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Evaluate the Efficacy and Safety of *Boswellia Plus* Tablets in the Management of *Sandhigata Vata* w.s.r. to Osteoarthritis

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ABSTRACT

Sandhigata Vata is most common articular disease after 4th decade of life. It is one of the *Vata vyadhi* which mainly occurs due to *dhatukshaya*. Being a *Vata vyadhi* located in *Marmasthisandhi* and its occurrence in old age makes it *kashtasadhya*. The description of the disease is quite similar to Osteoarthritis in modern science. Osteoarthritis is a degenerative joint disorder, where joint inflammation initially causes pain and later on swelling. Due to pain and swelling, the mobility of joints is restricted and on movement patients feel excruciating pain, which becomes unbearable. It is the most prevalent joint disorder of 22% to 39% in India. It is a major cause of morbidity limiting the daily activities and impairing the quality of life especially among the elderly. There is no absolute cure in modern medicine. Nowadays its management is going on analgesics, non-steroidal anti-inflammatory drugs and surgical interventions, which are costly and cause various untoward effects on health such as gastritis, renal function impairment. Drugs that slow down or halt the disease progression are much needed.

Ayurvedic treatment is a better conservative method for the treatment of *Sandhigata vata* without causing any side effects. The purpose of study was to establish the efficacy and safety of **Boswellia Plus Tablets** in the management of *Sandhigata vata*. The trial drug contains *Shallaki*, *Ashwagandha*, *Haridra*, *Sonth*, *Ananas* and *Suranjan*. The present clinical trial consisting of 30 patients of *Sandhigata vata* aged between 40 - 80 years of either sex were selected from the OPD and IPD of Kayachikitsa Deptt. of Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital Paprola, Kangra (H.P.). Diagnostic criteria were mainly based on the signs and symptoms of osteoarthritis. The registered patients were treated with trial drug for 30 days. The symptomatic improvement was observed with statistically significant results ($p > 0.001$). Result of this research study showed that **Boswellia Plus Tablets** are effective and clinically safe in the management of osteoarthritis.

KEYWORDS *Sandhigatavata*, *Vata vyadhi*, *Osteoarthritis*, *Boswellia Plus Tablets*



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INTRODUCTION

Osteoarthritis is a disease, the description of which is quite similar to that of *Sandhigata vata* described in *Ayurveda*. It is a degenerative joint disorder, where joint inflammation initially causes pain and later on swelling. Due to pain and swelling, the mobility of joints is restricted and patients feel excruciating pain. Pain becomes unbearable even on mild touch in the form of tenderness. The degenerative changes later results in manifestation of crepitus around involved joints.

It is most common rheumatologic problem with prevalence of 22% to 39% in India. It is more common in females than males. Almost all the persons by age of 40 years have some pathological changes in weight bearing joints. It limits everyday life activities such as walking, dressing, bathing etc. thus making individual handicapped. There is no absolute cure in modern medicine. The complications arising from the arthritis has been enlisted to the surgery, which too has limitations. Therefore to avoid all such factors we need some *Ayurvedic* treatment modality. Keeping all these factors in mind a study design was planned on the basis of *Ayurveda* to make the patient fully independent for his/her daily living activities.

Present study was planned to formulate an effective, safe and cost effective herbal remedy for osteoarthritis. Keeping all these facts in mind trial drug **Boswellia Plus Tablets** was selected for the trial which is an anubhuta yoga having Shallaki(*Boswellia serrata*), Ashwagandha (*Withania somnifera*), Haridra (*Curcuma longa*), Sonth (*Zingiber officinale*), Ananas (*Ananas comosus*) and Suranjan (*Colchium luteum*). In a clinical study, after 30 days of therapy, the result showed that all the symptoms of osteoarthritis were statistically significantly reduced which was evident when the scoring of the symptoms was considered. At the end of the study, efficacy and tolerance of treatment was excellent to good without any side effects.

AIMS AND OBJECTIVES

To establish the efficacy and safety of **Boswellia Plus Tablet** in the management of Osteoarthritis.

MATERIALS AND METHODS

SOURCE OF DATA:- The 30 patients diagnosed with osteoarthritis fulfilling the inclusion criteria were registered from OPD/IPD Deptt. of Kayachikitsa R.G.G.P.G.A.C.and Hospital, Paprola Distt. Kangra (H.P.), during July 2015- December



2015, irrespective of sex, caste and religion with the sign and symptoms of osteoarthritis.

The patients were diagnosed on the basis of *Ayurvedic* and modern parameters having pain, tenderness, swelling, pain during movements, restriction of flexion, local crepitations and morning stiffness. Patients who suffered from any other inflammatory joint disorders like RA, gouty arthritis, tubercular arthritis, psoriatic arthritis, diabetes mellitus, SLE and any other serious systemic disorder were excluded. Out of 30 patients there were 11 males and 19 females, aged between 40-80 years. All the patients had pain, tenderness, restriction of flexion

and movements and morning stiffness, 28 patients reported with swelling around the affected joint and 25 suffered from local crepitation. Hematological tests includes Hb_{gm}%, TLC, DLC and ESR, Biochemical tests includes FBS, B. Urea, S. Creatinine, S. Uric acid and RA Factor, Radiological test X-Ray of affected joints were carried out to rule out any major illness before and after the completion of treatment.

