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A Study on the Effectiveness of Bowel Nosodes in The Treatment of Rheumatoid Arthritis on The Basis Symptom Similarity

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Conflict of interest: Nil

Abstract

Background: Rheumatoid arthritis (RA) is the most common form of chronic polyarthritis, characterized by pain, swelling, tenderness and stiffness of multiple joints, mainly peripheral small joints, along with some extra-articular manifestations. Lack of proper management leads to joint deformities and other systemic co-morbidities, which cause functional disability, decreased quality of life and premature death. Homoeopathy has proved very serviceable in managing RA and other auto-immune diseases. Recent studies have established a promising role of bowel nosodes in the treatment of the different type of degenerative joint diseases like cervical spondylosis, Osteoarthritis and rheumatoid arthritis.

Material & Methods: This is an open, observational, prospective, clinical study on 30 (=n) participants between the age of 18-65 years, carried out at National Institute of Homoeopathy, Kolkata. The bowel nosodes were prescribed on the basis of symptom similarity presented by the patient to that of the bowel nosodes. The outcome from baseline to 4 months of treatment was assessed in terms of changes in disease activity and quality of life by applying the DAS-ESR scale and European quality of life-5dimension (EQ-5D-5L) scale respectively. The Erythrocyte sedimentation rate (ESR) of every patient was assessed before and after treatment as the secondary outcome measure. Inferences were drawn from statistical analysis.

Result: Samples paired t-test showed statistically significant results in terms of both reduced disease activity (p-value <0.05) and improved quality of life (p-value <0.05). In addition, the improvement was confirmed by the changes in ESR values before and after treatment (p-value <0.05).

Conclusion: The overall response of bowel nosodes was significant in the management of rheumatoid arthritis when selected based on symptom similarity, as there was a substantial reduction in the outcome scores of participants from baseline to 4 months, along with the decrease in the symptom severity of majority of participants.

Keywords: Rheumatoid arthritis, Bowel nosodes, Homoeopathy, Quality of life.

Introduction

Musculoskeletal (MSK) conditions are a major burden on individuals, health systems, and social care systems, affecting hundreds of millions worldwide. MSK conditions are the most common cause of severe long-term pain and physical disability in all continents and economies. Among the MSK disorders, Rheumatoid arthritis (RA) is the most common form of chronic polyarthritis, with a prevalence range of 0.28% to 0.7% in India. Rheumatoid arthritis is an auto-immune disease characterized by pain, swelling, tenderness and stiffness of multiple joints, mainly peripheral small joints, along with some extra-articular manifestations. These include subcutaneous nodules, vasculitis, pleuritis, anaemia, and inflammation of other serous membranes, interstitial inflammation of lungs, keratoconjunctivitis sicca, nodules in pulmonary and sclerotic tissues. Lack of proper management leads to joint deformities and other systemic co-morbidities which causes functional disability, decreased quality of life and premature death. Life expectancy is decreased among RA patients by 15 to 20% compared to the general population, and the life span is shortened by ten years in untreated RA cases. The disease may appear at any age, but it is most common among those aged from 40 to 70 years and its incidence increases with age.[1] The female/male ratio of RA prevalence is 2.5:1. The sex difference is most pronounced in those with early onset of disease. The ratio becomes almost equal by the age of 65.[2]

According to the modern system of medicine, no cure exists for rheumatoid arthritis, but disease activity and long-term disability can be improved with disease-modifying therapies, which include drug treatment, orthopaedic surgery and physiotherapy. But due to the lack of cost-effective treatment and the significant side effects of immunosuppressive drugs, RA treatment is challenging in countries like India. While many studies have proved the efficacy of individualized homoeopathic medicines in the treatment of rheumatoid arthritis,[3,4] some studies shows that the result of homoeopathic treatment was not promising in the management of RA.[5,6] There could be a list of reason for such unsatisfactory result which may include: improper selection of similimum or potency, maintaining causes in the form of obstacles from patients' side, not using an intercurrent or anti-miasmatic remedy when required, etc. The use of nosodes in such chronic cases can be think of having a great scope. Dr Swan and many other stalwarts believed and proved the fact that, if properly applied, nosodes can prevent the manifestations of chronic diseases.[7] Similarly, bowel nosodes can be used as a great source for the management of RA. Also, recent studies have proved a positive role of bowel nosodes in the treatment of different type of degenerative joint

diseases like cervical spondylosis, osteoarthritis, and rheumatoid arthritis.

