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Can individualized homoeopathic medicines bring a ray of hope the patients of rheumatoid arthritis: A pilot study

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Abstract

Background: Rheumatoid arthritis (RA) is one of the most common autoimmune disorders, affecting approximately 0.75% of the population in India i.e., around 7 million people. Clinical case reports, observational studies and RCTs show effects of homoeopathic medicine in the pain management and treatment of rheumatoid arthritis. Although no concrete inference can be drawn on the basis of these studies due to their small sample sizes and short study duration. Therefore, this pilot study is made to study the efficacy of the homoeopathic remedies in the treatment of RA as well as scope of further researches in this disease condition.

Material and Methods: The pilot study was undertaken in the Out Patient Department of State National Homoeopathic Medical College & Hospital, Lucknow, Uttar Pradesh, India from March 2021 to March 2022. Out of 40 patients screened, 22 patients fitted to the inclusion criteria were enrolled to receive individualized Homeopathic medicines in centesimal potency (30,200,1M or more). Patients were enrolled on the basis of American College of Rheumatology 2010 classification criteria. Out of these 22 patients, only 16 patients have completed the follow up of six or more months. Disease Activity Score 28 score was used to assess the patients at baseline and at 6 months. The objective of the study to assess the changes in Disease Activity Score 28 at the end of 6 months from the baseline.

Results: Paired t-test was applied to the DAS 28 score data obtained at baseline and the end of 6 months and comparison between the values is statistically significant (mean diff.- 2.136, 95% CI=1.640 to 2.632, p value= 0.00000315) favouring individualized homeopathy. The medicines were selected after detailed case taking and repertorization.

Conclusion: The study has clearly indicated that individualized homoeopathic medicines can be useful in the treatment of rheumatoid arthritis.

Keywords: Rheumatoid arthritis, individualized homoeopathic medicines, American college of rheumatology 2010 classification criteria, disease activity score 28.

1. Introduction

Rheumatoid arthritis (RA) is one of the most common autoimmune disorders, affecting approximately 1% of the population worldwide. It is more common in women than men. Two types of rheumatoid arthritis can be defined on the basis of symptom duration: Early RA, with symptom duration less than six months and Established RA with symptom duration more than six months [1]. The aetiology of RA remains unknown however some risk factors like age, sex, genetic factors, and environment factors might be responsible for the development of RA [2, 3].

RA is inflammatory processes in the synovium of the joint that eventually leads to the destruction of both cartilaginous and bony elements of the joint, with resulting pain and disability. Most commonly affected joints are of hands, wrist and knees and PIPs. Systemic inflammation associated with RA with a variety of extra-articular comorbidities, like cardiovascular disease, which is responsible for increased mortality in patients with RA. It is also associated with several psychosocial disorders [1, 2].

Diagnosis of RA is based on both clinical symptoms and lab investigations. For confirmatory diagnosis ACR classification of Rheumatoid arthritis 2010 is to be followed [4]. Clinical symptoms includes pain or aching, stiffness, swelling in more than one joint (the symptoms are symmetrical in nature), weight loss, fever, fatigue or tiredness, weakness [3].

Lab investigations include RA factor, Anti- CCP (Anti cyclic citrullinated peptide antibodies), CRP and ESR [1]. RA factor is not diagnostic for RA. Anti-CCP may raise in 50% patients of early arthritis and CRP, ESR are raised in active phase of RA.

X-ray of affected joints are usually obtained for the presence of erosions, the pathognomonic feature of rheumatoid arthritis, however, plain radiograph does not show early changes of the disease ^[1].

Conventional treatment focuses over reducing pain and limiting disability. It follows ACR guidelines for rheumatoid treatment 2015 ^[5] and disease activity is assessed at regular intervals by DAS28 ^[6]. Though proved beneficial, not all patients respond or maintain efficacy to desired standards ^[1, 6].

Homoeopathy is a system of drug therapeutics based on law of similia. Dhawle ML ^[7] has written in his book that disease is a total response of an organism to adverse environmental factors, external or internal; it is conditioned by constitutional factors, inherited or acquired; and it manifests through symptoms in three spheres – Emotional, Intellectual and Physical. This response is divisible into (a) Individual response (characteristic symptom which denote the constitutional type) and (b) Group response (diagnostic symptoms). Therefore, no two persons suffering from same set symptoms can have the same remedy. This develops the idea of individualization which is the backbone of this holistic system of medicine and the fundamental change from the conventional model of treatment approach.

