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Original Research Paper

Homeopathic

A STUDY ON THE EFFECTIVENESS OF CAUSTICUM 30 ON MUSCULOSKELETAL MANIFESTATIONS OF FIBROMYALGIA SYNDROME IN AGE GROUP BETWEEN 18-75 YEARS.

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ABSTRACT

BACKGROUND: Fibromyalgia is a disorder of chronic widespread pain & tenderness. FMS is now a recognized clinical entity causing chronic disabling pain, it is a symptom complex seen mostly in people with sedentary lifestyle & seen in all age groups these days. The exact incidence of this disease is yet to be worked in India, but a fair incidence of FMS is reported in Western countries. In India, prevalence of FMS is noted to be highest in Urban population 0.7% to 11.4%. the scope of Homeopathic Medicine in musculoskeletal & locomotor disorders is favourable. Homeopathic medicines are known well for their safe & harmless mode of action & also offer economic effects as adjuvant or alternative mode of therapeutics. Also dissatisfaction with conventional medicine can lead people to turn to Homeopathic medicine. The use of Homeopathic medicine for a wide range of acute & chronic conditions in increasing with high levels of patient satisfaction. This study was aimed to investigate whether the homeopathic medicine Causticum 30 has effect in reducing musculoskeletal complains of FMS or not.

METHOD: It is a prospective, single arm, single blind, Non-Randomised clinical trial. Study conducted at out patient department of BVDUHMC research centre Katraj, Pune & rural OPD Yawat. Total 32 patient (M,F) age group 18-75 years were enrolled in this study, out of which 2 patients were dropped out & 30 patients completed the follow ups. General & Local Examination with regards to tender point count & scoring with FIQ (FIROMYALGIA IMPACT QUESTIONNAIRE) was done appropriately at every visit.

RESULT: The final outcome was reduction in pain & stiffness & FIQ scores after 6-8 weeks of out ptient care. Pre test & Post test analysis was done using student paired " t" test. A significant reduction was oserved in the scoring values of pain in FMS patients before & after treatment. The mean reduction in scores was 30.14 (95%CI 6.18,6.25) after completion of study(6-8 weeks).

CONCLUSION: Homeopathic medicine Causticum 30 produced significant effect in reduction in pain intensity of FMS. Further studies with control group can provide more validation & authenticity in proving Causticum 30 is effective in alleviating musculoskeletal complains of FMS.

KEYWORDS : Fibromyalgia Syndrome, Causticum, Homoeopathy, Pain, Stiffness.

INTRODUCTION

Fibromyalgia is a disorder of chronic widespread pain and tenderness. Chronic indicates pain and tenderness are present continuously for atleast 3 months. Widespread means pain and tenderness are on both sides of the body, above and below the waist including the spine. [1] Fibromyalgia patients have symptoms of fatigue, unrefreshed sleep and cognitive dysfunction. The scope of Homoeopathic medicines in FMS is very favourable. Homoeopathy is a method of therapeutics based on Silimia Similibus Curantur. Homoeopathic medicines are well known for their safe & harmless mode of action & also offer economic effects as alternative % adjuvant mode of therapeutics when applies in various diseases. The publication of American College of Rheumatology (ACR) preliminary diagnostic criteria for fibromyalgia (FM) in 2010 (ACR 2010)1 eliminated the tender point examination, thus making it possible to study FM in survey and clinical research.

The diagnostic criteria for FM are satisfied if the following 3 conditions are met:

(1) the Widespread Pain Index (WPI) > 7 and the Symptom Severity Score (SS) > 5, or the WPI is 3–6 and the SS > 9
(2) symptoms have been present at a similar level for at least 3 months
(3) the patient does not have a disorder that would otherwise explain the pain.

Fibromyalgia (FM), chronic fatigue syndrome and multiple chemical sensitivity with low-level chemical intolerance, for which conventional medicine has limited options. Fibromyalgia is a chronic diffuse musculoskeletal pain disorder involving concomitant fatigue, sleep disturbance and, often, co-morbid depression [2]The prevalence in the United States is 2% Fibromyalgia disproportionately affects women.