The primary objective of this study was to assess the improvement in the symptoms of the participants by using the European Quality of Life-5 Dimension (EQ-5D-5L) and DAS28-ESR after treatment with bowel nosodes. The disease activity in RA cannot be measured by considering one variable only due to its vast clinical symptomatology. Hence, to measure disease activity in RA both in daily clinical practice as well as in clinical trials on a group as well as individual level the DAS28 have been developed and extensively validated. The DAS/DAS28 is a continuous measure of RA disease activity that combines information from swollen joints, tender joints, acute phase response and general health. The EULAR response criteria classify individual patients as non-, moderate, or good responders, dependent on the magnitude of change and level of disease activity reached.[8]

EQ-5D-5L scale was used to assess the changes in quality of life. When compared with other similar scales it is found that EQ-5D-5L scale detected larger differences between various health states with different adverse events, severity and pain relief, and produced larger changes in utility from baseline to endpoint.[9]

The secondary objective was to assess the changes in Erythrocyte Sedimentation Rate (ESR) before and after taking medicine.

Methods

Study Design

This was an open observational, non-randomized, clinical study carried out at OPD of National Institute of Homoeopathy. Participants from 18 to 65 years of age of both sexes were selected based upon the eligibility criteria. The study was conducted for a time-period of 1 year and 6 months starting from November 2019 to May 2021.

Selection of sample

Samples were selected per the eligibility criteria below from the participants visiting the NIH outpatient department. Due to the lack of relevant homoeopathic research papers evaluating the efficacy of homoeopathic bowel nosodes in RA based on symptom similarity, the formal effect size calculation was not possible. A recent study by Suri P. in Kolkata on 30 participants suffering from Osteoarthritis reported a baseline mean (± sd) of pain intensity to be 5.1 (standard error = 0.35). Lifestyle modifications were implemented in all the selected participants. A minimum of 30 clinical cases with RA of both sexes, different age groups and socio-economic status were registered in the Outpatient department (OPD) of the National Institute of Homoeopathy, Kolkata.

Participants from 18 to 65 years of age of both sexes, having a score more than ≥ 6/10 according to ACR criteria for the classification of Rheumatoid Arthritis were included in the study.

Participants having severe and life-threatening manifestations of RA like – scleritis, sclreomalacia or corneal melting, life-threatening cardiac involvements like heart block, cardiomyopathy etc. and nerve involvements as seen in atlantoaxial subluxation were excluded from the study.

Intervention

Following preliminary screening for Rheumatoid Arthritis symptoms and detailed screening using specified selection criteria, eligible patients were recruited in the trial. A detailed and thorough case taking of each eligible participants was done according to the format supplied by the Department of Organon of Medicine, N.I.H, Kolkata,

as per strict homoeopathic principles. Clinical examination or relevant investigations were done as per need. All participants were given medicines based strictly on homoeopathic principles. Participants were investigated timely to assess their response to homoeopathic treatment/management. Every patient was assessed periodically to follow up on the reaction to the remedy through clinical assessment, expert's opinion (opinions of teachers and guide), as well as relevant investigations. The usual follow-up wa s done at an interval of 4 weeks for four months and was recorded in follow-up sheets. After the completion of the study, the results were represented by using different statistical methods after analysing the results.