A complete and thorough case taking offers a full comprehension of the patient's personality, his constitution and his reaction to the environment in the form of production of symptoms (Subjective and objective) and fulfilled the purpose of individualized homoeopathic medicine. The sound principles of Homoeopathy aim at arresting further progress of the disease.

Few studies ^[6, 15] are conducted for role of homeopathic medicines in the treatment of rheumatoid arthritis and many of them shows promising results. It is clearly proved from the studies that only individualized homoeopathic medicines can bring a ray of hope in the patients suffering from RA. Although no concrete inference can be drawn on the basis of these studies due to their small sample sizes and short study duration.

Hence, a systematic study to assess the scope of Homoeopathy in the treatment of RA is the need of the hour. Therefore, this pilot study is made to study the efficacy of the homoeopathic remedies in the treatment of RA as well as scope of further researches in this disease condition.

Material & Methods

The observational study conducted at the outpatient department of National Homoeopathic Medical College & Hospital, Lucknow from March 2021 till February 2022. The study protocol was approved by the Institutional Ethical Committee dated 15 March 2021.

Patients were selected on the basis of inclusion and exclusion criteria. Consent form was signed by each patient prior to the study which carries the details of the study. Inclusion criteria: Patients considered above the age group of 10 years, irrespective of gender, ethnic group, socio economic status and occupation. Patients were screened and diagnosed on the criteria of American College of Rheumatology (ACR) classification of Rheumatoid arthritis 2010.

Patients who were below the age of 10 years, pregnant women and lactating mothers were not being included in the study. Along with this, patients who were not willing to give

their consent for study or not able to comply regular follow up, presenting with systemic RA, having another type of arthritis, uncontrolled diabetes, uncontrolled hypertension, chronic kidney disease, coronary artery disease or any other terminal illnesses were not included in the study.

Intervention

Detailed case taking as per the homoeopathic principles was being done to all the patients enrolled. After case taking, complete process of repertorization was being followed and Single individualised medicine was prescribed on each occasion taking into consideration presenting symptom totality, clinical history details, constitutional features, repertorization as and when required and due consultation with Materia Medica and most suitable, single remedy was prescribed. The remedy prescribed was in Centesimal potency (CM potency) in 30, 200, 1M or higher according to the case. This was given in single dose followed by placebo three times a day. However, in acute flare up of disease, mother tinctures or decimal potencies, LM potencies were also used.

Follow ups

Patients were followed up every 15 days and assessed by Visual Analog Scale. Patients were undergone Erythrocyte sedimentation rate (ESR)/C-Reactive Protein every month and assessed by Disease activity score (DAS 28). If any change was triggered after administration (improvement/deterioration), change of remedy was being done as per homoeopathic principles. Acute flare up of rheumatoid arthritis was common among patients during the treatment which was treated by most similimum, single remedy.

Lifestyle modification

Physical activity was advised as per the requirements of the patient. All participants were strongly encouraged to avoid alcohol and to stop smoking.

Outcome

To observe whether individualized homoeopathic prescription helps in the reduction of DAS28 score in the patients of Rheumatic arthritis.

Evaluation and Assessment

Patients were followed up every 15 days and assessed by Visual Analog Scale. Patients were undergone Erythrocyte sedimentation rate (ESR)/C-Reactive protein (CRP) every month and assessed by Disease activity score (DAS 28). It is the activity score to assess the patient response during the treatment of rheumatoid arthritis. Assessment of DAS 28 score is to be done as follows: ^[17] > 5.1 high disease activity, 3.2- 5.1 moderate disease activity, 2.6 and < 3.2 low disease activity, < 2.6 disease remission.

Statistical Technique

The principal analyses of outcomes employed the “per protocol” approach. Standard errors for inferences with 95% confidence intervals (CIs) are presented. Paired T-test is used between pre-treatment and post-treatment observations. Resulting P values for treatment-group effects are considered explorative, and $p < 0.05$ was considered statistically significant.

Results

Out of 40 patients screened, 18 (45%) patients were excluded and 22 (55%) were enrolled for the study during the period March 2021 and ends in Dec 2021. The reasons for exclusion were as follows: patients were not willing to give their consent for the study (n=7). Many patients who were already diagnosed with rheumatoid arthritis, were taking allopathic medicines and it was not possible to quit their doses instantly to include them in the study (n=9). In the beginning of the study, n=2 participants were dropped out and did not undergo for any of the investigations. At the end of the study, n=6 patients were dropped out, out of which at second month (n=4), at third month (n=2). Per protocol analysis is applied in the study. The flow chart of patients in the study is given in figure.

