Ancient Science of Life Vol : XXIII(1) July, August, September 2003 Pages 22 - 34

CLINICAL EVALUATION OF NIRGUNDI TAILA IN THE MANAGEMENT OF SANDHIVATA

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Received : 28-12-2002 Accepted: 10-04-2003

INTRODUCTION

Osteo-arthritis is a commonest among various articular disorders. It is chronic affection of synovial joints and is related to ageing process of tissues. It is not a single disease. Rather it is the end result of a variety of patterns of joint failure. To a greater or lesser extent it always characterized by both degeneration of articular cartilage and simultaneously proliferation of new bone, cartilage and connective tissue.

Osteo – arthritis is classified as primary if the aetiology is unknown and secondary when degenerative joint changes occur in response to a recognizable local or systemic factor. In Ayurveda the disease entity Sandhivata has been described in reference to the description of various pathological conditions caused by vata under ***vatavyadi. Charka*** has described the ***swelling in Sandhigata vata*** resembling air filled bag on touch with pain and restricted movement. Further ***Sushruta*** has added that along with swelling and pain there is complete disorganization of joints leading to severe disabilities.

Besides the above diseases some symptoms like joint pain, loss of function and strength of the joint and loss of flesh etc are also manifested when aggravated ***vayu*** located in ***majja and Asthivaha srotas.***

There are innumerable descriptions of medications covering various routes of administration and their actions are not yet evaluated with the advancement of the knowledge. Regarding this disease and its management scientists are trying to ascertain the positive source of remedies for many ailments including ***Sandhivata*** still posses and unsolved process to be handled carefully.

So the study entitled “Clinical evaluation of ***Nirgundi Taila*** in the management of ***Sandhivata”*** was planned to carry out.

MATERIALS AND METHODS:

This is a case control clinical study and comparison with known standard drug, carried out at P.G. Department of Kayachikitsa, Gopabandhu Ayurveda Mahavidyalaya, Puri during the period from December 1997 to September 1998. The cases resembling ***sandhivata*** reported at the out patient department at GAM Puri opted for under trial were screened and among them 32 cases were registered for the present study availing the criteria of selection.

SELECTION OF CASES :

The selected cases were asked to submit their written consent. The selection was based on availability of following cardinal clinical features.

i. Age above 40 years in either sex.
ii. Swelling of the joints
iii. Stiffness of the joints
iv. No pain on reset of the confined joint/joints
v. Loss of function of the joint/joints
vi. Crepitus and small effusion.

EXCLUSION CRITERIA:

Patients having below 40 years of age, rheumatoid arthritis, infective arthritis, gout and other joint diseases, hypertension, renal pathology, diabetes, pregnancy, lacation, history of carcinoma, reduction of joints space on x-ray.

STUDY DESIGN:

No. of patients : 32

Trial group : Group - I - 12 cases
Group - II - 12 cases

Control group : Group - III - 08 cases

Duration of study : 28 days

Drug : Nirgundi Taila, Diclophenac Sodium.
Dose : For Group I - Nirgundi Taila massage 20 ml. daily.
Group II - Nirgundi Taila 20 ml. for massage.
And 5 ml. to intake daily.
Group III - Diclophenac Sodium 50 mg thrice daily.

DIET AND REGIMEN ADVISED:

The patients were advised to take newly produced til and wheat, one year old ***Sali*** and ***sasthi*** rice, vegetables like snake guard, brinjal, drumstick, garlic etc., meat juice of aquatic and domestic animals, fruits like dadima-mango, riped palmex, greens as ***ganda prasarini, gokshura*** etc., milk of cow goat and buffalo.

The patients were also advised to avoid ***chinta, ratrijagarana, vegadharana, anasana*** etc., rice of bamboo, koda, water of river and pond, green gram, black gram, milk of donkey, dried meat, traveling on horse and elephant, walking, sexual intercourse and completely bed rest should be avoided.

PREPARATION OF TRIAL DRUG:

The drug was prepared according to the Principal of Ayurvedic formulary of India and ingredients were taken as described in Vata Vyadhi chapter of Charaka Samhita.

CLINICAL ASSESSMENT OF CASES:

The clinical assessment includes noting of changes of the following subjective and objective signs and symptoms as mentioned in assessment scale.

SUBJECTIVE SYMPTOM:

Pain (Sandhi sula) – As defined under assessment scale.

