



Research Article

THE EFFECTIVENESS OF PATRAPOTTALI SVEDA, THAILADHARA, AND PANCHATHIKTAKA KSHEERA GHRUTA TO TREAT OSTEOARTHRITIS OF KNEE (SANDHIVATA)

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ABSTRACT

Currently, arthritis is a throbbing illness that affects people all over the world. Osteoarthritis is the most common type of arthritis out of all the many variations. This is frequently observed in later stages of life. The effectiveness of *Patrapottali sveda*, *Thailadhara* for external administration, and *Panchathiktaka ksheera ghruta* for internal administration to treat osteoarthritis in the knee was investigated in light of the significant handicap caused by the condition. **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 21 days of treatment, included *Valuka sveda* for 1-3days followed by internal administration of *Panchatiktaka ksheera kwatha* and *Panchatiktaka guggulu ghruta* along with *Pradesika Patrapottali sveda* for 7 days along with internal medication *Pradesika thaila dhara* with *Ketakeemooladi thaila* was done, last 4 days, only internal medicines. Then in OP level for 24 days by the same internal medicines and application of *Ketakeemooladi thaila* on affected knee joint. The follow up for the completed cases were done after 15 days. **Results and Conclusion:** 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.

INTRODUCTION

Osteoarthritis is the most prevalent type of arthritis and is a chronic degenerative joint condition. The involvement of the hips or knees is blamed for the majority of this impairment burden. It advances gradually, with the typical signs and symptoms being pain, swollen and distorted joints, as well as a restriction in range of motion^[1]. In the present day, the growing prevalence of osteo-arthritis of the knee in society is mostly attributed to deteriorating living conditions, particularly poor eating habits, stress, and climatic changes.^[2]

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^[3].

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

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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^[4]. The assessments were done on baseline and followed periodically on 21st, 45th day and 60th day. The data generated in the study on clinical parameters, laboratory investigations before and after the treatment are tabulated and analyzed using appropriate statistical methods namely paired t- test and repeated measures ANOVA^[5].

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 sveda* was done. It was followed by internal administration of *Panchatiktaka ksheera kwatha* and *Panchatiktaka guggulu ghrita* along with *Pradesika Patrapottali sveda* for 7 days. In the next 7 days^[6], internal administration of *Panchatiktaka ksheera kwatha* and *Panchatiktaka guggulu ghrita* along with *Pradesika thaila dhara* with *Ketakeemooladi thaila* 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 thaila* on affected knee joint. The follow up for the completed cases were done after 15 days^[7].

Table 1: Treatment Regimen (Dose, Form and Route of Administration)

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

OP Treatment			
Days	Duration	Internal	External
22-45	24 days	<i>Panchatiktaka ksheera kwatha</i> (96 ml BD) before food (6am, 6pm) <i>Pancha tikta guggulu ghrita</i> (10gm BD) after food (9am, 9pm)	Local Application of <i>Kethakeemooladi Thaila</i>
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 Poverty 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

Characteristics	Category	Palpation			
		Right Knee		Left Knee	
		Frequency	%	Frequency	%
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

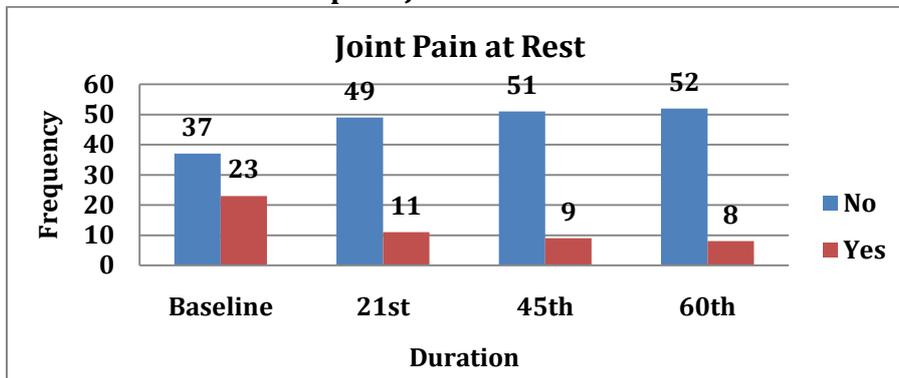
Characteristics	Category	Muscle power			
		Right Knee		Left Knee	
		Frequency	%	Frequency	%
Knee Flexor	Normal	57	95	57	95
	Abnormal	3	5	3	5
Knee Extensor	Normal	56	93	56	93
	Abnormal	4	7	4	7

