

*Research Article*

## EFFICACY STUDY OF OMEGA-3 MEDICATED MASSAGE OIL AS AN ADJUVANT THERAPY FOR RHEUMATOID ARTHRITIS

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**ABSTRACT:** The present study was designed to study the role of flaxseed oil in management of rheumatoid arthritis (RA). Chinchadi oil was selected for pain management, which is recommended by Ayurvedic physicians and flaxseed oil is well known for its anti-inflammatory action. Considering this, the objective was to develop omega-3 medicated massage oil and evaluate the efficacy of omega-3 medicated massage oil (prepared using chinchadi oil and flaxseed oil) in the management of Rheumatoid arthritis. This was an open clinical trial which recruited 32 subjects of either sex. The study participants were recruited in two groups. The first group serve as control group received whole body massage with plain chinchadi oil and the experimental group received whole body massage with omega-3 medicated massage oil. The whole-body massage was given for the period of 30 minutes each day for 14 days. Additionally, flaxseed oil softgel capsule (containing 1000 mg omega-3 fatty acid) was given to experimental group for the period of 90 days regularly. At the end of study period, there was significant improvement in grip power of right and left ( $p < 0.05$ ), however in case of walking time, non-significant alteration was observed. Further various other parameters such as morning stiffness, tenderness, swelling and joint pain showed positive alterations. The pathological assessment showed, no gross adverse outcome of massage oil treatment of omega-3 medicated chinchadi oil for two weeks and oral supplementation of flaxseed oil softgel capsule for the period of 90 days. In conclusion, 14-day whole body massage therapy with omega-3 medicated massage oil as topical application and 90 days' oral supplementation of flaxseed oil in the form of softgel capsules exhibited better clinical improvement over plain chinchadi oil based on pathological and clinical assessment, indicating better efficacy of omega-3 medicated massage oil in the control and management of RA.

**Keywords:** Chinchadi oil, Flaxseed, Joint pain, Medicinal plant.

### INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune disease which primarily affected by synovial joints linings and it also leads to progressive disability and premature death [1]. Its prevalence is multi-factorial such as environmental risk factors, genetic factors including under-reporting of the cases. Both lifestyle related and non-modifiable features (genetics and sex) are major risk factors for RA [2]. However, prevalence is comparatively more in industrialized and urban population [3]. The global prevalence rate is ranging between 0.5-1% [4], however, in India it is about 0.75% [5].

Systemic inflammation and autoimmunity are initiated well in advance before one can see the clinical symptoms of RA [6]. Omega-3 fatty acid (O-3) and omega-6 fatty acids (O-6) are poly-unsaturated and essential fatty acid. O-6 serves as inflammatory and O-3 work as anti-inflammatory [7]. Imbalanced O-6 to O-3 ratio is mainly responsible for cardiovascular disease, cancer, inflammatory and autoimmune diseases including RA [8]. Lowered O-6 to O-3 ratio responsible for controlling chronic disorders both in developing and developed countries [9]. O-3 has been shown to be effective in controlling the experimental arthritis and

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reduce the disease activity in RA [10]. In a double-blind randomized controlled trial of RA (receiving disease-modifying anti-rheumatic drugs therapy), daily administration of O-3 resulted in significant clinical benefit and reduced co-administration of analgesics [11]. Yates et al. (2014) reviewed anti-inflammatory potential of omega-3 fatty acid in chronic inflammatory disease including RA [12].

Apart from allopathic medications, there are various alternative approaches used by clinician for prevention and control of RA by physicians. These includes aromatherapy and reflexology, massage oil, essential oil therapy and various bioactive herbal components etc. [13, 14]. These therapy serves as non-pharmacological approach as a preventive measure or adjuvant therapy [15]. In the cross-sectional study of more than 2000 participants of North Carolina region, revealed increased trend of use complementary and alternative medicines for primary care and specialty settings of arthritis signs and symptoms [16]. Role of chinchadi oil in osteoarthritis management is reported earlier [17, 18, 19]. Ayurveda is one of the oldest traditional systems of medicine accepted globally and also by the World Health Organization [20, 21]. Further Panchakarma procedures of ayurveda is considered to be one of the effective ways for the cure or management of RA/amavata [22]. In this context, we selected chinchadi oil (classical ayurvedic formulation) in pain management as base oil. Further considering the importance of O-3 in RA, we selected flaxseed oil as source of O-3 for formulating medicated massage oil.