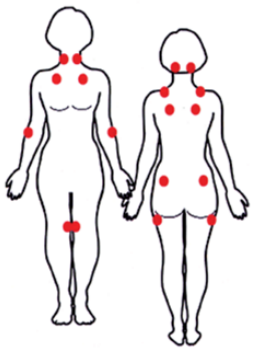
Fibromyalgia Syndrome is now a recognized clinical entity causing chronic and disabling pain. For several centuries, muscle pain has been known as rheumatism and then muscular rheumatism. [3] The first AMERICAN COLLEGE OF RHEUMATOLOGY CRITERIA (ACR) was published in 1990.The 2010 latest criteria of ACR allows for diagnosis with appropriate history. Fibromyalgia Syndrome is a symptom complex syndrome most commonly seen in women. The exact incidence of disease is yet to be worked in India but a fair incidence of this disease has been reported in Western countries to 3.6%.The prevalence of Fibromyalgia is divided into 4 categories:[4]

- Prevalance in General population 0.2% to 6.6%.
- Prevalance in Women 2.4% to 6.8%.
- Prevalance in urban and rural areas 0.7% to 11.4% and 0.1% to 5.2% respectively.
- Prevalance in Special Population 0.6 to 15%.

FM and CWP are characterized by widespread pain and tenderness. Other important features are fatigue, sleep disturbances, stiffness, symptoms of depression and anxiety and cognitive difficulties

CWP has been shown to be associated with older age, being an immigrant, lower socio-economic class, lower educational level and family history of chronic pain.. The majority of patients with FM and CWP experience work limitations due to their pain, fatigue and cognitive symptoms[6]

Widespread pain coexists in several other conditions. In rheumatic diseases such as rheumatoid arthritis, systemus lupus erythematosus and osteoarthritis, the prevalence of FM has been reported to be between 11 and 16 % and in myalgic encephalomyelitis (ME), the prevalence of FM has been estimated to be 55 %. CWP has also been shown to be present in 28 % of women with chronic low back pain consulting primary health care



Etiology

Pain is always subjective and can also be present when tissue damage is absent. The International Association for the Study of Pain (IASP) has defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"[5]

The pathogenesis of pain in FM is not entirely understood. Environmental factors such as physical trauma, certain infections, autoimmune disorders, emotional stress and other regional pain conditions may play a role in the triggering and maintenance of widespread pain in FM but there may also be a familial component.

Hyperalgesia and allodynia in FM have been shown to result from an increased sensitivity in central nervous mechanisms referred to as central sensitization In central sensitization, nociceptive neurons of the dorsal horn become hyper responsive to nociceptive, and sometimes non-nociceptive, somatic stimuli. This increased responsiveness leads to an increased input of signals to the cerebral cortex . Central sensitivity syndromes or central pain conditions are concepts emerging in research, implying that several overlapping chronic pain conditions, such as FM, ME, irritable bowel syndrome, interstitial cystitis and tension-type headaches, may all be results of central sensitisation Descending pain inhibiting pathways from the brain stem, utilizing neurotransmitters, have been shown to be deficient in patients with chronic pain. This reduced inhibition of pain in combination with the increased input of pain signals are considered to cause the hyperalgesia found in FM.Other neurobiological aberrations have been observed in the hypothalamic pituitary- adrenal (HPA) axis and the noradrenaline-sympathetic system in patients with chronic pain, which are components of the human stress response. These two components have been shown to be hypo-reactive in FM, which is also considered to be a possible part of the pathogenesis of FM.

To conclude, the maintenance of widespread pain in FM is considered to be due to an increase in pain facilitation and a decrease in pain inhibition. These alterations are influenced by cognitions, emotions and behaviors . While the etiology of pain in patients with FM is under continuous study, there is limited knowledge of the cause of their fatigue[7]

However, it has been suggested that the fatigue in FM can also be partly explained by central sensitization

Treatment

There is no cure for FM and CWP as yet, and the treatment is mainly symptomatic. The European league against rheumatism (EULAR) has suggested guidelines for treatment in FM . The most efficacious treatment of FM requires a multidisciplinary approach combining pharmacological treatment, exercise and cognitive behavioral therapy.