GROUPING

The present study was carried out in a single group only

TRIAL DRUG

Boswellia Plus Tablet Composition

(Table a)

Table a Boswellia Plus Tablet Composition

Sr. No.	Ingredients	Botanical Name	Drug quantity
1.	Salai Guggal	Boswellia serrate	300mg Extract
2.	Ashwagandha	Withania somnifera	100mg Extract
3.	Haridra	Curcuma longa	100mg Extract
4.	Sonth	Zingiber officinale	100mg Extract
5.	Ananas	Ananas comosus	70mg Extract
6.	Suranjan	Colchium luteum	50mg Extract

PREPARATION OF DRUG

Drug manufactured by Ayush Pharmaceuticals and Marketing Division, Nagrota Bhagwan, Himachal Pradesh, India.

ADMINISTRATION AND DOSE OF DRUG

Administration - Orally after meals

Dose - 2 tablets twice a day

Anupana - Water.

Duration of the trial and follow-up

The total duration of the trial was of 30 days. The patients were advised to come for follow up after 15 days of initiation of trial and at the end of trial to observe the effects and adverse effects of trial drug.

RESULTS

The symptomatic improvement was observed using student 't' test showed statistically significant results ($p > 0.001$).



Table 1: Assessment of Patients (Symptomatic improvement)

Table 1 Assessment of Patients (Symptomatic improvement)

Sr. No.	Assessment Criteria	No. of Patients	Improvement				% Relief
			No Relief	Mild	Moderate	Highly	
1	Visual Analog Scale	30	4(13%)	17	9	-	87%
2	Tenderness	30	4(13%)	4	14	8	87%
3	Restriction of flexion	30	4(13%)	5	15	6	87%
4	Oedema	28	4(14%)	2	6	16	86%
5	Pain during movements	30	4(13%)	3	6	17	87%
6	Walking distance	30	4(13%)	3	6	17	87%
7	Local crepitations	25	6(24%)	6	11	2	76%
8	Morning stiffness	30	2(6%)	-	8	20	94%

Table 2: Effect of Boswellia Plus Tablet on clinical features of Osteoarthritis after 30 days.

Table 2 Effect of Boswellia Plus Tablet on clinical features of Osteoarthritis after 30 days

Sr. No	Assessment criteria	Mean		% Diff.	S.D	S.E±	't'	P
		BT	AT					
1	Pain	8.67	3.73	56.9	1.30	16.7	16.7	<0.001
2	Tenderness	2.26	0.56	74.9	0.46	0.08	19.9	<0.001
3	Restriction of flexion	1	0.27	73	0.46	6.20	6.20	<0.001
4	Oedema	1.76	0.36	79.2	0.62	0.11	12.3	<0.001
5	Pain during movements	2.73	1.33	51.2	0.51	0.13	10.7	<0.001
6	Walking distance	2.43	0.5	79.4	0.78	0.14	13.4	<0.001
7	Local crepitations	1.33	1.00	24.8	0.49	0.13	2.05	<0.001
8	Morning stiffness	1.9	0.3	84.2	0.12	0.12	12.9	<0.001

BT: Before treatment; AT: After treatment; S.D: Standard deviation; S.E: Standard Error

DISCUSSION

Osteoarthritis is the most common form of arthritis which occurs mainly in middle aged and elderly persons. It is a chronic degenerative disorder of multifactorial etiology characterized by loss of articular cartilage and peri-articular bone remodeling. Mostly involved joint are knee followed by cervical spine, LS spine, ankle and shoulder. Till date no satisfactory treatment is available that can reverse or slow the disease

process. Modern science has only palliative treatment for osteoarthritis. **Boswellia Plus Tablet**, a herbal preparation contains Shallaki, Ashwagandha, Haridra, Sonth, Ananas and Suranjan. Salai guggul or Shallaki, the main constituents reduces pain and inflammation significantly that may be due to its inhibitory effect on inflammatory mediators. The key constituents of Shallaki are volatile oils, acid resin, gum and triterpenoids. It helps to preserve structural



integrity of joint cartilage and maintains a healthy immune mediator cascade at cellular level by inhibiting leukotriene synthesis.

Ashwagandha has anti-inflammatory effects which suppress the production of pro-inflammatory molecules. It has rasayana properties so helpful in reducing further oxidative injury to joint cartilage and reduces stress. Haridra (turmeric) active ingredient curcumin has been shown to inhibit key inflammation producing enzymes (like lipo-oxygenases, cyclo-oxygenases and phospholipase A2). Sunthi also has anti-inflammatory and analgesics property. Suranjan (Colchicine) helps in reducing inflammation.

The patients were strictly asked to modify their life style like avoid prolonged standing, kneeling, squatting position and obese patients consoled to reduce weight, these measures have great influence in relief of symptoms.

CONCLUSION

From the above observations and discussion, it can be concluded that, this formulation as a whole very effective in the treatment of Osteoarthritis. The present report emphasizes the effectiveness of **Boswellia Plus Tablet** in the patients of Osteoarthritis. Drug is effective to alleviate the symptoms of Osteoarthritis and remarkable relief is

noted in pain, tenderness, oedema and morning stiffness without any untoward side effects.



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