So the medicated massage oil consisting chinchadi oil and flaxseed oil likely to show improved efficacy in RA and same has been evaluated. Hence the objective was to formulate omega-3 medicated massage oil for RA using combination of chinchadi oil chinchadi oil and flaxseed oil and evaluate its efficacy in RA using clinical study.

## **MATERIALS AND METHODS**

### **Procurement and preparation of massage oil**

Chinchadi oil (Sahasrayogam) was purchased from the Arya Vaidya Pharmacy (Coimbatore) Limited, Kerala, India. This tailam (medicated oil) was used for A group-called as chinchadi oil. Further flaxseed oil was blended with chinchadi oil (used for B group-called as omega-3 medicated massage oil). The blending of chinchadi oil with flaxseed oil (in 80:20 proportion) was carried out using mechanical blender at about 35-40°C for 10-15 minutes. After blending is complete, the omega-3 medicated massage oil was filled and packed in amber coloured bottle, labeled and used for study.

### **Fatty acid analysis of experimental oils**

Both chinchadi oil and omega-3 medicated massage oil were subjected for fatty acid estimation using method as reported by Zanwar et al. (2014) [23]. Initially trans-esterification of each experimental oil was carried out. About 40 µl of chinchadi oil and omega-3 medicated massage oil was added in 0.6 N of methanolic hydrochloric acid and subjected for incubation at 80°C for 120 minutes. These methylated samples were subjected for extraction using n-hexane twice and n-hexane layer separation was carried out using centrifugation at 3000 rpm for 15 minutes at room temperature. This n-hexane layer was collected and dried using nitrogen gas in separate vial.

After which, methyl esters of fatty acid standard (FAME-Supelco, Bellefonte, PA. USA) was reconstituted using chloroform. The fatty acid analysis of both oil samples and standard FAME was carried out using gas chromatography (Agilent Technologies, Inc., USA - 7820A). Flame ionization detector was used. Capillary column (HP-88) fused silica (dimensions-30m\*0.25\*mm and 0.20 µm internal diameter) was used. Gas chromatographic condition: initial temperature was 140°C for 5 minutes which was increased to 230°C at 4 °C/minute and held for 2.5 minutes. The temperature of the detector and injector port was 250°C and split ratio was 25:1. Carrier gas - nitrogen (2.2 ml/minutes flow rate) and for igniting the flame zero air and hydrogen gases were used. Fatty acid of the oil was identified using retention time of the standard FAME. The results were expressed as % fatty acid [23,24].

### **Approval from institutional human ethics committee**

The protocol was approved by the human ethics committee (Reference no: BVDUCOA/EC/1553/2015-16). Study was initiated in collaboration with Panchakarma department, College of Ayurved and Hospital, Bharati Vidyapeeth (Deemed to be University), Pune, India.

### **Consent form from participating subject**

An oral explanation of the study, procedure, risks and benefits were given by individual personal interview method and the consent was duly signed after complete understanding of the clinical study by the subjects, however the subjects refusing consent were excluded in the present study and no information of such subject was recorded in any ways. Signed consent form from each of the participating subject in Marathi/English language was obtained.

### Study design

This was an open clinical study wherein total of 32 subjects fulfilling the criteria for inclusion and exclusion of either gender attending Bharati Vidyapeeth Medical Foundation's Bharati Ayurveda Hospital, Pune were selected for present clinical study. The details of exclusion and inclusion criteria are given below.

### Inclusion criteria

Subjects having age  $\geq 30$  years and  $\leq 65$  years were considered for recruiting in the study subject to any 4 criteria as proposed by American College of Rheumatology (according 1987, revised criteria). Subjects having morning stiffness in and around joints for an hour before maximal improvement ( $> 6$  weeks period), arthritis to 3 or more joints (minimum 3 joint areas, as diagnosed by physician simultaneously having pain with soft tissue swelling or joint effusion, not just bony over growth) ( $> 6$  weeks period), arthritis in case of hand joints ( $> 6$  weeks period), symmetric arthritis ( $> 6$  weeks period), rheumatoid nodules presence, positive test of rheumatoid factor in serum and radiographic changes of arthritis in case of posteroanterior view (hand & wrist radiograph) including erosions or unequivocal bony decalcification adjacent to involve joints.