Table 9: WOMAC & SF 36 correlation

	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

Graph 1: Joint Pain at Rest



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

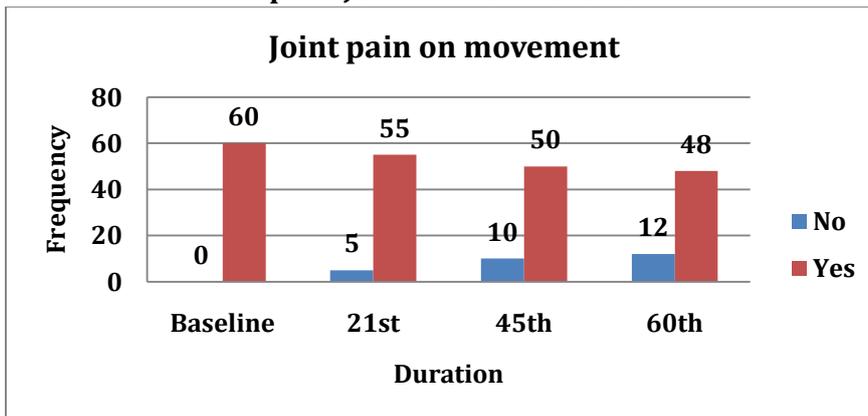
Table 10: Joint Pain on Movement

	Minimum	Maximum	Median	Mean	SD	P value
Base line	0	10	6	6.48	1.864	
21 st	0	7	3	2.78	1.648	.0001
45 th	0	7	2	2.57	1.917	.0001
60 th	0	8	2	2.5	1.935	.0001

Table 11: Joint pain on movement grade wise

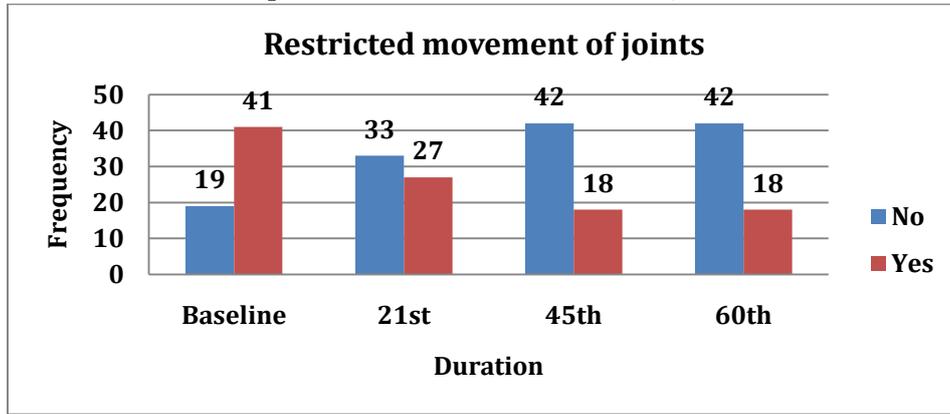
	G1			G2			G3		
	Median	Mean	P value	Median	Mean	P value	Median	Mean	P value
Base line	6	6.53±2.1		7	6.2±1.9		6	6.5±1.6	
21 st	3	2.3±1	.0001	3	2.5±1.4	.001	3	3.2±1.5	.0001
45 th	3	2.37±2	.0001	2	2.3±1.6	.001	2	2.8±1.9	.0001
60 th	2	1.89±1.9	.001	2	2.5±1.9	.003	3	2.9±1.8	.0001

