



## EFFECT OF MEDITATION IN THE MANAGEMENT OF RHEUMATOID ARTHRITIS

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**ABSTRACT**

**Objectives:** To study the effect of meditation in the management of Rheumatoid Arthritis

**Study design:** Sixty Rheumatoid Arthritis patients through randomization were divided into 2 groups - Experimental and Control group. Meditation was incorporated along with standard treatment of Rheumatoid Arthritis in the Experimental group and both groups were followed for 6 months. ESR was repeated every month to calculate Disease Activity scores 28(DAS28). The Control group received only the standard treatment of Rheumatoid Arthritis.

**Results:** Significant improvements were observed in the Tender Joint Count, Swollen Joint Count and Pain scores in the Experimental Group. However, there were no significant improvements in the ESR and Disease activity score.

**Conclusions:** Meditation may be used as adjunctive or complementary therapy in the management of Rheumatoid Arthritis. It is cost effective and has no side effects. However, it needs longer follow up to show positive effects.

**KEYWORDS :** Complementary and alternative medicine, Rheumatoid Arthritis, Meditation

**INTRODUCTION**

Rheumatoid arthritis is a chronic autoimmune disorder associated with symmetrical peripheral polyarthritis leading to severe forms of joint destruction resulting in various physical disabilities and psychological distress (1,2).

Usually, joint damage occurs within the first 2 years of diagnosis and prediction of long-term complications becomes difficult (3).

Researches have proved that genetic factors predispose to the occurrence of Rheumatoid arthritis as well as to its severity (HLA-DRB1 gene and the protein tyrosine phosphatase 22 gene (PTPN22)) (1).

Medical management includes use of Corticosteroids, Disease Modifying Anti-Rheumatoid Drugs (DMARDs), Non Steroidal Anti-Inflammatory Drugs (NSAIDs), biological therapies such as Tumor Necrosis Factor inhibitors (Infliximab, etanercept and adalimumab) and long-acting corticosteroid injection into tendon sheaths and inflamed joints. Ideally, there is no cure of Rheumatoid Arthritis (4).

In 1970s, DMARDs became the mainstay in treatment of Rheumatoid Arthritis. However, it was realized that the use of DMARDs is often associated with serious bacterial infections of lungs and soft tissues. The incidence of such infections increased by 2-4 fold when used in combination with anti-TNF medication. Hydroxychloroquine, a milder form of DMARD, with milder side effects, has been proven to improve joint pain and function, but has not been shown to slow down the damages radio-graphically (5,6,7).

The last three decades have seen a dramatic change in the overall treatment of RA. These changes have been attributed to improve in clinical assessment. It was also realized that every patient responds differently to the same treatment. Hence, individualized care is the need of the hour (8,9).

Question is, apart from standard treatment of RA, is there any alternative therapy or treatment to control the disease activity or delay its progression and whether the changes caused by disease activity are reversible?

The divine practice of meditation originated in India over thousands of centuries ago and is now attracting the attention of many health care providers who have gradually begun to understand the contribution of this mind-body coordination in improving physiological,

psychological and immunological well being (10).

Meditation has been proven to reduce stress and other psychological symptoms in cases of Rheumatoid arthritis (11). Hence, it may also play an important role in controlling its disease activity through its positive effects on the neurological system and sources of pain.

Meditation has also been proven to enhance the immune system (12). Imagine being caught in a rainstorm without a raincoat and without a towel. In a torrent of stress, Meditation acts as both, the raincoat (preventive) and the towel (palliative). This has been very well described in various studies.

People who meditated for years have enjoyed better health and a slower ageing process but many others has been skeptical to its benefits. Scientific evidences are available to show the positive effects of meditation and its influence on cell metabolism (13). So this study was undertaken to prove our hypothesis that meditation may help in the management of Rheumatoid Arthritis.

**MATERIALS AND METHODS**

The study was conducted in the Department of Orthopedics, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, India over a period of 12 months. Subjects were recruited from patients presenting in Orthopedics OPD/IPD with a primary diagnosis of Rheumatoid Arthritis and after obtaining written informed consent and approval of Institutional Ethical committee.

**Study Design:** This study was an Experimental type of study, which included 60 patients. Through randomization using random number table they were divided into 2 groups - Experimental and Control group.

