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Review Article

MANAGEMENT OF *SANDHIVATA* (OSTEOARTHRITIS) BY AN AYURVEDIC COMPOUND DRUG

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ABSTRACT

Sandhivata (osteoarthritis) is a disease of old age people and usually hampering the working hours and quality of life in number of peoples worldwide. We have found this Ayurvedic treatment very effective in the management of this disease. Hence a time bound clinical research work was framed for objective assessment of the improvement. The study was performed on osteoarthritis of knee joint over fifty patients. The diagnostic and assessment criteria were mainly clinical, along with visual analogue scale for pain and Algo Functional Lequesne Index (Knee) to assess the severity of knee osteoarthritis. The symptoms included were pain, swelling, stiffness, tenderness, joint crepitus and decreased movement. The drugs *Sanjeevani vati*, *Dashamula kwatha, Punarnava mandura* and *Yava kshara* were given for thirty days, with one follow up at fifteen days. There was a drop out of four patients during the trial. The pain (2.18±0.72), stiffness (1.93±0.72) and restriction of movements (2.28±0.81) are the three major complaints followed by crepitus (1.82±0.72), tenderness (1.43±1.10) and swelling (1.29±1.01). The initial score of severity of the disease was 9.75±4.16; which was reduced to 6.20±4.33 after 15 days and it was 3.49±1.16 at the end of the trial, this also gives a highly significant 't' and 'p' score i.e. 15.11 and p< 0.001 respectively. So, the effect of combined therapy was evaluated moderate to high in reducing severity of disease. Some patient even told that they have felt relief in symptoms just on the 2nd day after starting the treatment.

INTRODUCTION

Vata is described as most important biological factor for bodily functions and when aggravated causes various *Vata* disorders, which is described in Ayurveda treatise in a very elaborative manner. *Sandhivata* has come under *Vata vyadhi.* According to *Acharya Charak* when *Vata* get aggravated and affects the joints they will fill it like a bag full of air on touch; the joints become swell and extremely painful. The extension and flexion of the joint is always painful[1]. Whereas *Madhavkara* said that when *Vata* gets localized in the joints, it causes loss of function, pain and cracking sound in the joints [2]. Further osteoarthritis is defined as a degenerative joint disease characterized by destruction of articular cartilage and formation of new bone at the joint surfaces and margins. In most of the cases the exact cause does not know; however, obesity, genetics and heredity, occupation involving prolong standing, sports and multiple endocrine and metabolic abnormalities play a vital role [3].

It commonly affects the knee joint and hip joints, bilateral symmetrical involvement, common in older age groups, it results in valgus/varus deformity in later stages, pain poorly localized and disappears on walking, dull aching with mild swelling and early morning stiffness is usually present. On examination minimal tenderness and coarse crepitus can be elicited. X-ray of the affected joint is suggestive of loss of joint space (mostly on medial side), sclerosis, sub chondral cysts, osteophytes, bony collapse, loose bodies and deformity and mal-alignment [4].

Although many Ayurveda drugs are claimed for its management, but still numerous patients undergo for knee transplant, which gives financial burden and

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undue complications. According to Times of India in its report, more than 2.5 lakh people undergo total knee replacement (TKR) in India, every year, which is 2.5 times the number of such procedures conducted annually about 5 years ago [5]. After a long screening on Ayurveda drugs, we have observed this Ayurvedic treatment very effective in treating the disorder. Hence a time bound clinical research work was framed for objective assessment of the improvement.

MATERIAL AND METHODS

The principal objective of the present work was to ascertain the efficacy of *Sanjeevani vati*[6], *Punarnava mandura*[7], *Yava kshara*[8] and *Dashamula kwatha*[9] in the treatment of *Sandhivata*, and to establish a relationship between cell injury in osteoarthritis and its correlation with Ayurvedic *Agni* and *Ama* concept of *Rogotpatti*. The trial was carried out on 50 patients of Osteoarthritis selected from the Panchakarma OPD, S.S. hospital, IMS, BHU, Varanasi and the drugs were procured from the Ayurvedic pharmacy, BHU.

Inclusion Criteria

- Male/female patients, age between 40 to 70 years.
- The patients having pain, swelling and stiffness as main features with or without radiological changes were registered.
- Restricted movement of knee joint with or without crepitus.

Exclusion Criteria

- Age less than 40 and more than 70 years.
- History of trauma/road traffic accidents.
- Patients of rheumatoid arthritis/gouty arthritis were excluded.
- Severe comorbid illness like DM-II, paralysis were excluded.
- Severe osteoarthritis with fused joints were also excluded from the study.

