



# Evaluation of the effect of patrapottali sveda, Tailadhara externally and panchatiktaka Ksheera and ghruta internally in the Management of sandhivata(osteo arthritis-knee)

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## ABSTRACT

Arthritis being a major problem faced worldwide is a throbbing issue existing now. Out of the many types of arthritis, osteoarthritis is the major form. This is commonly seen in later stage of life. Taking into consideration the great disability in osteo arthritis a study was conducted to evaluate the effect of patrapottali sveda, tailadhara externally and panchathiktaka ksheera ghruta for internal administration to manage the osteo arthritis knee.

**Methodology** - In the present study 60 participants having osteo- arthritis of Knee and patients satisfying the inclusion criteria were recruited to the study. The total time period of the study was 60 days with 21 days of IP treatment and 24 days of OP treatment. The assessments were done on baseline and followed periodically on 21<sup>st</sup>, 45<sup>th</sup> day and 60<sup>th</sup> day. The 21 days of treatment, included Valuka sweda for 1-3days followed by internal administration of Panchatiktaka ksheera kwatha and Panchatiktaka guggulu ghruta along with Pradesika Patrapottali sweda for 7 days. In the next 7 days, internal administration of Panchatiktaka ksheera kwatha and Panchatiktaka guggulu ghruta along with Pradesika taila dhara with Ketakeemooladi taila was done. In the next 4 days, internal medicines only were continued and given complete rest. After completion of 21 days of IP treatment, patient was treated on OP level for further 24 days by the administration of internal medicines along with self external application of Ketakeemooladi taila on affected knee joint. The follow up for the completed cases were done after 15 days.

**RESULTS** - The responses of the treatment were satisfactory. The treatment results showed significant improvement in the functional ability of the patients. The functional parameters, VAS, WOMAC scale and SF36 showed significant improvement. The laboratory parameters used to evaluate the liver and kidney functions did not show any significant change that indicates the prescribed treatment is safe.

**CONCLUSION** - The treatment protocol was made for osteo arthritis.

**KEYWORDS** – Osteoarthritis knee, valuka sweda, panchatikta ksheera, pradeshika patrapotali sweda, ketakeemooladi thaila

## Introduction

Osteoarthritis is a chronic degenerative joint disease and is the most common form of arthritis. Most of this disability burden is attributed to the involvement of the hips or the knees. It progress slowly with usual signs and symptoms being pain, enlarged and deformed joints as well as the limitation range of motion<sup>1</sup>. In the present day, living conditions especially the improper food habits, stress and climatic variations are contributing factors for the increased incidence of osteo- arthritis of Knee in the society<sup>2</sup>. Hence, this study has been designed to evaluate the efficacy of classical methods of Ayurvedic intervention in the management of osteo- arthritis of Knee and to prove the safety of the therapy<sup>3</sup>.

## MATERIALS AND METHODS

The present study is prospective, open label, not randomized, single group clinical trial involving the classical line of treatment in the management of chronic joint disorders viz Osteoarthritis knee. The setting of the study was inpatient (IP) and outpatient (OP) department levels of Vaidyaratnam Ayurveda Foundation, Centre of Excellence for Ayurvedic Management of Chronic Joint Disorders, Ollur, Thrissur, Kerala and it was under the research program allotted by Ministry of AYUSH, Govt. of India

Sixty participants of osteo- arthritis of Knee patients satisfying the inclusion criteria were recruited to the study. Exclusion criteria include patient with Grade IV Kellgren & Lawrence Radiological scale, history of trauma/fractured joint/ recurrent dislocation/surgical/diagnostic intervention with reference to the affected joint(s), co-morbidities

Assessment of response of treatment was made before treatment, after treatment and after fifteen days of follow up, on the basis of structural and functional ability regained by the participant, by giving numerical scores for individual symptoms (Lakshanas) and also by comparing the laboratory investigations. Laboratory investigations were hemogram, urine routine examination; biochemistry for serum glucose, liver function test, and renal function test such as uric acid, serum creatinine, blood urea, CRP, ASO, , X- ray of the knee joints and ECG<sup>4</sup>. The assessments were done on baseline and followed periodically on 21<sup>st</sup>, 45<sup>th</sup> day and 60<sup>th</sup> day. The data generated in the study on clinical parameters, laboratory investigations before and after the treatment are tabulated & analyzed using appropriate statistical methods namely paired t- test and repeated measures ANOVA<sup>5</sup>.

