do 10 sit, and time taken to climb 10 steps were taken for analysis. The results of the study on each parameter are analysed statistically, calculating the mean, standard deviation, standard errors, and 'p' values by using the paired 't-test and signed-rank test within the group analysis. Paired t-test was used for parameters like swelling, range of movement, morning stiffness, and functional abilities like time required to walk 30 meters, time required to do 10 sit, and time taken to climb 10 steps. Wilcoxon signed-rank test was used for pain, tenderness, and WOMAC Score. The follow-ups were taken before and after treatment, and the mean scores were compared. The effect of treatment was analyzed by scoring and was assessed statistically to see the significance. It included the assessment of pain, swelling, morning stiffness, tenderness, restricted movements, and functional abilities, WOMAC score and its effect on the assessment parameters of the disease *janu sandhigata vata* such as *Sandhishoola (joint pain)*, *Sandhishopha (swelling)*,

*Prasaranaakunjanayopravriti (restricted movements)*, morning stiffness, tenderness womac score had a significant change in the score after treatment with a p-value of <0.001. the details of the above are given in the tables and illustrations.

### Overall assessment of treatment-

The overall effect of the treatment in this study, percentage improvement of the patients with respect to their score symptoms calculated in individual patients, showed that 0% of the patients fell into minor and no improvement, 90% into moderate improvement, and 10% into marked improvement category. None of the patients had no relief or aggravation of symptoms. Details of the same are given in the below table and figure.

## DISCUSSION

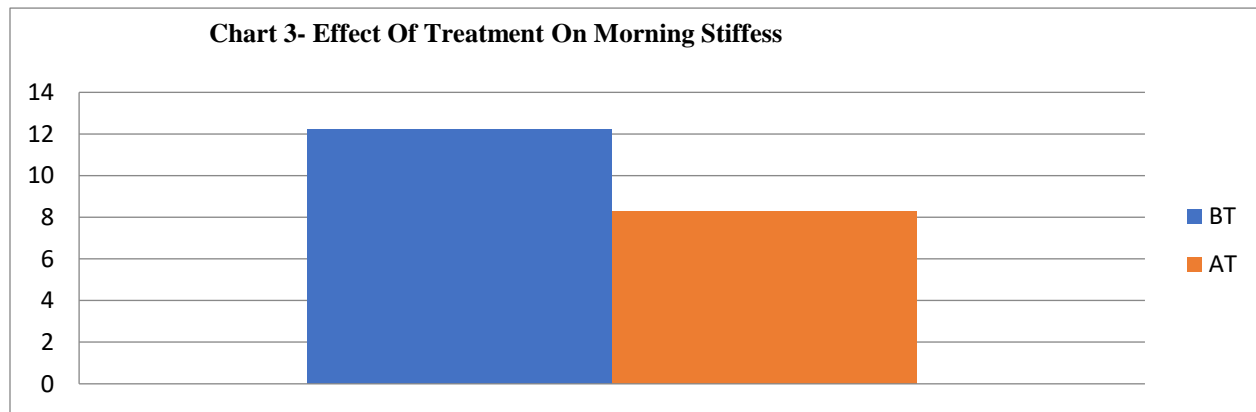
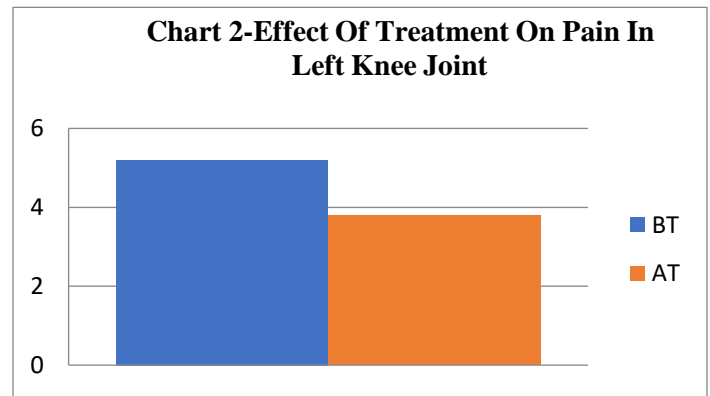
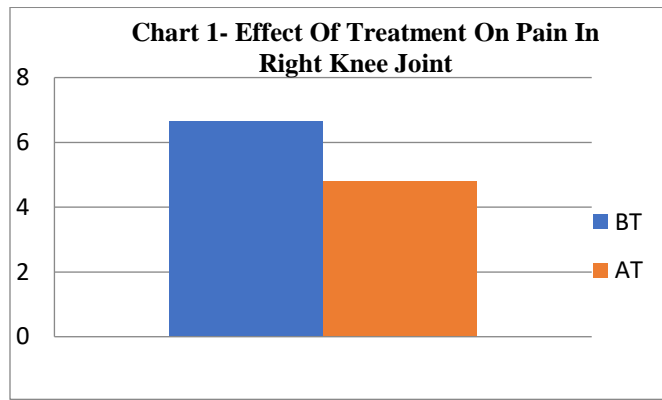
In a nut shell, 20 Patients of either gender suffering from *janu sandhigata vata* between the age group of 30 to 70 were subjected to an open, pragmatic clinical trial with a pre and posttest design, treated with Rasnadi ghrita showed statistically significant improvement in symptoms such as pain, swelling, tenderness, stiffness, restricted movements and functional abilities like time taken to walk 30 meters, to climb 10 steps, time is taken to do 10 sit-ups and WOMAC score of Sandhigata vata. Medicine Rasnadi Ghrita, in the form of shamana Snehana pa-