Diagnostic and assessment criteria were mainly clinical. Pain, swelling, stiffness, crepitus, tenderness at joints, restriction of movements and visual analogue scale for pain were the clinical points assessed. Algo Functional Lequesne Index (Knee) is also used to assess the severity of knee osteoarthritis. The gradation of symptoms was as following:

Gradation of pain score

0- Nil, no pain in the joints

1- Mild pain = Pain complained but tolerable

2- Moderate pain = Pain complained and disturbs the routine work schedule.

3- Severe pain = Severe pain completely interrupting the routine activities.

Gradation of swelling of joints

0- Nil, no swelling

1- Mild, feeling of swelling with heaviness of joints

2- Moderate, apparent swelling

3- Severe, huge swelling

Gradation of tenderness of joints

0- Nil, no tenderness

1- Mild, caused on much pressure

2- Moderate, caused on moderate pressure

3- Severe, caused even on slight touch

Restriction of movement

0- Absence of movement restriction

1- 10% restriction of movement

2- 25% restriction of movement

3- > 50% restriction of movement

Stiffness

0- Nil, no morning stiffness

1- Mild, morning stiffness of 5 to 10 minute

2- Moderate, morning stiffness of 10 to 15 minute

3- Severe, morning stiffness of 10 to 30 minute

Crepitus

0- Absence of crepitus

1- Mild, perception on touch

2- Moderate, audible on attention

3- Severe, clearly audible

Clinical criteria for calculation of the severity of Knee Osteoarthritis

Knee Osteoarthritis Lequesne Algo functional Index Calculator [10]

Pain or discomfort
Night
0 - None
1 - Only on movements and in certain postures
2 - Even motionless, without moving
Morning stretching
0 - None / less than 1 minute
1 - Between one to 15 minutes
2 - More than a quarter to an hour

Does standing or trampling in place for 30 minutes increase the pain?
0 - No
1 - Yes
walking pain
0 - No
1 - Only after some distance
2 - From the beginning of walking and then increasing
Can you get up from a chair without using your arms?
0 - No
1 - Yes
Walking perimeter
Perimeter (regardless of pain)
0 - Unlimited
1 - Limited but greater than 1000 meters
2 - About 1000 meters (about 15 minutes)
3 - 500 to 900 meters (about 8 to 15 minutes)
4 - 300 to 500 meters
5 - 100 to 300 meters
Aids needed
+0 - No cane or crutch is required
+1 - A cane or crutch is required
+2 - Two canes or two crutches are required
Other difficulties of daily life
Can you go up a floor?
0.0 - Without difficulty
0.5 - Quite easily
1.0 - With difficulty
1.5 - With great difficulty
2.0 - Not possible
Can you go down one floor?
0.0 - Without difficulty
0.5 - Quite easily
1.0 - With difficulty
1.5 - With great difficulty
2.0 - Not possible
Can you squat or stay on your knees?
0.0 - Without difficulty
0.5 - Quite easily
1.0 - With difficulty
1.5 - With great difficulty
2.0 - Not possible
Can you walk on uneven ground?
0.0 - Without difficulty

0.5 - Quite easily
1.0 - With difficulty
1.5 - With great difficulty
2.0 - Not possible

Scores	**Handicap**	**Total Score (0 -24)**
> 16	Severe	
8-15	Moderate	
0-7	Mild	

Visual analogue scale (VAS)

It is the easiest way to measure the intensity of pain and can be analyzed quickly. It provides simple efficient and minimally intrusive measures of pain intensity.

The most common VAS consists of a 10cm horizontal (Huskisson 1983) or vertical (Sriwatanakul el.al., 1983) line with the two end points labeled "no pain and worst pain ever". The patient is required to place a mark on the 10cm line at a point which corresponds to the level of pain intensity he or she presently feels. The distance in centimeters from the lower end of the VAS to the patient's mark is used as a numerical index of the severity of the pain. In the present study vertical plane of VAS was used.

Drug review

The trial Ayurvedic drugs given to all the selected patients for 30 days with one follow up at 15 days were summarized in table no-1.

