

## A COMPARATIVE CLINICAL TRIAL EVALUATING THE THERAPEUTIC EFFECT OF SVACCHANDA BHAIRAVA RASA IN JANU SANDHIGATAVATA (OSTEO ARTHRITIS)

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### ABSTRACT

The objective of the study was to assess the effect of the formulation *swacchanda-bhairava rasa*, an oral medication in reducing the symptoms of *janu sandhigata vata* (Osteoarthritis knee). Among the various diseases mentioned in the classics, *vatavyadhi* is a disease that requires special focus. *Vata* is considered as the most vital among the *tridosha* and when there are alterations to the normal physiological functioning of *vata*, it leads to the formation of morbid *vata dosha* which in turn gives rise to *vatavyadhi*. Due to various aetiological factors, *vata* attains the status of vitiation, thereby affecting the joints leading to the genesis of the disease *sandhigata vata* (Osteoarthritis). There is high prevalence of osteoarthritis worldwide and the incidence is high above the age group of 40 years. The symptoms of osteoarthritis are joint pain, stiffness, swelling, tenderness and restricted movements<sup>1</sup>. Literature explains duo treatment modalities i.e the alleviating therapy and elimination therapies. Alleviation therapy mainly tackles *vata dosha*, provides rejuvenating effect and relieves pain and stiffness. On this basis the *Svacchandabhairava rasa* was taken for the study, as an oral medication in osteoarthritis. Objectives of the study were to evaluate the therapeutic effect of *Svacchandabhairava rasa* in patients suffering from *Janusandhigata vata* (OA). The study revealed that there was marked improvement in reducing the symptoms of pain, stiffness, swelling, tenderness and restricted movements. Thus the therapeutic usage of *swacchanda-bhairava rasa* as an oral medication in osteoarthritis was proved.

**Keywords:** Osteoarthritis; Janu Sandhigata vata; Svacchandabhairava rasa

### INTRODUCTION

Disease is formed due to the vitiation of the *dosha*, and to be free from diseases the *dosha* has to be in its normal form. When there is a fluctuation in the normalcy of *dosha*, may it be any of the three *dosha*, it causes wide spread fluctuations in the body as the ripples across a waterbody created by an untoward anomaly. Similarly when the *vata* becomes mor-

bid it leads to the formation of *vatavyadhi*. *Sandhigata vata* is described under the chapter of *vatavyadhi* where *vata* is following the principle of *gatavata*<sup>2</sup>. The affliction of joints by morbid *vata* is mentioned in the pathogenesis expressing the specific symptoms related to it<sup>3</sup>. It is a disease that is difficult to cure and mainly occurs due to the etiological factors which

are classified as *dhatukshayajanya* and *margavaranajanya*. The symptomatology includes pain, stiffness, swelling, crepitus, and restricted movement of the joints.

The modalities of treatment mentioned in the contemporary science include non-pharmacological and pharmacological measures. Exercises, lifestyle changes and proper medication such as analgesics play an important role in reducing the symptoms. In circumstances where the conservative management is not able to tackle the situation at hand, surgery is an option. If not treated properly it will lead to further complications which may even make the patient restricted to bed<sup>4</sup>.

In *Ayurveda* point of view, *vatavyadhi* is best treated by principles of treatment that includes alleviating and eliminative therapies<sup>5</sup>. And further, alleviating therapies can be classified as internal and external methods of treatments. There are many alleviating therapies mentioned that are useful in the conditions like osteoarthritis. It includes decoctions, tablets, linctus, ghee preparations, bandaging, oil application et al. So to analyse the therapeutic effect of the alleviating therapy like the oral medication in the morbid condition of *vatavyadhi*, the present work was done.

## MATERIALS AND METHODS

### Source of data

15 patients suffering from *sandhigataavata* irrespective of sex and caste were selected from OPD and IPD of SDM Ayurveda Hospital, Udupi.

### Study design

It was an open labelled clinical trial with pre-test and post-test design.

### Method of collection

Patients were subjected to detailed clinical history, assessment and complete examination. The details were recorded in proforma.