## Treatment and Medicines

Course of treatment includes both inpatient and outpatient level. IP treatment was for 21 days and OP treatment was for 24 days. Out of the 21 days of treatment, initial 1-3 days was Washout period during which Valuka sweda was done. It was followed by internal administration of Panchatikta ksheera kwatha and Panchatikta guggulu ghrita along with Pradesika Patrapottali sweda for 7 days. In the next 7 days<sup>6</sup>, internal administration of Panchatikta ksheera kwatha and Panchatikta guggulu ghrita along with Pradesika taila dhara with Ketakeemooladi taila was done. In the next 4 days, internal medicines only were continued and given complete rest. After completion of 21 days of IP treatment, patient was treated on OP level for further 24 days by the administration of internal medicines along with self external application of Ketakeemooladi taila on affected knee joint. The follow up for the completed cases were done after 15 days<sup>7</sup>.

Table – 1

## Treatment regimen (Dose, form and route of administration)

IP treatment			
Days	Duration	Internal	External
1-3	3 days	Washout Period	Valuka Sveda
4-10	7 days	Panchatiktaka ksheera kwatha (96 ml BD) before food (6am,6pm) Pancha tikta guggulu ghruta (10gm BD)after food (9am, 9pm)	Pradesika Patra pottali Sveda
11-17	7days	Panchatiktaka ksheera kwatha (96 ml BD) before food (6am, 6pm) Pancha tikta guggulu ghruta (10gm BD) after food (9am, 9pm)	Pradeshika Taila Dhara with Kethakeemooladi Taila
18-21	4 days	Panchatiktaka ksheera kwatha (96 ml BD) before food (6am, 6pm) Pancha tikta guggulu ghruta (10gm BD) after food (9am, 9pm)	Rest

OP treatment			
Days	Duration	Internal	External
22-45	24 days	Panchatiktaka ksheera kwatha (96 ml BD) before food (6am,6pm) Pancha tikta guggulu ghruta (10gm BD) after food (9am, 9pm)	Local Application of Kethakeemooladi Taila
45-60 (follow up)	15 days	-	-

The raw medicines were identified and undergone strict quality control evaluation as per the procedures described in Ayurvedic Formulary of India in the laboratory of Vaidyaratnam Oushadhasala Pvt. Ltd. And Care Keralam and prepared in the pharmacy attached with Vaidyaratnam Oushadhasala Pvt Ltd, Thrissur according to the SOP.

**OBSERVATIONS –**

**Table 2**  
**Distribution of Patients According Age and Gender**

Age group	Male		Female		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
35-45	0	0	3	7	3	5
46-55	7	47	22	49	29	48
56-65	8	53	20	44	28	47
Total	15	100	45	100	60	100

**Table 3**  
**Distribution of Patients with Socio-Demographic Characters wise**

Characteristics	Category	Frequency	Percentage
Marital status	Married	51	85.0
	Widow	9	15.0
Educational status	Illiterate	1	1.7
	Lower School	13	21.7
	High School	30	50.0
	Graduate	14	23.3
	Post graduate	2	3.3
Occupation	Manual Labour	17	28.3
	Driver	1	1.7
	House hold work	29	48.3
	Others	13	21.7
Socio economic status	Above poverty line	43	71.7
	Below P0verty line	17	28.3
Habitat	Urban	8	13.3
	Semi Urban	35	58.3
	Rural	17	28.3
Religion	Hindu	48	80.0
	Christian	7	11.7
	Muslim	5	8.3

**TABLE 4**  
**CHIEF COMPLAINTS**

Chief complaints	Frequency	Percentage
JP at Rest	23	38
JP at Movement	60	100
Restrictions	41	68
Crepitus	59	98
Weakness	42	70
Swelling	43	72
Enlargement	39	65
Stiffness	56	93
Tenderness	55	92
Warmth	22	37

**Table 5**  
**CHARACTERISTICS**

Characteristics	Category	Frequency	Percentage
Duration of illness	<1years	7	11.7
	1-2years	14	23.3
	2-5years	18	30
	>5 years	21	35
Onset of disease	Acute	9	15.0
	Insidious	51	85.0
Pre episodes	No	10	16.7
	Yes	50	83.3
Any aggravating factor	No	13	21.7
	Yes	47	78.3
Reliving factor	No	7	11.7
	Yes	53	86.7
History of previous illness	No	48	80.0
	Yes	12	20.0