### Criteria for exclusion

Subject having secondary complication of RA, or other serious illness, *e.g.* hepatic/renal failure, subjects having arthritis like gouty arthritis, tuberculosis arthritis etc., subject on treatment or subject sensitive or showing reactions to oil based body massage.

Further in case of any of the complications observed in the participating subject, then subject need to be withdrawn immediately. Such complications include worsening the disease condition, stoppage or change of the prescribed treatment in course of the study period due to any serious complications.

### Study groups

The participants were divided into two groups with sample size of 16 subjects in each group.

Group A- Internal medicine + sarvanga abhyanga with chinchadi oil

Group B- Internal medicine + sarvanga abhyanga with omega-3 medicated massage oil

Both the groups received gandharvahanstadi kadha (3 tsp/day) and shallaki tablets (2 tab/day) as a primary treatment (internal medicine) to RA subjects as per Ayurvedic physician's suggestions. Additionally, two omega-3-fatty acid softgel capsule (containing 1000

mg of O-3 i.e.  $\alpha$ -linolenic acid) was supplemented to B group only.

### Justification of the sample size

The following formula was used for calculating the sample size:

Sample size =  $4PQ/L^2$

here, 'P'=prevalence rate of the disease, 'Q'=(1-P), 'L'=experimental error i.e., to 10%. The sample size coming by 'N' using 1% (Worldwide Prevalence is 1% [25].

'P' is 0.01, 'Q' is 1-P= 0.99, Experimental error is 5% i.e., 0.0025, Sample size =  $4 \times 0.01 \times 0.99/0.0025 = 15.84 = 16$ . Therefore, 16 subjects in each group were selected for this study.

### Ingredients of chinchadi oil

Chinchadi oil is generally prepared using blends of various herbs such as Chinchu, Eranda, Prasarini, Shigru, Sesame, Mustard and Neem oils etc. [26]. The key ingredients of chinchadi oil are in the form of liquid, oil and few are for preparation of paste, the details of the same are given here. For kalka (paste preparation)- Siddhartha/Swetha sarshapa (Brassica juncea), Amadaru/Devadaru (Cedrus deodara), Sigru (Moringa oleifera), Saindhava lavana/rock salt (Saindhava), Vishwa/Shunti (Zingiber officinale). Sneha dravya (oily substance) - Til taila (Sesamum indicum). Drava Dravya (liquid material) - Chinchu (Tamarindus indica), Eranda (Ricinus communis), Varuna (Crataeva magna), Snuhi (Euphorbia neriifolia), Arka (Calotropis gigantea), Prasarini (Merremia tridentata), Gandira (Cayratia trifolia), Jambeera (Citrus limon), Satapatra (Moringa oleifera). Grinjana Rasa (Allium ascalonicum), dadhi (Curd) and Amla Shukta (vinegar) [19,27].

### Ingredients of flaxseed oil

Palmitic acid (4.90 to 8%), stearic acid (2.24 to 4.59%), oleic acid (13.44 to 19.39%), linoleic acid (12.25 to 17.44) and alpha-Linolenic acid (39.90 to 60.42%) [28]. Of this palmitic acid and stearic acid together called as saturated fatty acid (approx. 9%), oleic acid as omega-9 fatty acid (approx. 18%), linoleic acid as omega-6 fatty acid and alpha-linolenic acid as omega-3 fatty acid.

### Treatment details

For sarvanga abhyanga (i.e., whole body massage), plain chinchadi oil was used for group A and omega-3 medicated massage oil was used for group B. All the internal medicines were given for 3 months. The

sarvanga abhyanga and thapa swedana treatment was given every day for initial 14 days only.

### Abhyanga details

Initially both the experimental oils were kept in lukewarm water for 10 minutes and thereafter these oils as per respective groups were used for whole body massage for 30 minutes every day. Abhyanga was never done on full stomach. After abhyanga patient was advised to take rest for at least for 15-20 minutes. Then subjects undergone thapa swedana. After thapa swedana subjects was advised to take hot water bath. The duration of abhyanga therapy and thapa swedana was for 14 days and internal medicine were given for 3 months and subjects were followed upto 3 months periodically.

