RESEARCH ARTICLE

A clinical trial of abhadi vati in sandhigatavata w.s.r. to osteoarthritis

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ARTICLE INFO	ABSTRACT
	Background: *Sandhigatavata* vis-à-vis osteoarthritis is multi-factorial, non-inflammatory degenerative joint disorder. The incidence of osteoarthritis in India is as high as 12%. It is estimated approximately 4 out of 100 people are affected by it. It is observed in the 3rd- 4th decade of life and is extremely common by age of 70 years. Almost all persons by age of 40 years have some pathological change in the weight bearing joint. 20% females and 16% males have symptomatic osteoarthritis. South Asian countries like India, Bangladesh, Nepal, Sri-lanka are having higher incidence. **Aim & Objective:** To evaluate the efficacy of *Abhadi Vati* in Specific subjects of *Sandhigatavata.* **Study Design:** The study was conducted on total 17 subjects of *Sandhigatavata,* Of which 15 subjects completed the treatment all along the study period. The patients were selected from the OPD of Sri Danappa Gurusidappa Melmalagi Ayurveda Medical College & Hospital, Gadag, Karnataka for the respective clinical trial. **Assessment criteria:** Criteria of assessment are set aside on the basis of relief in the signs and symptoms of *Sandhigatavata* both objectively and subjectively. **Results**: Among 15 subjects 06 responded moderately, 02 markedly mild improved and 03 responded well and 04 did not respond to the treatment. **Interpretation and Conclusion:** Though the criteria of assessment and statistical analysis reveal the efficacy of the study, the very fact that the mode of action of the drug is the base of the relief in signs and symptoms cannot be ignored. Conclusively the treatment was satisfactorily effective in the subjects.

INTRODUCTION

Sandhigatavata is a major problem as a large percentage of population suffers from this. *Sandhigatavata* is one of the 80 *nanatmaja vata vikara* and it is *yapya Vyadhi* (Yadavji trikamji Acharya, 2006). *Acharya Charaka* has explained it as one among the *Vatavyadhi* and characterized by *"vata purna druti sparsha"* associated with *Shotha* and pain during the movement of the joint (Vaidya Yadavji trikamji Acharya, 2006). *Acharya Bhavaprakasha* while explaining *Vatavyadhi* explained about *Sandhigatavata* (Bhishakratna Shree Brahma, 2005). The *nidana panchaka of Sandhigatavata* has been

elaborately dealt in the *brhatrayee,* other *ayurveda* classics and is tabulated. Table no.01 Showing the *Nidana, Lakshana and Samprapti* of *Sandhigatavata* (Siddharth N. Shah, 2003; Prof. Yadunadana Upadhyaya, 2000) *Sthoulya* is another causative factor for *Vata prakopa*. The *Meda-avarana* of*Vata* is the mechanism causing inter-relationship between *Sthoulya* and *Vatavyadhis* (Agnivesha, 1994). All types of *avaranas* are also important vitiating factors of *Vata. Vardhakya avastha* is dominated by *Vata*, during this period, *Dhatukshaya* occurs which causes *Vata prakopa*. Living in *Jangaladesha* is another cause of *Vata prakopa*. *Vata* gets vitiated in the end of day and night (Sushruta, Sushrutasamhita Suthrasthana, 1980). *Vata prakriti* persons are more susceptible to *Vata vikaras*. Persons who are *Ruksha-kashaya-katu-tikta Rasa satmya* are also more susceptible to *Vata vikaras* (Vagbhata *et al*., 1982).

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Contemporary science has failed to find a solution for this disease. It is said that current treatment for Osteoarthritis is purely control of symptoms because there is no disease modifying Osteoarthritis drug yet (Harrisons principles of internal medicine, 1987). *Ayurveda* is an established medical system, which has been developed by various ancient *Acharyas* after experiments and examinations. But in the present day it is compulsory to prove the *Ayurvedic* truths on the modern parameters, without modifying its basic structure as methodical approach is the backbone of research. Research is a scientific study through which one can establish new facts, discarding the old facts or modifying the present facts. Utmost care is taken in designing the methodology for conducting this study.

Aim and Objective of the study

The main aim & objective of the trial is to clinically evaluate the efficacy of *Abhadi Vati* (Tripathi Indradeva and Tripathi Dayashankar, 2011) in specific subjects of *Sandhigatavata.*

All the drugs to be taken in equal quantity and made into fine choorna and then bhavana can be given with swarasa of shunthi and guduchi.