**TABLE 6**  
**MUSCULO-SKELETAL INSPECTION**

Characteristics	Category	Inspection			
		Right		Left	
		Frequency	Percentage	Frequency	Percentage
Gait	Normal	39	65.0	37	62
	Abnormal	21	35.0	23	38
Deformities	Normal	56	93.3	54	90
	Abnormal	4	6.7	6	10
Inflammation	Absent	32	53	39	65
	Present	28	47	21	35
Twitch	Absent	43	72	46	76
	Present	17	28	14	24
Swelling	Absent	21	35	27	45
	Present	39	65	33	55
Muscle Wasting	Absent	60	100	60	100
Asymmetry	Absent	60	100	59	98
	Present	0	0	1	2
Redness	Absent	60	100	60	100
Scars in and around the joints	Absent	60	100	59	98
	Present	0	0	1	2

**TABLE 7**  
**PALPATION**

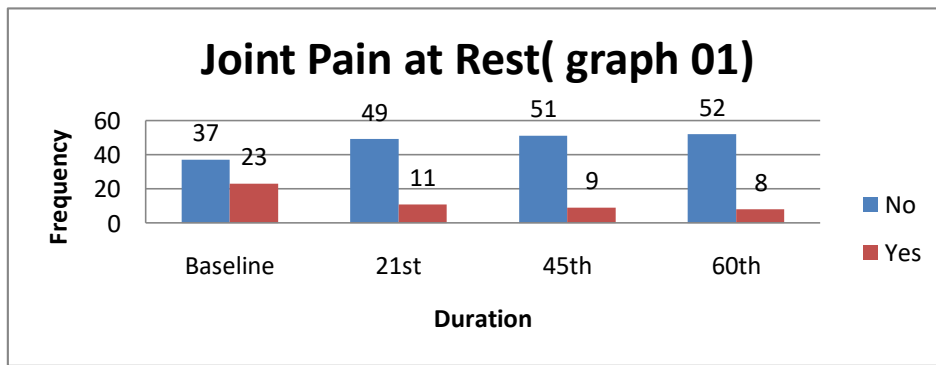
<b>Palpation</b>					
<b>Characteristics</b>	<b>Category</b>	<b>Right Knee</b>		<b>Left Knee</b>	
		<b>Frequency</b>	<b>%</b>	<b>Frequency</b>	<b>%</b>
Warmth	Absent	37	62	42	70
	Present	23	38	18	30
Tenderness	Absent	10	17	13	22
	Present	50	83	47	78
Swelling	Absent	21	35	27	45
	Present	39	65	33	55
Crepitus	Absent	6	10	9	15
	Present	54	90	51	85
Active movement	Normal	26	43	33	55
	Abnormal	34	57	27	45
Passive movement	Normal	27	45	33	55
	Abnormal	33	55	27	45
Muscle spasm protective	Absent	54	90	53	88
	Present	6	10	7	12

**Table 8**  
**MUSCLE POWER**

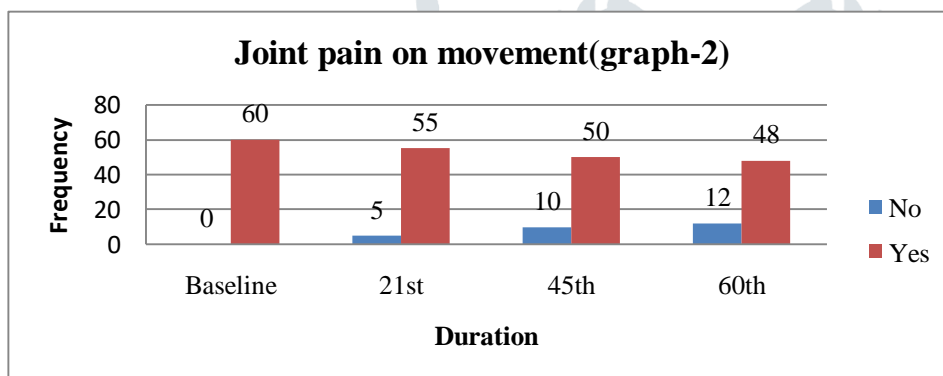
<b>Muscle power</b>					
<b>Characteristics</b>	<b>Category</b>	<b>Right Knee</b>		<b>Left Knee</b>	
		<b>Frequency</b>	<b>%</b>	<b>Frequency</b>	<b>%</b>
Knee Flexor	Normal	57	95	57	95
	Abnormal	3	5	3	5
Knee Extensor	Normal	56	93	56	93
	Abnormal	4	7	4	7

