

ORIGINAL ARTICLE

To evaluate the role of homoeopathic medicines as add-on therapy in patients with rheumatoid arthritis on NSAIDs: A retrospective study

Tapas K. Kundu¹, Afroz F. Shaikh², Sindhu M. Jacob

ABSTRACT

Background: Conventional management of Rheumatoid Arthritis (RA) includes administration of Non- Steroidal Anti- Inflammatory Drugs (NSAIDs), disease modifying anti-rheumatic drugs (DMARDs) like Methotrixate and anti-tumor necrosis factor α monoclonal antibody (anti-TNF α). Gastric ulcers, bleeding and perforation are the most common known adverse reactions found associated with excessive consumption of NSAIDs. The homoeopathic system of medicine improves the general well being, that is, Quality of Life (QoL) in addition to reducing the pain and disability. **Objective:** To evaluate the patients with RA receiving homoeopathic medicines with respect to QoL, Disease Activity Score (DAS), Erythrocyte Sedimentation Rate (ESR), morning stiffness/pain and frequency of analgesics after homoeopathic intervention. **Design:** This is a retrospective analysis of the role of homoeopathic medicines in RA. Patients diagnosed as sero-positive for RA antigen receiving homeopathic medicines were analysed for DAS, QoL, frequency of analgesics, ESR and pain/morning stiffness. **Materials and Methods:** Ten cases testing sero-positive for RA with at least four clinical signs were evaluated from single homoeopathic Out-Patient Department (OPD) from February 2009 and February 2011. Cases were analysed to find out the role of homoeopathic constitutional similitum in people with RA. Changes in DAS, ESR, pain/morning stiffness and QoL were considered as outcome measure. **Results:** Homoeopathic constitutional medicines were found to reduce the intensity of pain in patients with RA ($t = 4.3733$, $P < 0.01$) along with reduction in consumption of NSAIDs ($t = 2.4$, $P < 0.05$). The DAS reduced in all 10 patients ($t = 2.67$, $P < 0.01$). The QoL was also found to improve under homoeopathic medication ($t = 4.044$, $P < 0.01$) and no further deterioration joint/disability was observed in any of the 10 patients. Mean ESR improved to 19.5 from 38.1 ($t = 2.235$, $P < 0.05$). Out of 10, 3 (30%) patients were found to be sero-negative after homoeopathic constitutional similitum. **Conclusion:** Homoeopathic constitutional similitum improves the QoL of patients with RA by reducing intensity of pain, limiting disability and reducing disease activity, thus causing improvement in general and disease condition in particular. It also limits the need of analgesics and DMARDs in RA.

Keywords: Deformity, Homoeopathy, Disease Activity Score, Analgesics, Rheumatoid arthritis

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INTRODUCTION

Rheumatoid Arthritis (RA) is a chronic inflammatory disease characterised by progressive, symmetric joint inflammation and subsequent deformity. If left untreated, RA is associated with significant patient morbidity and accelerated mortality. The disease affects females four times more frequently than males in 4:1 proportion, and the reported prevalence of RA varies from 0.5% to 3.8%.^[1] Subsequent destruction of articular cartilages leads to joint stiffness and limited mobility affects daily household activity.

The extent of use of complementary and alternative medicine in chronic diseases like OA or RA is about 58%. Nearly 15% of people with RA use homoeopathy as complementary alternative medicine with prime objective to reduce pain.^[2] Conventional treatment of RA focuses over reducing pain and limiting disability and involves administration of non-steroidal anti-inflammatory drugs (NSAIDs), disease modifying anti-rheumatic drugs (DMARDs) like methotrixate and anti-tumor necrosis factor α monoclonal antibody (anti-TNF α) and steroids. Though proved beneficial, not all patients respond or maintain efficacy to desired standards.^[3] Gastric ulcers, bleeding and perforation are the most common known adverse reaction found associated with excessive consumption of NSAIDs.^[4] Currently available therapeutics is suboptimal as regards both their efficacy and tolerability.^[5] With increasing complexity of life and underlying immunopathogenesis, the severity of disease has led to elevate the goals of treatment of RA.^[3]