### Inclusion criteria

- Patients with *prathyatma lakshana* of *janu sandhigata vata*.
- Patient with signs & symptoms of osteoarthritis.
- Age groups between 30 years to 70 years were selected.

### Exclusion criteria

- Age group below 30 years and above 70 years.
- Patient with Tuberculosis, Rheumatoid Arthritis, Systemic Lupus Erythematosus, Psoriatic Arthritis, Gouty Arthritis.

### Assessment criteria

Assessed and graded based on the parameters of pain (Table no.1), stiffness (Table no.2), swelling (Table no.3), tenderness (Table no.4) and range of movement (Table no.5).

### Subjective parameters

- Knee Joint pain
- Swelling
- Stiffness

### Objective parameters

- Pain
- Swelling- Girth of joint was measured with measuring tape.
- Restricted movement of joints- Measured with Goniometer.
- WOMAC- Index for osteoarthritis.

### Investigations

- **Haematological investigations:**  
Haemoglobin %  
TC, DC, Erythrocyte Sedimentation Rate, Random blood sugar
- **Urological investigations:**  
Sugar, Albumin & Microscopic
- **Radiological investigations:**  
X-ray: AP& Lateral view of knees.

### Intervention

*Svachchanda Bhairava rasa*<sup>8</sup> 250 mg was administered once a day in the morning with the *anupana* of *Rasnadi kashaya* 96 ml for 14 days.

## Follow up

All the patients were assessed with follow up period of 14 days after treatment with weekly interval. Total duration of study was 28 days with 14 days of study and 14 days of follow up.

## RESULTS

Out of the 15 patients who was diagnosed as osteoarthritis knee had undergone the study with the oral medication i.e *swacchandabhairava rasa*. *Swacchanda-bhairava rasa* in a dosage of 250mg OD was given to the patient. The effect of the medication on the symptoms was assessed before, during and after the treatment. The results thus obtained was further analysed statistically with paired t test.

Among the overall assessment of the parameters (Table no.6), the parameters like effect on pain of right knee joint(Figure no.1), effect on pain of left knee joint(Figure no.2), effect on morning stiffness of right knee joint(Figure no.3), effect on tenderness of right knee joint (Figure no.7) showed statistically significant changes with  $p < 0.001$ .

Effect on morning stiffness of left knee joint (Figure no.4) had statistically significant value with ( $p=0.041$ ). Effect on swelling right knee joint (Figure no.5) and left knee joint (Figure no.6) was statistically not significant ( $p=0.164$ ). Effect on tenderness on 14th day of left knee joint (Figure no.8) was statistically significant ( $p=0.006$ ). Effect on range of movement of right knee joint (Figure no.9) was statistically significant ( $p=0.011$ ). Effect on range of movement of left knee (Figure no.10) was statistically not significant ( $p=0.092$ ). Effect on WOMAC score (Figure no.11) was statistically significant with  $P=0.001$ .

## Overall effect of improvement of symptoms

Considering the overall effect (Table no.7) in this treatment, percentage of improvement of the patients with respect to their symptoms showed that 46.66% each of the patients fell into mild and moderate improvement category respectively.

## DISCUSSION

### Mode of action

Maximum reduction in the symptoms was found during the 14 to 28 days of the study. This was during the after the treatment period and the follow-up period. From day 1 to day 14 there was significant reduction in the symptoms, while from 14<sup>th</sup> day to 28<sup>th</sup> day there was moderate reduction in symptoms. The results were statistically significant for pain, tenderness and morning stiffness. Significance of varying degrees was observed for other symptoms. There was gradual but identifiable reduction in the symptoms over the period of 28 days i.e. the whole duration of the study. This study shows that with the trial drug the symptoms have got reduced and the patients got relief.