### Routine examination and assessment

This includes recording of medical history initially on the day of recruitment. Then the pathological assessment such as hemoglobin, blood sugar, urea, creatinine, aspartate transaminase (AST), alanine transaminase (ALT) and bilirubin were done at pathological laboratory using commercial kits and standard operating procedure as per protocol provided by manufacturer on the day of recruitment and on day 90 to understand the safety of the participants. Functional assessments of the participating subjects were carried out using grip power assessment and walking time. In grip power the participating subjects were supposed to squeeze the cuff of sphygmomanometer for 500 mmHg and based on the increased levels of the mercury column the grip power assessed. In case of walking time analysis, the participating subjects were supposed to walk 150 feet distance and time required to walk the same was recorded. This functional assessment was carried out on day 0 (initially), 15, 30, 60 and 90. Further overall clinical examination (joint pain, morning stiffness,

tenderness and swelling) of the participating subjects on day 0 (initially), 15, 30, 60 and 90.

### Clinical Assessment

Grade based (0 to III) clinical assessment was conducted on day 0 (initially), 15 and 90.

### Parameter wise grading is given below

The participating subjects were examined at regular intervals for any untoward effects if any seen during the study period. Further the participants were examined personally through interview method and observational methods at regular intervals as mentioned above. If any adverse effects were seen during the study, then either treatment or period of treatment was reduced/stopped as per the physician's advice. In case of any adverse effect and intercurrent illness observed or reported by subject/s was recorded. These adverse effects were treated as per symptoms and disease according to ayurvedic or modern line of treatment.

### Study monitoring

The entire clinical monitoring was done by lab/treatment visits by concern physicians from Department of Panchakarma, Bharati Vidyapeeth Medical Foundation's Bharati Ayurveda Hospital, Pune, India. In the present study, protocol for study design, criteria for inclusion/exclusion/withdrawal of the subject, routine examination and assessment, method of assessment of treatment (functional assessments, clinical assessment, assessment of efficacy, assessment on pathological changes and assessment of safety of subjects) and study monitoring/recording of clinical data etc., were adopted as per clinical research protocols proposed by Central Council for Research in Ayurveda and Siddha, Government of India [29].

### Statistical data analysis

One-way ANOVA followed by post hoc Bonferroni test or student t-test was considered for statistical analysis with the help of Prism 5.00, GraphPad Software, San Diego, CA, USA. Where, the P value less than 0.05 was considered as significant (www.graphpad.com).

## RESULTS AND DISCUSSION

Inflammation and deformity of joints are key issues in Rheumatoid arthritis being a chronic autoimmune disorder. It is a prime disease that cripples a person and makes one unfit for independent working. The disease is chronic, incurable and involves complications, and complex in nature [30]. The patients suffer from various clinical signs and symptoms at multiple anatomical

| Grade | Joint Pain  | Morning stiffness                           | Tenderness                 | Swelling                                       |
|-------|---|---|----------------------------|--|
| 0     | No pain   | No stiffness                                | No Tenderness              | No swelling                                    |
| I     | Occasional pain that can be managed without drug        | Early morning stiffness upto 30 min         | Bearable tenderness        | Just covering the bony prominences             |
| II    | Frequent pain that can be managed with some pain killer | Early morning stiffness between 30 - 45 min | Tender and winced          | Above the land marks may be with + fluctuation |
| III   | Persistent pain which is unmanageable even with drugs   | Early morning stiffness >45 min             | Tender winced and withdraw | -  |



