

Research Article

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A CLINICAL STUDY ON EFFICACY OF TRAYODASHANGA GUGGULU IN THE MANAGEMENT OF SANDHIVATA (OSTEOARTHRITIS)

Biswal Debasis *, Arawatti Siddaram, Murthy Seema Krishna Major S.D. Singh P.G. Ayurvedic Medical College, Farrukhabad, India

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*Corresponding author

Dr. Biswal Debasis, Assistant Professor, Kaya Chikitsa Department, Major S.D. Singh P.G. Ayurvedic Medical College, Farrukhabad, India E-mail: dewasisbiswal23@gmail.com

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ABSTRACT

Sandhivata is a type of degenerative and articular disorder affecting mainly in the weight bearing joint, in advancing age. In Ayurveda, the disease is being prevalent from the primitive time and still exists among the mankind. Osteoarthritis is predominant in females as compared to males. In radiographic survey it was observed that 2 % of females who are less than 45 years old, 30% of 45 to 65 years age and 68% in older than 65 years are affected by this disease. The aim of the present study was to find out efficacy of Trayodashanga Guggulu in comparison to modern analgesics. In present study total 40 patients were taken, divided into 2 groups. In group-1: 30 patients were treated with oral administration of trial drug that is Trayodashang guggulu 2 tab twice a day and in group-II: 10 patients were treated with control drug that is Diclofenac Sodium 1 tab twice a day orally. After conducting clinical trial on 40 patients, observation and results were obtained. Statistical analysis shows that both trial and control drug were significantly effective to reduce the cardinal symptoms. As compared to trial drug the effect of control drug is better to reduce pain and swelling. However as compared to side effects and contra-indications of the control drug, it is advisable to use Trayodashang Guggulu for the treatment of Sandhivata for a long period.

Key words: Sandhivata, Osteoarthritis, Trayodashanga Guggulu, Guggulu, Diclofenac Sodium, Vatavyadhi.

INTRODUCTION

Ayurveda the science of life, a healthy and higher longevity are always desirable from it. Metabolic and degenerative disease of connective tissue and joint problem are quite affluent today¹. During different stages of the human life disease prevalence is common due to genetic, infection, infestation, systemic, environmental age related and so on². In Ayurveda Sandhivata gets its entity in the chapter of Vata vyadhi3 which obviously are co-related with neuromuscular disorder including disease of the joints. This disease mostly affects the elder group of 40 yrs. Occur in all classes of people are affected, due to their diet, occupational and other environmental factors⁴. Intake of excess cold items like freezing water, ice -cream, increase the Sheeta guna (cold property) of Vata dosha and the poor people taking less diets or less quantity of oil substances diets thereby increasing Vata dosha make the people susceptible to be affected by Sandhigata vata. This socioeconomic disease cripples the human life and has posed a challenge to medical science. Sandhivata is a Vataja disease mainly occur due to dhatukshaya (degeneration of tissue) so generally snehana (oleation therapy), swedana (fomentation), mridu samsodhana (mild purification therapy), vasti (enema) etc. can be adapted keeping an eve on the etiology³.

According to modern point of view it is called Osteoarthritis, is most common joint disease of humans and it is also erroneously called as degenerative joint disease⁵. Risk factors include genetics, sex, past trauma, advancing age and obesity⁶. Osteoarthritis represents failure of a diarthrodial (freely movable) joint. To a greater or lesser extent, it is always characterized by both degeneration of articular cartilage and simultaneously proliferation of new bone cartilage and connective tissues⁷. The proliferative response results in some degree of remodeling of the joint counter. Inflammatory changes in the synovial fluid are usually minor and secondary. However patients with Osteoarthritis, especially in younger age group have mild and relatively a symptomatic disease.

Need of study

According to modern point of view it is mentioned that Osteoarthritis (OA) shows a strong association of ageing, produces pain and disability in the elderly. In the present era, modern medicines have gained wide acceptance and the knowledge regarding the disease and treatment has ascended to its peak. A lack a satisfactory regimen is not yet available in the field of health which can roll back the wear and tear of joints. So in order to obtain a permanent and safest remedy this problem was selected in the present study with trial drug as Trayodasanga guggulu.

In modern medicines there are various kinds of antiinflammatory and analgesic are available but these medicines are having their own side effects such as G.I disturbances, renal abnormalities⁸, peptic ulcer, dizziness, skin rashes etc. Hence these modern medicines can't be used for longer period as a treatment of choice. Also these drugs are having temporary action as an analgesic and antiinflammatory etc. All these above reasons indicate that modern medicines are not suitable and safe for Osteoarthritis (OA) patients for longer duration. Hence in the present study an effort was made to treat the osteoarthritis (OA) by Ayurvedic remedy i.e. Trayodashanga guggulu.

Aims and Objectives

- 1. A critical study of Sandhivata (OA)
- 2. To evaluate the efficacy of Tryodashanga guggulu in the management of Sandhivata.
- 3. To compare the efficacy of Trayodashanga guggulu with Diclofenac Sodium in the management of Sandhivata.