**TABLE 9**

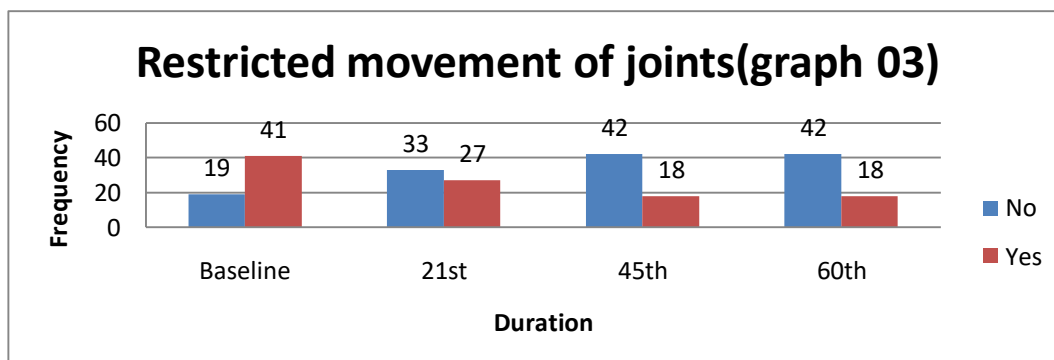
	Minimum	Maximum	Mean	Std. Deviation
Womac RT	0	85	37.72	20.881
Womac LT	0	82	37.83	23.177
SF36	78	605	324.73	160.394

**RESULTS - .****JOINT PAIN AT REST**

In case of Joint pain at rest, statistical significant result was not obtained on 21<sup>st</sup> day and on 60<sup>th</sup> day when compared with baseline in Grade 1 patients, but statistical significance ( $p < 0.05$ ) was obtained on 45<sup>th</sup> day in Grade 1 patients. Statistical significance ( $p < 0.05$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day when compared with baseline in Grade 2 patients. In Grade 3 patients, statistical significance was obtained on 21<sup>st</sup> day ( $p < 0.01$ ), 45<sup>th</sup> day ( $p < 0.05$ ) and 60<sup>th</sup> day ( $p < 0.05$ ) when compared with baseline

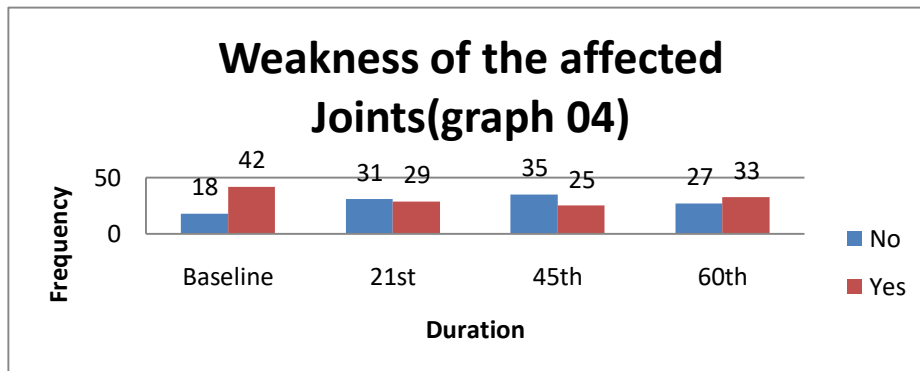
**JOINT PAIN ON MOVEMENT**

In case of Joint pain on movement, Crepitus, swelling, joint stiffness and Bony tenderness, statistical significance was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day ( $p < 0.01$ ) in comparison with baseline in Grade 1, Grade 2 and Grade 3 patients