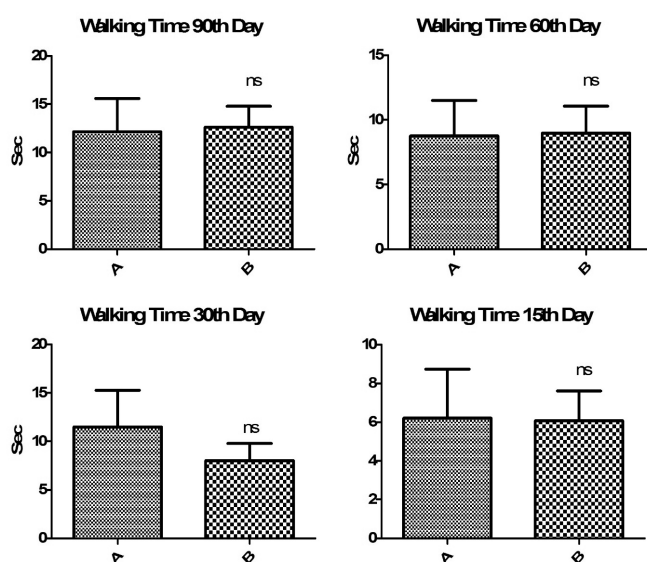
sites. Rheumatic patients suffer from severe pain, swelling, stiffness at both small and large joints and its close association with skeletal manifestations is well known [31]. So, in this context management of

pain along with inflammation is the key challenge in RA [32]. In the present investigation, comparative assessment of chinchadi oil (pain reliever) and omega-3 medicated massage oil (pain and inflammation reliever)

**Table 1. Fatty acid analysis of plain chinchadi oil and omega-3 medicated massage oil.**

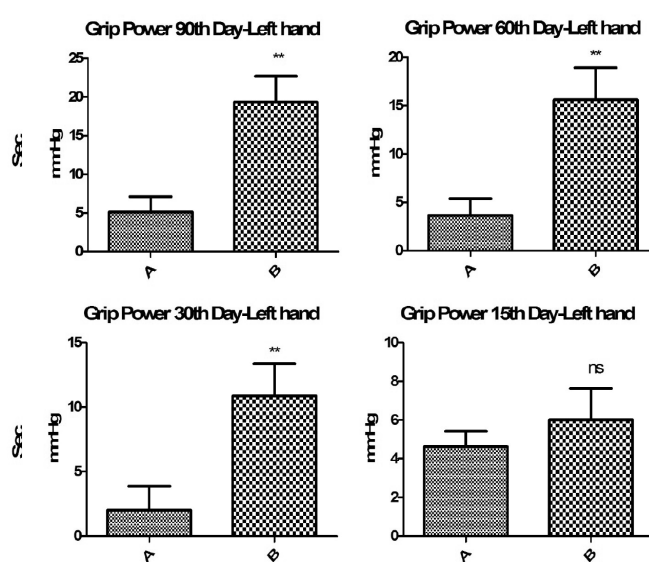
| Name of experimental oil      | Palmitic acid    | Stearic acid     | Oleic acid       | Linoleic acid    | $\alpha$ -Linolenic acid | SFA              | MUFA             | PUFA             | Ratio O6/O3      |
|-------------------------------|------------------|------------------|------------------|------------------|--------------------------|------------------|------------------|------------------|------------------|
| Plain Chinchadi oil           | 10.04 $\pm$ 0.03 | 6.415 $\pm$ 0.16 | 43.15 $\pm$ 0.24 | 39.58 $\pm$ 0.03 | 0.82 $\pm$ 0.08          | 16.45 $\pm$ 0.13 | 43.15 $\pm$ 0.24 | 40.39 $\pm$ 0.11 | 48.78 $\pm$ 4.62 |
| Omega-3 medicated massage oil | 8.88 $\pm$ 0.16  | 6.46 $\pm$ 0.15  | 39 $\pm$ 0.05    | 34.32 $\pm$ 0.12 | 11.33 $\pm$ 0.24         | 15.34 $\pm$ 0.32 | 39 $\pm$ 0.05    | 45.65 $\pm$ 0.37 | 3.02 $\pm$ 0.05  |

Where: SFA-saturated fatty acid (Palmitic acid + Stearic acid), MUFA-mono-saturated fatty acid (Oleic acid), PUFA-poly-unsaturated fatty acid (Linoleic acid +  $\alpha$ -Linolenic acid).



**Fig. 1. Effect on grip power right hand.**

[Recording of grip power of right hand on day 15, 30, 60 and 90. Here all the study participants were supposed to squeeze the cuff of sphygmomanometer for 500 mmHg and based on the increased levels of the mercury column the grip power assessed].