DRUG REVIEW

In the present study Trayodashanga Guggulu was used as trial drug and same Trayodashanga Guggulu effect was compared with the control group drug that is Diclofenac Sodium.

S.N	Drug Botanical Name		Part Used	Quantity		
1	Babool	Acacia arabica Wild	Twak sara (bark extract)	1 part		
2	Aswagandha	Withania somnifera (Linn)	Root	1 part		
3	Hauber	Juniperus communis (Linn)	Whole plant	1 part		
4	Guduchi	Tinospora cordifolia Wild	Stem	1 part		
5	Satavari	Asparagus recemosus Wild	Roots	1 part		
6	Gokhura	Tribulus terrestris	Fruit, root, whole plant	1 part		
7	Vridhadaruk	Argyriea speciosa (sweet)	Seeds, leaves, stem	1 part		
8	Rasna	Pluchea lanceolata (C.B. clarke)	Whole plant	1 part		
9	Saunf Foeniculum vulgare (Mills)		Fruit	1 part		
10	Kachura	Curcuma zedoaria Rose	Rhizome	1 part		
11	Yavani	Trachyspermum ammi (Linn)	Seed	1 part		
12	Sunthi Zingiber officinale Ruscee		Rhizome	1 part		
13	Guggulu	Commiphora mukul Engl	Gum, Resin	12 part		
14	Ghrita	Cow ghee		6 part		

Table 1: Ingredients of Trayodashanga Guggulu⁹

Preparation of Trayodashanga Guggulu⁹

From Babool to Shunthi all the above 12 drugs were taken in equal quantity in powder form (sukshma churna) and mixed thoroughly. To this mixture equal quantity of shudha (purified) guggulu was added. Then to this mixture adds Ghee, $\frac{1}{2}$ of the quantity of Guggulu, the total mixture was once again thoroughly mixed and vatis (tablets) were prepared of size 1 gram.

MATERIALS AND METHODS

The present clinical study was conducted in P.G Dept. of kayachikitsa, Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India. In this study total number of 40 patients was registered for the research work and the patients were collected from both O.P.D and I.P.D of hospital attached to the Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India, based on the criteria of selection. Out of 40 patients 30 and 10 patients were treated with trial drug and control drug respectively. Ethical clearance number Obtained for this study was with the reference number GAM/08/339/E-8987-2009.

Source of Data

Literary Data: Taken from various Ayurvedic Samhitas, Text books, Journals, magazine's articles and also from various conferences.

Clinical Data: were taken from O.P.D and I.P.D of Gopabandhu Ayurveda Mahavidyalaya, Puri, Odisha, India, irrespective of age, sex, religion, socioeconomic status etc.

STUDY DESIGN

Total numbers of 40 patients were registered for the study. 40 patients were divided in to 2 group i.e.

Group I - 30 patients were treated with Trayodashanga Guggulu 2 tab twice a day with Luke warm water.

Group II- 10 patients were treated with Diclofenac Sodium 50 mg twice a day with normal water.

Observation Period: 0 days, 10th days, 20th days, 30th days.

Follow up: at 3 months and at 6 month.

Selection Criteria: The willingness was obtained from patients registered for trial in especially designed case sheet proforma. Cases which were reported to O.P.D and I.P.D of kayachikitsa, resembling to osteoarthritis were strictly screened for their suitability to be included under trial. A selection criteria was followed keeping behind the clinical signs and symptoms mentioned in Ayurveda samhita regarding Sandhivata and confirmation through the radiological exposure for the selection of patients multipage, simple, random sampling method was adopted.

Inclusion criteria

- Patients between the age of 40 years to 70 years and both sexes were included for the study.
- Patients who were ready to give written informed consent.

Exclusion criteria

- Age-below 40 years and above 70 years.
- Tenderness
- Pregnancy and lactation
- Diabetes Mellitus.
- Hypertension.
- Heart disease.
- Renal pathology.
- Rheumatoid arthritis.
- Past history of Koch's.
- Carcinoma.

Assessment Parameters Subjective Parameter

• Pain

Objective Parameters

- Stiffness
- Tenderness
- Swelling
- Range of movement
- Walking time
- Crepitation
- Radiological assessment

Clinical Assessment of Result

It was made as per the following criteria. Maximum Improvement: On an average $\geq 75\%$ improved of the cardinal signs and symptoms viz – Pain, Swelling, Tenderness, Restricted movement, Walking time. Moderate Improvement: On an average $\geq 50\%$ and <75% improvement of the above mentioned cardinal signs and symptoms. Mild Improvement: On an average $\geq 25\%$ and <50% improvement of the above mentioned cardinal signs and symptoms. No Improvement: Less than 25% improvement of the above mentioned cardinal signs and symptoms.