Outcome Assessment

Primary outcome measure

Disease Activity Index 28 ESR (DAS28-ESR) scoring system [10] – A valid and reliable tool. It combines single measures into an overall, continuous measure of rheumatoid arthritis (RA) disease activity. The DAS28-ESR includes 28 tender joint counts, 28 swollen joint counts, erythrocyte sedimentation rate, and a general health assessment on a visual analogue scale. The 28 tender joint counts (28TJC) and 28 swollen joint counts (28SJC) both range from 0 to 28. ESR may range from 0 to 150, and General Health (GH) ranges from 0 to 100. The range of the DAS28- ESR is 0–9.4. The level of RA disease activity can be interpreted as low (DAS28-ESR $\leq$ 3.2), moderate (3.2 < DAS28-ESR $\leq$ 5.1), or as high disease activity (DAS28-ESR >5.1). A DAS28-ESR < 2.6 corresponds with being in remission according to the ARA criteria. A change of 1.2 in DAS28-ESR is considered a meaningful change because changes that large is unlikely to be the result of random measurement error ($P \leq 0.05$). The EULAR response criteria classify participants as good, moderate, or non-responders, using the change in DAS28-ESR as >1.2, >0.6 and $\leq$1.2 and $\leq$ 0.6, respectively. It was administered at baseline and after four months of treatment.

European Quality of Life-5 Dimensions (EQ-5D-5L)[11] - The EQ-5D-5L consists of 2 pages – the EQ-5D-5L descriptive system and the EQ Visual Analogue scale (EQ VAS). The descriptive system comprises five dimensions, i.e., mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for five dimensions can be combined in a 5-digit number describing the respondent's health state. It should be noted that the numerals 1-5 have no arithmetic properties and should not be used as a cardinal score. The EQ VAS records the respondent's self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine'. This information can be used as a quantitative measure of health as judged by the individual respondents. The respondent is asked to 'mark an X on the scale to indicate how your health is today' and then to 'write the number you marked on the scale in the box below'. It was administered at baseline and after four months of treatment.

Secondary outcome measure: Erythrocyte Sedimentation Rate (ESR)

The outcomes were assessed initially at baseline and after four months. A specially designed Microsoft MS Office

Excel 2019 spreadsheet (master chart) was used for data extraction and was subjected to statistical analysis.

Statistical Methods and Data Analysis

After the completion of the study, the results were represented by different standard statistical methods.

Proper analysis was done for varieties of clinical presentations & effects of Homoeopathic prescription.

DAS-28 and EQ-5D-5L scores obtained at baseline and four months after treatment were compared using paired t-tests. P values less than 0.05 was considered statistically significant.

Ethical Issues

The study protocol was by following the latest revision of the Helsinki Declaration on Human Experimentation. The intended work did not apply any invasive method. No study or investigations were done without the consent of the participant. However, Homoeopathic medicines proposed to be used during the study were Homoeopathic Pharmacopeial Preparations (no new drug was proposed to be tried). The necessary clearance from the Ethical Committee was obtained before initiating the study. Inter-current illness, adverse or severe adverse event(s) were recorded and treated accordingly as per homoeopathic principles, and participants who were not responding were referred for conventional treatment. Prior to enrolment, each patient was provided with a patient information sheet in the local vernacular Bengali language detailing the objectives, methods, risks and benefits of participating, and confidentiality issues. Subsequent to that, written informed consent was obtained.

Results

Study flow

As per the pre-specified inclusion and exclusion criteria, 48 participants suffering from rheumatoid arthritis were screened; 15 were excluded on account of various reasons (listed in Figure 1); 33 met the eligibility criteria and were enrolled in the study. After four months of intervention, outcome data were recorded again. Due to the ongoing COVID-19 pandemic and the imposed lockdown situations, 3 participants were not able to complete follow-ups; 30 completed the trial. (Figure 1)

Among the participants enrolled, 50% were from the age group of 34-50 years, and 73% were female. The majority of the participants (60%) were of lower socio-economic status. Family history of RA was positive in 36.6% of the participants. The majority of the participants were chronic sufferers of RA with a mean duration of presenting complaints of 36.4 months (sd±2.4).

