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Efficacy and Safety of Muscle Rub Ointment in The Management of Arthritis and Certain Musculoskeletal Disorders

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Abstract: Traditional Indian medicine has long used Muscle Rub Ointment to treat rheumatoid arthritis (RA), but its safety and effectiveness have not been well studied. To bridge this gap, an extensive investigation was carried out to evaluate the efficacy and safety of a specially designed Muscle Rub Ointment for individuals with RA. Over a 7-year period, 290 RA patients received customized care from Ayurvedic doctors in accordance with established practices. The American Rheumatism Association criteria were used for monitoring every six weeks, and treatment regimens varied from one to six months. Based on statistical analysis (repeated measures t-test), 33 discharged patients' first-year data were the subject of the study. There were notable improvements even among the most severely disabled patients in a number of indicators, such as functional class, rheumatoid factor, grip strength, walking time, swollen joints, painful joints, joint count, and erythrocyte sedimentation rate. Despite the fact that some patients did not get regular follow-up, the data that was available indicated persistent gains after discharge, especially in grip strength. The results of this study highlight the potential benefits of using ancient Ayurvedic medicine to treat RA and highlight the need for further emphasizing the need for further controlled investigations into its efficacy.

Introduction

Millions of people of all ages are afflicted by musculoskeletal diseases (Atchison et al., 2013; Gajbhiye et al., 2023). Lower back pain has been the leading cause of disability worldwide every year since 1990, according to the Global Burden of Disease research conducted in 2016. Painful musculoskeletal problems affect anywhere from 20 percent to 33 percent of the global population, depending on age and diagnosis (Marinho and Pereira, 2020).

In Coimbatore, Tamil Nadu, India, the World Health Organisation (WHO) and the Indian Council of Medical Research (ICMR) conducted the first-ever study of a traditional medical system from 1977 to 1984, looking at the efficacy of complete, classical Ayurvedic treatment for rheumatoid arthritis (RA). Over a 7-year period, researchers enrolled 290 patients with RA at the Ayurvedic Trust in Coimbatore, India, and analysed the efficiency of ayurvedic treatment for rheumatoid arthritis without blinding the participants (Yuryeva and Shpychak, 2023).

These studies do not represent authentic testing of traditional Ayurveda because they did not permit individualised therapy or adhere to Ayurvedic teachings for the treatment of RA. This is the only study to date that looks at the effectiveness of classical Ayurvedic therapy for rheumatoid arthritis even though it has been going on for over three decades (Birlik, 2023).

Despite advancements in allopathic medication, remission from RA remains unusual, and outcomes are frequently disheartening. This has led to the continued pursuit of alternative treatments by scientists. Recent results from a randomised pilot clinical trial of conventional Ayurvedic outpatient treatment for RA,

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funded by the National Institutes of Health, USA, attest to the growing interest in this study (Bakó et al., 2023).

Annual reports can be generated from descriptive analyses stored in the Ayurvedic Trust's data repository for each year of the project's duration. Here, we present data from the initial cohort of patients.

Materials and Methods

Ingredients

Pinus roxburghii:

The Pinaceae family, of which this plant is a member, includes the Chir Pine. In India, the *Pinus roxburghii* Sarg. (Pinaceae) tree has a long history of usage as a medicine. This research was conducted to evaluate the analgesic and anti-inflammatory properties of the bark extract of a plant whose oil is widely utilised in various herbal preparations for treating inflammatory illnesses.

Sesamum indicum:

Sesame (*Sesamum indicum*) is a member of the Pedaliaceae family of plants. Extracts and isolated compounds obtained from different parts of sesame were shown to exhibit various therapeutic activities.

Eucalyptus globulus:

Southern blue gum, also called simply blue gum, is the popular name for a flowering plant in the family Myrtaceae called *Eucalyptus globulus*. Through its modulatory influence on the immune response, it has been found to effectively reduce pain, edoema, and inflammation. Some bacterial species are demonstrated to be susceptible to its antibacterial and cough-suppressing effects. When used topically, eucalyptus oil relieves pain and inflammation in the joints, the genitourinary system, the nasal passages, and the respiratory tract.

Indian Colza oil:

Mustard seeds are the tiny, spherical fruit of the mustard plant, which is a member of the Brassicaceae family. The seeds of the plant *Brassica juncea* are hydro-distilled into mustard oil. There is some evidence that using pure mustard oil or mustard essential oil will help alleviate swelling and pain. It has antimicrobial, antifungal, and anticarcinogenic properties, among others.