Both pharmacological and non-pharmacological treatments have been shown to have an effect on symptom severity and physical function. The treatments need to be tailored with consideration to pain, fatigue, function and other features associated with FM

HOMOEOPATHY FOR FRIBROMYALGIA

Homoeopathy off late has been the choice of treatment for a huge population for many disease conditions. The concept of "Individualisation" in Homeopathy implies a specific remedy for a specific patient[8]. Every pt with FMS has their own story, their own constellation if symptoms, trigger factors etc. homoeopathic treatment focuses on these important characteristic factors regarding an individual. Homoeopathy has a vast scope in musculoskeletal & locomotor disorders. Homeopathy has a wonderful scope in reducing muscular pain & fatigue of FMS with remedies having specific actions on the muscular tissues & fibres.[9]

CAUSTICUM (Hahnemman's Tictura Acris Sine Kali): It manifests mainly in chronic Rheumatism, Arthriris, Paralytic affections indicated by tearing and drawing pains in muscular and fibrous tissue with progressive loss of muscular strength

OUTCOME ASSESSMENT:

Outcome was assessed using Fibromyalgia Impact questionnaire.

Outcome will be assessed with the difference between the score in the FIQ at every follow up, before treatment and after treatment.

Interpretation of Scores:

0 to <39- Mild,
<59- Moderate
>59 to 100- Severe.

These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise of the treatment.

MATERIAL & METHOD

Study setting: -This study was conducted at outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Karaj, and Pune. It was a prospective, single arm, single blind, and non randomized, interventional study to see the effect of Causticum 30C in musculoskeletal manifestations of Fibromyalgia syndrome in age group between 18-75 years.

Case definition :- Minimum 30 patients were taken for study. Cases of both sexes and age group between 18-75 years having symptoms of fibromyalgia syndrome fulfillinf ACR diagnostic criteria for Fibromyalgia were taken and cases fulfilling inclusion and exclusion criteria. The case taking was done by standard case taking proforma as per homoeopathic principles.

- **Intervention:-** Drug- All the selected samples will be prescribed the homoeopathic remedy Causticum
- Potency- 30 potency was used as I have conducting this study to evaluate the role of causticum in 30 potency.
- Dispensing- Globule no 30
- Route of administration- Oral Route
- Repetition- 3 pills 3 times daily
- Preparation of remedy- medicine was prepared from standard homoeopathic pharmacy, which are GMP certified as per norms of homoeopathic pharmacopoeia (HPI) will be used.
- Storage- storage was according to standard homoeopathic pharmacy stored in BVDU pharmacy katraj Pune. Drug will stored as per the rules of homoeopathic pharmacopoeia. We will maintain log and batch number of each drug. Medicine was stored in amber coloured bottles and will be kept in dark place away from sunlight.

Declaration- the drug used here is not harmful to human beings, remedy available in the homoeopathic literature, was well proved on healthy human beings and is harmless and has no side effects.

STUDY DESIGN: Prospective, Single arm, Single blind, Non-Randomised Clinical Trial.

SELECTION OF SAMPLE: By Simple Non-Randomised Sampling Technique who fulfill inclusion & exclusion criteria according to Inclusion & Exclusion Criteria.[29]

Sampling procedure and follow up: -Patients were enrolled in this study from Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital, peripheral OPD, Various rural & urban camp series, OPD and IPD from 2019-2021 (Approximately 52 weeks). Total 34 Cases (male & female) age groups of 18-75 yrs were selected based on inclusion and exclusion criteria those who wanted to participate willingly in research. Participants were enrolled in the study only after signing the informed consent form. Each case was followed up for approx 2 months