At the end of 6-month, assessment has been done by calculating VAS score, CRP/ ESR and DAS 28 score. Paired t- test is applied to compare pre and post treatment scores and results of the analysis are statistically significant in the favour of individualized homoeopathy. Per protocol analysis was applied to the patients who have completed six months study duration according to the protocol and the results showed statistically significant difference between pre and post treatment data. DAS28 score (mean diff.-2.136, 95% CI=1.640 to 2.632, p value= 0.00000315), VAS score (mean diff.=5.875, 95% CI=5.660 to 6.089, p value=0.000000000600), C-Reactive protein (mean diff.=5.450, 95% CI=1.921 to 8.978, p value= 0.0115).

Disease activity is also lowered at the end of the study. At baseline, 10 (62.5) patients had the DAS 28 of more than 5.1 and come under high disease activity while 6 (37.5) patients had DAS28 score between 3.2 to 5.1 and belong to moderate disease activity. At the end of 6 months, only 1(6.25) patients have high disease activity. 7 (43.75) patients have reduction in their disease activity from moderate to low disease activity. No patients could come in the category of remission (DAS28=<2.6). Overall, 15 (93.75) patients have reduction in DAS 28 score from baseline while 1(6.25) patient have shown increase in DAS 28 score.

However, there is no significant change in Rheumatoid factor and Anti- CCP findings at the end of 6 month. n=1, 16.66% of patients out of n=6, 37.5% of patients who were negative for both rheumatoid factor and anti-CCP and x-ray of their affected joint had erosive pathology showed mild improvement in x-ray findings along with improvement in DAS 28 score and VAS score.

The clinical symptoms which the patients reported and sought treatment were given in Table. In some cases, there is acute flare of the disease. 5 patients out of 16 in the duration of 6 months showed acute episodes. The most common symptoms during acute episodes were severe joint pain (VAS score= 7-10), stiffness, swelling and redness of joints. Sometimes fever and body ache were also noted by the patients. 4 patients out of 5 were treated with homoeopathic medicines and one patient could not find any relief and was referred to conventional treatment.

The prescribed homoeopathic medicines are Aurum metallicum (n=1), Capsicum (n=1), Colchicum (n=1), Cyclamen (n=1), Ignatia (n=2), Kali carb (n=1), Lac. Caninum (n=1), Lachesis (n=1), Phosphorus (n=2), Pulsatilla (n=2), Staphysagria (n=1). Medicines given in acute flare up were Pulsatilla 0/4-0/6 (n=1), Bryonia (n=1), Colchicum (n=1), Sabina (n=1).

Discussion

There were three situations that were faced during the study. One type of patients who had mild to moderate category of pain with less tenderness and swelling of the joint. They were treated with constitutional medicines by taking mental generals and physical generals into consideration along with their pathological symptoms.

Second type of patients n=5, (36.66%) were seeking for their treatment for rheumatoid arthritis had come with acute disease condition. They have symptoms joint tenderness, swelling, redness, fatigue, mental irritability etc.

The most important finding during the treatment was that pathology of disease should be taken into consideration along with mental generals, physical generals and peculiar symptoms. Thus, the study strongly recommends the view of Dr. Boger, who gave much importance to pathological symptoms. Although, this is not seen in all cases especially in mild to moderate type of cases.

Another finding during the study was that when many rubrics were taken into account, they mislead the case. Therefore, only peculiar, queer, rare symptoms should be taken to find the most correct remedy. The finding reproves Aphorism 157 of Organon of Medicine by Dr. Hahnemann^[16]. The study shows that individualized homoeopathic medicines reduce tenderness and swelling of joints by reducing inflammation of the synovial fluid which is actually important from the point of view of acute flare of rheumatoid arthritis. The results again correspond to the studies wherein individualized homoeopathic medicines were used^[17-20].

Further, it becomes clear from the study that only n=2 patients out of 9 patients who were positive for rheumatoid factor at baseline were found negative at the end of the study and these were taken treatment for more than 12 months. Other patients were positive for rheumatoid arthritis at baseline as well as at the end of the study. This confirms that long duration follows ups needed to get cured in cases of rheumatoid arthritis. Similarly, only n=2 out of 5 patients who were positive for Anti- CCP were negative at the end of the study and these patients have also completed their follow ups more than six months of treatment.