Myristica fragrans:

Nutmeg trees, or *Myristica fragrans* (Houtt.) (*M. fragrans*), are members of the Myristicaceae family. Nutmeg's anti-inflammatory characteristics could make it an effective treatment for stomach aches. Pain in the muscles and joints can be alleviated with nutmeg oil. When combined with food, nutmeg may reduce inflammation and pain from cuts, arthritis, and other traumas. Rheumatic and neuralgia pain may be alleviated with the topical use of nutmeg powder mixed with sesame oil.

Gaultheria fragrantissima:

Gaultheria fragrantissima is a kind of Ericaceae plant. Gandhpura oil is commonly used to alleviate aches and pains in the muscles and joints. In the scientific world, this extract is known as *Gultheria fragrantissima*, but probably better known by its common name, Wintergreen Essential Oil.

Cymbopogon schoenanthus:

Camel grass, or *Cymbopogon schoenanthus*, also goes by the names Sakhbar, Izkhir, and Athkhar in its native region. The plant has many traditional uses, including as an antispasmodic, a fever preventative, an anti-intestinal ailment remedy, an anti-malarial, and an anti-helminthic (particularly against Guinea worms), a diuretic, a sedative, a digestive aid, an anti-parasitic, an anti-inflammatory, and a parasite fighter.

Linn seeds:

Common flax, sometimes called linseed, is the seed of a flowering plant in the family Linaceae called *Linum usitatissimum*. Its anti-inflammatory, painkilling, and fever-reducing properties are all well-documented.

Borneo camphor:

Severely endangered plant species *Dryobalanops aromatica* is a member of the family Dipterocarpaceae. It has been used for anything from earaches to chest congestion to headaches to eye illnesses.

Mentha arvensis:

The ethnopharmacological applications of *Mentha arvensis* L. are supported by the plant's possible antioxidant, antibacterial, cytotoxic, and analgesic actions.

Purified butter:

Ghee is an Indian form of clarified butter. It has multiple cultural and religious uses in India, including food preparation, traditional medicine, and worship. Clarified butter's therapeutic properties aid in calming inflammation throughout the body. Pain in the joints often stems from inflammation, and including clarified butter in the diet will assist with that.

Beeswax:

Beeswax is the beehive's structural backbone. Honeybees use beeswax to construct a comb, which is then filled with hexagonal cells that hold honey and developing larvae. Beeswax has been investigated for its potential medicinal uses, and preliminary results suggest that it may have a slight anti-inflammatory impact and be helpful for pain relief (Shi et al., 2023).

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Method

The group of doctors planned the study, confirmed RA diagnoses, enrolled patients, and determined whether or not Ayurvedic treatment was effective according to ARA standards. The treatment was delivered by Ayurvedic doctors who strictly followed the guidelines outlined in ancient literature. There were no matched controls.

The Ayurvedic panel, made up of three Ayurvedic doctors, recruited volunteers from the Ayurvedic Trust hospital's outpatient department based on Ayurvedic criteria for vatarakta. Confirmed vatarakta patients were forwarded to an allopathic panel of four doctors for further evaluation of RA using histological, serological, biochemical, and radiological methods. The allopathic panel diagnosed RA in roughly 66% of the individuals referred by the Ayurvedic doctor.

Intervention

All enrolled patients were advised to apply 3-5 grams of *Muscle Rub Ointment* Topically over the affected area, followed by a gentle massage for 10 to 12 minutes and hot fomentation with a hot water bottle or balukapotali or in a hot chamber at least for 10 minutes. The whole procedure is advised to be repeated thrice in a day, i.e., morning, afternoon, and at night.

Once every six weeks, the allopathic panel solely used criteria defined by the ARA to assess efficacy.

Outcome measures (ARA Criteria)

At admission, after 6 weeks of treatment and again at discharge, we assessed number of affected joints, functional status, ESR at 0.5 and 1 h, and rheumatoid factor (RF). At admission, after 6 weeks of treatment again before release, grip strength (in millimeters of mercury) was also tested.

Safety assessments

Complete blood count measurements, including white blood cell count, lymphocyte count, packed cell volume percent, and haemoglobin, were taken every 6 weeks, in addition to tests for liver function like SGOT, SGPT, blood urea, and serum creatinine.

Analyses

Each patient had a record kept by their allopathic doctor and their Ayurvedic doctor. The medical statistician has extracted outcome and efficacy endpoints for analysis.