OBJECTIVE SYMPTOMS:

a. Stiffness - As defined under assessment scale.
b. Tenderness - As defined under assessment scale.
c. Range of Movement - As defined under assessment scale.
d. Walking time - As defined under assessment scale.
e. Crepitation - As defined under assessment scale.

TOXICITY PROFILE:

During the course of trial attention was given to note the development of any adverse effects, intolerance, toxicity, etc.

ASSESSMENT SCALE:

The following pattern of Assessment Scale was made for estimation of percentage of relief. PAIN: Pain is a subjective feeling, hence an accurate measurement of pain become very difficult. Response of stimulation of pain also differs from person to person. However for the present study following gradation of scales was adopted for measuring the intensity of pain.

G – 0	Absent or no pain
G I – Mild	Perception of pain, but not interfering his normal activity
G II – Moderate	Perception of pain, interfering normal activities and looking painful.
G III – Severe	Excessive pain, associated with painful cries, agoinising look and interfered normal activities.

RESTRICTED JOINT MOVEMENT:

"HANTI DANDHIGATA SANDHIN" is the cardinal symptom of ***sandhivata hanti*** means loss of joint function. Besides other functions clinically it is evidently found that FLEXION is the first movement to go off. For the present study flexion of joint was taken for restricted movement. Gradation of the different joints as under.

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		Knee	Hip	Sholder	Spine
G 0	**Normal range of flexion**	**130^0**	**90^0**	**90^0**	**5cm**
G I	**Mild**	**120^0-130^0**	**80^0-90^0**	**80^0-90^0**	**4cm-5cm**
G II	**Moderate**	**60^0-119^0**	**40^0-79^0**	**40^0-79^0**	**2cm-4cm**
G III	**Severe**	**0^0-59^0**	**0^0-39^0**	**0^0-39^0**	**0cm-2cm**

The range of joint movements were measured with the help of specially designed device for measuring the angles, the A side of apparatus was placed on the joint line which corresponds to 180 degrees, then B side of the apparatus was moved to the side of maximum possible joint movement. Now the angle apparatus was measured with the help of a protractor.

STIFFNESS :- (Early morning stiffness = EMS)

Stiffness was recorded on the basis of duration of time and graded as under

G	0	Absence of stiffness
G I	Mild	30 min
G II	Moderate	31 min to 60 min.
G III	Severe	61 min and above.

CREPITATION:

Structural abnormally causes crepitus which is emphasized in criteria for measuring OA. Gradation scale for measuring crepitus as under :-

G 0		Absent or no crepitus
G I	Mild	Crepitus complained by patient but not felt on examination
G II	Moderate	Crepitus felt on examination.
G III	Severe	Crepitus felt and heard on examination.

TENDERNESS:

Tenderness was evaluated on the basis of standard criteria of “RAI” as under

G 0		Absent or no tender
G I	Mild	Tender
G II	Moderate	Tenderness and wincing.
G III	Severe	Tenderness, wincing and withdrawal.

WALKING TIME:

Grading of walking speed for 20mts. distance without support. For this purpose patients were asked to walk 20 mts distance in a straight line with maximum possible of speed. The time taken to cover 20 mts were recorded with help of stop watch in seconds. Male patients were asked to wear underpants and female patients were asked to lift saree up to the knee joint and then walk with naked feet.

G 0	Normal	20 mts. In 20 sec
G I	Mild	20 mts. In 30 sec
G II	Moderate	20 mts. In 40 sec.
G III	Severe	20 mts. In 50 sec.

(Patients with OA of knee, hip and spine were only included for walking time assessment. Those with other joint affection, those who are bed ridden and those walking with the help of certain aids were excluded from this criteria of assessment).

RESULT

On assessment of result in trial group – 1 after 14 days of treatment no patient got maximum improvement, 25% got moderate improvement, 33.33 % got mild improvement and no improvement was observed in 41.67% of cases. But after 28 days of treatment 8.33% patients got maximum improvement, 16.67% got moderate improvement, 66.67% got mild improvement and 8.33% got no improvement.

In trial group – 2 after 14 days of treatment no patients were observed in maximum improvement. 16.67 % got moderate improvement, 41.67 % got mild improvement and another 41.67 % got no improvement. After 28 days of treatment 16.67% patients got maximum improvement, 41.67 % each got moderate and mild improvement respectively.