*Swacchandabhairava rasa* is mentioned in the chapter of *vatavyadhi* treatment. In this *hareetaki*, *visha* and *mundi* are *tridhoshha shamaka*. They are having anti-spasmodic action. *Visha* showed its effect on chronic rheumatism. *Hareetaki* also has a rejuvenative action which acts on *vatavyadhi* caused due to depletion of *dhatu*. *Pippali*, *maricha*, *agnimantha*, and *nirgundi* have *vatahara* and *kaphahara* properties<sup>9, 10, 11, 12</sup>. *Maricha* has action of enhancing the digestive fire which aids in pathology related to *margavarana*. *Agnimantha* has anti-arthritis properties which also have helped in reducing the symptoms of osteoarthritis. The aqueous extract of *agnimantha* was found to be effective in reducing the edema of formalin induced arthritis. External application of alcoholic extract

was also found to be effective in reducing the edema.

*Rasoushadhi* like *parada*, *lohabhasma*, and *tapyra* present in the formulation: *swacchandabhairava rasa* acts as *tridosahara*<sup>13, 14</sup>. They are having rejuvenating power i.e. which helps in *dhatukshayaja vatavyadhi*. It also has action against oedema. *Gandhaka*, *haratala* and *tankana* are the trio that helps to reduce *vata* and *kapha* and help to enhance the *agni*. *Lohabhasma* has its action on oedematous condition.

In *Svacchandabhairava rasa* most of the drugs are *vata kaphahara*, so that it helps in alleviating the morbid *vata* as well as *kapha dosha*. The majority of the drugs in the formulation have hot potency so that the stiffness of joints occurring due to cold potency of *vata* gets neutralized.

The anti-arthritic and anti-inflammatory effect of the drugs helps to pacify the symptoms of osteoarthritis. The presence of *rasaoushadhi* and also *anupana kwatha* aids in relieving the symptoms. The *anupana kwatha* contains the drugs like *rasna*, *eranda* and *devadaru* which have the property to relieve pain and swelling. The aqueous extract of *rasna* was found to be effective in reducing the edema of formalin induced arthritis. External application of alcoholic extract of *eranda* was also found to be effective in reducing the edema<sup>15, 16</sup>. The *guggulu*<sup>17</sup> is having the anti-inflammatory action and *vatahara* and *kaphahara* property. This also helps for the remission of inflammation. In short *swacchandabhairava rasa* is a combination which acts on the pathology of *vatavyadhi*. Whether it be *margavarana-janya* or *dhatukshayajanya vatavyadhi*, *swacchandabhairava rasa* is a combination which gives promising results in reducing the symptoms.

## CONCLUSION

The morbidity of *vata* by either of the aetiology like *dhathukshaya* or *margavarana* is the main cause for *vatavyadhi*. Pain, stiffness, swelling, tenderness and restricted movements of the knee are the cardinal features of osteoarthritis knee.

*Svacchandabhairava rasa* has proved to be effective drug in reducing the symptoms like pain, stiffness, restricted movements and functional abilities and WOM-AC score with statistically significant values for which  $p < 0.05$  for all the parameters.

The overall effect showed that 46.66% each of the patients fell into the category of mild and moderate improvement with the use of *svachhandabhairava*<sup>18</sup>. Adverse drug reactions were not observed during the follow-up of the patients. Thus *svachhandabhairava rasa* is effective in reducing the symptoms of osteoarthritis.

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## ILLUSTRATIONS AND TABLES

### Grading of Parameters

Table no.1: grading of pain

Pain	Score
Nil Pain	0
Not very severe	1
Quite severe	2
Severe	3
Very severe	4

Table no.2 Grading of stiffness

Stiffness	Time(Hours)	Score
None	0	0

<b>Mild</b>	0 – 1:15hrs	<b>1</b>
<b>Moderate</b>	1:15 – 1:30hrs	<b>2</b>
<b>Severe</b>	1:30 – 1:45hrs	<b>3</b>
<b>Extreme</b>	1:45 - 2hrs	<b>4</b>

**Table no.3 Grading of swelling**

Swelling	Measurement(Cms)	Score
<b>None</b>	<b>0</b>	<b>0</b>
<b>Mild</b>	0-35cm	<b>1</b>
<b>Moderate</b>	35-40cm	<b>2</b>
<b>Severe</b>	40-45cm	<b>3</b>
<b>Extreme</b>	45-50cm	<b>4</b>

