

THE EFFICACY OF TRAYODASHANGA GUGGULU ON JAANUSANDHIGATAVATA (KNEE JOINT OSTEOARTHRITIS)

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ABSTRACT

Jaanusandhigataavata (Knee joint Osteoarthritis) is the one of the most common disease encountered in clinical and surgical practice. It seen in above 40 years of age, female, obese, occupational knee bending, physical labour etc. In this study an attempt has been made to treat the “disease” with *Trayodashanga guggulu*. The study was open trial clinical study, Phase-II, Total 100 patients were selected by simple randomized method, Total study period was ninety days in that thirty days was treatment and sixty days was follow-up. In this Clinical research study symptomatic relief was their during treatment period and after treatment, up to the first follow up, and again little aggravates symptoms during second follow up. Minimum contraindications and nil complications make it acceptable choice of treatment in *Jaanusandhigataavata* (Knee joint O.A.)

Keywords: *Jaanusandhigataavata*, Knee joint Osteoarthritis, *Trayodashanga guggulu*.

INTRODUCTION

1*2*3*6* The disease Knee joint Osteoarthritis may be regarded as a reward of longevity. *Jaanusandhigataavata* may be correlated with degenerative joint disease or Knee joint osteoarthritis, which in turn cripples the patient to the maximum, extends and reduces the total working capacity of the person. According to World Health Organization (W.H.O.) It is the second commonest Musculo-skeletal problem in the world population after back pain. It is seen in above 40 years of age, female, obese, occupational knee bending, physical labour etc. Almost all persons by Age 40 years have some pathologic change in weight bearing joint. 25% females and 16% Males have symptomatic Knee joint OA. Arthritis is second only to heart disease as a cause of

work disability. It limits everyday activities such as walking, dressing, bathing etc., thus making individual handicapped. No treatment is available which can prevent or reverses or blocks the disease process. In Allopathic science, mainly analgesics, anti inflammatory drugs or surgery are the options for the treatment. These don't give satisfactory relief and also causes great adverse effect. The Present study is a humble effort to observe the effect of drug, as well as to establish the safety of drug on prevent and reliving the syndrome of the disease *Jaanusandhigataavata*.

AIM: To evaluate the efficacy of *Trayodashanga guggulu* in *Jaanusandhigataavata* (Knee joint O.A.).

OBJECTIVES

1. Primary efficacy objective - Study of the effect of *Trayodashanga guggulu* on changes in parameters - pain, swelling, crepitus, circumference of knee joint, X-ray findings and range of movement, from Baseline to after treatment in *Jaanusandhigatavata* (knee joint O.A.)
2. Secondary efficacy objective - Study of the effect of *Trayodashanga guggulu* on changes in parameters - pain, swelling, crepitus, circumference of knee joint, X-ray findings and range of movement, from Baseline to after 1st and 2nd follow up in *Jaanusandhigatavata* (knee joint O.A.)

HYPOTHESIS 4**Jaanusandhigatavata* can be correlated with Degenerative Joint disease or Knee joint O.A. which in turn cripples the patient to the maximum extends and reduces the total working capacity of the person.. 50% of the patients are suffering with more or less symptoms of the disease. Modifiable factors are joint trauma without structural changes, Obesity Repetitive stress e.g. vocational and non-modifiable factors - Congenital / Developmental defects, Prior inflammatory joint disease, Metabolic / Endocrine disorders, Age, Female, Race, Genetic factors causes Knee joint O.A. *Trayodashanga guggulu* has very good property of *vatashaman* (decreases vata) and slows down the degeneration when given orally in guggulu form. Because of above stated properties, assuming that the drug will reduce the severity of signs and symptoms of Knee joint O.A. and the drug is plan to prescribe, Believing that there will be improvement in results. Chances to have partially reappearance of the symptoms when drug intervention will stop.

Trayodashanga guggulu may show significant change in the subjective and objective parameters. This proposed operative Hypothesis for the present study is derived on the basis of

1. The description in the classical Ayurvedic and Modern texts.
2. The clinical experiences of doctors in contemporary medicine and as well as in classics.
3. The survey of the literature regarding contemporary research on *Jaanusandhigatavata*

This Hypothesis was subjected to testing by using Open trial clinical study, Phase – II.