In control group 87.5% of patients got maximum improvement and 12.5% got moderate improvement after a period of 14 days treatment and after completion of 28 days treatment 100% got maximum improvement.

From the above response it is evident that the response is elevated with ***pana*** and ***Abhyanga*** treatment and it is comparatively more effective than other two groups. The drug for ***pana*** and ***Abhyanga*** seems to be effective as ***balya, vatahara*** and ***vedana stapaka.***

Comparatively the trial drug seems to be much more effective than control drug. The reason may be due to trial drug having nutritive effect, so to get the maximum improvement it requires more duration of treatment and the possibility of reoccurrence of the disease is less.

Control drug ***(diclophenac sodium)*** exhibited with shorter span of time limit involving certain risks like acidity, gastric discomfort etc. The effect on the cardinal symptoms obtained through the control drug was not sustained and satisfactory. It is for the reason that symptoms like pain could be controlled without any repairment to the bone surface. Soon after withdrawal of drug there was appearance of the sign and symptoms again.

TOXICITY:

We could not observe any toxic effect of trial drug. Only two patients were complaining of coated tongue and tastelessness for sometimes after intake of Taila. In case of control group some patients were complaining of loss of appetite after 14 days of treatment.

SUMMARY & CONCLUSION:

It has been statistically analaysed that the application of drug -1 *(Abhyanga)* is significantly effective to reduce pain, stiffness, restricted movement, tenderness and walking time after 14 days of treatment. But after 28 days treatment it becomes highly significant. In case of crepitation it was insignificant after 14 days treatment and becomes highly significant after 28 days of treatment.

After 14 days of treatment in trial group- 2 drug showed significantly effective to reduce all cardinal sign-symptoms and becomes highly significant after 28 days of treatment. In case of crepitation it was highly significant after 14 days of treatment.

In control group of effectives of the drug was highly significant after 14 days treatment.

As trail drug has no toxic effect on every sign and symptoms it may be taken for better treatment for Sandhivata.

MAJOR FINDINGS:

Approximately 60% patients belonged to middle age groups (40-60 years) and 40% belonged to old age group. The males were 75% and females 25%.

More than 80% of the patients used to take ***ruksha*** and ***sita ahara.***
Approximately 69% of patients were having ***krurakostha.***
More than 80% of the patients were having ***krusha*** and ***swabhavika akriti.***
Approximately 69% patients were having ***visamagni.***
Approimately 66% patients were having ***vata prakruti*** and ***vata nadi.***

The treatment for a period of 28 days could derive satisfactory improvement in most of the cardinal sign and symptoms observed among trial group – 1 and 2 patients.

Keeping in view of the relief status and percentage of recovery the trial drug can be accepted as a therapeutic regimen in case of Sandhivata. However duration of more than 28 days may be taken so as to obtain maximum benefit.

Among the control group patient's recovery was faster in all cardinal symptoms but sustainable. The disadvantage like acidity, abdominal discomfort were observed with the control drug. There was relapse soon after the drug was withdrawn. The Victims were observe with craziness for drug, which established the drug being unsuitable.

The improvement obtained from massage and oral use of ***Nirgundi Taila*** was demonstrated more complementary and acknowledgeable than the massage alone.

There is no apprehension left in prescribing the drug in case of ***Sandhivata*** of various severity for a period of 28 days.

The above treatment was demonstrated without any adverse effect or intolerance thus declared safe.

THE CLINICAL AND STATISTICAL FINDINGS ARE AS FOLLOWS:

Sl. No.	**Clinical Assessment**	**TRIAL GROUP -1**		**TRIAL GROUP – 2**		**Control Group**	
		AT-14	**AT-28**	**AT-14**	**AT-28**	**AT-14**	**AT-28**
1	Maximum Improvement	00	01	00	02	07	08
2	Moderate Improvement	03	02	02	05	01	00
3	Mild Improvement	04	08	05	05	00	00
4	No Improvement	05	01	05	00	00	00

The disease ***Sandhivata*** is not fatal but the working capacity of the individual is declined.

It is concluded that ***snehana(Abhyanga*** and ***pana)*** has definite role on ***Sandhivata*** to induce some benefits up to satisfaction.

Though the drugs having this ingredient may not provide a miraculous change in the treatment of ***Sandhivata*** at present, the present work focuses on a basic data and documentation of ideas to the future researchers to try this drug in combination with internal medicines which may evolve more satisfactory recipe for the treatment of Sandhivata.