Graph 2: Joint Pain on Movement



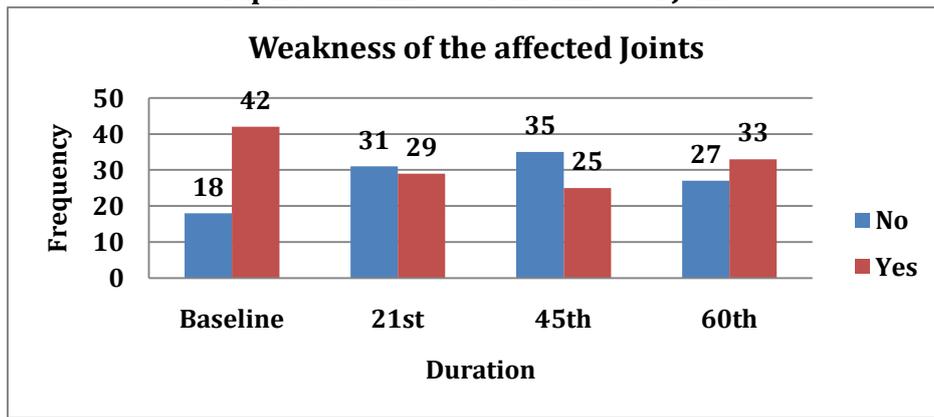
In case of joint pain on movement, crepitus, swelling, joint stiffness and bony tenderness, statistical significance was obtained on 21st day, 45th day and 60th day ($p < 0.01$) in comparison with baseline in Grade 1, Grade 2 and Grade 3 patients.

Graph 3: Restricted Movement of Joints



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

Graph 4: Weakness of the Affected Joints

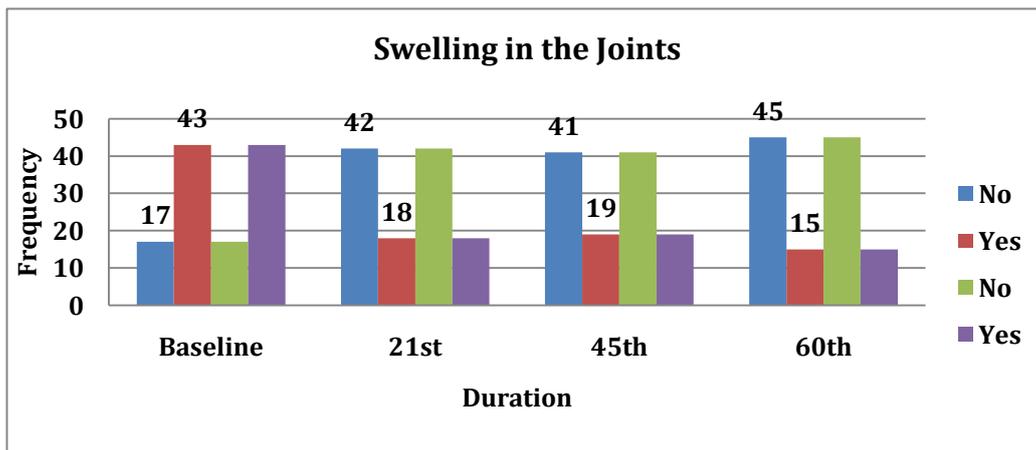


Weakness of the affected joints

	G1			G2			G3		
	Median	Mean	P value	Median	Mean	P value	Median	Mean	P value
Base line	7	4.8±4.1		6	4.2±.3		6	4.9±3.3	
21 st	2	2.1±2.1	.0001	1.5	2.2±2.7	.048	0	1.5±2.3	.0001
45 th	0	1.6±2.2	.0001	1	1.7±2.1	.014	0	1.1±2	.0001
60 th	1	1.6±1.9	.0001	2	2.2±2.4	.027	0	1.5±2	.0001

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

Graph 5: 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 21st day 45th day and 60th day