**Selection of Subject:**

- Control Group (n = 28)
- Experimental Group (n = 32)

**I. Inclusion Criteria**

All patients above the age of 18 years who have been diagnosed Rheumatoid arthritis based on the American College of Rheumatology/European League Against Rheumatism criteria 2010(14) were included in the study.

**ii. Exclusion Criteria:**

Patients with uncontrolled Diabetes, Osteoarthritis, Gout, Ankylosing spondylitis, other Metabolic diseases were excluded.

### Study Tools:

i. Structured study instrument (case recording form) was developed, and used to generate data.

ii. Disease Activity Score 28 (15).

iii. American College of Rheumatology/European League Against Rheumatism (2010) diagnostic criteria (14) for diagnosing Rheumatoid Arthritis.

### Study Protocol

1. All the patients who were diagnosed with Rheumatoid arthritis according to the American College of Rheumatology/European League Against Rheumatism (2010) diagnostic criteria were divided into two groups: Control Group and Experimental group. The division of patients was done using simple randomization using random number table.

2. Each patient underwent a detailed clinical examination by different Orthopedic surgeons who were not a part of the study including detailed present history, past history, family history, treatment history (if any) and complete general and systemic examination as per the Case recording form.

3. All the patients were subjected to the following laboratory investigations: Rheumatoid factor, Complete Blood Count, Erythrocyte Sedimentation Rate, C-reactive Protein, Anti Citrullinated Protein antibody, Uric acid, HLA B27, Glycosylated Hemoglobin. Their disease activity was evaluated using the Disease Activity Score 28 form.

4. After the initial evaluation both groups were given standard treatment for Rheumatoid arthritis in consultation with a Rheumatologist. In addition to the standard medical treatment given to both the groups, a well-designed meditation protocol was incorporated in the Experimental group. Meditation was taught by our Holistic health advisor who followed a standard protocol of a scheduled regular meditation sessions of over 45 minutes which included:

a) Makarasana (crocodile pose)-5 minutes, b) Joint exercises-10 minutes, c) Shavasana relaxation (corpse pose)-10 minutes, d) Diaphragmatic breathing – 5 minutes followed by e) Meditation-15 minutes-Annexure 5.

Meditation was taught once in a week to every patient (Figure 1) till they were competent enough to carry out the same at their homes.

5. Each patient was followed after one week and then subsequently every four weekly till six months. At every follow up, patients were evaluated for disease activity as per the DAS28 form in which all the tender and swollen joints were counted. ESR and VAS were also recorded.



### Data Management & Statistical Analysis:

- Statistical testing was conducted with SPSS 17.0.
- Continuous variables are presented as mean $\pm$ SD and categorical variables are presented as absolute numbers and percentages.
- The comparison of normally distributed continuous variables between the groups was done using Student's t test.
- Nominal categorical data between the groups were compared

using Chi-squared test or Fisher's exact test as appropriate.

- $P < 0.05$  was considered statistically significant.

### RESULTS

Total 60 patients were enrolled in the study and were randomized into Experimental and Control group. Experimental Group consisted of 32 patients (n=32) and Control group had 28 patients (n=28). The mean age of patients in Experimental group was 43.59  $\pm$  12.26 and in Control group it was 49.11  $\pm$  14.07 as shown in Figure 2.

There were 30 females (93.8%) and 2 males (6.3%) in Experimental group. Whereas, there were 23 females (82.1%) and 5 males (17.9%) in the Control group as shown in Table 1.

The initial baseline values of Tender Joint Count in both the groups had no significant differences with a mean of 9.09  $\pm$  2.57 in Experimental group and 8.25  $\pm$  2.81 in Control group respectively with p-value of 0.229. At the end of 2 months, there were no significant differences in both the groups with mean of 8.25  $\pm$  2.46 in Experimental group and 7.89  $\pm$  2.79 in Control group with p-value 0.601. However, there was significant improvement in the p-value in the intra group follow up on comparing with the baseline values in the both Experimental and Control groups with p value of 0.003 and 0.005 respectively. This further improved at the end of 6 months in both the groups. Tender Joint Count in Experimental Group being 4.34  $\pm$  1.73 with a p-value of 0.001 in comparison to baseline and 5.79  $\pm$  2.75 in Control Group with p-value of 0.001 in comparison to the baseline. At the end of 6 months, it was also observed that there was significant improvement in the Tender Joint Count in Experimental group in comparison to the Control group with mean of 4.34  $\pm$  1.73 and 5.79  $\pm$  2.75 respectively with a p-value of 0.021 as shown in Table 2.

