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CLINICAL STUDY OF THE EVALUATION OF ANTI-INFLAMMATORY AND PAIN RELIEVING ACTIVITY OF A POLYHERBAL OIL PREPARATION- CUREON IN MUSCULOSKELETAL DISORDERS

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ABSTRACT

The musculoskeletal disorders are one of the most common chronic disorders in the world. According to *Ayurveda*, joint and muscular pains are primary *Vata* disorders due to the accumulation of toxins (Ama) in the joints which lead to developing musculoskeletal disorders.

This study elucidates the effects of polyherbal oil on external local application in musculoskeletal disorders with the main objective being to study the efficacy of *Ayurvedic*polyherbal oil to relieve joint pain, stiffness, inflammation, swelling and sprain (contusion).

In the present study, 60 patients were selected randomly and treated with the external application of the polyherbal drug preparation for 3 weeks over the course of which, proper assessment of the patients before and after treatment led to significant reduction of pain, inflammation and stiffness.

Out of the 60 patients observed, 18 patients (30%) showed 75-100% relief (Cured) symptomatically. 28 patients (46.67%) were markedly improved (50-75%). 9 patients (15%) showed improvement (25-50%) in the symptoms. 5 of the patients were found to get relief below 25%.

Thus, we could conclude that the polyherbal preparation was effective in curing musculoskeletal disorders caused by *Vata* vitiation due to trauma.

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INTRODUCTION

Musculoskeletal disorders are oneofthe most common chronic disorders^{[1][2]} in the world. According to Ayurveda backache, joint pain, body ache, contusion, sprain, pain are due to a vitiated Vata.

Symptoms: The main symptom is pain causing loss of movements and often stiffness of muscles. "Pain" is generally described as a sharp ache, or a burning sensation in the associated muscles and tendons. When the affected local part is moved or touched, patients may experience muscle spasm and inflammation and inability to do movements. Humid and cold weather increases the pain in many patients [1-3]. Thats why I have selected the above said topic.

CureOn Oil (Anti Inflammatory and Muscle Relaxant Herbal Massage Oil): It is thebest herbal oil which not only gives a sure relief in joint and muscular pain but also strengthens the bone tissues, the skeletal and the

*Corresponding author: Rajeshwar Reddy K M.A.Podar Medical College, Worli, Mumbai neuromuscular systems, enabling comfortable movements of joints and muscles. How it works has been described in short as below. $^{[4][5][6]}$

Til oil –Enriched with Vitamin 'E'. Natural Antioxidants having good penetration increases resistance power of body Ganhapurav-Warms and relaxes muscles. Ensures free joint movements.

Nirgundi-Reduces pain.relaxes fatigued muscles. Makes movements of joints easy.

Shatavari-Strenthens joints, tendons, and muscles, lubricates the joint help in easing the movements of joint. Ashwagandha-Anti-inflammatory. Useful in diseases due to vitiated *Vata*. Sahachar-Relieves pain in low-backache, sprains and traumatic injury. Ark-Relieves chronic joint pain. Sooths inflammation and oedema.

It is a powerful antioxidant and increases the energy level. Cureon oil does fastest cure through deep penetration on theaffected area. Because of its strong antioxidant, anti-inflammatory action. It removes stiffness and improves mobility of limbs. It brings relief from backaches, muscular strains e.g. sprain, contusion and various painful

inflammatory conditions, and joint pains etc. [6]

Being a herbal oil it is a time-consuming approach to relieve the pain and inflammation of affected area. Cureon oil helps reduce local congestion and improve the blood circulation. Moreover, this oil also helps as muscle relaxant, in the affected area.

It is a pain relieving, fast acting and long lasting blend of natural oils that provides rapid transdermal penetration and gives quick relief from the pain as wellas reduces stiffness in joints and muscles and removes ache. Moreover it is nongreasy and non-staining. It is an age old product. Every ingredient in cureon oil works to relax the muscles and nerves by improving blood circulation in the affected area.

MATERIALS AND METHODS

Subjects attending surgery OPD were screened for the eligibility criteria. If a patient satisfied the eligibility criteria, he/she was recruited into the study after signing a written informed consent form. At the baseline visit, detailed history including onset of the disease were recorded.