Limitations & Recommendations

Although the study showed statistically significant result in the favor of homoeopathy, there is not much change in rheumatoid factor and Anti-CCP values. More follow-ups are required to estimate the effect of individualized homoeopathic remedies in the cure of rheumatoid arthritis. Sample size is small in the study and proper follow ups cannot be arranged due to epidemic during the study. Generalization of results and conclusion could not be so effective.

The assessment scales could not be fool proof and human errors are possible. VAS score totally depends on the patient experiences hence, over and underestimation of DAS 28 score can be possible. Certain variables like quality of medicines, dispensing of medicines and placebo effect could not be controlled well.

Conclusions

The study showed that individualized homoeopathic medicines are beneficial in reducing DAS28 score. It reduces inflammation of joints as indicated by lowering in CRP values and thus reduces joints tenderness, swelling and

redness which facilitate the movement. As mentioned above, short duration of study and small sample size were limitations of the study, longer duration

for the study with large sample size is warranted in direction to cure the disease.

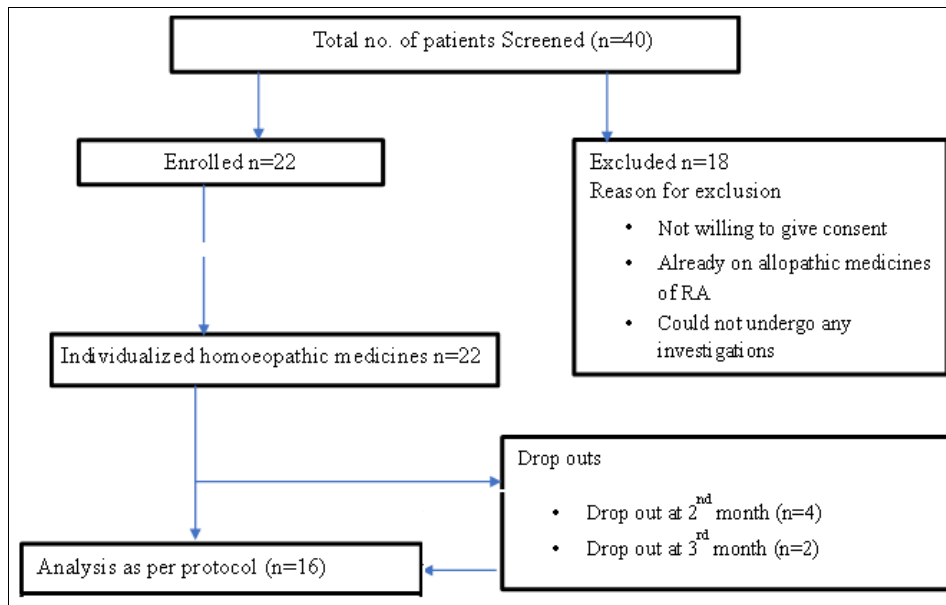


Fig 1: Flow Chart of the Study

Baseline Characteristics

Table 1: Baseline Characteristics of the Patients

Variable	No. of Patients (n=16)
Age	42.18±15.02
Male	4(25)
Female	12(75)
Sedentary	2(12.5)
Moderate	13(81.25)
Heavy	1(6.25)
Type of occupation	
Teacher	3(18.75)
Retired Clerk	1 (6.25)
Field Officer	1(6.25)
House wife	8(50.0)
House maid	1(6.25)
Students	2(12.50)
Family History	
Yes	5 (31.25)
RA	2(40)
Joint pain	2(40)
Joint pain with other co-morbidities	1(20)
No	11(68.75)
ACR Classification Score	
6/10	2(12.5)
7/10	8(50.0)
8/10	2(12.5)
9/10	4(25.0)
Disease Activity	
High (>5.1)	10(62.5)
Moderate (<5.1-3.2)	6(37.5)
Low (<3.2)	0(0.0)
Rheumatoid Factor and Anti-CCP	
Both Positive	4(25)
Both Negative	6(37.5)
RA factor positive & Anti-CCP negative	5(31.25)
RA factor negative & Anti-CCP positive	1(6.25)