The distribution of sample according to ACR scoring is given in Table no. 1

Table 1: Distribution of sample according to ACR scoring

ACR Score	Frequency	Percentage (%)
6	5	16%
7	8	27%
8	7	23%
9	6	20%
10	4	13%
Total	30	100%

Statistical Analysis

Changes in Disease Activity Index 28 (DAS28-ESR) scoring system:

The disease activity was compared before and after treatment, applying the DAS28- ESR criteria. At baseline, 8 participants (27%) and 22 participants (73%) presented moderate and high disease activity, respectively. After treatment intervention, 3 participants (10%) had mild disease activity, and 15 (50%) & 12 (40%) had moderate and severe disease activity, respectively [figure 1].

Test of significance: standardized test statistic value for pre and post-treatment is 11.74, whereas the p-value is <0.001. Therefore, the difference between pre and post-scores of DAS28-ESR from baseline to 4th month is statistically significant, and hence, the null hypothesis is rejected.

Figure 1:

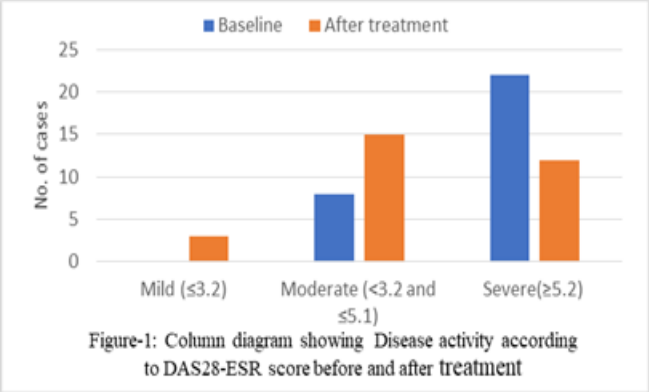

Figure-1: Column diagram showing Disease activity according to DAS28-ESR score before and after treatment

Table 2: Post-treatment improvement status of DAS28-ESR Score

Level of improvement	DAS28-ESR score reduction	No. of participants	Percentage
Significant Improvement	>1.2	9	30%
Moderate Improvement	>0.6 to ≤1.2	18	60%
No Improvement	≤ 0.6	03	10%

Changes in QOL Scoring (EQ-5D-5L):

Pre-treatment QOL score was compared with the post-treatment QOL score by applying paired t-test for sample of means using MS Excel 2019.

Test of significance- t static for pre and post-treatment QOL is -11.6985 whereas the p-value [(T<=t) two-tail] is 8.39×10^{-13} which is <0.001. Therefore, the difference between QOL Scores from baseline to 6th month is statistically significant. QoL was significantly improved in 23% of participants, moderately improved in **40%** of participants, and mildly improved in 30% of participants. No improvement and aggravation of complaints are seen in 3% of cases each.

Changes In Vas Scoring (QOL)

Pre-treatment VAS (QOL) Score was compared with the post-treatment VAS (QOL) score by applying paired t-test for a sample of means using MS Excel 2019.

Test of significance- t static for pre and post-treatment VAS (QOL) is -12.548 whereas the p-value [(T<=t) two-tail] is 3.04×10-13 which is <0.001. Therefore, the difference between QOL Scores from baseline to 4th month is statistically significant.

VAS (QOL) was cured in 4% of participants, significantly improved in 26% of participants, moderately improved in 34% of participants, and mildly improved in 36 % of participants (Table 3).