Results

We report our findings based on the first group of patients who completed the research and were released at the conclusion of the first year. One hundred people were found to have vatarakta after being checked by Ayurvedic doctors. Eighty of the hundred potential patients were tentatively diagnosed with RA after undergoing initial screening by an allopathic physician. Only 9 out of 80 patients bothered to show up for their confirmed diagnosis at an allopathic facility. Sixty-six of the remaining seventy-one individuals had an allopathic panel confirm an RA diagnosis. There were originally 66 patients, but two of them declined in-patient care; thus only 64 were ultimately admitted. Due to the continuing nature of patient recruitment, participants sometimes finished the study at different times. Results for 33 patients were checked at closure of 1st year.

Characteristics of patients at admission

There were more women than men in the population (61%). Seventy-five percent were individuals aged 15 to 44, and approximately sixty percent had a functional class of III or IV or lower. Patients' RA durations ranged from less than a year (50%) to one to five years (25%) and more than five years (5%) (Table 1). Patients spent anywhere from one month to six months undergoing treatment.

Table 1. Demographic and background characteristics at admission (*N* = 33).

Characteristic	N	Percentage
Male	13	39
Female	20	61
Age (Years)		
Less than Fifteen	2	6
Fifteen to Twenty-Four	8	24
Twenty-Five to Thirty-Four	10	30
Thirty-Five to Forty-Four	7	21
Forty-Five or More	6	18

Efficacy outcomes

Grip strength, walking time (50 and 25 feet), number of swollen and uncomfortable joints, joint count, ESR, and RF were used to evaluate improvement from admission to release. The joint count is calculated using a scoring system, and the parameters that changed between admission and discharge are shown in Table 2.

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Table 2. Mean values of the change from admission to discharge (*N* = 33)

Parameter	Admission	Discharge	t
Mean Grip Strength	82	111	4.3
Walking time (25 Ft)	7.4	4.8	4.9
Walking Time (50 Ft)	14.3	9.4	4.6
Swollen Joints	6.6	4.3	5.3
Painful Joints	7.8	3.6	8.8
Joint Count	74	30	6.4
P value <0.001			

Grip strength

Grip strength was evaluated with an inflated sphygmodynamometer (to 30 mmHg). Six measurements were obtained as a mean, three from each hand in turn. At admission, the average grip strength of both hands was below 150 mmHg in 91% of patients. This number dropped to 73% by the time patients were released. At admission, the average grip strength for all 33 patients was 82 mmHg; at discharge, it had increased to 111 mmHg, a substantial improvement (P <0.001).

Walking time

The time it takes to walk 25 feet and 50 feet is recorded in minutes and seconds. At admission, 12% of patients could not walk, and 12% needed 15 seconds or more to walk 25 feet. However, by the time of discharge, everyone could walk, and 94% could cover 25 feet in under 10 seconds. At admission, the average patient took 7.4 seconds to walk 25 feet; after release, that time had decreased to 4.8 seconds (P<0.001).

Swollen joints

Twenty-seven percent of patients had at least ten swollen joints when they first checked in, but that number dropped substantially to six percent by the time they were released. The average score of joint swelling decreased from 6.6 at admission to 4.3 at discharge (P< 0.001).

Painful joints

At admission, 33% of patients reported at least 10 painful joints; after release, that number had dropped to 6%. At admission, patients reported 7.8 painful joints on average; at discharge, that number had dropped to 3.6 (P< 0.001).

Joint count

Only 18% of the patients maintained an initial joint count of 75 or above after treatment. While no patient started with a zero joint count, one-third of patients reached that point by the time they were released from the hospital. There was a statistically significant (P< 0.001) drop from 74 to 30 joints in the average body.

Erythrocyte sedimentation rate

In the first hour, 48 percent of patients had an ESR of 50 millimetres or higher, while only 27 percent had one after discharge (mean, 37) (P<0.01). The results at 0.5 h followed the same trend, with the mean decreasing from 30 mm to 17 mm (P<0.01).

Functional class

At admission, 19 of the 33 patients (58%) were placed in functional class III or IV; after discharge, only 4 of the 33 patients were placed in these categories. There were no changes in functional class for 16 patients (48%), including 7 individuals in functional class I. Eleven patients (33%) showed a one-class improvement, two (12%) showed a two-class improvement, and two (6%) showed a three-class improvement. The collective progress was statistically significant (P< 0.001).