- All the patients were duly followed and details of the symptomatic, clinical, investigative changes were recorded and prognoses were studied with the help of scorings.
- Follow up differed from patient to patient.
- Usually first follow-up was within 7-10 days seventh day.
- 2nd follow up and onward follow up were after 7 days or earlier/later according to need of the patients
- Standard Follow-up was prepared giving details.
- It was based on Homoeopathic principles.
- All participants were also asked to continue with their prescribed medication for duration of the study. Medical history, physical examination (including vital signs, systemic examination)

Provision of standard line of prevalent treatment:-
Patients were asked for his/her daily routine, his life style and eating pattern. I have suggested the patient to follow the below written things with homeopathic medicine to achieve better results. Effective lifestyle modifications also helpful in reducing the musculoskeletal as well as cognitive symptoms of Firomyalgia Syndrome and also improving the general well being of the patient. Combinations of two or more lifestyle modifications can achieve even better results.

- Maintain normal body weight for adults (e.g. body mass index 20–25 kg/m^2)
- Engage in regular aerobic physical activity such as brisk walking, exercice, Yoga etc (≥30 min per day, most days of the week)
- Avoid/ Limit alcohol consumption to no more than 3 units/day in men and no more than 2 units/day in women
- Consume a diet rich in fruit and vegetables (e.g. at least five portions per day)

SELECTION OF TOOLS:
- ACR latest criteria to diagnose FMS
- FIQ- Fibromyalgia Impact Questionnaire
- Serological Investigations

INVESTIGATIONS-
ESR- to rule out inflammatory diseases.
RA factor- to rule ot Rheumatoid arthritis

Parameter used: -
- Fibromyalgia Impact Questionnaire Score
- Allocation: Single arm study.
- End point classification:effectiveness.
- Condition: musculpskeletal manifestations of Fibromyalgia Syndrome
- Intervention: Homoeopathic medicine Causticum 30C
- Masking :Single blind
- Primary purpose: reduction in FIQ score and alleiviating musculoskeletal manifestations of Fibromyalgia syndrome.
- Mode of intervention : Orally

INCLUSION:
1) Patients who fulfill criteria to diagnose FMS according to latest ACR criteria.
2) Patients between18-75 years
3) Patients of both sexes
4) Patients with pain and tenderness for more than 3 months.
5) Patients who fulfill case definition.
6) Patients without any other systemic diseases.
7) Patients giving written consent form.

EXCLUSION:
- Autoimmune diseases.
- patients with Psychiatric diagnosis.
- pregnant and lactating women.
- patients with degenerative bone diseases.
- malignancy cases.
- recent major surgery.
- Immunocompromised cases.
- Patients on Allopathic medications
- Patients requiring emergency medical care
- Patients who have participated in any other Research study in last 6 months

OUTCOME ASSESSMENT:
Outcome was assessed using Fibromyalgia Impact questionnaire.

Outcome will be assessed with the difference between the score in the FIQ at every follow up, before treatment and after treatment. Interpretation of Scores: 0 to <39- Mild, <59- Moderate >59 to 100- Severe.These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise of the treatment.

The statistical analyses were conducted for FIQ score values by using the student paired "t" test. The test helps to establish whether the changes observed before and after treatment were significant or not. [10]

OBSERVATION & RESULT:
There is significant difference between the mean before & after treatment, therefore the null hypothesis stated earlier is rejected & the alternate hypothesis is accepted which says, Causticum in 30 potency helps in reducing the musculoskeletal complaints in Fibromyalgia Syndrome.