**Table no.4 Grading of tenderness**

Tenderness	Score
<b>None</b>	<b>0</b>
<b>The patient says the joint is tender</b>	<b>1</b>
<b>The patient winces</b>	<b>2</b>
<b>The patient winces and withdraws the affected part</b>	<b>3</b>
<b>The patient will not allow the joint to be touched</b>	<b>4</b>

**Table no.5 Grading of range of movement**

Range of movement	Degree	Score
<b>None</b>	>130°	<b>0</b>
<b>Mild</b>	130°-120°	<b>1</b>
<b>Moderate</b>	120°-110°	<b>2</b>
<b>Severe</b>	110°-100°	<b>3</b>
<b>Extreme</b>	100°-90°	<b>4</b>

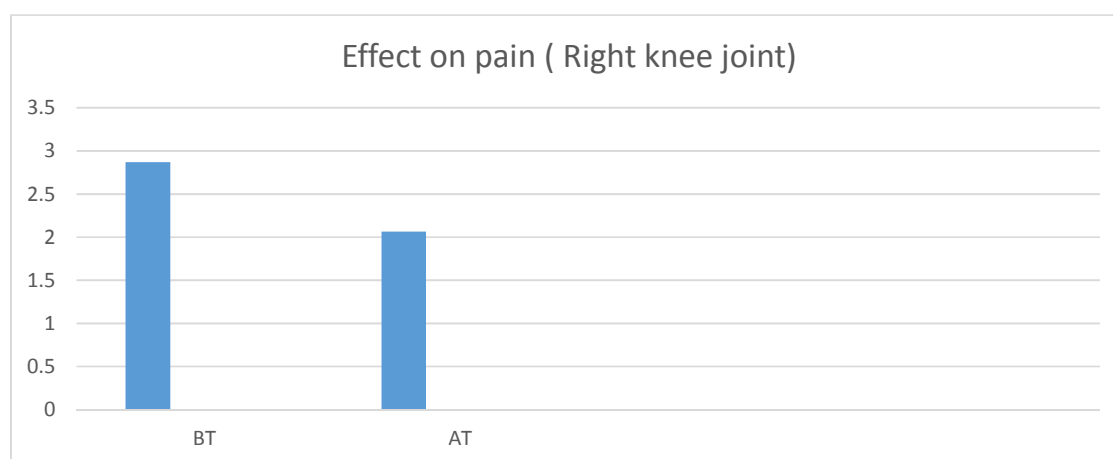
**Table No.6 Overall assessment of the Symptoms**

Parameter	Mean		Difference in Mean	Paired 't' test			
	BT (±SE)	AT (±SE)		S.D	S.E.M	't'	P
<b>Pain (Right knee joint)</b>	2.867 ±0.307	2.067 ±0.267	0.800	0.414	0.107	7.483	p<0.001
<b>Pain (Left knee joint )</b>	2.200 ± 0.312	1.467 ± 0.256	0.733	0.458	0.118	6.205	p<0.001
<b>Stiffness(Right knee joint)</b>	1.067 ± 0.153	0.600 ± 0.163	0.467	0.516	0.133	3.500	p<0.001
<b>Stiffness(Left knee joint)</b>	0.800 ± 0.145	0.533 ± 0.133	0.267	0.458	0.118	2.256	P=0.041

<b>Swelling(Right knee joint )</b>	1.533 ± 0.236	1.267 ± 0.248	0.265	0.458	0.118	2.256	P=0.164
<b>Swelling (Left knee joint )</b>	0.867 ± 0.215	0.733 ± 0.228	0.133	0.352	0.0909	1.468	P=0.164
<b>Tenderness(Right knee joint )</b>	2.733 ± 0.182	1.933 ± 0.182	0.800	0.561	0.145	5.527	P<0.001
<b>Tenderness( Left knee joint)</b>	2.400 ± 0.254	1.867 ± 0.215	0.533	0.640	0.165	3.228	P=0.006
<b>Range of movement right knee joint )</b>	155.067 ± 6.038	158.667 ± 5.437	3.600	4.778	1.234	2.918	P=0.011
<b>Range of movement ( Left knee joint)</b>	159.400 ±6.009	161.267 ±5.571	1.867	3.998	1.032	1.808	P=0.092
<b>WOMAC</b>	2.867 ±0.0909	2.333 ±0.159	0.533	0.516	0.133	4.000	P=0.001