Homoeopathic system of medicine aims at improving the general well being of the individual (i.e., quality of life; QoL) in addition to reducing the pain and disability, which fulfils the criteria of improvement laid by American College of Rheumatology (ACR). A controlled clinical trials conducted for this degenerative disease in the field of Homoeopathy examined the enhanced response of those on conventional therapy with homoeopathic medicines over those on conventional medicine with placebo. This measure valued the therapy in the management of patients with RA.^[6] Randomised control trial of homoeopathy in RA conducted by Fisher and Scott identified significant pain relief with placebo than homoeopathic medicine. The study suggested that active homoeopathic medicines does not improve the symptoms of RA patients who are stabilised

with NSAIDs/DMARDs. These results could be the effect of blinding.^[7] Similarly a randomised clinical trial regarded the clinical benefit of homoeopathic intervention in RA attributable to the consultation process and not the therapy itself.^[8] The present paper examines the clinical assessment including QoL of the patient with homoeopathic constitutional similimum (selected on the basis of mental generals, physical generals and particular symptoms).

In this study, the patients with RA receiving homoeopathic medicine were analysed for QoL, disease activity score (DAS), erythrocyte sedimentation rate (ESR), morning stiffness/pain and frequency of analgesics as outcome measures.

MATERIALS AND METHODS

Setting and Study Design

The present study was conducted at private homoeopathic OPD located at Upnagar, Nashik, Maharashtra, India. The data of ten patients under homoeopathic treatment for more than three months, over a period between February 2009 and February 2011, were retrospectively analysed to investigate the efficacy of homoeopathic medicines in patients with RA.

Methodology

Ten cases of RA (age 32-60 years) under homoeopathic treatment were evaluated from the single private homoeopathic out-patient clinic. Those under the homoeopathic treatment for a period of more than 3 months, between February 2009 and February 2011, were analysed. These were diagnosed cases of RA and confirmed clinically by presence of at least four clinical signs or symptoms as swelling of two or more joints, morning stiffness lasting for more than 1 hour for at least 6 weeks, symmetric arthritis, that is simultaneous involvement of same joint area on both sides of body, presence of rheumatoid nodule over bony prominences/extensor surface or juxtra articular region.^[9] These patients were not satisfied with conventional treatment. These cases were analysed to find out the role of homoeopathic constitutional similimum in people with destructive joint disease, that is RA. Patients receiving NSAIDs, DMARDs or anti-TNF α were also analysed after homoeopathic medicines, as to check frequency of the use of such drugs when the patient is receiving homoeopathic medicines as a complementary therapy [Table 1].

Table 1: Findings of individual patient under study

Age/ sex	Symptoms (pain/swelling of the joints)	Duration of disease	Period of treatment (months)	Using NSAIDs (mg)	Frequency of analgesics		Constitutional similimum	Acute similimum
					Before	After		
58/F	Rt elbow, IPJ, B/L knee	15 years	19	Proxym 300	Daily	SOS (once in 15 days)	<i>Cocculus 1M</i>	<i>Bryonia alba 6C</i>
47/F	Rt ankle, B/L knees	8 months	16	Fluproxy 100	SOS	Stopped	<i>Belladonna 1M</i>	
36/F	Rt wrist, both knees, lt ankle	4 years	17	Fluproxy 100	SOS	Stopped	<i>Pulsatilla 1M</i>	
34/F	MCPJ, IPJ, MT, sacrum	5 years	22	Proxym 300	Once in 2-3 days	Stopped	<i>Silicea 200C</i>	
60/M	IPJ, B/L knees	3 years	15	Proxym 300	Daily	Stopped	<i>Bryonia alba 6C</i>	
41/F	B/L elbows, shoulders, knees, ankles	2 years	2	Fluproxy 100	Daily	SOS	<i>Sepia 1M</i>	
32/M	lt TMJ, B/L knees, toes, rt clavicle	2 years	23	Proxym 300	Daily	SOS	<i>Causticum 200C</i>	
65/F	IPJ, B/L elbow and knee, ankles	22 years	23	Proxym 300	Once in 4-5 days	Stopped	<i>Calcarea carbonicum 200C</i>	<i>Rhus toxicodendron 6C</i>
35/M	Both knee, elbow, shoulders, back, IPJ	8 years	20	Fluproxy 100	Daily	SOS	<i>Aurum metallicum 1M</i>	<i>Rhus toxicodendron 6C</i>
38/F	Both knees, shoulders, ankles	8 years	17	Proxym 300	SOS	Stopped	<i>Nux vomica 1M</i>	

IPJ: Interphalangeal joint; MT: Meta Tarsal Joint; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs

Inclusion criteria

Patients tested sero-positive for RA, patients who took homeopathic medicine for 3 months or more were included in the study.