The initial baseline values of Swollen Joint Count in both the groups had no significant differences with a mean of 9.94  $\pm$  2.97 in Experimental group and 8.14  $\pm$  2.81 in Control group respectively with p-value of 0.060. At the end of 2 months also there were no significant differences in both the groups with mean of 8.75  $\pm$  2.76 in Experimental group and 7.79  $\pm$  2.90 in Control group with p-value 0.192. However, there was significant improvement at the end of 2 months in the p-value in the intra group follow up on comparing with the baseline values in the both Experimental and Control groups with p-value of 0.001 and 0.005 respectively. This further improved at the end of 6 months in both the groups. Swollen Joint Count in Experimental Group being 4.25  $\pm$  1.83 with a p-value of 0.001 in comparison to baseline and 5.82  $\pm$  2.74 in Control Group with p-value of 0.001 in comparison to the baseline. At the end of 6 months, it was also observed that there was significant improvement in the Swollen Joint Count in Experimental group in comparison to the Control group with mean of 4.25  $\pm$  1.83 and 5.82  $\pm$  2.74 respectively and a p-value of 0.013 as shown in Table 3.

The initial baseline values of Visual Analogue Scale in both the groups had no significant differences with a mean of 46.09  $\pm$  7.04 in Experimental group and 44.64  $\pm$  8.38 in Control group respectively with p-value of 0.469. At the end of 2 months also there were no significant differences in both the groups with mean of 38.09  $\pm$  7.92 in Experimental group and 36.61  $\pm$  7.21 in Control group with p-value 0.452. However there was significant improvement at the end of 2 months in the p-value in the intra group follow up on comparing with the baseline values in the both Experimental and Control groups with p-value of <0.001 in both the groups. This further improved at the end of 6 months in both the groups. Visual Analogue Scale score in Experimental Group was 20.16  $\pm$  4.49 with a p-value of 0.001 in comparison to baseline and 26.79  $\pm$  9.83 in Control Group with p-value of 0.001 in comparison to the baseline. At the end of 6 months, it was also observed that there was significant improvement in the Visual Analogue Scale in Experimental group in comparison to the Control group with mean of 20.16  $\pm$  4.49 and 26.79  $\pm$  9.83 respectively and a p-value of 0.002 as shown in Table 4.

There was no significant improvement in the Erythrocyte sedimentation rate in Experimental group as compared to the Control group at the end of 6 months with mean of 16.59  $\pm$  13.97 and 18.11  $\pm$  18.78 respectively and p-value of 0.947. However, there was marked improvement when the baseline value was compared to the end of 2nd week's value in the intra group follow up in the Experimental group with mean being 39.69  $\pm$  21.83 and p-value of <0.001. This further

improved till the end of 6 months in Experimental group with mean value being  $16.59 \pm 13.97$  and p-value of 0.003. Similarly, there was marked improvement when we compared the baseline value to the end of 2nd week value in the intra group follow up in Control group also with mean being  $33.93 \pm 33.18$  and a p-value of  $<0.001$ . This further improved till the end of 6 months in the Control group with mean being  $18.11 \pm 18.78$  and a p-value of 0.001 as shown in Table 5.

#### Disease Activity Score 28 (DAS28)

There was no significant improvement in the Disease Activity Score in Experimental group as compared to the Control group at the end of 6 months with mean of  $3.64 \pm 1.01$  and  $4.15 \pm 1.25$  respectively and p-value of 0.084.

However, there was marked improvement when we compared the baseline value to the end of 2th month value in the intra group follow up in Experimental group with mean being  $5.23 \pm 0.76$  and p-value of  $<0.001$ . This further improved till the end of 6 months in Experimental group with mean being  $3.64 \pm 1.01$  and a p-value of  $<0.001$  also.