**Fig. 2. Effect on grip power left hand.**

[Recording of grip power of left hand on day 15, 30, 60 and 90. Here all the study participants were supposed to squeeze the cuff of sphygmomanometer for 500 mmHg and based on the increased levels of the mercury column the grip power assessed].

in RA subjects using whole body massage as per Panchkarma therapy of traditional Ayurveda system was carried out during 2017-2020.

#### Fatty acid analysis of experimental oils

Table 1 shows fatty acid analysis of plain chinchadi oil and omega-3 medicated massage oil. The base oil of this chinchadi oil was sesame oil. There were non-significant changes in palmitic acid and stearic acid *i.e.*, total

saturated fatty acid content. Further the omega-9 fatty acid *i.e.*, oleic acid and omega-6 fatty acid *i.e.*, linoleic acid levels were slightly reduced in omega-3 medicated massage oil. However as expected, there was significant increase in  $\alpha$ -linolenic acid (O-3) and thereby ratio of O-6 to 3 ratio was also significantly reduced, indicating addition of flaxseed oil was responsible for modulation of the composition of the fatty acid in omega-3 medicated massage oil as compared to plain chinchadi oil.

### Functional assessments

#### Grip power

Initially (15th day and 30th day) there was a non-significant improvement in grip power of right hand was observed in case of group B as compared to group A. Gradually statistically significant improvement was

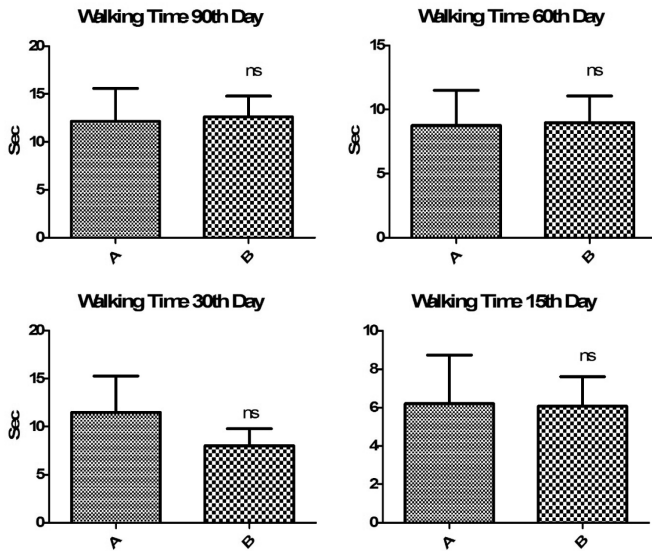
seen on day 60 ( $p<0.5$ ) and on day 90 ( $p<0.001$ ) (Figure 1). In the case of left hand, improvement was more prominent, as significant improvement ( $p<0.01$ ) was seen on the 30th day itself and this significant change remain till 90th day B group when compared to that of A group (Fig. 2). Muscle weakness is well established in RA [33]. Grip power is an important indicator of functional disability in RA and there is close correlation between grip power and RA with respect to the activity and length of disease [34]. Reduced grip power leads to reduced performance of the individual and it also effects day-to-day activities also [35]. There is a direct co-relation between handgrip strength and quality of life in RA, weaker handgrip strength leads to significantly reduces quality of life [36].

#### Walking time

There was non-significant improvement in walking time was noted in group B when compared to A group at every time point (Figure 3). Walking capacity is important for routine activity and impairment in walking capacity in RA patient is well known [37,38].