Selection of homoeopathic medicine

The homoeopathic medicines were selected as per the law of similia and prescribed singly at one occasion. The analysis was done as per Kentian school of philosophy, that is mental general, physical general and characteristic particular. Detailed case taking, its recording and interpretation of the symptoms were the steps followed for repertorisation. The symptoms were classified and evaluated to erect the totality. The repertorial results were analysed and importance given to the essence of the patient considering life space situation, predominant mental/emotional state (diagnosis of the person as a whole) for final selection of medicine. Placebo was continued with improvement in general condition of the patient. The selection of acute medicine was based on acute totality. In cases where medicine was changed Gibson–Miller remedy relationship was followed.^[10] The potency and repetition of medicine was decided by individual susceptibility.^[11] Synthesis repertory (Version 09) was used for repertorisation using RADAR 10 software.

Assessment of the progress

Consultations were planned at one month of interval or early if needed and recorded with standardised

detail with respect to clinical history, current symptoms, mental/emotional states and medication. Individualised homoeopathic prescription was given in pills. The potency of the medicine during subsequent consultations was raised based on the progress of the case or the medicine was changed in cases where no change in the symptoms observed following Gibson–Miller remedy relationship. ESR tested at 3 months of duration. Each individual patient was assessed for DAS set by ACR. Joint count is one of the components to measure DAS and includes swelling, tenderness, pain on motion, limited motion and deformity. The other components to measure DAS are ESR and patient's global assessment on visual analogue scale (VAS). Pain/morning stiffness was measured on VAS rated from 0 to 10. In addition to DAS, morning stiffness and QoL were also considered as outcome measures [Table 2]. QoL measured as Grade I (no handicap, can carry daily activities) Grade II (moderate restrictions of activities but independent), Grade III (marked restriction of activities mostly limited to self care, needs assistance) and Grade IV (bed/chair bound, incapacitated and dependant). The grading was done according to Steinbroker's classification (modified).^[11] +2 variation in pain score on VAS, reduction of ESR towards normal value, changes in QoL to the subsequent lower side, improvement in DAS to Grade I and reduction in the

consumption of analgesics and NSAIDs to SOS were considered as baseline parameter for improvement.

Statistical Analysis

The results are the comparison of components in the variable before and after the treatment modality using paired tail *t*-test. Pain score, DAS and QoL were analysed on 0.01 level of significance. DAS calculated as $0.5 \sqrt{\text{Tender}} + 0.06 \sqrt{\text{Swollen}} + 0.33 (\text{ESR}) + 0.007 (\text{Global health on VAS})$. DAS is classified >3.6 as high disease activity, between 2.4 and 3.6 as moderate disease activity, between 1.6 and 2.4 as low disease activity and below 1.6 as experiencing remissions.^[12] ESR and frequency of use of analgesics were analysed at the confidence level of significance of 0.05. Non-parametric test–Spearman’s rank correlation–was employed to find out the correlation between each variable before and after homoeopathic medication [Table 3]. As Spearman’s correlation coefficient is close to 1, it proves that there is positive correlation in decrease in pain score, due to the homeopathic treatment, which proves that the treatment worked successfully [Table 4].

RESULTS

In the present trial, seven females and three males were found to have sero-positive RA. Homoeopathic similimum were found to reduce the intensity of pain in patients with RA. Mean pain score reduced to 3.0 from 7.5. ($t = 4.3733, P < 0.01$) along with reduction in consumption of NSAIDs and DMARDs. Five patients were taking analgesics daily, two patients were consuming analgesics at an interval of 3-5 days, whereas three patients were taking analgesics as SOS. After being treated with add-on homoeopathic medicines, six patients completely stopped analgesics and four continued to do so as SOS. One patient was treated with Methotrixate (mild immunosuppressant) 2.5 mg twice a day, who after being treated by homoeopathic medicine, reduced the said drug to once a day from second subsequent month then alternate day from third to fifth month and finally stopped at the end of fifth month. The mean frequency of analgesics fell from 2.2 to 1.4 and standard deviation (SD) from 0.918 to 0.516. ($t = 2.4, P < 0.05$). The disease activity reduced in all 10 patients. Mean DAS improved to 2.0585 from 3.23, and SD to 0.759 from 1.163 ($t = 2.67, P < 0.01$). The QoL was also found to improve under