Table-1. Gender Wise Distribution Of The Study Participants

GENDERWISE DISTRIBUTION OF PATIENTS N= 30		
GENDER	NO. OF PTS	(PERCENTAGE)%
MALE	16	53.3%
FEMALE	14	46.7%

Table-2. Age Wise Distribution Of The Study Participatants

AGE GROUP	NO. OF PATIENTS	PERCENTAGE	MEAN		
20-29	10	33.3 %	Male	Female	Total
30-39	2	6.7 %	Mean age= 47.12 years	Mean age= 46.07 years	Mean age= 46.6 years
40-49	1	3.4 %			
50-59	5	16.6 %			
60-69	10	33.3 %			
70-79	2	6.7 %			

Table-3. Occupation Wise Distribution Of The Study Participants

OCCUPATION WISE DISTRIBUTION OF PATIENTS N= 30		
OCCUPATION	NO.OF PTS	(PERCENTAGE)%
STUDENTS	2	6.7%
HOUSEWIVES	2	6.7%
RETIRED	7	23.3%
WORKING	19	63.3%

Table 4. Descriptive Statistics Of The Fiq Score At Different Follow-ups

OBSERVATION	N	MEAN	STD. DEVIATION	MINIMUM	MAXIMUM
FIQ1 score at First follow up	30	62.18	6.18	52.60	77.30
FIQ score at Second follow up	30	57.28	6.21	46.50	72.60
FIQ score at Third follow up	30	49.23	6.68	37.00	64.10
FIQ score at Fourth follow up	30	41.45	7.86	21.10	57.50
FIQ score at Fifth follow up	30	35.67	7.01	23.50	51.30
FIQ score at Sixth follow up	30	32.04	6.25	21.60	46.00

Table-5- Paired Differences Of Fiq Score Between First Follow-up And Last Follow-up

							95% CI OF Difference				
FIQ SCORE	N	MEAN	SD	SEM	MIN	MAX	LOWER	UPPER	T	DF	P Value
AT FIRST FOLLOW-UP	30	62.18	6.18	1.12	52.60	77.30	29.01	31.26	54.88	29	0.000*
AT SIXTH FOLLOW-UP	30	32.04	6.25	1.14	21.60	46.00					
MEAN OF DIFFERENCE	30.14										

*p value <0.001 statistically highly significant

N= Total no. of patients. SEM= Standard error of mean DF= Degree of freedom. SD= Standard deviation.

FIQ scores at 1st and last follow-up were compared using Student Paired t-test. This comparison showed statistically highly significant differences (p value <0.001) between 1st and last follow-up. This suggests that there was a significant decrease in the mean FIQ score value from 1st follow-up to last follow-up.

Table 6 - Intergroup Comparison Of Fiq Scores Between Different Follow-up Visits

FIQ Scores	Sum of Squares	df	Mean Square	F	P value
Between different follow-ups	21636.173	5	4327.235	95.483	.020*

*p value <0.05 statistically significant

Intergroup comparison was done to assess significant differences between the different follow-ups using One-way Analysis of Variance (ANOVA). This comparison showed statistically significant differences (p value <0.05) between different follow-ups. This suggests that there were significant differences in the mean values of FIQ scores at each follow-up.

Table 7 - Pairwise Intergroup Comparison Of Fiq Scores Between Different Follow-up Visits

(I) FOLLOW-UPS	(J) FOLLOW-UPS	MEAN DIFFERENCE (I-J)	P VALUE	95% CONFIDENCE INTERVAL	
				LOWER BOUND	UPPER BOUND
FU 1	FU 2	4.90	.059	-.1090	9.9090
	FU 3	12.94	.011*	7.9377	17.9557
	FU 4	20.73	.023*	15.7210	25.7390
	FU 5	26.51	.001**	21.5010	31.5190
	FU 6	30.14	.000**	25.1310	35.1490

*p value <0.05 statistically significant, **<0.001 statistically highly significant

Pairwise Intergroup comparison was done between the different follow-ups using Post hoc Tukey's test. This comparison showed statistically significant differences (p value <0.05) between first follow-up and 3rd and 4th follow-up and highly significant differences (p value <0.001) between first follow-up and 5th and 6th follow-up.

This suggests that after the treatment, the FIQ scores of the patients have gradually decreased with the subsequent follow-up visits.