MATERIALS: A) PATIENTS

– 100. B) DRUG –

Trayodashanga guggulu

C) INSTRUMENTS - Measuring tape, X- Ray, Goniometer

PREPARATION **OF**

TRAYODASHANGA GUGGULU: 5*7*All dravyas like Abha, *Ashwagandha*, *Hapusa*, *Guduchi*, *Shatavari*, *Gokshura*, *Vrudhadaraka*, *Rasna*, *Shatapushpa*, *Shati*, *Yavani*, *Shunti* all are taken in equal quantity and powdered, Guggulu equal to the above(total) and ghee half of *guggulu* all are pounded well and made into pills.

METHODOLOGY 4*the study was open trial clinical study, Phase-II, Selected the patients on the basis of inclusion criteria's. Test medicine was *Trayodashanga guggulu*, dose was 2.5 gram, in morning and night at 12 hours interval, after meals with luke warm water. Total 90 days trial period in that 30 days treatment and 60 days follow up period in that 30 days interval. Data were taken before treatment (1st day), after treatment(30th day), after 1st follow up(60th day) and after 2nd follow up(90th day) on

subjective and objective criterias and entered in a special clinical Proforma which was prepared with relevant *ayurvedic* and allied science. A written informed consent was obtained from all patients. Total 110 patients were incorporated, out of which 100 continued till end of the study.

ASSESSMENT CRITERIAS

Subjective criteria: 1. Pain, 2. Swelling, 3. Crepitus.

Objective criteria: 1. Circumference of joint, 2. X-Ray Finding, 3. Range of Movement.

INCLUSION CRITERIA

1. Patients willing to participate in the study.
2. Patients irrespective of sex, religion, socioeconomically status, and marital status were selected.
3. Patients were selected in between 35 to 70 years age group.
4. Jaanusandhigatavata(Knee joint O.A.) diagnosed according to classical and

modern signs and symptoms, on examinations and investigations.

EXCLUSION CRITERIA

1. Age below 35 years and above 70 years.
2. Obese persons and Lean persons (B.M.I.- above 30 and below 18)
3. Debilitating disorders as Tuberculosis, Rheumatoid arthritis etc.
4. Any systemic disorders as Anemia, Malignancy etc...
5. Secondary Osteoarthritis.

ASSESSMENT OF VARIABLES:

Clinical assessment was made in gradings for the severity of the disease and for the clinical improvement of individual subjective and objective parameters as well as for overall parameters. Assessment was framed as four point scale (1-4). The gradings of 6 variables is given along with clinical proforma especially designed for the study on *Jaanusandhigatavata*. The severity of each variable ranging from Normal – 1, Mild – 2, Moderate – 3, Severe – 4.

Table No. 01. Effect on Pain

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value	Remarks
	BT			BT-AT						
PAIN	3.17	AT	2.10	1.07	33.75	0.355	0.035	30.10	<0.001	HS
		1 st FU	1.38	1.79	56.47	0.456	0.045	39.25	<0.001	HS
		2 nd FU	1.53	1.64	51.73	0.542	0.054	30.28	<0.001	HS

Statistical analysis showed that the mean score which was 3.17 before the treatment, was reduced to 2.10 after the treatment with 33.75% improvement. After the 1st follow up mean score became 1.38 with 56.47%

improvement and 2nd follow up mean score became 1.53 with 51.73 % improvement, and there was statistically highly significant change. (P<0.001)

Table No - 02. Effect on Swelling

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value	Remarks
	BT			BT-AT						
SWELLING	2.16	AT	1.43	0.73	33.80	0.446	0.044	16.36	<0.001	HS
		1 st FU	1.09	1.07	49.54	0.537	0.053	19.94	<0.001	HS

	2 nd FU	1.04	1.12	51.85	0.573	0.057	19.53	<0.001	HS
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Statistical analysis showed that the mean score which was 2.16 before the treatment was reduced to 1.43 after the treatment with 33.80% improvement. After the 1st follow up mean score became 1.09 with 49.54%

improvement and 2nd follow up mean score became 1.04 with 51.85 % improvement, and there was statistically highly significant change. (P<0.001)

Table No - 03. Effect on Movement

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value	Remarks
	BT			BT-AT						
MOVEMENT	2.82	AT	1.82	1.00	35.46	0.142	0.014	70.35	<0.001	HS
		1 st FU	1.24	1.58	56.03	0.516	0.051	30.62	<0.001	HS
		2 nd FU	1.31	1.51	53.55	0.522	0.052	28.92	<0.001	HS