**RESTRICTED MOVEMENT OF JOINTS**

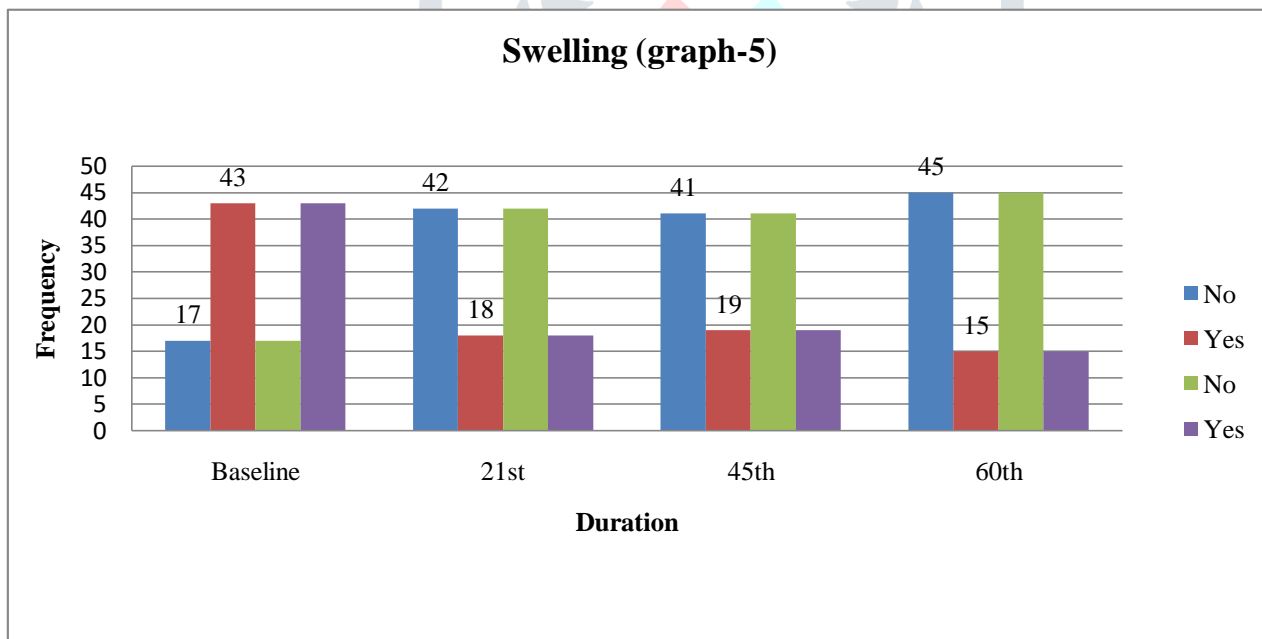
In case of Restricted movements of joints, statistical significance was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day ( $p < 0.01$ ) in comparison with baseline in Grade 1 and Grade 3 patients while statistical significance ( $p < 0.01$ ) was obtained on 21<sup>st</sup> and 45<sup>th</sup> day and 60<sup>th</sup> day ( $p < 0.05$ ) in Grade 2 patients.

### WEAKNESS OF THE AFFECTED JOINTS



In case of Weakness of affected joints statistical significance ( $p < 0.01$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day when compared with baseline in Grade 1 and Grade 3 patients while statistical significance ( $p < 0.05$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day when compared with baseline in Grade 2 patients.

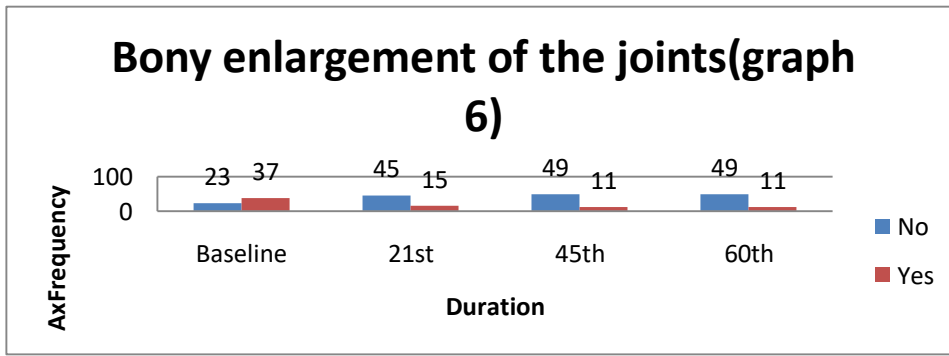
### SWOLLEN JOINTS



Graph 5 shows the comparison of visual analogue score for swollen joints among different time period using Wilcoxon sign rank test. A significant decrease in VAS was found from first day to 21<sup>st</sup> day 45<sup>th</sup> day and 60<sup>th</sup> day