Similarly, there was marked improvement when we compared the baseline value to the end of 2th month value in the intra group follow up in Control group with mean being  $4.99 \pm 0.92$  and p-value of  $<0.001$ . This further improved till the end of 6 months in Control group with mean being  $4.15 \pm 1.25$  and a p value of  $<0.001$  as shown in Table 6.

Lastly, there were no study related adverse events at the end of study or at any time during the study.

#### Tables

**Table 1: Gender Distribution in Experimental and Control Groups**

Sex	Experimental (n=32)		Control (n=28)		P Value
	Frequency	%	Frequency	%	
F	30	93.8%	23	82.1%	0.235
M	2	6.3%	5	17.9%	
Total	32	100%	28	100%	

**Table 2: Tender Joint Count at various follow up of Experimental and Control Group**

Tender Joint Count (Follow Up)	Experimental (n=32)		Control (n=28)		P Value
	Mean $\pm$ SD	P value (From Baseline)	Mean $\pm$ SD	P value (From Baseline)	
Baseline	$9.09 \pm 2.57$		$8.25 \pm 2.81$		0.229
2nd week	$9.25 \pm 2.77$	0.420	$8.21 \pm 2.81$	0.573	0.156
2nd Month	$8.25 \pm 2.46$	0.003	$7.89 \pm 2.79$	0.005	0.601
3rd Month	$7.31 \pm 2.35$	$<0.001$	$6.82 \pm 2.48$	$<0.001$	0.434
4th Month	$6.28 \pm 2.17$	$<0.001$	$6.57 \pm 2.7$	$<0.001$	0.647
5th Month	$5.16 \pm 2.02$	$<0.001$	$5.96 \pm 2.6$	$<0.001$	0.181
6th Month	$4.34 \pm 1.73$	$<0.001$	$5.79 \pm 2.75$	$<0.001$	0.021

**Table 3: Swollen Joint Count at various follow up of Experimental and Control Group**

Swollen Joint Count (Follow Up)	Experimental (n=32)		Control (n=28)		P Value
	Mean $\pm$ SD	P value (From Baseline)	Mean $\pm$ SD	P value (From Baseline)	
Baseline	$9.94 \pm 2.97$		$8.14 \pm 2.81$		0.060

2nd week	$9.72 \pm 2.82$	0.22	$8.18 \pm 2.83$	0.326	0.069
2nd Month	$8.75 \pm 2.76$	$<0.001$	$7.79 \pm 2.90$	0.005	0.192
3rd Month	$7.69 \pm 2.22$	$<0.001$	$6.68 \pm 2.53$	$<0.001$	0.105
4th Month	$6.59 \pm 2.18$	$<0.001$	$6.50 \pm 2.82$	$<0.001$	0.885
5th Month	$5.16 \pm 1.99$	$<0.001$	$6.04 \pm 2.66$	$<0.001$	0.149
6th Month	$4.25 \pm 1.83$	$<0.001$	$5.82 \pm 2.74$	$<0.001$	0.013

**Table 4: Visual Analogue Scale score at various follow up of Experimental and Control Group**

VAS (Follow Up)	Experimental (n=32)		Control (n=28)		P Value
	Mean $\pm$ SD	P value (From Baseline)	Mean $\pm$ SD	P value (From Baseline)	
Baseline	$46.09 \pm 7.04$		$44.64 \pm 8.38$		0.469
2nd week	$43.81 \pm 7.27$	0.006	$43.04 \pm 7.86$	0.071	0.692
2nd Month	$38.09 \pm 7.92$	$<0.001$	$36.61 \pm 7.21$	$<0.001$	0.452
3rd Month	$32.31 \pm 7.6$	$<0.001$	$33.04 \pm 7.12$	$<0.001$	0.706
4th Month	$29.16 \pm 6.24$	$<0.001$	$31.07 \pm 8.75$	$<0.001$	0.329
5th Month	$23.75 \pm 6.09$	$<0.001$	$27.86 \pm 10.58$	$<0.001$	0.078
6th Month	$20.16 \pm 4.49$	$<0.001$	$26.79 \pm 9.83$	$<0.001$	0.002