Table 1: The Drugs Used During the Trial with Doses, *Anupana*, Duration and Follow Up

S.No	Drug name	Dose/ day	*Anupana*	Duration	Follow up
1	*Dashamula kwatha*	100ml BD (made by 50gm of raw drug)	---	30 days	15 days
2	*Sanjeevani vati*	250mg BD	Mixed in lukewarm *Dashamula kwatha*	30 days	15 days
3	*Punarnava mandura*	500mg BD	Mixed in lukewarm *Dashamula kwatha*	30 days	15 days
4	*Yava kshara*	250mg BD	Mixed in lukewarm *Dashamula kwath*	30 days	15 days

OBSERVATION

The following table shows the statistical analysis of the symptoms concerned and their improvement after first follow up and after the completion of the treatment, total 50 patients were registered but only 46 patients had come for complete follow-up. The three major complaints were Pain, stiffness and decreased range of motion. Most of the patients have already received NSAID (Non-steroidal anti-inflammatory drugs), but had temporarily relief. (Table no.-2 & 3)

Table 2: Statistical Analysis of Symptoms and VAS Score for Pain

S.No.	Symptom	Score mean ± S.D. (N= 46)			Comparison (paired 't' test)	
		BT	FU1	AT	BT-FU1	BT-AT
1	Pain	2.18±0.72	1.64±0.87	1.18±0.72	0.54± 0.51 t = 5.58 p < 0.001	1.00± 0.61 t = 8.69 p < 0.001
2	Swelling	1.29±1.01	0.89±1.07	0.61±0.96	0.40± 0.49 t = 4.18 p < 0.001	0.68± 0.55 t = 6.55 p < 0.001
3	Tenderness	1.43±1.10	0.64±0.78	0.79±0.63	0.79± 0.63 t = 6.60 p < 0.001	0.93± 0.72 t = 6.86 p < 0.001

4	Restriction of movement	2.28±0.81	1.86±0.89	1.18±0.97	0.42± 0.50 t = 4.50 p < 0.001	1.10± 0.69 t = 8.55 p < 0.001
5	Stiffness	1.93±0.72	1.36±0.73	0.96±0.64	0.57± 0.50 t = 6.00 p < 0.001	0.97± 0.51 t = 10.05 p < 0.001
6	Crepitus	1.82±0.72	1.68±0.72	1.39±0.63	0.14± 0.36 t = 2.12 p < 0.05	0.43± 0.50 t = 4.50 p < 0.001
7	VAS score for pain	6.82±2.00	4.16±2.63	2.93±2.18	2.643±1.339 t = 10.45 p < 0.001	3.890±1.343 t = 15.38 p < 0.001

BT =Before treatment; AT = After treatment; FU=Follow-up; S.D.= Standard deviation; N= number of patients; VAS = Visual analogue scale

Table 3: Mean Change in the Severity of the Disease Algo Functional Lequesne Index (Knee)

	Severity of Disease, Mean score ± SD (N= 46)			**Difference, Paired 't' test**	
	BT	**FU1**	**AT**	**BT-FU1**	**BT-AT**
Severity of the disease	9.75 ± 4.16	6.20 ± 4.33	3.49 ± 1.16	3.30 ± 1.52 't' = 13.26 P < 0.001	6.33± 1.18 't' = 15.11 P < 0.001