Graph 6: Bony Enlargement of the Joints

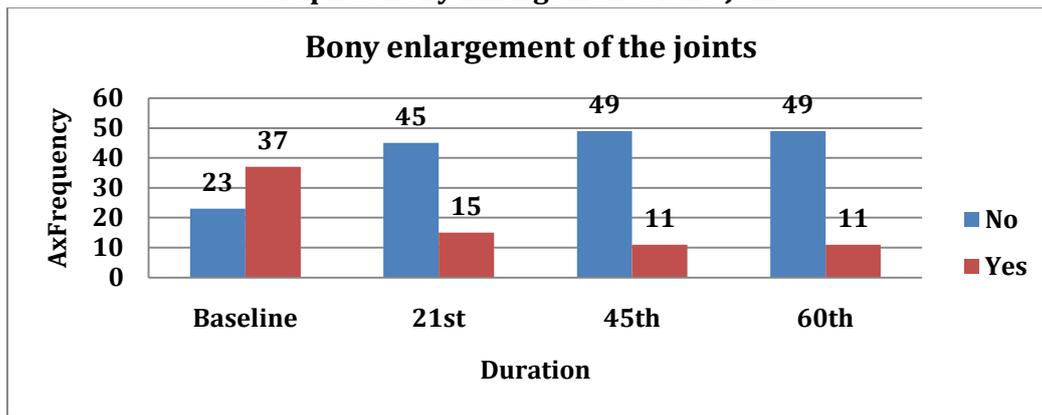


Table 12: Bony Enlargement of the Joints

	G1			G2			G3		
	Median	Mean	P value	Median	Mean	P value	Median	Mean	P value
Base line	5	4.4±3.5		1	2.4±2.6		3	3.2±2.8	
21 st	0	.79±1.1	.002	0	.36±.9	.017	0	.78±1.5	.0001
45 th	0	1±1.9	.002	0	.29±1	.017	0	.59±1.3	.0001
60 th	0	.53±1.4	.002	0	.29±.7	.017	0	.67±1.4	.0001

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

Graph 7: Palpable Warmth in the Affected Joints

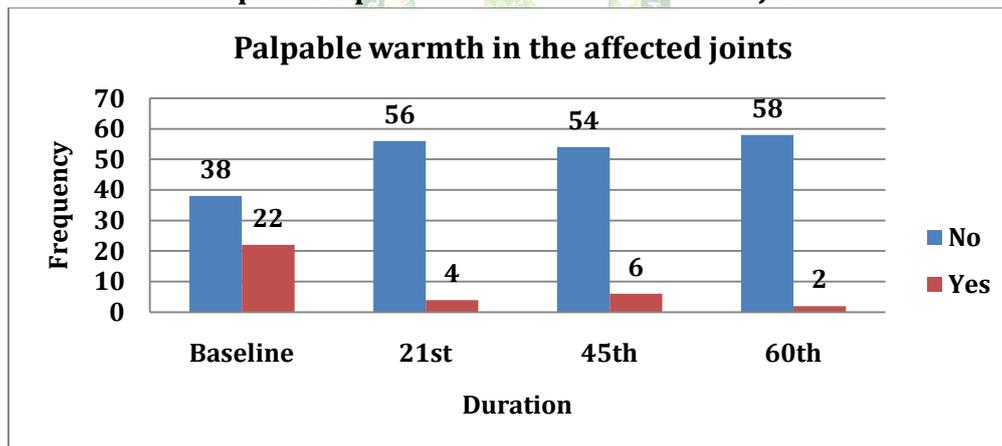
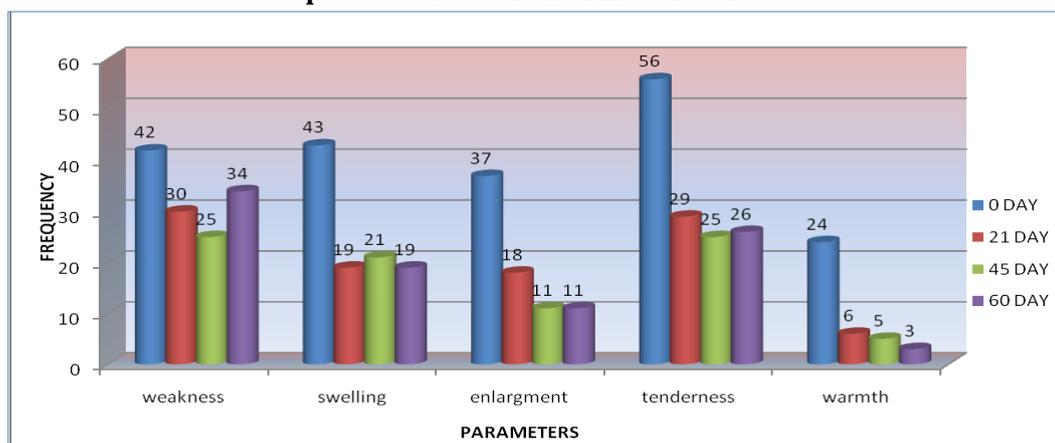