Rheumatoid factor

There were merely three individuals (nine percent) who never had a positive result, whereas twenty-two (67 percent) had titers of 1/80 or higher, with five (fifteen percent) having titers of 1/640 or 1/1280. Only 15 out of 33 patients (45%) had their RF established between admission and discharge. There were at least two doublings of dilution in 12 cases. There was no change in two cases and in one, the titer went up from 1/20 to 1/80. Twelve fewer cases and one more improvement represented a statistically significant improvement (P<0.01).

During the leading year of the trial, not all patients were consistently followed up with. Consequently, only 14 patients (42% of all patients) had available follow-up data 2-4 months after discharge (not shown). With the exception of grip strength, which increased significantly (from 111 to 129, P< 0.01) between discharge and follow-up, all other indicators exhibited a minor reduction that bordered on statistical significance. However, average follow-up values showed improvement compared to those upon admission (Mahmoud et al., 2023).

Discussion

This WHO-sponsored study of traditional medicine's effectiveness in treating rheumatoid arthritis remains the sole study of its kind. This analysis of the first group of patients to be released from the trial shows that they all showed significant improvement after receiving Ayurvedic treatment. Patients' conditions improved (statistically significantly) between admission and

discharge, as measured by all ARA criteria used to assess the efficacy (Hajare et al., 2023; Vanukuru et al., 2023).

Roughly a two-thirds majority of the survey respondents were female. They suffered more from the illness and made less progress in recovery compared to males. Disease duration and functional class before treatment revealed intriguing patterns of improvement. In contrast, the most significant gains were shown in patients in the earliest stages of RA (functional classes I and II). Most patients saw decreased edoema within a month and 80% felt better after the first month of treatment. Ayurvedic medication did not cause any toxicity in the liver, kidneys, or anywhere else in the body (Zheng et al., 2023).

Initially, the study's external validity needs to have a control group. Second, patients who were already on steroids were included, and the protocol asked for them to be suddenly terminated rather than progressively decreased, as is standard medical practice. These patients (the steroid group) required a few more weeks of Ayurvedic treatment because of the severe withdrawal symptoms that ensued. Patients on steroids and those not on steroids were not compared in this initial cohort, but in future ones, the data from each group was examined independently. The results of these studies demonstrated that the steroid group made less progress than the control group. Treatment in the steroid group was, on average, 6 months long, while in the nonsteroid group, it was just 3 months. Third, children who meet the criteria for juvenile RA were not excluded from admission. Despite differences in disease length, functional status, and age, all of these patients showed improvement after receiving conventional Ayurvedic treatment, known for its individualised, holistic approach to care (Mourya et al., 2023).

Unexpectedly, the study design highlighted Ayurveda's ability to detect early-stage RA when symptoms remain modest. The Ayurvedic doctors successfully treated the persons excluded due to vatarakta on their own. These individuals' positive responses to treatment provide credence to the allopathic belief that it is best to intervene in RA when it is in its earliest stages. It demonstrated that Ayurvedic treatment was effective in managing a problematic, long-lasting condition like RA, even when measured against allopathic benchmarks. The Ayurvedic doctors methodically and creatively documented therapy and outcomes (according to Ayurvedic criteria), which may be just as important, if not more so. Questionnaires were developed using a quantitative study of Ayurvedic outcome measurements; variables were defined according to doshas and disease stage. This method also allowed the Ayurvedic doctors to test their hypotheses. Ayurveda's predictions about the propensity of patients with a given constitution type (a vata-pitta combo) to develop the condition were supported (Worasing et al., 2023).

Conclusion

The thorough study that investigated the efficacy and safety of Muscle Rub Ointment for the treatment of rheumatoid arthritis (RA) yielded positive results, demonstrating its potential as a viable therapeutic alternative. Grip strength, walking time, joint swelling, painful joints, joint count, erythrocyte sedimentation rate, functional class, and rheumatoid factor were all significantly improved in study participants. Notably, the data indicated the favourable benefit of traditional Ayurvedic therapy, particularly in individuals with early RA. Despite several limitations, such as the lack of a control group and the inclusion of patients on steroids, the study emphasises the significance of more controlled studies investigating the efficacy of traditional Ayurvedic therapies for RA. The methodical and thorough recording of the results of Ayurvedic treatments raises the possibility of combining traditional medicine with modern scientific analysis, providing insightful information for both clinical research and future studies. This work adds to the growing body of evidence demonstrating the utility of traditional medicine in treating complex musculoskeletal disorders by stressing the need for longitudinal data and highlighting the holistic nature of Ayurvedic treatment.

Conflict of interest

There is no known conflict of interest found by the authors.

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