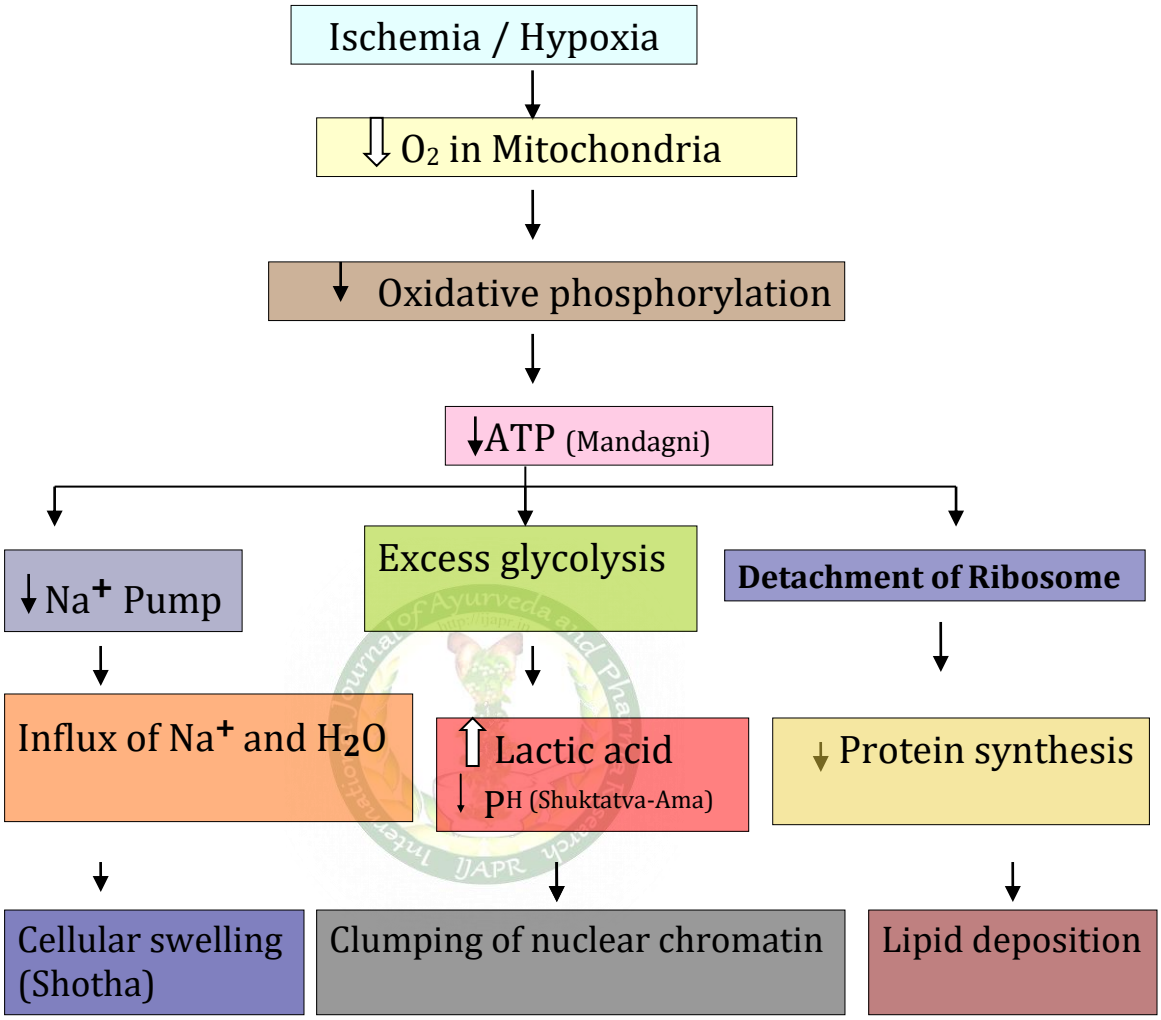
DISCUSSION

The *Asthi-Sandhi* disorders are raising day by day due to faulty diet, life style and abnormal postures, which leads to pain and disability. We have used an Ayurvedic compound drug for the healing of Osteoarthritis affected knee joints, with a view of role of '*Agni*' and '*Ama*' in the beginning of cell injury [11], especially for the cells involved in the formation of knee joint like cells of bone, cartilage, muscles, ligaments and tendons.

Total 50 patients were registered for the above clinical study but 4 patients have not turned up for complete follow up. Out of 50 patients 29 were female and 21 were male. Number of female patients are high probably due to high body weight and lack of physical movement in comparison to males. Mean change in each symptom has been analyzed separately and overall assessment of severity of disease has been also made. Pain (2.18±0.72), stiffness (1.93±0.72) and restriction of movements (2.28±0.81) are the three major complaints followed by crepitus (1.82±0.72), tenderness (1.43±1.10) and swelling (1.29±1.01). Visual analogue scale (VAS) for pain is also on the higher side (6.82±2.00) at the start of the treatment. The pain was settled to 1.64±0.87 after first follow up and was 1.18±0.72 at the end of the trial. Similarly swelling was 1.29±1.01 at the beginning but was reduced to 0.89±1.07 and 0.61±0.96 respectively after the trial. The other features too subsequently get subsided at the end of the trial. The results were highly significant to all the clinical features except the crepitus score which is just significant. It is evident from the statistical data that almost 50 to 75% improvement is observed at the end of the trial. The 't' and 'P' value are also highly significant at this stage. The combined therapy *(Sanjeevani vati + Dashamula kwath + Punarnava mandura + Yava kshara*) exhibited moderate to high degree of clinical improvement in reduction of pain, swelling, tenderness, restriction of movement, stiffness and crepitus. The initial score of severity of the disease was 9.75±4.16; which was reduced to 6.20±4.33 after 15 days and it was 3.49±1.16 at the end of the trial, this also gives a highly significant 't' and 'p' score i.e., 15.11 and p< 0.001 respectively. So, the effect of combined therapy was evaluated moderate to high in reducing severity of disease and VAS pain score. Some patient even told that they have felt relief in symptoms just on the 2nd day after starting the treatment.