RESULTS AND OBSERVATION

Table 2: Demographic Observation

Geographic observation	Predominance	Percentage	No. of patients	
Age	40-50 years	37.5%	15	
Sex	Females	62.5%	25	
Course of Disease	Progressive	77.5%	31	
Family History	Osteoarthritis	55%	22	
Nidana (etiology)	Consuming dry, very cold, light, less quantity of food	55%	22	
Agni (Digestion capacity)	Mandagni (less)	45%	18	
Kostha	Madhya	45%	18	
Prakruti (nature of patient)	Vata Kapha	42.5%	17	
Chief Complaints	Pain in joints	100%	40	
Chronicity	<1 year	75%	30	
Joint Affected	Knee	82.5%	33	
Walking Habit	Long walk by foot	52.5%	21	
Obesity	Absent	52.5%	21	
Nature of work	House wife	42.5%	17	

Table 3: Percentage of patients got improvement with respect to the sign and symptoms both trial and control group

SN	Sign and Symptoms	AT1		Α	T2	AT3		
		T.G%	C.G%	T.G%	C.G%	T.G%	C.G%	
1	Pain	100%	100%	100%	100%	100%	100%	
2	Tenderness	61.9%	33.33%	100%	100%	100%	100%	
3	Swelling	42.87%	80%	71.42%	100%	71.42%	100%	
4	Restricted Movement	47.61%	66.66%	85.71%	83.33%	100%	100%	

Table 4: Average percentage of change (Improvement) of different sign and symptoms after treatment in trial and control group of patient

SL.	Sign and Symptoms	AT1		A	AT2	AT3		
No		T.G.px	C.G.px	T.G.px	C.G.px	T.G.px	C.G.px	
1	Pain	48.7%↓	40.67%↓	79.6%↓	74.5%↓	93.4%↓	84.74%↓	
2	Tenderness	35.1%↓	20%↓	75.6%↓	80%↓	86.4%↓	86.66%↓	
3	Swelling	30%↓	50%↓	50%↓	62.5%↓	50%↓	87.5%↓	
4	Restricted Movement	27.5%↑	28.57% ↑	52.5% ↑	35.71% ↑	70% ↑	71.43%↑	

Table 5	: Im	provement	of	clinical	assessment

SL.	Clinical Assessment		AT1 AT2			AT3							
NO.		T.G		T.G C.G		T.G	C	C.G		T.G	C	C.G	
		F	Р	F	Р	F	Р	F	Р	F	Р	F	Р
1	Complete relief 100%					6	20%	3	30%	17	56.66%	3	30%
2	Maximum Improvement (75-74%)					3	10%			4	13.33%	5	50%
3	Moderate Improvement (50-74%)	3	10%	1	10%	12	40%	4	40%	7	23.33%	1	10%
4	Mild Improvement (25-49%)	10	33.33%	1	10%	7	23.33%	3	30%	1	3.33%	1	10%
5	Unsatisfactory (<25%)	17	56.66%	8	80%	2	6.66%			1	3.33%		

T.G = Trial Group, C.G = Control Group, Px = Average percentage of change (improvement), AT1 = After treatment 10 days, AT2 = After treatment 20 days, AT

AT2 = After treatment 20 days, AT3 = After treatment 30 days, F=Number of patients, P=Percentage, \uparrow and \downarrow = Arrow marks indicates the trade of improvement in upward and downward direction

	Trial drug	Control drug
Complete relief	56.66%	30%
Maximum Improvement	13.33%	50%
Moderate Improvement	23.33%	10%
Mild Improvement	3.33%	10%
No Improvement	3.33%	00

DISSCUSION

Among the disease of locomotory system Osteoarthritis is the most commonly encounter painful condition in this degenerative wear and tear process occurring in joint. In present study results shows Diclofenac Sodium and Trayodashanga Guggulu both has significant role in Osteoarthritis. The control drug is highly significant then trial drug to reduce the cardinal symptoms but the trial drug also has significant effect on pain, because it contains major amount of guggulu. Guggulu has properties like snigdha, picchila (stickiness), ushna virya (hot in potency), vatanasaka. sothahara (anti-inflammatory) and vedanasthapaka¹⁰ (analgesic action). This trial drug contains Guggulu, Guduchi, Kachura, Yavani all are antiinflammatory properties that is why this trial drug is effective in reducing swelling.

Restricted movement and Tenderness cause due to capsular fibrosis impaction of loose bodies in joint capsule because of osteophytes which alter the counter of joint and remodeling of bone, according to finding the trial drug repair the irregularity of articular cartilage this may happened due to enhancement in the blood flow resulting availability of nutrients to the affected part. As per Ayurveda concept, the effect of rasayana (rejuvenation) and snigdha guna¹¹ attributed to the drug must have worked in the repairing process leading to improvement in the restricted movement and tenderness. Mainly trial drug contains Ashwagandha, Satavari, Ghee, Guduchi, Vridhadaruka, Yavani, Kachura so it is very effective.

CONCLUSION

It is an age related disease and may persist for rest of the life of the patients. As compared to trial drug the effect of control drug is better to reduce pain and swelling. However as compared to side effects and contra-indications of the control drug, it is advisable to use Trayodashang Guggulu for the treatment of Sandhivata for a long period. The trial drug is capable of curing more than 56% cases, whereas maximum improvement in 13.33% patients, moderate in 23.33% and mild improvement in 3.33% cases. Only 3.33% cases are not benefited by this trial drug. This indicates that this trial drug is effective in case of Sandhivata. Further detailed clinical and experimental studies are required to assess the mode of action of the herbal compound Trayodashanga Guggulu.

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