**Table no.7 Percentage of improvement**

<b>IMPROVEMENT</b>	<b>PERCENTAGE OF IMPROVEMENT (%)</b>	<b>NUMBER OF PERSONS</b>	<b>PERCENTAGE (%)</b>
<b>Mild</b>	< 25	7	46.67
<b>Moderate</b>	25-50	7	46.67
<b>Marked</b>	50-75	1	6.67
<b>Good</b>	>75	0	0



**Figure no.1 Effect on pain (Right knee joint)**

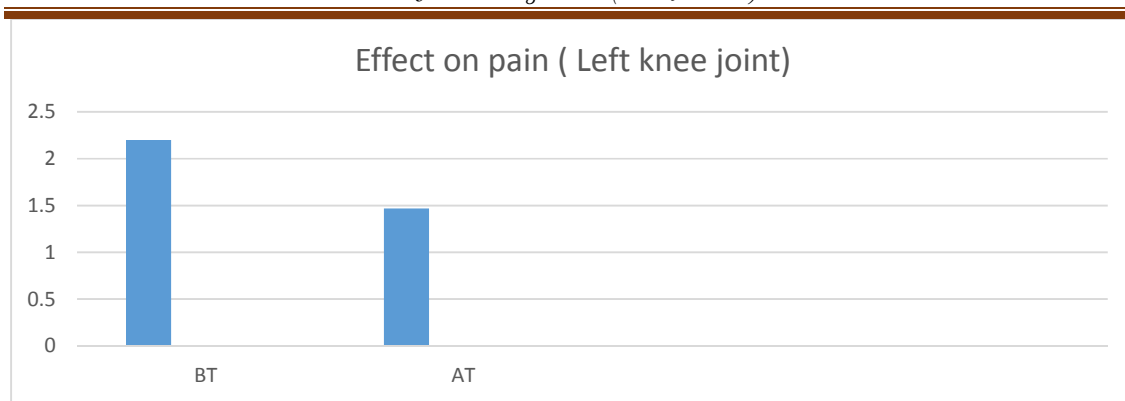


Figure no.2 Effect on pain (Left knee joint)

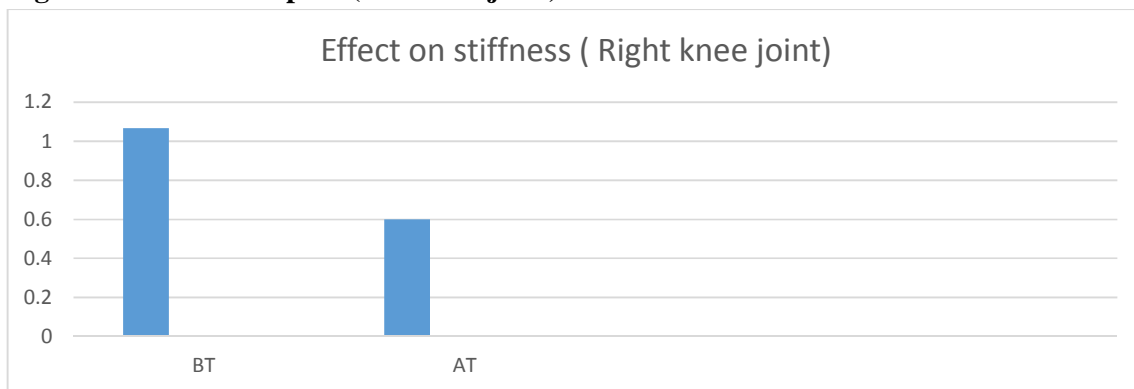


Figure no.3 Effect on stiffness (Right knee joint)