General and systemic examinations were done to rule out any significant clinical findings. Local examination was done in which signs & symptoms of various joint and muscular pains were graded and scored as per specification given. Sample size -60, which were selected randomly by computer generated method.

Diagnosed patients of muscle and joint pain, body ache back ache, legsprain, and cramp. Each patient was provided a study medication stock for 3 weeks. They were instructed to bring back the empty containers of medicine or any unused medication during the next visit. At each follow-up visit, the patients were assessed with respect to signs & symptoms of various musculoskeletal disorders recorded at baseline. He/she was asked for occurrence of adverse events and subsequent action was taken for the management of any adverse event which was recorded.

All laboratory investigations performed at baseline were repeated after completion of treatment.

Inclusion criteria

- 1. Both sexes of any age group.
- 2. Randomly selected & well diagnosed patients of muscle and joint pain, body ache back ache, legsprain, and cramp and contusion.
- Patients ready to abide trial procedure and give informed consent.

Exclusion criteria

- Painful inflammatory conditions with fractures and dislocations.
- 2. Joint effusions, haemarthosis, Pott's spine,
- Patients having any severe systemic diseases like renal, hepatic, and cardiac Disorders.

Ingredients of cureon oil

Tiloil(99%) Ganhapurav(1%) Nirgundi(10gm) Shatavari(5gm) Ashwagandha(5gm) Sahachar(5gm) Ark(5gm)

Assessment criteria

Pain

Grade 0 = no pain

Grade1=mild pain but no difficulty in walking **Grade2**=moderate pain but difficulty in walking **Grade3**=severe pain with difficulty in walking

Tenderness

Grade 0 = no tenderness

Grade1= patient says tenderness **Grade2**= winching of face on touch

Grade3=does not allow to touch the joint

Swelling

Grade 0 = no swelling

Grade1= slight swelling

Grade2=moderateswelling **Grade3**= severe swelling

Stiffness

Grade 0 = no stiffness

Grade1= mild stiffness

Grade2=moderatestiffness **Grade3**= severe stiffness

Baseline Assessment

General systemic examination -

T.P, R, B.P. pallor, cyanosis, clubbing, edema, R.S., C.V.S., C.N.S., genital examination.

Ethical consideration

Institutional Ethics Committee (IEC) approval was obtained.

Ref.No.: RAP/V.V.-2/IEC/9334/2010

OBSERVATIONS AND RESULTS

Clinical efficacy of therapy during the study

Table 1 Effects of cureon oil on assessment of criterias.

Sr.No.	Symptoms	BT	AT	Diff.	% of relief
1	Pain	2.133333	0.716667	1.416667	66.40
2	Tenderness	1.767	0.533333	1.233	68.86
3	Stiffness	0.566667	0.166667	0.4	70.50
4	Swelling	1.333333	0.35	0.983333	73.75

Pair

The % of relief observed in 60 patients was 66.40 %

Tenderness

The % of relief observed in 60 patients for this symptom was 68.86%

Stiffness

The % of relief observed in 60 patients for this symptom was 70.5%

Swelling

The % of relief observed in 60 patients for this symptom was 73.75%

Statistical Analysis of the Results by Wilcoxon - Matched - pairs

Signed - Ranks Test (Non -Parametric Test)

Swelling

Sum of all ranks -1035 No. of pairs -45 Value of Z - 3.82 P value - <0.0001

Table 2 Assesment Criteria score before and after Treatment

				SE of			Val		
Assesment Criteria		Mean (in Grades)	SD		\mathbf{W}	N	ue	p	results
		(III GI aues)		Diff.			of Z		
	BT	2.133	0.4682	0.0604			or E		Extremely
Pain	AT	0.7167	0.4903	0.0633	1596	56	5.89	< 0.0001	significant
	DIFF BT	1.417 1.767	0.6712 0.4997	0.0867 0.0645					
Tendernes									Extremely
	AT	0.533	0.5031	0.0649	1596	56	5.89	< 0.0001	
S									significant
	DIFF	1.233	0.5635	0.0727					
	BT	0.5667	0.6979	0.0900					
									Extremely
Stiffness	AT	0.1667	0.3758	0.0485	253	22	0.93	< 0.0001	
									significant
	DIFF	0.4000	0.5584	0.0721					
	BT	1.333	0.7759	0.099					Extremely
Swelling					1035	45	3.82	< 0.0001	
	AT	0.3500	0.4810	0.0621					significant
	DIFF	0.9833	0.7009	0.0904					

Symptom wise Statistical Analysis of the results

Pain

Sum of all ranks -1596 No. of pairs -56 Value of Z - 5.89 P value - < 0.0001

Extremely Significant According to this test Z value for the 60 patients was 5.89, P<0.001, which was statistically significant.