Table 13: Palpable Warmth in the Affected Joints

	G1			G2			G3		
	Median	Mean	P value	Median	Mean	P value	Median	Mean	P value
Base line	6	5.8±3.2		0	1.4±2.1		0	1.1±2	
21 st	0	1.9±2.5	.011	0	.07±.26	.042	0	.04±.19	.007
45 th	0	1.4±2.2	.017	0	.29±.72	.086	0	.07±.38	.016
60 th	0	1±1.5		0	.1±.01	.039	0	.11±.57	.007

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

Graph 8: Parameters in Different Visit



DISCUSSION

In this study, a modified protocol based on the care of "*Asthisandhikshaya*" (a disorder characterized by the degeneration of joint cartilage and related components) has been tried to assess its effectiveness and safety in *Sandhivata* (osteoarthritis knee). The assessment criteria, which included the visual analogue pain rating scale, Womac score, SF 36 questionnaire, and grading for the disease's primary complaints, were accepted internationally. These criteria were used to select cases for osteoarthritis diagnosis. The lab investigation report obtained before and after treatment was used to evaluate the safety of the treatment methods.

Snehana (internally and externally) and *Snigdha sveda* are the lines of treatment for *Dhathukshaya janya* (degenerative) *Vatavydhi*, in accordance with Ayurvedic principles. The major goals of all the therapeutic techniques in this protocol are *Vata samana* (pain alleviation) and *Brumhana* (regenerative)^[8].

The observational data gathered from the study participants did not yield any meaningful information due to the small sample size, but all of the observations were consistent with the earlier investigations. According to the *Prakriti*-wise classification, the bulk of the study's patients belong to the *Pitha kapha* group, which is thought to be predisposed to the early onset of degenerative diseases.

To rule out "*Amatva*," which is likely to be present locally, a brief course of *Amapachana* measures by the application of *Valuka sveda* for three days was provided before to the main treatment. When *Vata* and *Kapha* are appropriately assessed before the administration of *Snehana*, this is typically indicated. This was done, and then *Patra pottali sveda* began, which is essentially *Svedana* but also *Snehana* because some *Sneha* was added during preparation and application. This *Svedana* method uses heated bolus bags filled with medicinal herbs to raise body warmth and activate the sympathetic nervous system.

Epinephrine, norepinephrine, cortisol, and thyroid hormones are released as a result of enhanced sympathetic activity, speeding up metabolism. Increased metabolism raises the need for oxygen and nutrients, which are given by the improved local blood flow brought on by vasodilatation. Waste materials and metabolites are also eliminated simultaneously. All of these procedures serve to relieve pain, edema, and stiffness by clearing the *Ama* (channel obstruction).

Regarding the effectiveness of the treatment, it is important to emphasise that such initial course of IPD level treatment, which consists of *Svedana-pathra pottali sveda*- followed by *Snehana-thaila dhara*- along with internal medications, significantly relieves the most distressing symptoms of the disease, including pain during rest and movement, joint stiffness, crepitus, swelling restricted movements, etc. Furthermore, it should be mentioned that during the second round of OPD level treatment, which included the application of *Thaila* externally and the administration of internal drugs, all the favorable results were maintained or steadily enhanced. However, a small number of patients have complained of mild pain while moving and walking during the follow-up phase. This may be because of household tasks that put strain on the joints during the treatment period because they were fully prohibited.

Kethakeemooladi thaila 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^[9].

In this study *Thiktha rasa Snehana* with *Thikthaka Ghritha* and *Kshira Kashaya* was administered internally to pacify *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 *Asthimajagata 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^[10].

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 results of the statistical analysis of the therapy's response clearly show that the prescribed management strategy has a highly substantial impact on the treatment of knee osteoarthritis. The patients' functioning abilities have significantly improved as a result of treatment. Furthermore, there were no appreciable differences between the results of the biochemical and pathological studies conducted before and after the course of treatment to assess the changes in liver and kidney function. It shows that the treatment plan is secure and has no complications or negative 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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