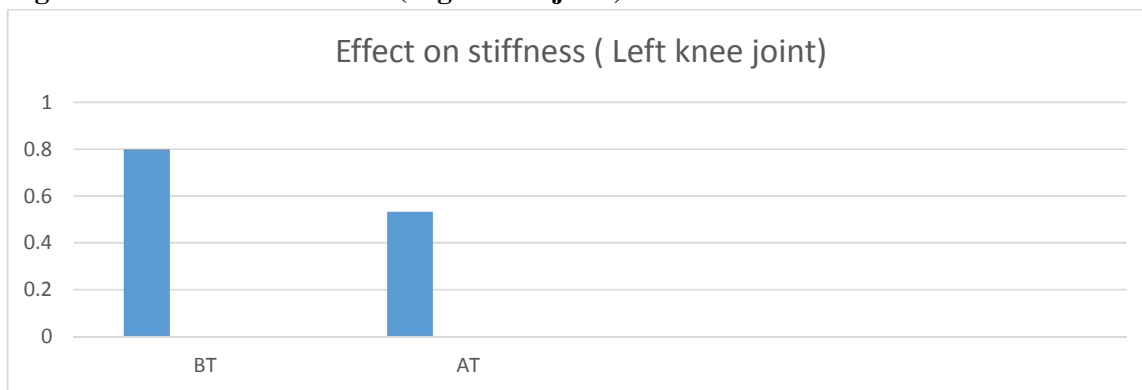


Figure no.4 Effect on stiffness (Left knee joint)

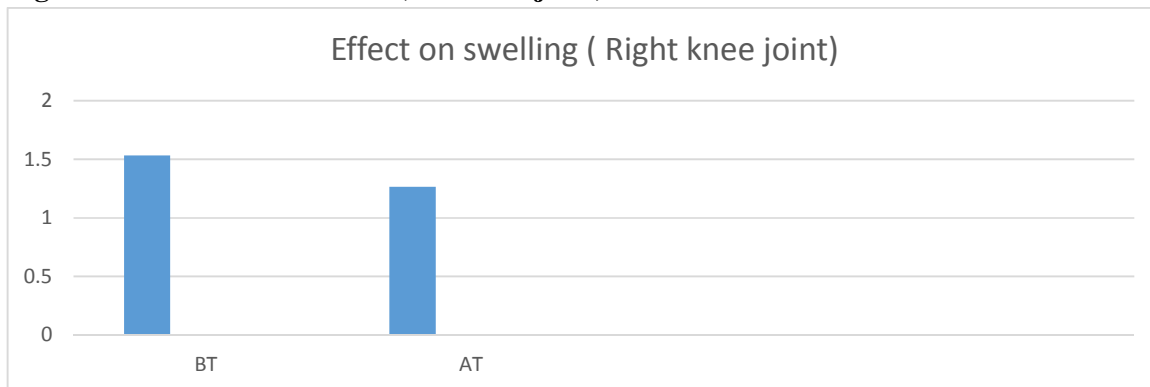


Figure no.5 Effect on swelling (Right knee joint)



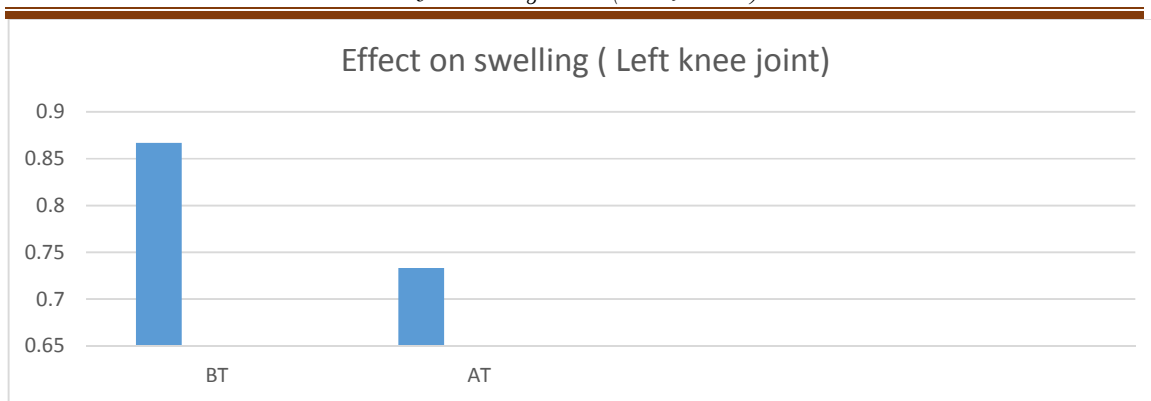


Figure no.6 Effect on swelling (Left knee joint)