Further study on the large number of patients is invited for the establishment of medicine for its wider use.

STATISTICAL ASSESSMENT

For the purpose of statistical assessment the mean ± S.D. before treatment of each sign/symptoms has been compared with mean ± S.D. value after treatment. Paired t-test is used for the purpose of test of significance. The effectiveness of the drug is assessed through the P-value.

Table No.1
Showing Statistical analysis showing the effectiveness of T.D. (1) to different sign/symptoms.

Sl. No.	Sign/Symptoms	Treatment	Mean ± S.D	d.f.	t-Value	P-Value	Remarks
1	Pain	B.T.	2.67 ± 0.47	11	3.93	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
2	Stiffness	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
3	Restricted Movement	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
4	Crepitation	B.T.	1.75 ± 0.72	11	1.45	<0.05	Significant
		A.T. (14)	1.58 ± 0.49		10.56	<0.001	Highly
		A.T. (28)	0.58 ± 0.49				Significant
5	Tenderness	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.76	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
6	Walking Time	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant

Tabulated t-values are as follows $t_{1\%11} = 3.11$, $t_{0.1\%11} = 4.59$, $t_{5\%11} = 2.20$

Table No.2
Showing Statistical analysis showing the effectiveness of T.D. (2) to different sign/symptoms.

Sl. No.	Sign/Symptoms	Treatment	Mean ± S.D	d.f.	t-Value	P-Value	Remarks
1	Pain	B.T.	2.67 ± 0.47	11	3.93	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
2	Stiffness	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant
		A.T. (14)	2.08 ± 0.76		5.67	<0.001	Highly
		A.T. (28)	1.5 ± 0.76				Significant
3	Restricted	B.T.	2.67 ± 0.47	11	3.39	<0.01	Significant

	Movement	A.T. (14) A.T. (28)	2.08 ± 0.76 1.5 ± 0.76		5.67	<0.001	Highly Significant
4	Crepitation	B.T. A.T. (14) A.T. (28)	1.75 ± 0.72 1.58 ± 0.49 0.58 ± 0.49	11	1.45 10.56	<0.05 <0.001	Significant Highly Significant
5	Tenderness	B.T. A.T. (14) A.T. (28)	2.67 ± 0.47 2.08 ± 0.76 1.5 ± 0.76	11	3.39 5.76	<0.01 <0.001	Significant Highly Significant
6	Walking Time	B.T. A.T. (14) A.T. (28)	2.67 ± 0.47 2.08 ± 0.76 1.5 ± 0.76	11	3.39 9.63	<0.01 <0.001	Significant Highly Significant

Tabulated t-values are as follows $t_{1\%11} = 3.11$, $t_{0.1\%11} = 4.44$

Table No.3

Showing Statistical analysis showing the effectiveness of C.D to different sign/symptoms.

Sl. No.	Sign/Symptoms	Treatment	Mean ± S.D	d.f.	t-Value	P-Value	Remarks
1	Pain	B.T. A.T. (14) A.T. (28)	2.67 ± 0.48 0.12 ± 0.33 0 ± 0	11	9.02	<0.001 <0.001	Highly Significant Highly Significant
2	Stiffness	B.T. A.T. (14) A.T. (28)	2.67 ± 0.48 0.12 ± 0.33 0 ± 0	11	9.02	<0.001 <0.001	Highly Significant Highly Significant
3	Restricted Movement	B.T. A.T. (14) A.T. (28)	2.62 ± 0.48 0.12 ± 0.33 0 ± 0	11	9.02	<0.001 <0.001	Highly Significant Highly Significant
4	Crepitation	B.T. A.T. (14) A.T. (28)	1.75 ± 0.66 0.12 ± 0.48 0 ± 0	11	6.95	<0.001 <0.001	Highly Significant Highly Significant
5	Tenderness	B.T. A.T. (14) A.T. (28)	2.62 ± 0.48 0.12 ± 0.33 0 ± 0	11	9.02	<0.001 <0.001	Highly Significant Highly Significant
6	Walking Time	B.T. A.T. (14) A.T. (28)	2.62 ± 0.48 0.12 ± 0.33 0 ± 0	11	9.02	<0.001 <0.001	Highly Significant Highly Significant

Tabulated t-values are as follows : $t_{0.1\%7} = 5.41$

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