Outcome at the end of 6 months

Table 2: Outcome of the study after analysis

	Baseline (mean ± SD)	6 months (mean ± SD)	Change (Baseline -6 month) (Mean diff.±SD)	Confidence Interval (95% CI)	P value (0.05)
DAS 28 score	5.368±0.828	3.365±0.980	2.136±0.859	1.640 to 2.632	0.000000*** <0.05
VAS Score	9.125±1.258	3.250±1.290	5.875±1.500	5.660 to 6.089	0.00000000*** <0.05
C-Reactive protein	8.816±8.034	3.750±2.013	5.450±6.110	1.921 to 8.978	0.0115<0.05
Disease Activity Baseline					At 6 months
High			10(62.5)	1(6.25)	
Moderate			6(37.5)	8(50.0)	
Low			0(0.0)	7(43.75)	
Rheumatoid Factor and Anti-CCP					
Both Positive			4(25)	3(18.75)	
Both Negative			6(37.5)	9 (56.25)	
RA factor positive & Anti- CCP negative			5(31.25)	4 (25.0)	
RA factor negative & Anti-CCP positive			1(6.25)	0(0.0)	

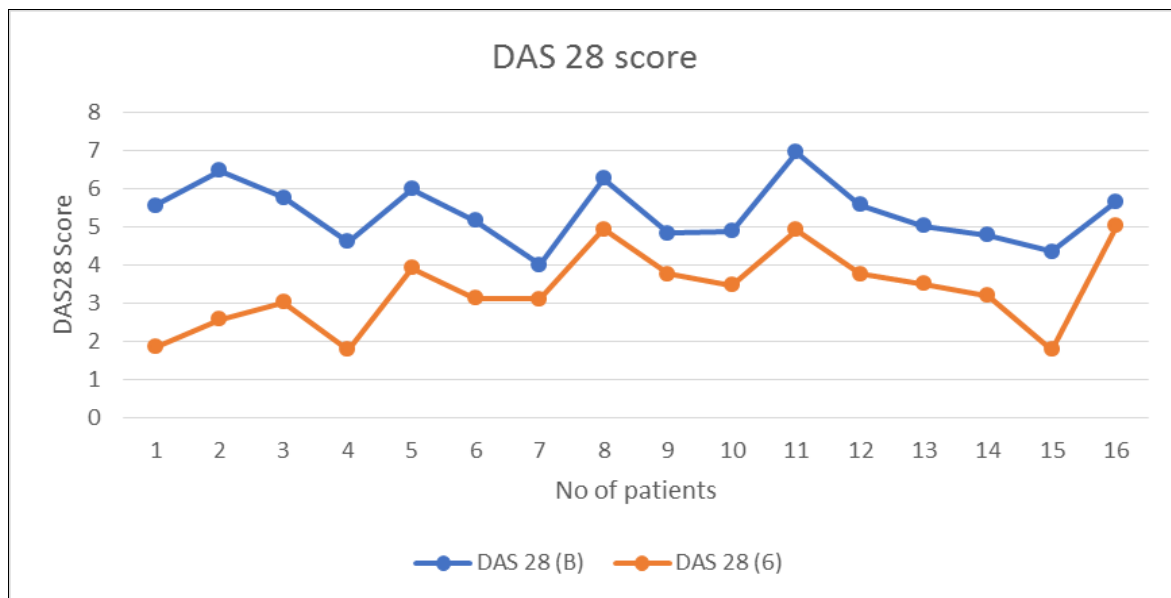


Fig 2: Changes in Disease Activity Score 28 score at Baseline and at 6 months

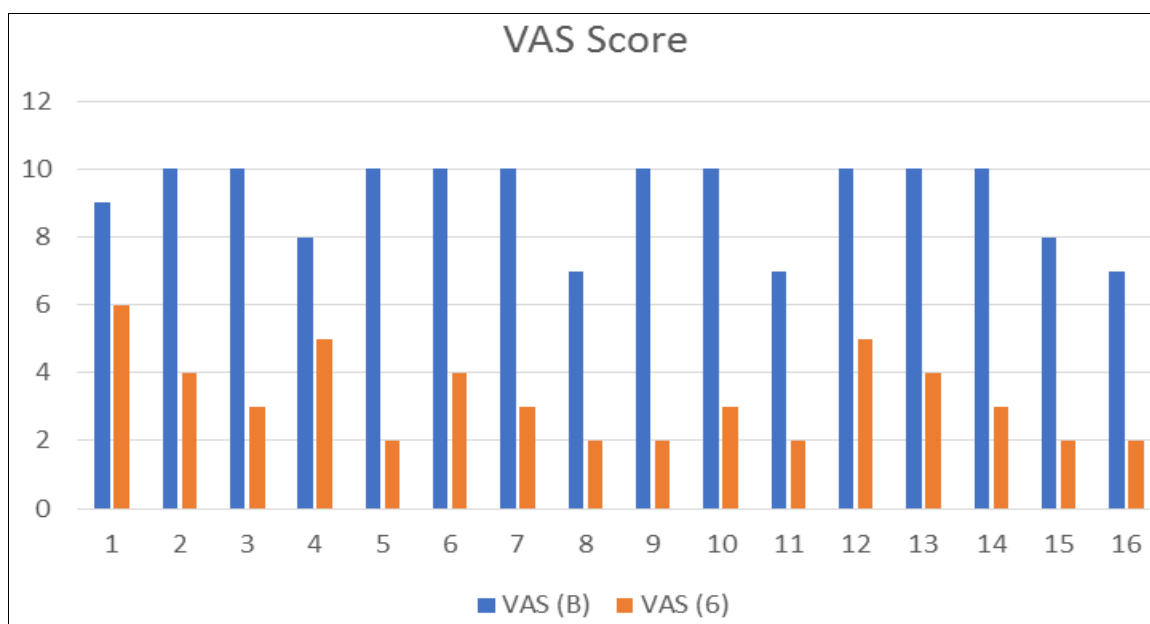


Fig 3: Changes in Visual Analog score at Baseline and at 6 months

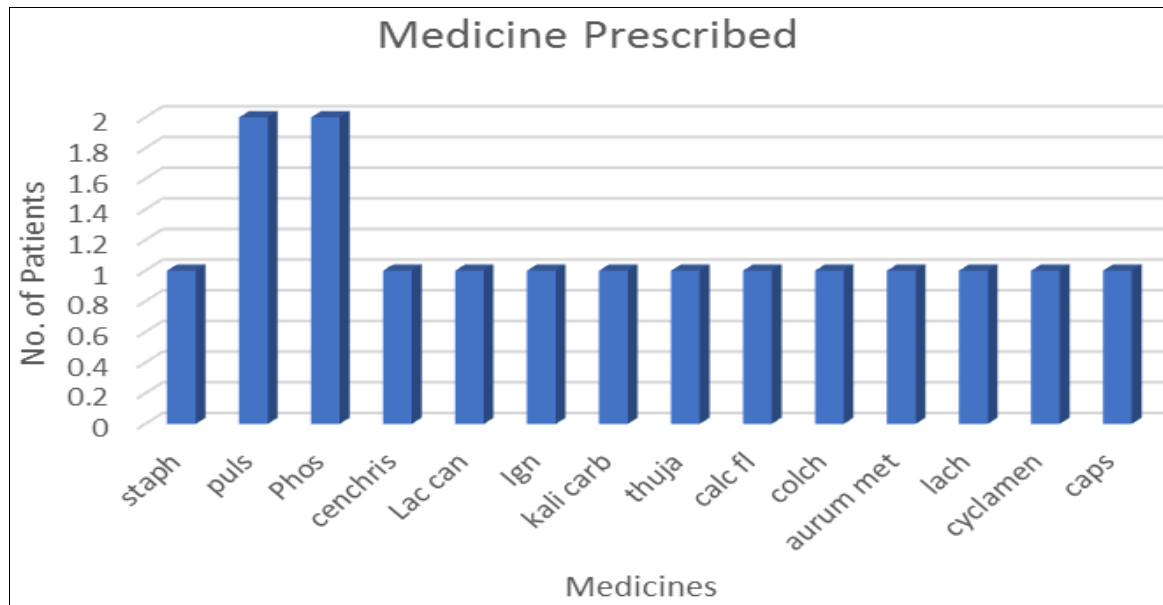


Fig 4: Medicine used in the patients during the study

Clinical symptoms reported by the patients during the study

Table 3: Clinical symptoms commonly found during the study

Physical Symptoms	Mental generals	Physical generals
Joint pain, swelling, redness of joints	Weeping when in pain	Constriction around neck
Joint pain, small joints	Aversion from being disturbed	Heaviness lower abdomen after eating food
Pain muscles rheumatic	Anxiety about health	Perspiration profuse
Pain joints broken as if	Delusion worthless he is	Dreams of falling from height
Joints nodes	Delusion of being raped	Dreams of lost somewhere
Joints crackling sound	Mind Jealousy	Dream of killing snakes
Weakness, fatigue, lethargic	Delusion legs are cut of	Dreams of death of relatives
Pain muscles belly of	Fear of loss of social position	
Stiffness joints morning	Sensitive to rudeness	
Stiffness joints morning movement amelioration	Fear of loss of position	
Pain heel morning when obliged to walk	Fear of snakes	
Joint pain, swelling etc evening aggravation	Fear of ghost, of being alone	
	Anxiety of conscience	

Conflict of Interest

Not available

Financial Support

Not available

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