Table 3: Post-treatment improvement status of VAS Score (QOL)

Level of improvement	VAS score reduction	No. of participants	Percentage
Cured	≥80%	00	00%
Significant Improvement	60%- 80%	08	27%
Moderate Improvement	40% - 60%	15	50%
Mild Improvement	40%-20%	04	13%
No Improvement	≤ 20%	02	7%
Aggravation		01	3%

Changes in Erythrocyte Sedimentation Rate (ESR)

Test of significance- t stat. For pre and post-treatment VAS (QOL) is 4.505, whereas the p-value [(T<=t) two-tail] is 0.0001001036, which is <0.001. Therefore, the difference between QOL Scores from baseline to 4th month is statistically significant [figure 5].

Figure 2:

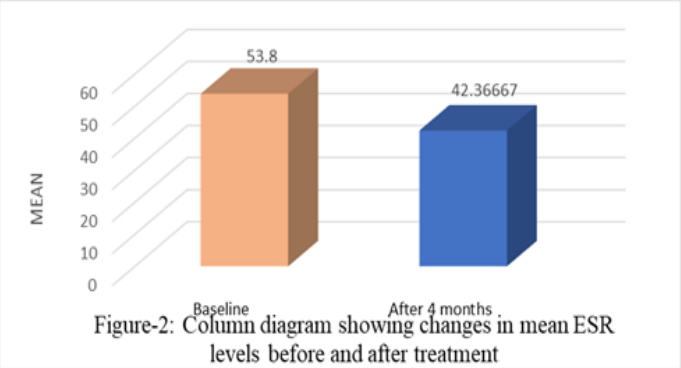

Figure-2: Column diagram showing changes in mean ESR levels before and after treatment

Distribution of sample according to medicines (bowel nosodes) prescribed (Table 4 and Figure 3)

Table 4: Distribution of samples according to medicines prescribed

Medicine	Potency	Frequency	Percentage
Sycotic compound	L. M	6	33.3%
	Centesimal	4	
Morgan Pure	L. M	4	20%
	Centesimal	2	
Morgan Gaertner	L. M	4	16.6%
	Centesimal	1	
Dysentry compound	L. M	4	13.3%
	Centesimal	0	
Bacillus no. 7	L. M	1	6%
	Centesimal	1	
Proteus	L. M	2	6%
	Centesimal	0	

Figure 3:

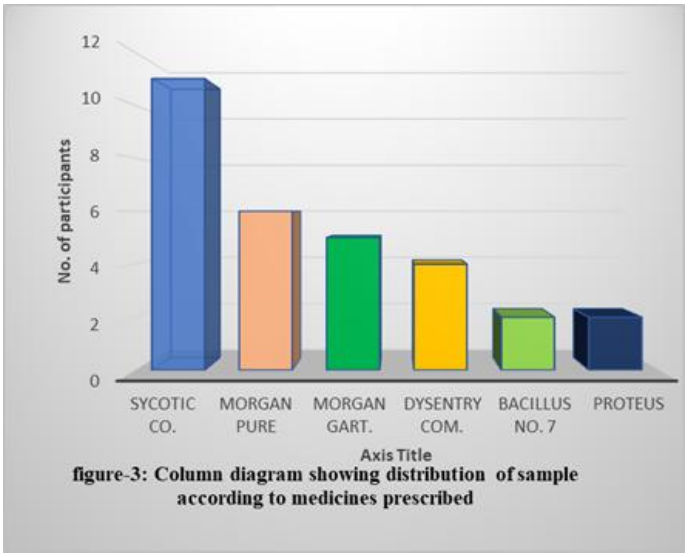

figure-3: Column diagram showing distribution of sample according to medicines prescribed

Discussion

This open, observational, prospective clinical study on 30 participants diagnosed with rheumatoid arthritis (RA) aimed to evaluate the therapeutic effectiveness of homoeopathic bowel nosodes in managing RA symptoms. Participants were enrolled following strict inclusion criteria based on ACR criteria, ensuring a consistent and clinically appropriate selection process. The study spanned four months and employed validated tools, including the DAS28-ESR scoring system and EQ-5D-5L scale, alongside laboratory assessments such as erythrocyte sedimentation rate (ESR), to evaluate the outcomes.