MATERIALS AND METHODS

Study design: A Simple randomized comparative clinical prospective trial.

Sample size and grouping: A minimum of 15 patients suffering from *Sandhigatavata* were randomly selected and administered with *Abhadi Vati.*

Preparation of the trial drug (*Abhadi Vati*): The trial drug *Abhadi Vati* is a classically mentioned formulation in *Sandhigatavata*. The collection of raw materials and preparation of the formulated drug was carried in the institutional premises.

Table 1. The Nidana, Lakshana and Samprapti of Sandhigatavata (Siddharth N. Shah, 2003; Prof. Yadunadana Upadhyaya, 2000)

NIDANA	Sannikrushta Hetu:	*Ativyyayama, Abhighata, Marmaghata, Bharaharana, Sheeghrayana, Pradhavana, Atisankshobha.*
	Viprakrushta Hetu:	*Rasa– Kashaya, Katu, Tikta*
		Guna – Ruksha, Sheeta, Laghu
		Dravya – Mudga, Koradusha, Shyamaka, Uddalaka, Masura, Kalaya, Adaki, Harenu, Shushkashaka, Vallura, Varaka
		Aharakrama – Alpahara, Vishamashana, Adhyashana, Pramitashana
		Viharaja – Atijagarana, Vishamopachara, Ativyavaya, Shrama, Divasvapna,Vegasandharana, Atyucchabhashana, Dhatu Kshaya.
		Manasika – Chinta, Shoka, Krodha, Bhaya
Lakshana	*Shula, Vata purna druti sparsha, Shopha,Prasarana Akunchanayoho, Savedana pravrutti, Hanti sandhi, Atopa.*	
Samprapti ghatakas	*Dosha – Vata – Vyana vata vridhi, and Kapha – Shleshaka kapha kshaya*	
	Dushya – Asthi, Majja, Peshi, Snayu, Sleshmadhara kala	
	Srotas – Asthivaha, Medovaha, Majjavaha, Mamsavaha	
	Agni – Jatharagni, Asthidhatwagni,	
	Ama – Jatharagni mandyajanya, Asthidhatwagni mandyajanya,	
	Udbhavasthana – Pakvashaya	
	Rogamarga – Madhyama	
	Adhisthana – Sandhi	
	Vyaktasthana – Sandhi	

Preparation of Trial Drug

A formulation must contain the ingredients of potential effects for which it is used. In other words, the action of a medicine depends upon the sum total effect of the ingredients in it. These drugs well known for their *Vatashamaka* properties and these drugs are also having *Amapachaka Guna*, so the combine effect of drugs will be seen on the disease. Moreover desired effect of therapy depends mostly on the ingredients of drugs given and for *Kapha pradhana Vyadhis kaphahara* line of treatment should be followed.

Table 2. The constituents of *Abhadi Vati* (Prof. P.V.Sharma's *et al*., 1999; Dr. Rama Chandra Reddy, 1998)

S.No.	Drug Name	Latin Name	Proportion
1.	Abha	Acasica Arebica	1 part
2.	Rasana	Plucha lansiolata	1 part
3.	Guduchi	Tinospora cardifolia	1 part
4.	Shatavri	Asparagus recemosa	1 part
5.	Shunthi	Gingeber officinalis	1 part
6.	Shatapushpa	Anethum sowa	1 part
7.	Ashwagandha	Withenia sominifera	1 part
8.	Hpusha	juniperous communies	1 part
9.	Vidhara	Desmodium gungenticum	1 part
10.	Yavani	Roxburghiamum ammi	1 part
11.	Ajmoda	Apiumgraveolans	1 part

Source of Data: Patient suffering from *Sandhigatavata* were selected from O.P.D and I.P.D. of D.G.M.A.M.C & H., Gadag after fulfilling the inclusion and exclusion criteria.

Selection Criteria: The cases were carefully and strictly chosen as per the pre-set inclusion and exclusion criteria.