Tenderness

Sum of all ranks -1596 No. of pairs -56 Value of Z - 5.89 P value -<0.0001

Extremely Significant According to this test Z value for the 60 patients 5.89, P<0.0001, which was statistically significant.

Stiffness

Sum of all ranks – 253 No. of pairs – 22

Value of Z - 0.93 P value - < 0.0001 Extremely Significant

Z value for was 0.93, P<0.0001, which was statistically significant.

Table 3 Total Effect of Therapy on 60 Patients of Musculo- Skeletal disorders

	No. of	
Results		%
	pts.	
Cured	18	30
Markedly improved	28	46.66
Improved	9	15
unchanged	5	8.34

Highly Significantt According to this test Z value for the 60 patients was 3.82, P<0.0001, which was statistically significant.

Clinical Efficacy of Therapy

Results after therapy on each symptom (Table 1, 2) I.PAIN

66.40% of relief was achieved at the end of the therapy.

By Wilcoxon Signed Rank test, the results were highly significant Z=5.89, p< 0.0001

From Statistical analysis it can be supposed that there is significant relief in pain.

Tenderness

. 68.86% of relief was achieved at the end of the therapy.

By Wilcoxon Signed Rank test, the results were highly significant Z=5.89, p< 0.0001

From Statistical analysis it can be supposed that there is significant relief in tenderness.

Stiffness

70.50% of relief was achieved at the end of the therapy.

By Wilcoxon Signed Rank test, the results were highly significant Z=0.93, p< 0.0001

From Statistical analysis it can be supposed that there is significant relief in stiffness.

Swelling

73.75% of relief was achieved at the end of the therapy.

By Wilcoxon Signed Rank test, the results were highly significant Z=3.82, p< 0.0001 From Statistical analysis it can be supposed that there is significant relief in swelling. Out of the 60 patients observed, 18 patients (30%) showed 75-100% relief (Cured) in the symptoms. 28 patients (46.67%) were

markedly improved (50-75%). 9 patients (15%) showed improvement (25-50%) in the symptoms. 5 of the patients were found to get relief below 25%.

DISCUSSION

The study aimed at studying the effects of CureOn Oil in various Inflammatory Musculo-Skeletal disorders with the prime objective of providing an effective alternative therapy for their treatment.

The parameters which were taken in to consideration for were pain, tenderness, stiffness and swelling. 60 patients were selected, divided randomly and treated by the local application of CUREON oil. The results of the study were significant on all the parameters.

However this cureonoilis being applied localy and it has shown effect on pain relief. And also it has limitations in action varing patients to patients due to absorption of cureonoil. Being a herbal oil it is a time-consuming approach to relieve the pain and inflammation of affected area.

Patients were treated as per the pre-designed protocol of the study. They were followed-up for a period of 3 months, as well as routine investigations of the patients' condition was done before and after the treatment. The data thus generated was put to proper statistical analysis and the following conclusion was drawn from the results obtainedby using software the system 'Instat'.

CONCLUSION

Patients reportedly started experiencingrelief after 3 days of application of Cureon oil in the 1st week and progressively got significant relief as per the clinical symptoms presented. At the end of the treatment, no adverse effects of the treatment were observed or reported by the patients.

Following conclusions can be drawn from the study:

- 1. Clinical symptoms like pain, tenderness, stiffness, swelling and various painful inflammatory conditions decrease progressively.
- 2. Cureonoil proves its analgesic, anti-inflammatory action & instant relief on various muscle pains, backache, leg sprain, traumatic injury and all types of arthritis.
- 3. Cureon oil gives instant relief in stiffness of joints helping in painless movement of the joints and relaxing of the muscles. Cureon oil helps inmaintaining the level of lubrication in the affected parts.

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