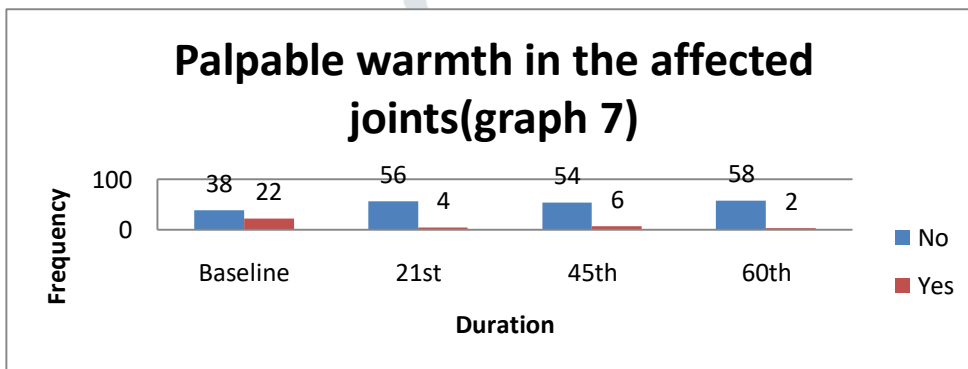


**BONY ENLARGEMENT OF THE JOINTS**

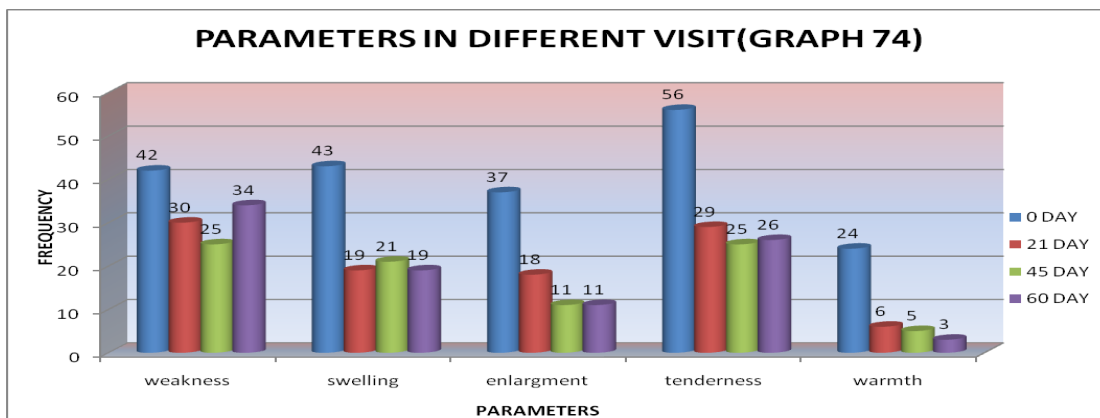


In case of Bony enlargement of the joints, statistical significance( $p < 0.01$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day in comparison with baseline in Grade 1 patients and Grade 3 patients while statistical significant result ( $p < 0.05$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day when compared with baseline in Grade 2 patients.

**PALPABLE WARMTH IN THE AFFECTED JOINTS**



In case of Palpable warmth in affected joints, statistically significant result ( $p < 0.05$ ) was obtained on 21<sup>st</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> day in comparison with baseline in Grade 1 patients. Statistically significant result( $p < 0.05$ ) was obtained only on 21<sup>st</sup> day and 60<sup>th</sup> day in comparison with baseline in Grade 2 patients. In Grade 3 patients, statistically significant result( $p < 0.01$ ) was obtained on 21<sup>st</sup> day and on 60<sup>th</sup> day and significance( $p < 0.05$ ) was obtained on 45<sup>th</sup> day when compared with baseline in Grade 3 patients.



## Discussion

In this study a modified protocol based on the principles of management of “asthisandhikshaya”(degenerative condition of joint cartilage and associated structures) has been tried to evaluate its efficacy and safety in sandhivata ( osteoarthritis knee).The diagnostic criteria used during the selection of cases was approved for osteoarthritis and the assessment criteria was accepted internationally such as visual analogue pain rating scale, Womac score, SF 36 questionnaire, grading for the chief complaints of the disease etc. The safety of the treatment procedures were also assessed with reference to the lab investigations report taken before and after treatment.