Inclusion criteria

1. Patients suffering from classical sign and symptoms of *Sandhivata*
   a) Shula
   b) Shotha
   c) Sthambha
   d) Sparshasayyata
   e)Sphutana
   f) Aakunchan Prasaran vedna etc at the joints
2. Patients between the age group of 40-75 years
3. No discrimination of sex
4. Patient without any anatomical deformity (genu valgum / genu varum)

Exclusion criteria

1. Patient below 40 and above 75 years of age

2. Pregnant woman
3. Acute joint trauma
4. Rheumatoid arthritis
5. Diabetes mellitus
6. Gouty arthritis (vata rakta)
7. Complete loss of articular cartilage
8. Polymyalgia Rheumatica
9. Phiranga Roga (Syphilis)
10. Psoriatic arththritis
11. S.L.E

Posology

Abhadi vati: To be taken internally 500mg 2 tab. Tid with Luke warm water

Study duration

Total study duration- 60 days
Treatment duration: - 30 days
Follow up: - after 30 days

Criteria for Assessment: The diagnosis is mainly based on clinical presentation of the patient according to signs and symptoms of *Sandhigatavata* mentioned in classical texts, which are described under subjective and objective parameters.

Subjective parameter

1. Sandhi vedana (Pain)
2. Sthambha (Stiffness)
3. Sandhi Shotha (Swelling)

Objective parameters

1. Sandhi Atopa (Crepitations)
2. Sparshasayyata (Tenderness)
3. Range of motion
4. Walking time (approximate 21metres of distance).

Certain gradations and declarations are made about the data and all these parameters of baseline data to post-medication data will be compared for clinical assessment of the results. The parameters are as follows:

Overall Assessment of Clinical Response

- Good Response: 70 % and more improvement in overall clinical parameters.
- Moderate Response: 50%-70% improvement in overall clinical parameters.
- Mild Response: 30%- 50% improvement in overall clinical parameters.
- No Response: Nothing has been changed.

Table 3. The Subjective & Objective Parameters

Subjective Parameters	
Sandhi vedna (Pain)	Grade 0 – No Complaints
	Grade 1 – Tells on Enquiry
	Grade 2 – Complaints Frequently
	Grade 3 – Excruciating condition
Sthambha (Stiffness)	Grade 0 – Absent
	Grade 1 – Present
Sandi Shotha (Swelling)	Grade 0 – No Complaints
	Grade 1 – Slightly obvious
	Grade 2-covers well over the bony prominence
	Grade 3-Much elevated
Objective parameters:	
Sparshasayyata (Tenderness)	Grade 0 – No Complaints
	Grade 1 – Says the joint is tender
	Grade 2 – Winces the affected joint
	Grade3 –Winces and withdraws the affected joint.
Sandhi Atopa (Crepitation's)	Grade 0 – None
	Grade 1 – Felt
	Grade 2- Heard
Range of motion	Grade 0-Full movement 120° - 140°
	Grade 1-Limited 70° – 90°
	Grade 2-Nill
Walking time:	Grade 0 - up to 20 seconds.
	Grade 1- 21-30 seconds.
	Grade 2- 31-40 seconds.
	Grade 3 - 41-50 seconds.
	Grade 4 – 51-60 second

SIGN & SYMPTOMS	MEAN			% RELIEF	S.D	S.E	T- VALUE	P VALUE	REMARKS
	BT	AT	AF						
Sandhi Vedana	2.733	1.067	1.667	60.95%	0.617	0.159	10.458	<0.001	H.S
Sthambha	0.467	0.133	0.133	71.52%	0.488	0.126	2.646	0.019	S
Sparshasayyata	1.733	.867	0.867	49.97%	0.516	0.133	6.500	<0.001	H.S
Sandhi Shotha	1.000	0.467	0.400	53.3%	0.516	0.133	4.00	<0.001	H.S
Sandi Atopa	0.867	0.867	0.867	000%	0.000	0.000	0.000	1.00	N.S
Range Of Movement	2.867	1.667	1.533	41.81%	0.414	0.107	11.225	<0.001	H.S
Walking Time	8.3	4.2	4.3	58%	5.576	1.439	7.873	<0.001	H.S

In the trial, 15 patients received *Abhadi vati*, the result shows highly significant in all parameters. Patients got better result in *Sandhi Vedna* and Walking time. By comparing the t-values, the study shows significant result.