STATISTICAL ANALYSIS:

(A) P Value of more than (>) 0.05 was considered non-significant.
(B) P value of less than (<) 0.05 was considered to be statistically significant.
(C) P value of less than(<) 0.001 was considered to be statistically highly significant

DISCUSSION

Fibromyalgia is a lifestyle diseases which has a worldwide prevalence. It has prevalence rate of 95% and if not treated on time it may lead to physical & .mental disabilities.

The present study was primarily aimed to investigate the effectiveness of the homoeopathic medicine Causticum30C in the management of cases of Fibromyalgia between the age group 18-75 years. Since it was a single arm study, only one group was involved in this study without any control group. Many researches have been done in homeopathic system on fibromyalgia but very little work has been done on individual homoeopathic medicine. Therefore single remedy Causticum 30C was selected for this study.It has got action on musculoskeletal system producing neuromuscular relaxation and help in reducting pain & stiffness. In this study 32 cases (male & female) of Fibromyalgia in age group 18-75 years

were included..2 patients dropped out from this study after 1or 2 follow up while rest 30 patients completed the study. They were subjected for 6-8 weeks of treatment with homoeopathic medicine Causticum 30C after proper case taking. They were administered Causticum 30C and the change in FIQ scored before and after the treatment & at every follow up were evaluated, which showed a positive effect on the pain intensity, stiffness & sleep disturbances of the patients in the study sample. This effect was demonstrated by the results of the statistical analysis (FIQ scores) using student paired "t" test, which manifests that the pretreatment and post treatment values of FIQ scores are indeed, different. It proves that Causticum 30C has scope in treatment of Fibromyalgia..

Age wise distribution –Age wise distribution was calculated by taking out the mean. The mean age is calculated as 46.6 years. Mean age of male patients is 47.12 years and mean of female patients is 46.07 years. Most of patients were found in age group of 40-50 years. This suggests that advanced age has more risk for developing essential hypertension.

Sex wise distribution–Sex wise distribution was also calculated in percentage, where it was found that Out of 30 cases, 16 were male & 14 were female (which indicates that prevalence of Fibromyalgia is more common in males as compared to females. Some limitations which require to be solved in further studies conducted in future.

- Sample size: Another limitation is related to small sample size. Due to this the question arises about the generalizability.
- Duration of study: Study duration also one of the limitation. As the study was of 2 months for each case therefore it doesn't reflect the efficacy of Causticum 30C in long term.
- Lack of control group: The study becomes more reliable when we do randomized study with control group, but in present study there was absence of control group.
- Age distribution: Although the age group selected for the study had wide range i.e. from 18-75 years of age, most of the cases are falling in the range of years age group. This factors may possibly confound there results obtained.

Finally this study data proposes that homoeopathic medicine Causticum30C has significantly favorable effect in patients suffering from Fibromyalgia.. It can be adopted as an alternative public health approach in restraining the high prevalence of Rheumatic symptoms of Fibromyalgia worldwide.

CONCLUSION:

Fibromyalgia is a symptom complex comprising of chronic musculoskeletal pains, sleep disturbances & behavioural changes. Persistant pain leads to disabilities & hampers daily chores & activities. FMS is a lifestyle disorder & has a severe impact especially on adults & working population with sedentary lifestyle. 30 patients completed this study. The results indicate that there was a significant reduction in pain, stiffness & other musculoskeletal complaints in cases of FMS patients. Treatment with Causticum 30 has produced significant reduction in symptoms & FIQ scores & also has proven as safe & effective choice of remedy for symptomatic relief. Also it has been noticed that maintaining causes i.e factors like sedentary lifestyle, inappropriate dietary & sleeping habits, stress, lack of exercise are important hurdles for complete recovery. Councelling for behavioural disturbance plays an important role. It can also be concluded that Fibromyalgia is a lifestyle diorder. Since it is a study on a small sample size, further studies on huge mass & large sample sizes with randomized placebo controlled groups can provide a greater resource for proving that causticum 30 is effective in the treatment of Fibromyalgia.

CONFLICT OF INTEREST

The authors have no conflict of interest among them regarding the research.

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