According to Ayurvedic principles Snehana (internally and externally) and Snigdha sveda are the line of treatment for Dhathukshaya janya(degenerative) vatavydhi. All the treatment procedures included in this protocol are mainly aimed at Vata samana (pain relief) and brumhana(regenerative)<sup>8</sup>.

The observational data collected from the study subjects didn't provide any significant information as the sample size was small but all the observations were agreeing with the studies conducted earlier. The *prakriti* wise classification showed that the majority of patients studied in this study belongs to *pitha kapha* group who are suspected to be prone to the early occurrence of the degenerative disease

Prior to the main procedure a short course of amapachana measures by the application of valuka sveda for three days was given to rule out ‘amatva’ likely to be present locally. It is usually advised before the administration of snehana where vata is associated with kapha which is being evaluated properly. Followed by this procedure patrapindasveda was started which is basically svedana but snehana also due to the addition of certain amount of sneha during its preparation and application. This swedana procedure with heated bolus bags with proper medicines, causes for the increase of temperature that stimulate the sympathetic activities. Because of increased sympathetic activities hormones like Epinephrine, Norepinephrine, Cortisol, Thyroid hormones are released which accelerate the metabolic rate. As a result of increased metabolism, there is an increased demand for oxygen and nutrients which are supplied through the enhanced blood flow locally resulted due to vasodilatation. Simultaneously waste products and metabolites are also removed. All these process will clear the ama(obstruction in the channels) and it will help to reduce swelling, stiffness and pain.

Regarding the response of treatment, it is to be highlighted that the most distressing symptoms of the disease, pain in rest and movement, joint stiffness, crepitus, swelling restricted movements etc are relieved significantly with the initial course of IPD level treatment which includes swedana-pathrapindasweda- followed by snehana-taila dhara- along with internal medications. Further it may be noted that all the positive changes were sustained or progressively improved during the second course of OPD level treatment with external application of taila and internal medications already followed. But few of them have reported mild pain on moving and walking during the follow up period and it may be due to house hold activities that putting strain to the joints which was completely restricted during the treatment period.

*Kethakeem ooladi taila* is indicated for *Asthigathavata* and it will reduce Vata and delays the degeneration by Brmhana. In Sandhigata vata, Asthi and Majja are the Dhathus involved since Sandhi and Asthi are the source of origin of Majjavaha srotus. In diseases of Asthi and Majja, Bahya and Abhyantara Snehana are advised<sup>9</sup>.

In this study *Thiktha rasa* Snehana with *Thikthaka Ghritha* and Kshira Kashaya was administered internally to passify Vata in the body. It reduces the Ruksha guna of Vata and makes body Mrudu. According to Ayurvedic classical guidelines, Panchatiktaka ksheera is advisable for kevala vathika condition. Guggulu tiktaka ghritha and panchathikthaka ksheera is made of all Tiktarasa dravya and which cures Asthimajjagata vata. Sarpi does the Asthidhatu poshana because of their Snigdha Guna, Tikta Rasa gives strength to Asthi and it improves especially the Khara Guna of Asthi due to its Soshana Guna. Being an Akasha Mahabhutha Dravya,Tikta rasa act as a medium to reach their destination. Panchathikthaka Siddha kshira helps to reduce

Vata. Kshira kashaya will act as Balya and Rasayana also. Ghee act as a good solvent for many metabolic waste products & it enters the cells easily because cell wall is made up of phospholipids<sup>10</sup>.

The report of the laboratory investigations were compared before and after treatment and observed that there is no significant difference in the values which is an indication of the safety of the treatment. No significant variations was noted in the liver and kidney function tests done before and after the course of treatment also emphasise that the medicines are safe without any side effects.

### Conclusion

The result derived from the statistical analysis of the response of the therapy clearly indicate that the prescribed method of management have highly significant effect in the management of osteoarthritis of knee. The treatment has shown significant improvement in the functional ability of the patients. More over the biochemical and pathological investigations to evaluate the changes in liver and kidney function carried out before and after the course of treatment did not show any significant variations. It indicates that the treatment program is safe without producing any complication or side effects

Since the prescribed line of treatment with the combined procedures of external therapies and internal medications have been proved its effect in the management of OA, the procedures may be included in the approved treatment protocol of the disease osteoarthritis of Knee.

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