na, was selected to evaluate the efficacy in reducing the symptoms of Sandhigatavata. Ghrita has mainly vatahara, balya, vrishya, and Rasayana guna, and its contents, such as Rasna, gokshura, bilva, shigru, are vatashamaka, shopha, and shulahara. The herbal drugs which regulate the shoola and shotha are providing the easy movements of the joint. Rasayana dravyas help to nourish the dhatus and further con-

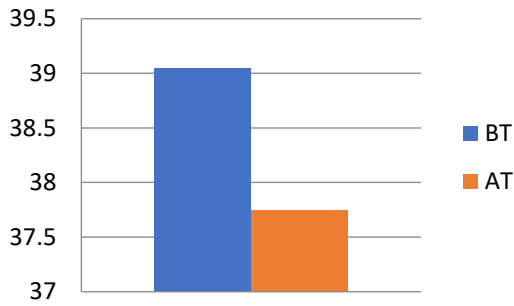
trol the disease. The prognosis of the disease Sandhigatavata is poor depending upon the risk factors. On assessing each left and right knee joint, the effect of the medicine is observed on almost all the symptoms. It is continued throughout the interventions also, but the efficacy is more during the treatment period.

**Table No. 4, Shows the overall effect of treatment on individual patients in all groups:**

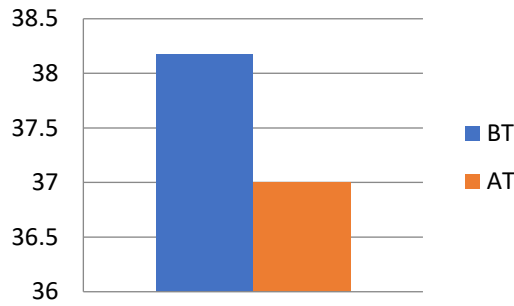
| Improvement     | Marked Improvement | Moderate Improvement | Mild Improvement | No Improvement |
|-----------------|--------------------|----------------------|------------------|----------------|
| Reduction in %  | >75%               | 50% to 75%           | 25% to 49%       | < 25%          |
| No. of patients | 2                  | 18                   | 0                | 0              |
| Percentage      | 10%                | 90%                  | 0%               | 0%             |



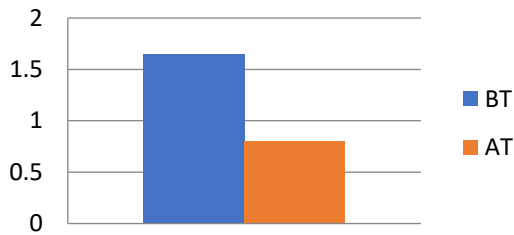
**Chart 4-Effect Of Treatment On Swelling In Right Knee Joint**



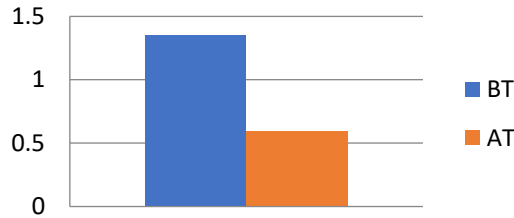
**Chart 5-Effect Of Treatment On Swelling In Left Knee Joint**



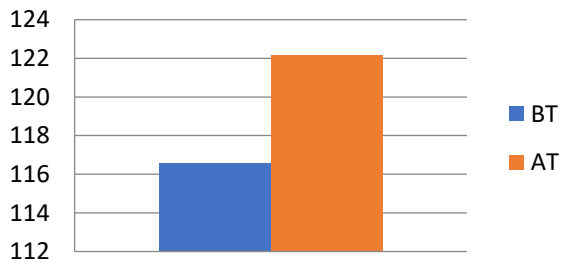
**Chart 6-EFFECT OF TREATMENT ON TENDERNESS IN RIGHT KNEE JOINT**