Statistical analysis showed that the improvement was statistically significant ($P<0.05$) for the time period analyzed (0-4 months), indicating that improvement occurs within four months. This was true for all three parameters, i.e., 'disease activity' and 'quality of life' and ESR changes.

The bowel nosodes used in this study were Sycotic co. (11 participants), Morgan-Gaertner (5 participants), Morgan-Pure (6 participants), Dysentery co. (4 participants) and Bacillus no. 7 (2 participants) and Proteus in 2 participants. From the view of bowel nosodes used in the study, Sycotic co. was more frequently administered homoeopathic bowel nosode. Out of 11 participants administered with Sycotic co.,3 cases showed marked improvement, 3 cases showed moderate improvement, and 5 cases showed mild improvement.

Comparison with Other Studies

Previous work which proves the efficacy of bowel nosodes in the treatment of rheumatoid arthritis is done by Dr Chaturbhuja Nayak. This article is entitled "Managing rheumatoid arthritis- The bowel nosode way', published in CCRH Quarterly Bulletin vol. 23, 2001. In this study, a total of 38 participants of both sex and different age groups were selected based on the inclusion criteria. Whereas in the present study, a total of 30 participants were selected.

The selection of medicine (bowel nosode) in this study was based on symptom similarity (10 cases), stool culture (2 cases), as a complementary medicine (13 cases), bowel nosodes related to a group of medicines, covering the totality (7 cases), and bowel nosodes indicated after partial relief by several medicines (6 cases), while in the present study the medicine was prescribed solely on the basis of symptom similarity.

No validated questionnaire was used in the previous study, whereas two valid and reliable questionnaires, the DAS28-ESR scoring system and European quality of life-5 dimension scale, along with laboratory findings in the form of changes in ESR levels, were included in the present study to strengthen the results.

In the previous study, the improvement rate in the participants was as follows: marked improvement in 31.58% of cases, moderate improvement in 28.95% of cases, mild improvement in 23.66% of cases and no

response in 15.79% of cases. Whereas in the present study significantly improved in 7 participants (23%), moderately improved in 12 participants (40%), and mildly improved in 9 participants (30%). No improvement and aggravation of complaints is seen in 3% of cases each.

Strengths of the Study

The study was transparent in terms of the declaration of protocol, ethical conduct, data collection, analysis and reporting. Each patient was well informed about the trial and was provided with a patient information sheet in English, Hindi, and local vernacular (Bengali), explaining the study aims and objectives, methods, risks and benefits of participating and confidentiality and ethical issues. Subsequent to this, written informed consent was obtained from the patient. All the collected data (in the form of case records and scales) was converted into an analyzable and reproducible master chart (soft copy), from where all the data was extracted systematically and underwent statistical analysis subsequently. The before and after treatment changes were recorded in all possible ways covering the subjective plane (quality of life assessment), objective plane (disease activity assessment) and laboratory findings (ESR values).

Limitations of the Study

The study was the very first of its kind in homoeopathy; hence exploratory. Therefore, sample size calculation was completed based on assumption. The sample size used for the study was small (n = 30). Effect size could not be calculated on account of the absence of any study of a similar design. The study duration was small, as it was four months.

Conclusion

In this prospective, non-randomized clinical study carried out at the National Institute of Homoeopathy on 30 participants suffering from Rheumatoid arthritis, the outcomes analyzed from different scales showed that bowel nosodes have an influential role in the management of RA.

The research question for this study was, “Is there any significant role of homoeopathic bowel nosodes in the treatment of Rheumatoid arthritis”. This study has proved itself strong evidence in favour of Bowel nosodes that were found to be effective in managing the case of Rheumatoid arthritis, both in acute and chronic cases. The disease activity was noticeably reduced, and quality of life was improved during the interval of 4 months. In addition, the improvement was confirmed by decreased value of the Erythrocyte sedimentation rate in most participants after treatment.

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