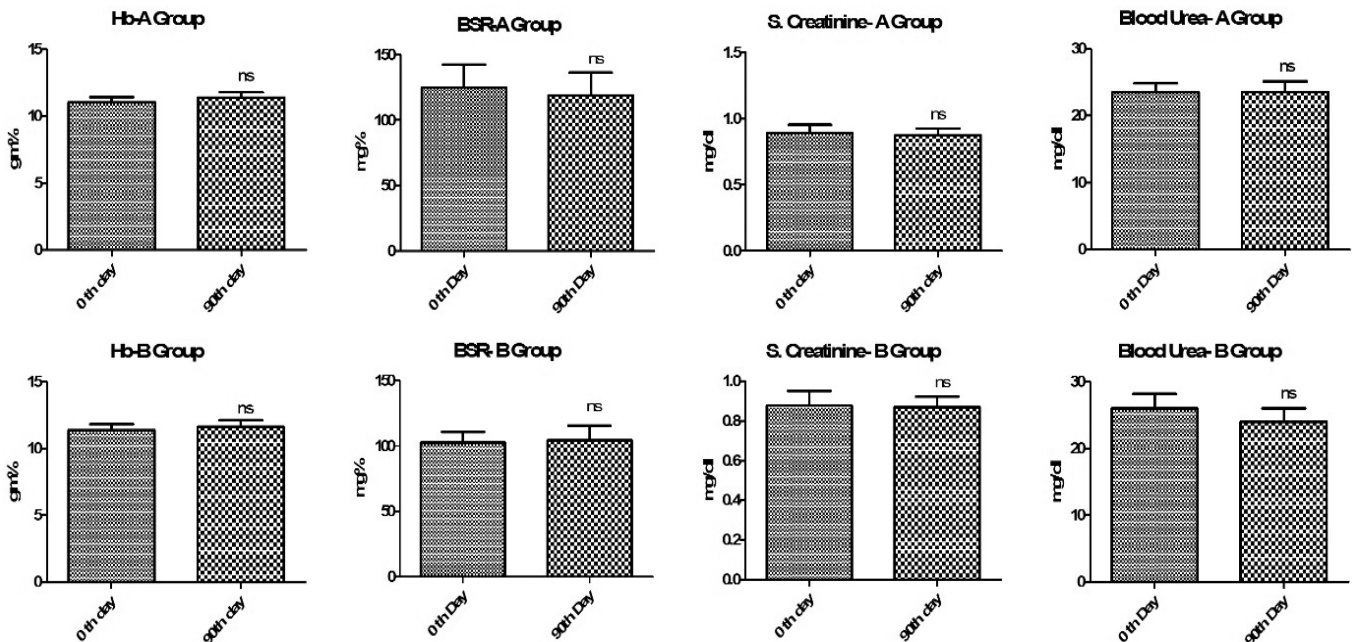
#### Clinical assessment

We observed that even in group A, almost all participating subjects showed improved (grade III to II). On other hand in case of group B, it also showed



**Fig. 3. Effect on walking time.**

[Recording of walking time on day 15, 30, 60 and 90. The participating subjects were supposed to walk 150 feet distance and time required to walk the same was recorded].



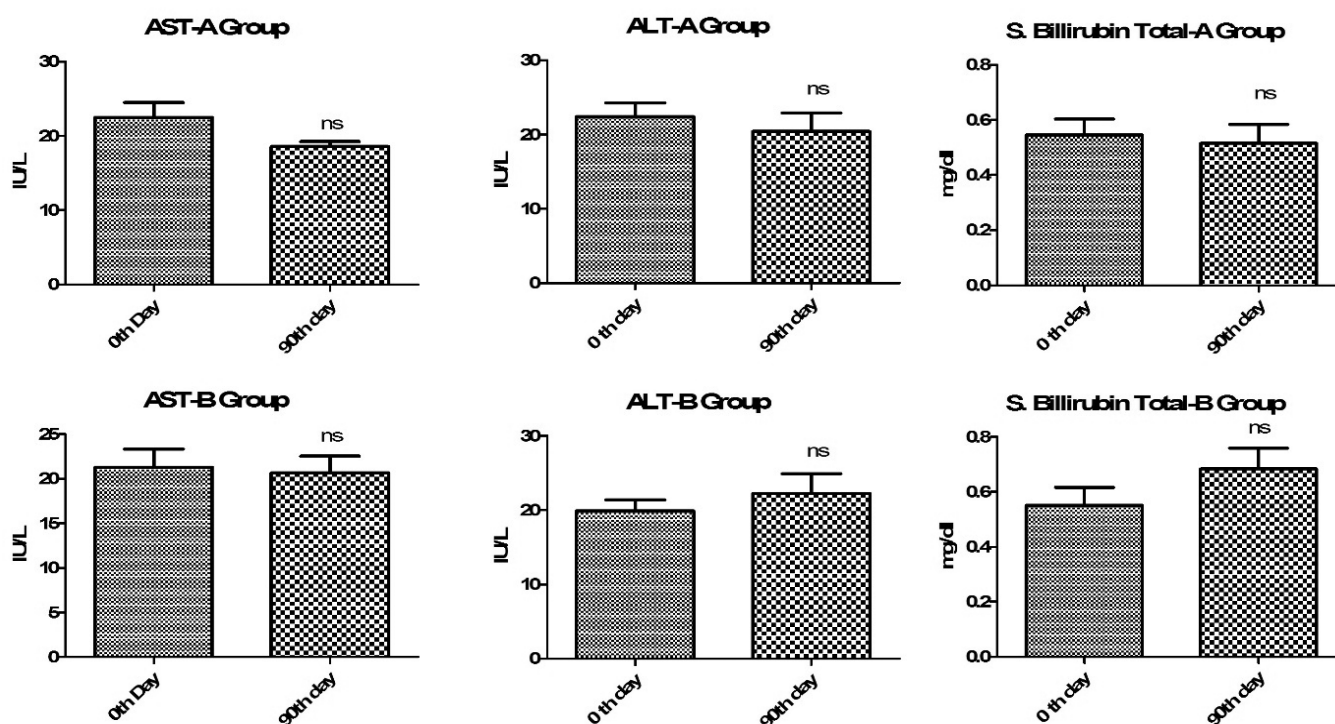
**Fig. 4. Effect on hemoglobin, blood sugar, creatinine and urea levels.**