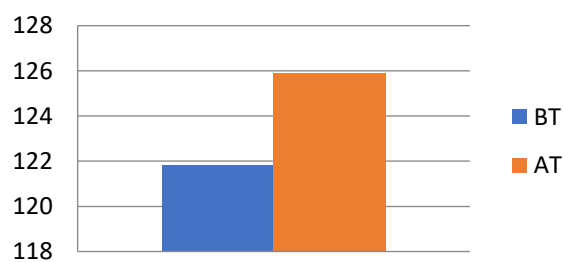
**Chart 7-EFFECT OF TREATMENT ON TENDERNESS IN LEFT KNEE JOINT**

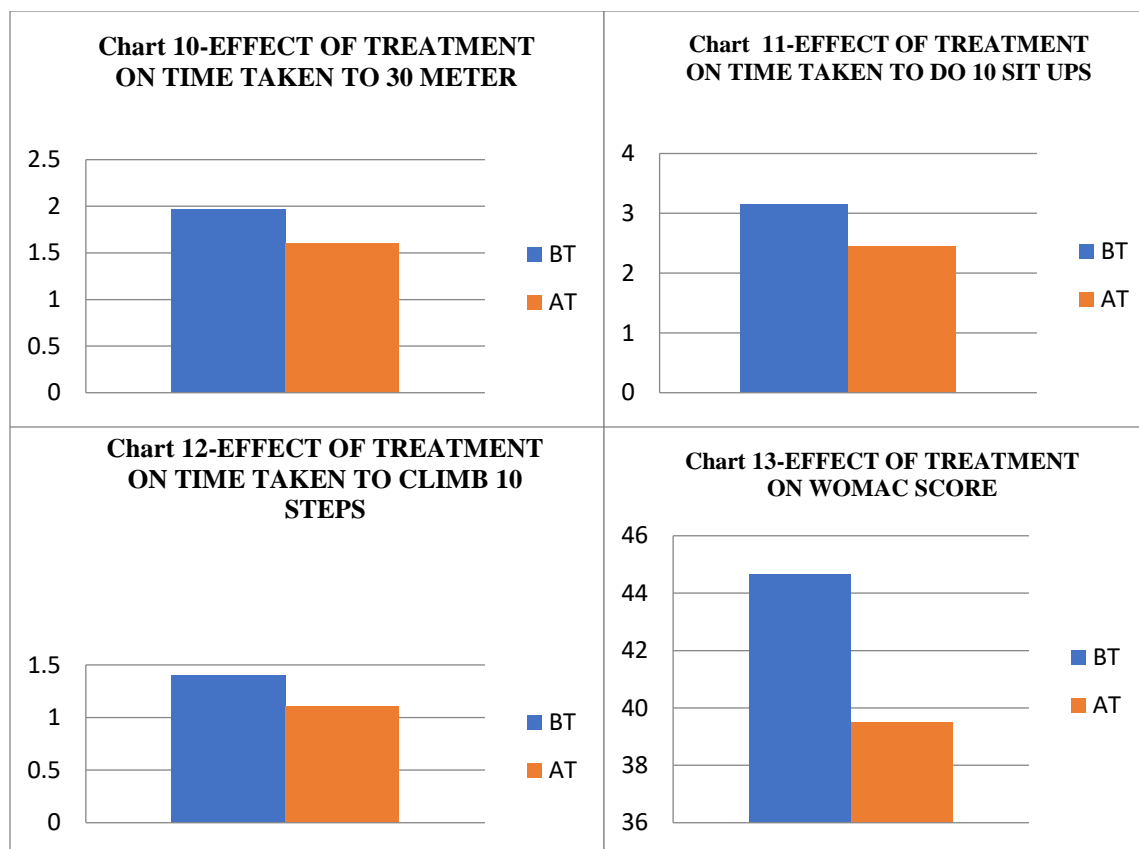


**Chart 8-EFFECT OF TREATMENT ON RANGE OF MOVEMENT IN RIGHT KNEE JOINT**



**Chart 9-EFFECT OF TREATMENT ON RANGE OF MOVEMENT IN LEFT KNEE JOINT**





## CONCLUSION

Janusandhigatavata (Osteoarthritis of the Knee) is a degenerative inflammatory joint disorder, mainly occurring in middle and old age people, and the incidence of osteoarthritis is increased with age. Janusandhigatavata is one among the Maharoga, and it is kashta Sadhya roga because it is situated in Asthi Sandhi and marma, so it is difficult to treat, and it requires prolonged treatment. The morbidity of Vyanavayu is the main cause for the manifestation of Sandhigata Vata. the pathogenesis can categorize as – Dhatukshayajanya and Margaavaranjanya. On Statistical comparison between before and after treatment, statistically significant results were observed in pain, swelling, restricted movements, functional abilities like time taken to walk 30-meter, time taken to do 10 sit-ups to climb 10 steps, and WOMAC score. The overall effect showed that 0% fell into mild and no improvement, 90% of the patients fell into moderate

improvement, and 10% of patients into marked improvement group by the treatment of Rasnadi Ghrita.

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