Table 2: Response to therapy

Age/ sex	DAS		Pain score		QoL (grade)		ESR	
	Before	After	Before	After	Before	After	Before	After
58/F	3.0402	2.396	8	4	III	II	23	15
47/F	1.5982	1.32	6	0	II	I	8	4
36/F	2.3948	0.528	6	0	II	I	36	16
34/F	4.2461	2.6665	8	2	III	II	42	25
60/M	3.7767	2.8455	8	4	IV	II	52	30
41/F	2.4953	1.7538	8	4	III	II	24	17
32/M	3.2525	2.9925	6	4	II	I	32	30
65/F	3.3985	2.285	8	2	IV	II	36	12
35/M	5.7164	2.1622	10	6	IV	II	100	30
38/F	2.3874	1.636	8	4	II	I	28	16

DAS: Disease Activity Score; QoL: Quality of Life; ESR: Erythrocytic Sedimentation Rate

Table 3: Statistical outcome of variables

Attribute	First	Median	Third	Interquartile
	quartile		quartile	range
Pain score before	6	8	8	2
Pain score after	2	4	4	2
DAS before treatment	2.3948	3.14635	3.7767	1.3819
DAS after treatment	1.636	2.224	2.667	1.030
No of joints affected before	4	4.5	7	3
No of joints affected after	1	2.5	4	3
ESR before	24	34	42	18
ESR after	15	16.5	30	15
QoL before	Grade II	Grade III	Grade IV	Grade II
QoL after	Grade I	Grade II	Grade II	Grade I

QoL: Quality of Life; DAS: Disease Activity Score; ESR: Erythrocytic Sedimentation Rate

homoeopathic medication. Mean QoL improved from 0.525 to 0.85 ($t = 4.044, P < 0.01$) [Table 5] and no further deteriorations (joint disability) was observed in any of the 10 patients. Mean ESR improved to 19.5 from 38.1 ($t = 2.235, P < 0.05$). Three of ten (30%) patients tested sero-negative after homoeopathic constitutional similimum.

DISCUSSION

RA, a destructive joint disease, affects the articular cartilages leading to limited movement at the affected joint or in advance cases causing deformity of the joint making the patient disabled and dependent. The diagnosis is made by the clinical signs and symptoms along with positive serological tests. Joint count is a major component of DAS. Joint tenderness, joint swelling and ESR are measures of inflammatory activity and are included

Table 4: Spearman's correlation between pain score before and after

Pain score before	Pain score after	Rank before	Rank after	D	D ²
8	4	6.5	7	0.5	0.25
6	0	2	1.5	0.5	0.25
6	0	2	1.5	0.5	0.25
8	2	6.5	3.5	3	9
8	4	6.5	7	0.5	0.25
8	4	6.5	7	0.5	0.25
6	4	2	7	5	25
8	2	6.5	3.5	3	9
10	6	10	10	0	0
8	4	6.5	7	0.5	0.25

$\sum D^2=44.5$, Spearman's rank correlation coefficient = $1 - (6 \sum D^2/n(n^2-1)) = 1 - (267/990) = 1 - 0.26 = 0.74$

Table 5: Changes in pain score, DAS, frequency of analgesics, ESR and quality of life of patients with Rheumatoid Arthritis

Parameters	Mean (treatment)		Standard deviation (treatment)		P value
	Before	After	Before	After	
DAS	3.23061	2.05855	1.163	0.759	< 0.01
ESR	38.1	19.5	24.767	8.872	< 0.05
Pain score	7.5	3.0	1.264	3.076	< 0.01
Frequency of analgesics	2.2	1.40	0.918	0.516	< 0.05
QoL	0.525	0.85	0.2188	0.1902	< 0.01