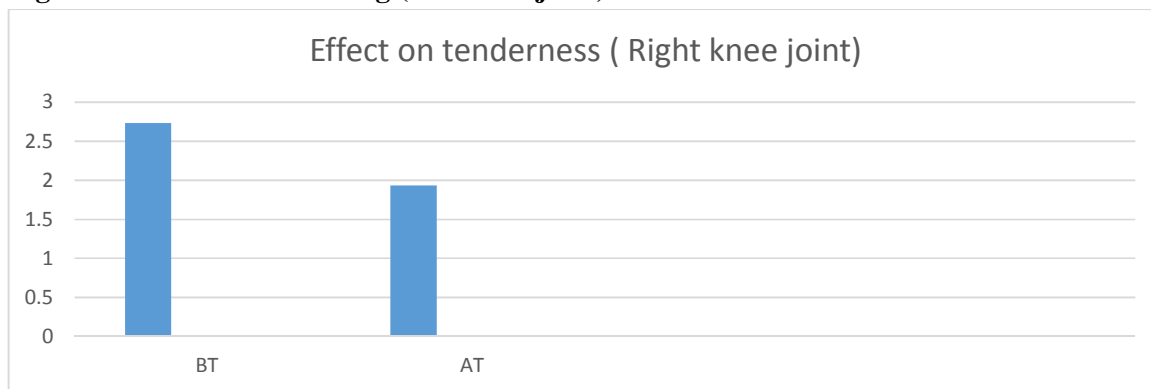


Figure no.7 Effect on tenderness (Right knee joint)

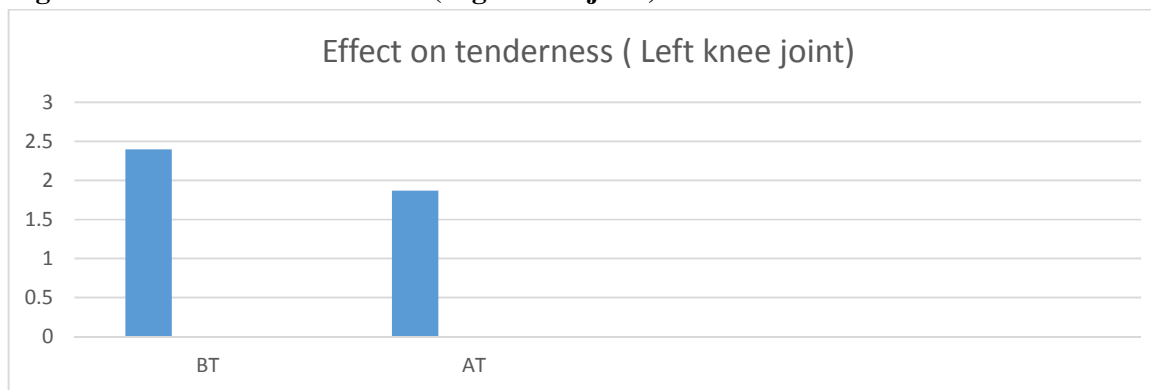


Figure no.8 Effect on tenderness (Left knee joint)