Observation

- Maximum of 10 (66.66%) patients belong to the age group of 60-75 years.
- Maximum of 14 (93.33%) patients were under grade 2 (Sandhi vedna).
- Maximum of 10(66.66%) patients were under grade 2 (Sandhi Shotha).
- Maximum of 12(80%) patients were under grade 2 (Sparshaasayyata).
- Maximum of 13 (90%) patients were under grade 1 (Sandhi Atopa).
- All 15(100%) patients were under grade 1 (Sandhi sthamba).
- After observing the clinical parameters, the effect of the therapy has been graded into four, they are Good response, Moderate response, Mild response, No response.
- Out of fifteen patients, 03(20%) show Good response to the treatment. 06 (40%) were shown Moderate response and 02 (13.33%) patients shown Mild response. 04(26.66%) patients shown No response.

Summary and Conclusion

Sandhivata is the most common joint disorder rising with superior number of affected population in the world. It comes under the *Vatavyadhi prakarana*. In case of *Gatavata* the aggravated *Vata* finds an appropriate place for its lodgement. The appropriate place may possibly such as *Dhatu, Upadhatu, Ashaya, and Avayava.* Here *Sandhigatavata* is a *Vatavyadhi* caused by the localization of vitiated *doshas* in the *Asthi and Sandhi* of the body. The *Lakshanas* of *Sandhigatavata* explained in the classics are having the resemblance to the symptomatology of Osteoarthritis explained in contemporary science. The multi-compound formulation implicated in the present clinical trial was *Abhadi Vati*.

Probable mode of action of Abhadi Vati

- *Acharya Yogaratnakara* has mentioned *Abadi Vati* in context of *Vatavyadi chikitsa*. This is indicated for all types of *vatavyadhi* so it considered treating *Sandhigatavata*. The ingredients of this compound drug are acting as *shoolahara, balya. Deepana, pachana and rasayana,* this has been discussed as follows.
- The ingredients such as *Ashwagandha, Shatavari, Guduchi* act as *Rasayana*. This is very helpful in the management of *Sandhivata* in which the *dhatu kshaya* is the main symptom.
- The same drug is combined with *Shunthi, Ajavayana, and Shoupha* will act as *deepana and pachana* in action because of *katu rasa pradhanyata* which helps in *samprapti vigatana of sandhivata*, and does *sroto shodhana.*
- The *teekshna guna* of drugs like *Ajmoda, Yavani, Shoupha* and *Hpusha* act as *kapha vatahara.*

- *Laghu guna* of *shunthi, ashwagandha, and guduchi* leads to *sroto shodhna* as it is responsible for *ushna virya* which inturn is *vatahara.*
- The drugs like *Ajamoda, Yavani, Hapusha, Shoupha and Shunthi* does the *Shoola prashamana* and act as *shoothahara.*
- *Rasayana* action of vidara, *shatavari, ashwagandha and guduchi* along with *vedana shaman* property of rasna is observed.
- The above commemoration of the specific property and action of the individual drug draws a conclusion that Abha151 and its ingredient as a whole reduces the *pratyatma lakshanas* like *Sandhi vedana, Atopa, Shotha, Sthambha, Sparshaasayyata etc.*

Metabolism of Abhadi vati: (Koracevic, Cosic, 2001; Motchnik and Frei, 1994; Hammer, 2002)

- There is an understanding of the specific anti-inflammatory, anti-oxidant, immune stimulant and spasmodic action of the drugs like *Abha, Rasana, Guduchi.* Also the drugs like *Shatavari, Ashwagandha and Shoupha* exhibit anti-inflammatory and anti-oxidant activity.
- *Abha* possesses anti-inflammatory and anti-oxidant properties.
- *Rasana* exhibits anti-inflammatory, anti-oxidant and spasmolytic action.
- *Guduchi* has anti-stress, immune-modulatory, anti-inflammatory, anti-oxidant and anti-spasmodic effect.
- *Shatavari* is both anti-inflammatory and immune-modulator in action.
- *Satapushpa* acts on inflammation hence reducing the oedema in the OA.
- *Ashwagandha* is immune-modulatory, anti-inflammatory and immune stimulant in action. It also reduces the debility due to stress.

The vitiation of *Vata dosha* is the main causative factor of the disease. The trial drug utility is based on the fact that it directly acts on *Vata dosha, Asthi and Sandhi.* All the drugs individually as well as collectively possess the characteristics to curb the signs and symptoms of disease when implicated in the formulation. Undoubtedly the drug efficacy over the disease could be inferred.

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