DAS: Disease activity score; ESR: Erythrocyte Sedimentation Rate; QoL: Quality of Life

in the core data set of measures of DAS for use in clinical research and control of inflammatory activity according to these measures is regarded as an effective strategy to prevent long-term damage.^[13] Joint score includes swelling, tenderness and pain on motion, limited motion and deformity. Holistic treatment of the disease involves relief of the symptoms of disease, that is pain, tenderness and limited mobility of joints, and also the improvement in the QoL to carry out daily activities independently. In this observational study, 10 diagnosed patients of RA (sero-positive) and receiving homoeopathic medicines were evaluated. Out of these 10 patients, 3 (30%) tested sero-negative after homoeopathic similimum. One patient improved with *Pulsatilla*, whereas the other two patients received *Belladonna* 30 and *Aurum Met* 30 (raised slowly to IM over a period of 2 years), respectively, and serum turned negative for rheumatoid factor, one was rated high for DAS and the other two with moderate DAS.

Three of ten patients were found to have deformity of the most affected joints. Two patients had ulnar deviation of both the wrist joints, whereas the third patient had swan neck deformity at inter-phalangeal joints. The pain score/joint count improved in all the 10 patients with reduction in consumption of NSAIDs. A minimum difference of 4 in pain scale was considered significant. ESR was performed at 3-4 months interval, which also showed reduced disease activity. After assessment, three patients were classified with high DAS, four with moderate DAS, two with low DAS and one with remissions. After homoeopathic constitutional similimum, three patients were classified with moderate DAS, four with low DAS and three with remissions. QoL also was found to improve under homoeopathic constitutional similimum. The change from one grade to another was considered as significant. *Arsenic album*, *Belladonna*, *Calcarea carb*, *Lachesis*, *Pulsatilla*, *Causticum*, *Nux vomica*, *Silicea*, *Cocculus*, *Sulphur*, *Sepia*, *Aurum metallicum* were used as constitutional similimum given singly at one occasion depending upon the totality of symptoms [Table 1]. The potency, dose and its repetition was done according to the individual susceptibility. *Rhus tox* and *Bryonia alba* were prescribed in cases where patient did not respond after administration of constitutional drug for next 2 days in acute phase. This prescription was made according to acute totality as SOS in 3 of 10 cases, 4 pills to be taken at 6 hours interval for 3-5 days. In cases where medicine was changed Gibson-Miller remedy relationship was followed. The totality of the symptoms was constructed considering mental generals, physical generals and particular symptoms of the patient and repertorisation done using Synthesis repertory (Version 09).

The dose of NSAIDs/DMARDs was slowly reduced as per the improvement found in general and disease condition of the patient. Appetite, thirst, bowel habit and sleep were considered for improvement in general condition. Whereas intensity of pain on VAS, duration of morning stiffness and ESR were the parameters to evaluate the disease condition. Five patients were taking analgesics daily, two patients were consuming analgesics at an interval of 3-5 days, whereas three patients were taking analgesics as SOS. The analgesics were slowly tapered down to alternate day, followed by reducing it to SOS and then stopping it completely in patients who were consuming it daily. Whereas those who

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were consuming the analgesics at an interval of 3-5 days were suggested to take it as SOS followed by complete stoppage of the medicines. Those who were taking analgesics as SOS stopped it as there was improvement in the general condition. After being treated with add-on homoeopathic medicines, six patients completely stopped analgesics and four continued to do so as SOS.

The patients are continuing homoeopathic medicines as required on account of pain caused by climactic variation or any other exciting cause. These acute exacerbations are managed with administration of constitutional similimum selected on the basis of mental general, physical general and particular symptoms or based on the acute totality as required. Though the deformity in three patients did not improve under the treatment, no further deterioration of the affected joint or the deformity of any new joint was reported.

There were two distinct observations during the study. i) Patients revealed negative rheumatoid factor on laboratory investigations still complained of occasional arthralgia on weather change. ii) Where the serum is positive for rheumatoid factor but no or minimal physical symptoms are complained by the patients. These varied reactions to the immunogens during the treatment period with homoeopathic medication to the individual susceptibility and sensitivity, need to be further studied by considering large samples. The results of this observational study lead to investigate the efficacy of homoeopathic medicines in such degenerative disorders from controlled trials on large sample.