**Table 5: Erythrocyte Sedimentation Rate at various follow up of Experimental and Control Group**

ESR (Follow Up)	Experimental				Control				On Comparison
	Mean $\pm$ SD	Median	Min - Max	P Value (From Baseline)	Mean $\pm$ SD	Median	Min - Max	P Value (From Baseline)	
Baseline	$39.41 \pm 22.19$	33.50	5 - 80	0.626	$34.48 \pm 35.43$	29.00	4 - 201	0.622	0.153
2nd week	$39.69 \pm 21.83$	38.50	5 - 79	0.003	$33.93 \pm 33.18$	28.50	5 - 190	0.001	0.106
2nd Month	$31.16 \pm 16.63$	30.00	4 - 70	$<0.001$	$28.18 \pm 30.86$	23.00	3 - 176	$<0.001$	0.121
3rd Month	$29.06 \pm 19.32$	26.50	5 - 90	$<0.001$	$21.36 \pm 15.34$	20.00	3 - 75	$<0.001$	0.101
4th Month	$25.81 \pm 16.98$	25.00	3 - 70	$<0.001$	$20.21 \pm 15.42$	18.50	2 - 70	$<0.001$	0.150
5th Month	$21.56 \pm 15.61$	20.50	2 - 61	$<0.001$	$18.32 \pm 16.42$	18.00	2 - 80	$<0.001$	0.207
6th Month	$16.59 \pm 13.97$	13.50	2 - 52	$<0.001$	$18.11 \pm 18.78$	14.00	2 - 94	$<0.001$	0.947

**Table 6: Disease Activity Score 28 at various follow up of Experimental and Control Group**

DAS28 score (Follow Up)	Experimental (n=32)		Control (n=28)		P Value
	Mean $\pm$ SD	P value (From Baseline)	Mean $\pm$ SD	P value (From Baseline)	
Baseline	$5.65 \pm 0.75$		$5.23 \pm 0.93$		0.057
2nd week	$5.62 \pm 0.76$	0.085	$5.20 \pm 0.88$	0.550	0.059

2nd Month	5.23 ± 0.76	<0.001	4.99 ± 0.92	<0.001	0.271
3rd Month	4.92 ± 0.77	<0.001	4.68 ± 0.86	<0.001	0.264
4th Month	4.60 ± 0.80	<0.001	4.53 ± 1.10	<0.001	0.786
5th Month	4.13 ± 0.94	<0.001	4.27 ± 1.24	<0.001	0.616
6th Month	3.64 ± 1.01	<0.001	4.15 ± 1.25	<0.001	0.084

## DISCUSSION

We conducted a study consisting of 60 patients suffering from Rheumatoid Arthritis. The objective of the study was to see the effect of meditation in the management of RA. Only those patients were enrolled who met the inclusion criteria and who consented to participate in the study. The patients were randomized into 2 groups, the Experimental and Control group. In the Experimental group, a well-scheduled protocol of meditation and joint exercises was incorporated along with standard medical treatment and both groups were followed for a period of 6 months.

The impact of this intervention on the disease activity in patients with RA was studied. To our knowledge, this is the first study of meditation to be conducted with patients with RA in India.

In our study, we had 93.8% of Females in the Experimental group and 82.1% of females in the Control group, which is consistent with the fact that Rheumatoid Arthritis is more pre-dominant in females than males with ratio of 2-3:1 (1). The reason that RA is more common in females is also because that it is an autoimmune disease and females are more pre-disposed to autoimmune disease as shown by S.T. Ngo, F.J. Steyn and P.A. McCombe in their review in 2014 (16).

We studied the effect of meditation through disease activity score. Disease activity score consists of Tender Joint Count, Swollen Joint Count, Erythrocyte Sedimentation Rate and Visual Analogue Scale score. We took baseline values of all the above parameters followed by regular follow-ups. The initial baseline values of Tender Joint Count in both the groups had no significant differences with a mean of  $9.09 \pm 2.57$  in Experimental group and  $8.25 \pm 2.81$  in Control group respectively with p-value of 0.229. At the end of 2 months also there were no significant differences in both the groups with mean of  $8.25 \pm 2.46$  in Experimental group and  $7.89 \pm 2.79$  in Control group with p-value 0.601. However, at the end of six months there was marked improvement in the Tender Joint Count in the Experimental group in comparison to the Control group with a p-value of 0.021. This result was in concordance with a randomized control trial done by Fogarty FA et al in 2014 (17). In their study, the initial baseline values of Tender Joint Count were comparable in both the groups, which by the end showed a significant improvement in results with a p-value of 0.02.