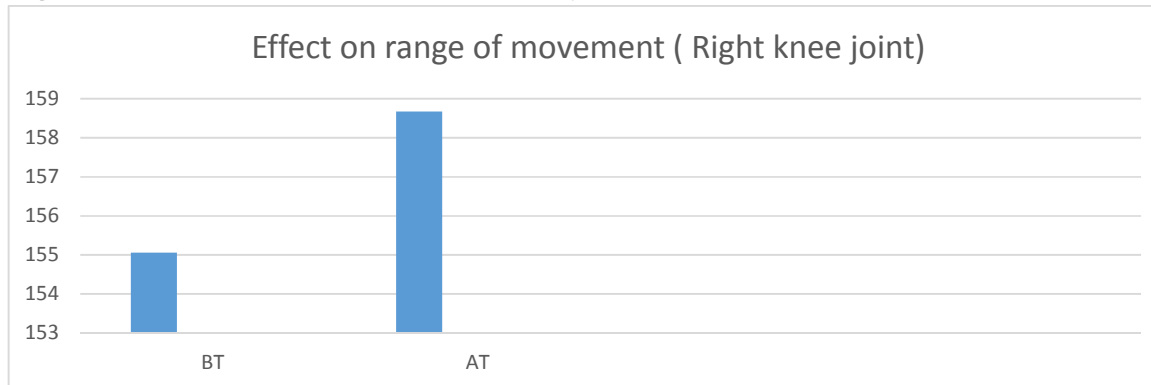


Figure no.9 Effect on range of movement (Right knee joint)

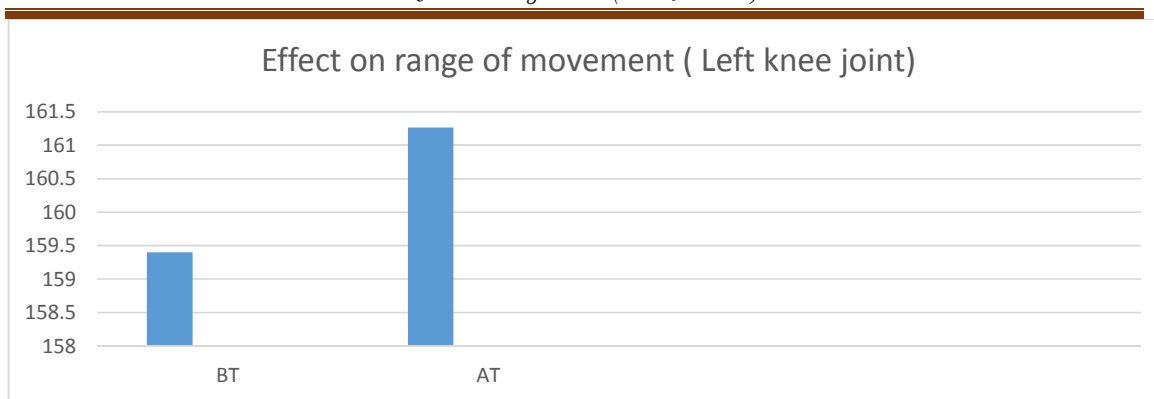


Figure no.10 Effect on range of movement (Left knee joint)

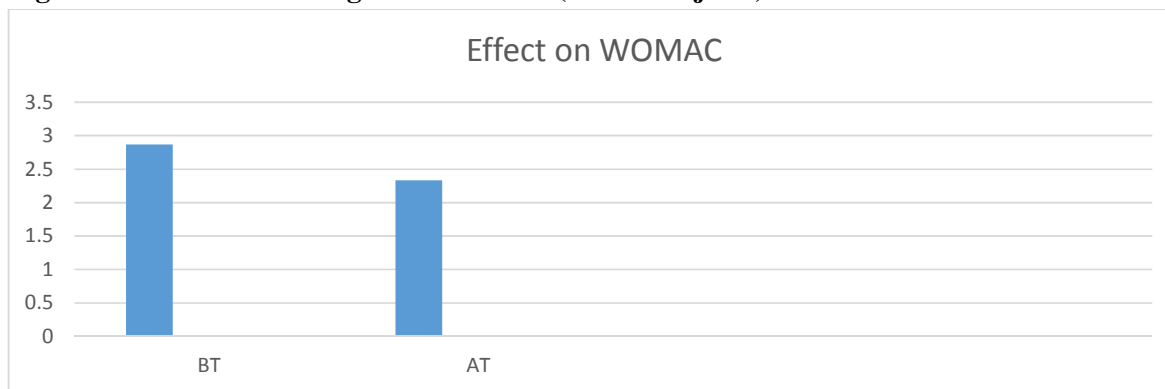


Figure no.11 Effect on WOMAC

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