CONCLUSION

Homoeopathic constitutional similimum improves the QoL of patients with RA by reducing intensity of pain, limiting disability and reduces the disease activity. Thus the improvement in general and disease condition limits the need of analgesics and DMARDs in RA.

Scope of further research

The present study is an observational one where patients diagnosed as having RA by sero-positivity along with presence of at least four clinical signs of

RA, under homoeopathic medication were analysed. Similar research could be done with a greater sample size to investigate the role of homoeopathic medicines considering two different samples, namely sero-negative and sero-positive RA.

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पृष्ठभूमि: नॉन स्टिरॉयडल एंटी इनफ्लेमेटरी ड्रग्स रोग संशोधित प्रतिसंधिवातीय दवायें जैसे कि मेथोट्रिक्सेट और प्रति अवुर्द्धि परिगलन कारक अल्फा एंटीबाँडी (α) का प्रशासन संधिवातीय गठिया के व्यवहारिक प्रबन्धन में सम्मिलित है। पेट का अल्सर, रक्त बहाव व वेध, गैर उत्तेजक प्रतिसूजक औषधियों का अत्यधिक प्रयोग करने से होने वाले विपरीत प्रभाव हैं। होम्योपैथी दर्द व असशक्तता में कमी कर जीवनशैली की गुणवत्ता में सुधार करती है।

उद्देश्य: होम्योपैथिक हस्तक्षेप के बाद गठिया रोगियों में जीवनशैली, रोगक्रिया स्कोर, इरिथ्रोसाइट अवसादन दर, प्रातः कठोरता/दर्द और एनाल्जेसिक की बारम्बारता का आकलन करना।

प्रारूप: संधिवात गठिया में होम्योपैथी की भूमिका का विश्लेषण करने के लिये यह एक अवलोकनार्थ अध्ययन है। होम्योपैथिक दवा लेने वाले संधिवात गठिया के लिये सीरो पोजिटिव मरीजों में जीवनशैली, रोगक्रिया स्कोर, इरिथ्रोसाइट अवसादन दर, प्रातः कठोरता/दर्द और एनाल्जेसिक की बारम्बारता के आधार पर विश्लेषण किया गया।

सामग्री और विधियाँ: फरवरी 2009 और फरवरी 2011 में एकल होम्योपैथिक बाह्य चिकित्सा विभाग से कम से कम गठिया/संधिवात एन्टीजन सीरो पोजिटिव के 10 मामलों का आकलन किया गया। संधिवात से पीड़ित व्यक्तियों में होम्योपैथिक संगठनात्मक सिमिलिमम की भूमिका का पता लगाने के लिये मामलों का विश्लेषण किया गया व जीवन शैली, रोगक्रिया स्कोर, इरिथ्रोसाइट अवसादन दर, प्रातः कठोरता/दर्द में परिवर्तनों का अवलोकन किया गया।

परिणाम: संगठनात्मक होम्योपैथी दवाइयों ने संधिवात रोगियों में नॉन स्टिरॉयडल एंटी इनफ्लेमेटरी ड्रग्स के प्रयोग में कमी के साथ-साथ दर्द की तीव्रता में भी कमी की। सभी दस मामलों में रोग तीव्रता स्कोर कम हुआ। सभी दस मामलों में होम्योपैथिक उपचार के बाद जीवनशैली में भी सुधार (टी=2.67, पी <0.01) पाया गया तथा असशक्तता में वृद्धि नहीं पाई गई। माध्य इरिथ्रोसाइट अवसादन दर में सुधार, 38.1 से 19.5 (टी=2.235, पीसी 0.05) हुआ। होम्योपैथिक संगठनात्मक सिमिलिमम के बाद दस में से तीन रोगी (30%) सीरो नेगेटिव पाये गये।

निष्कर्ष: संधिवात रोगियों में होम्योपैथिक संगठनात्मक सिमिलिमम, दर्द घटाकर, असशक्तता को सीमित कर व रोग क्रिया में सुधार कर जीवन शैली में सुधार करती है। इस प्रकार संधिवात रोगियों में सामान्य एवं रोग स्थिति में सुधार, एनाल्जेसिक व रोग संशोधित प्रति संधिवातीय दवाओं की आवश्यकता में कमी करती है।