Similarly, the initial baseline values of Swollen Joint Count in both the groups had no significant differences with a mean of  $9.94 \pm 2.97$  in Experimental group and  $8.14 \pm 2.81$  in Control group respectively, the p-value being 0.060. At the end of 2 months also, there were no significant differences in both the groups with mean of  $8.75 \pm 2.76$  in Experimental group and  $7.79 \pm 2.90$  in Control group with p-value being 0.192. However, there was significant improvement at the end of 2 months in the Swollen Joint Count value in the intra group follow up on comparing with the baseline values in both Experimental and Control groups with p-value of 0.001 and 0.005 respectively. At the end of 6 months, it was also observed that there was significant improvement in the Swollen Joint Count in Experimental group in comparison to the Control group with mean of  $4.25 \pm 1.83$  and  $5.82 \pm 2.74$  respectively and a p-value of 0.013. But this result was not in concordance with the study by Fogarty FA, Booth RJ, Gamble GD (17). In their study, the p-value at the their follow ups was 0.55 which was not significant. They also observed the effects of meditation in improvement in duration of morning stiffness however it was not a part of our study.

RA has been classified to be the most prominent cause of chronic pain. This pain will affect every RA patient at some point of time during his or her life, resulting in suffering and reduced quality of life (18). In our study at the end of 6 months, it was also observed that there was

significant improvement in the Visual Analogue Scale score in Experimental group in comparison to the Control group with mean of  $20.16 \pm 4.49$  and  $26.79 \pm 9.83$  respectively and a p-value of 0.002. Fogarty FA, Booth RJ, Gamble GD (17) also had similar observations. They also observed significant improvement in pain in the intervention group with a p-value of 0.04.

Even small changes in the severity of pain can positively influence a patient's well being. Dhanani et al observed that a change in pain of 1cm on 10cm Visual Analogue Scale score was associated with appreciable changes in quality of life in Rheumatic diseases (19).

At the end of 6 months, we observed significant improvement in the Tender and Swollen Joint Count and Visual Analogue Scale score but there was no significant improvement in Disease activity score in comparison to Control group. We found that the effect of meditation started after the third month in follow up in the Experimental group. Since meditative practices take long time to show effect at a cellular level, they require long duration for it to be reflected in blood picture (ESR). Six months time is a very short time. If patient continues meditation with compliance, we may observe positive results. Pradhan et al (11) saw similar results in their study. They also did not see any significant improvement in the DAS28 score, however they observed improvement in psychological well being of patients at the end of 6 months.

There were many limitations to the study. First, the sample size in our study was very small; Second, patients that were included were from mixed socio-economic background. Not only this, patients we included in the study were also from different religious background as well. Every patient had a different opinion towards meditation and hence their sincerity and regularity for the same might have differed. Third, there was no definitive tool to assess whether the patient is doing meditation regularly at home and if they were doing meditation regularly also, there was no tool to assess whether they were doing it sincerely or not. We had just taught them the method to do meditation but it needs supervision under a close environment for them to do it properly. It is very difficult to supervise every patient in a close environment for 6 months. And lastly, as we already discussed, meditative practices take longer time to show effects, six months is a short duration of time and if they continued the meditative practices for 1 year or longer, we might observe significant results.

If we leave the limitation aside, we also have many advantages to our therapy. This therapy is cost effective. It did not cost anything extra to the patients. Our therapy is harmless and there were no side effects related to it. We do not advise that our therapy can be a replacement to the standard treatment but it may be used as an adjunct to it. We as clinicians should encourage patients with patience to enjoy life optimally and fully despite of their chronic medical conditions. Meditation is a powerful tool that can foster improved coping and well-being. There is a great deal more that we need to learn, but it seems certain that meditation-based therapies do have a future in both medicine and society.

## CONCLUSIONS

1. Meditation may be used as adjunctive or complementary therapy in the management of Rheumatoid Arthritis but it needs longer follow up to show its positive effects.

2. Meditation is cost effective and has no side effects.

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## Author Disclosure Statement

No competing financial interests exist.

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