Statistical analysis showed that the mean score which was 2.82 before the treatment, was reduced to 1.82 after the treatment with 35.46 % improvement. After the 1st follow up mean score became 1.24 with 56.03 % improvement and 2nd follow

up mean score became 1.51 with 53.55 % improvement, and there was statistically highly significant change. (P<0.001)

Table No. 04. Effect on Circumference of Joint

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value	Remarks
	BT			BT-AT						
CIRCUMFERENCE OF JOINT	1.96	AT	1.38	0.58	29.59	0.496	0.049	11.69	<0.001	HS
		1 st FU	1.05	0.91	46.43	0.570	0.057	15.96	<0.001	HS
		2 nd FU	1.03	0.93	47.45	0.590	0.059	15.75	<0.001	HS

Statistical analysis showed that the mean score which was 1.96 before the treatment, was reduced to 1.38 after the treatment with 29.59 % improvement. After the 1st follow up mean score became 1.05 with 46.43 %

improvement and 2nd follow up mean score became 1.03 with 47.45 % improvement, and there was statistically highly significant change. (P<0.001)

Table No-05. Effect on X-Ray finding

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
X-Ray	2.05	AT	2.05	0	0	0	0	0	0
		1 st FU	2.05	0	0	0	0	0	0
		2 nd FU	2.05	0	0	0	0	0	0

Statistical analysis showed that the mean score which was 2.05 before the treatment was not reduced after the treatment, 1st follow up and 2nd follow up. There is no statistically significant change.

Table No.- 06. Effect on Goniometry

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value	Remarks
	BT			BT-AT						

GONIOMETRY	2.72	AT	1.79	0.93	34.19	0.256	0.025	70.35	<0.001	HS
		1 st FU	1.19	1.53	56.25	0.521	0.052	30.62	<0.001	HS
		2 nd FU	1.19	1.53	56.25	0.540	0.054	28.92	<0.001	HS

Statistical analysis showed that the mean score which was 2.72 before the treatment, was reduced to 1.79 after the treatment with 34.19 % improvement. After the 1st follow up mean score became 1.19 with 56.25 % improvement and 2nd follow up mean score became 1.19 with 56.25 % improvement,

and there was statistically highly significant change. (P<0.001)

OVERALL EFFECT OF THE TREATMENT

Table No – 07. Overall Result after 30 days of Treatment

Over All Result		Result After 30 Days	
Criteria (Grades)	Evaluation Of Result	No.Of Patients	Percentage
> 75%	Marked Respond	00	00%
50% To 74%	Improvement	00	00%
< 49%	Stable	100	100%
0%	Detorioration	00	00%

Table No – 08. Overall Result after 60 days of Treatment

OVER ALL RESULT		RESULT AFTER 60 DAYS	
CRITERIA (GRADES)	EVALUATION OF RESULT	NO.OF PATIENTS	PERCENTAGE
> 75%	MARKED RESPOND	00	00%
50% TO 74%	IMPROVEMENT	36	36%
< 49%	STABLE	64	64%
0%	DETORIORATION	00	00%

Table No – 09. Overall Result after 90 days of Treatment

Over All Result		Result After 90 Days	
Criteria (Grades)	Evaluation Of Result	No. Of Patients	Percentage
> 75%	Marked Respond	00	00%
50% To 74%	Improvement	25	25%
< 49%	Stable	75	75%
0%	Detorioration	00	00%

DISCUSSION AND CONCLUSION

During treatment period and after treatment with medicine (30th day) that is 1st day to 30 days there was improvement in results, than up to 1st follow up without medicine (60th day) that was 31 to 60 days there was further improvement in results,

than up to 2nd follow up without medicine (90th day) that was from 61 day to 90 day there was deterioration in the result as compare to 1st follow up but still good score than before treatment and after treatment. This suggests that decrease in dose or stopping of medicine causes partially

reappearance of the symptoms and action of *Trayodashanga guggulu* was up to 60 days as well as there was significant change in the objective parameters like circumference of joint, range of movement but no change in X-Ray findings. In this Clinical research study symptomatic relief was their during treatment period and after treatment, up to the first follow up, and again little aggravates symptoms during second follow up. Minimum contraindications and nil complications make it acceptable choice of treatment in *Jaanusandhigatavata* (Knee joint O.A.).

RESULTS *Trayodashanga guggulu* helps in providing an effective and safe treatment on *Jaanusandhigatavata* (Knee joint O.A.).

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