According to *Vagbhatta* the root cause of all diseases is a state of low body fire (*Mandagni*), which will lead to the formation of byproducts, known as *Ama* (morbid factors). Weakened body fire (*Agni*) will not disintegrate the nutritive particles in to its minute form, so that undigested particles will change in to toxic substance (*Ama*) and can be termed as endotoxins. This *Ama* is slimy, putrid, thick, sticky and obstructive in nature. The basic living unit of the body is cell, and body composed of 100 trillion or more cells.

Basically, all cells follow the same rule for energy production. Mitochondria are powerhouse of the cell, and their number varies from hundred to several thousands in a cell[12]. Essentially all cellular functions would cease with low energy due to reduced mitochondrial function, which is very much similar to the concept of *Mandagni*. ATP (adenosine tri phosphate) is called as the energy currency of a cell; it is just like *Agni* (metabolic fire) which gives energy for all the metabolic activities of the body. Each high energy phosphate bond contains 12,000 calories of energy per mole of ATP. Important functions of ATP are membrane transport, synthesis of chemical compounds and muscular work [13].



Schematic pathway of cell injury

Cell injury begins right from the insult by hypoxia and ischemia, infectious agents, immunologic reactions, chemical agents, nutritional imbalances, physical injury, genetic defects and aging and their consequences will lead to the deranged cellular functions[14]. The consequences are ATP depletion, generation of reactive oxygen species, loss of calcium homeostasis, defects in plasma membrane permeability, mitochondrial damage and diminished protein synthesis. By far ischemia or hypoxia is the most common type of cell injury in clinical medicine. It will result in to marked reduction in the generation of intracellular ATP, which will further lead to reduced activity of plasma membrane driven Na^+ pump with the subsequent accumulation of Na^+ and water inside the cell i.e. cellular swelling. Anaerobic glycolysis will also result in the accumulation of lactic acid from the pyruvic acid pathway, thus lowering the intracellular pH. This decreasing ATP and pH levels causes ribosomes to detach from the endoplasmic reticulum and polysomes to dissociate into monosomes with a resultant reduction in protein synthesis [15].

On the basis of analysis based on reverse pharmacology, it is clear that there are two main factors to produce a cell injury one is diminished ATP production and other is generation of metabolic byproducts. Diminished ATP production is similar to *Mandagni* and formation of metabolic byproducts is similar to formation of *Ama*, both of these events are important to cause cell injury and related consequences. To reverse the pathogenesis, we select a medication that has the property to improve the metabolic fire, clears the obstructed *Srotas* (Channels of circulation), reduces the swelling and other signs of inflammation and has the property to neutralize the acidic pH. Further on the evaluation of the pharmacological action of the drugs used it can be assumed that the use of *Sanjeevani vati* and *Dasamula*

kwatha will enhance the ATP production at mitochondrial level (*Agni vardhak*), clears the obstructed *Srotas* (*Sroto shodhak*) and suppresses the formation of lactic acid and other metabolic by products (*Ama pachana*). Whereas cellular swelling (*Shotha*) and a low cellular pH (*Suktatva*) are the two main consequences of cell injury, the diuretic drug *Punarnava mandura* has decrease the swelling while strong alkaline material *Yava kshara* has neutralizes the excessive acidic pH environment within and outside the cell.

Photo of the Trial drugs

CONCLUSION AND RESULT

The above clinical study has shown excellent result on the management of Osteoarthritis of Knee joint, many patients declined knee replacement surgery and has good movement with Ayurveda medication. The drugs *Sanjeevani vati*, *Dashamula kwatha, Punarnava mandura* and *Yava kshara* are very common Ayurveda drugs and available on all major Ayurveda stores. Not a single patient has reported any unpleasant action of medication. So, it can be concluded that the concept of general metabolic fire *Agni* can be correlated with the ATP in modern medicine. As per modern pathology almost all cellular injury begins from a low cellular ATP level i.e. ischemic cell injury. Similarly in Ayurveda, behind causation of every disorder "*Agni*" is claimed to be the main culprit i.e., *"Rogah sarveapi mandagne".* Lactic acid is the byproduct of cell metabolism and can be correlated with *'Ama'* in this case. Designed drug have shown excellent response over the patients of *Sandhivata* (osteoarthritis), the symptoms and disease severity score were reduced significantly.

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