[Recording of pathological parameters such as hemoglobin, blood sugar, creatinine and urea levels on the day of recruitment and on day 90].

improvement from grade III to II and some also improved up to grade I, indicating higher efficacy of omega-3 medicated massage oil over plain chinchadi oil. Here, chinchadi oil was responsible for reduction in pain only in A group and in case of B group chinchadi and omega-3 oil together responsible for pain and inflammation both, hence more prominent effect was observed in group B. The important clinical parameters such as joint pain, swelling, morning stiffness and tenderness etc. are key clinical sign and symptoms during RA [39].

### Assessment of safety of study subjects

Apart from these various clinical signs and symptoms, various biochemical parameters such as hemoglobin, blood sugar, urea, creatinine, AST, ALT and bilirubin were also monitored during the study period to assess the safety of chinchadi oil in combination with flaxseed oil supplementation for the period of 3 months in both group A and B (Fig. 4 and 5). There were no significant changes observed with respect to these above-mentioned parameters indicating safety of flaxseed oil omega-3



**Fig. 5. Effect on aspartate transaminase, alanine transaminase and bilirubin.**

[Recording of pathological parameters such as aspartate transaminase, alanine transaminase and bilirubin on the day of recruitment and on day 90].

medicated massage oil during the study period of 3 months, indicating safety of the treatment.

Further all the participants were examined by physician of Panchakarma department at regular interval for any adverse reaction/allergies if any seen during the study period. These participants were examined personally through interview methods and observational methods at regular intervals and there were no adverse effects seen by physician or reported by study participants due to the treatment.

### CONCLUSION

Based on the comparative clinical evaluation, whole body massage therapy using omega-3 medicated massage

oil (group B) and oral administration of flaxseed oil in the form of softgel capsules exhibited better clinical outcome when compared with plain chinchadi oil (group A). Functional assessment showed significant improvement in left and right hand in case of grip power ( $p < 0.05$ ), however there was non-significant reduction was noted in case of walking time for the period of 3 months. In qualitative evaluation of joint pain, swelling, morning stiffness and tenderness in the form of grading showed comparative more relief in omega-3 medicated massage oil group as against plain chinchadi oil group. Further, based on pathological assessments, overall clinical parameters showed that no gross adverse effect of topical use of omega-3 medicated massage oil along



with oral supplementation of omega-3 soft-gel capsules during the treatment period.

The treatment period of 14 days massage therapy using omega-3 fatty acid massage oil and 90 days internal medicine of omega-3 softgel capsules supplementation does significantly improved signs and symptoms of rheumatoid arthritis based on pathological and clinical parameters as compared to plain chinchadi oil. This proved improved indicated efficacy omega-3 medicated massage oil and omega-3 soft-gel capsules without any adverse effect. A flaxseed oil based value-added product for the prevention and control of RA has been validated using clinical study. This treatment approach can serve as an adjuvant therapy in Rheumatoid arthritis along with allopathic or ayurvedic treatment.

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