

Comparative study of efficacy of *Gunja Beeja lepa* and *Shunthi Churna lepa* in Inflammatory Conditions of Arthritis - A Randomized Controlled Single Blinded Clinical Study

Research Article

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Abstract

Background: Life style disorders are an emerging problem in India where various types of arthritis are hampering the routine activities of people due to severe pain and inflammation. In such circumstances, everybody wants quick relief with the symptoms. *Visha dravya* used in Ayurveda are known for their quick action. *Gunja* (*Abrus precatorius* Linn) is a *visha* indicated in various diseases for internal and external use. Objectives: A randomized clinical study was conducted to assess the efficacy of *Gunja beeja lepa* to manage the local inflammatory conditions of Arthritis in comparison with a standard anti-inflammatory Ayurvedic drug *Shunthi* (*Zingiber officinalis* Linn) to provide a potent anti-inflammatory drug for the purpose of clinical practice. Material and methods: Patients suffering from transient mono or bi-arthropathies of knee were applied *Gunja beeja lepa* in comparison with local application of standard anti-inflammatory Ayurvedic drug *Shunthi*. Assessment was done with the help of Disease Activity Score (DAS-28-3) including three variables viz; tender joint score (Range 0-28), Swollen Joint Count (Range 0-28) and Erythrocyte sedimentation rate. Statistical comparisons were performed by both paired, unpaired student's t test by using Sigma stat software (version 3.1) for both the experimental the groups at $p < 0.05$ (level of significance). Result: Intervention with *Gunja beeja lepa* was statistically significant ($p = 0.003$) in comparison with the intervention with *Shunthi churna lepa*. Conclusion: *Gunja Beeja lepa* is effective in comparison with standard anti-inflammatory Ayurvedic drug *Shunthi* in inflammatory conditions of Arthritis.

Key Words: *Gunja Beeja lepa*, Arthritis, Life style disorders, *Shunthi*, Disease Activity Score.

Introduction

Arthritis is a joint disorder featuring inflammation which is frequently accompanied by joint pain. Now a day, it is a very common condition due to today's modern life style and early ageing process. Because of it many people suffer from number of joint diseases which even hamper their routine activities.

Symptoms of common arthritis include swelling, pain, stiffness in joints and decreased range of motion. Symptoms may be intermittent or continuous. They can be mild, moderate or severe even. The condition may remain same for years, or it may progress or get worsen over time span. Arthritis can cause permanent joint changes resulting in chronic pain, inability to do daily activities and make it difficult to walk or climb the stairs.

There are more than 100 different types of arthritis and related conditions. People of all ages, gender and races can have arthritis and it is the leading cause of disability. More than 50 million adults and 300,000 children have some or the other type of arthritis. It is the most common among women and occurs more frequently as people gets older. (1)

The focus of treatment for arthritis is limited to control pain, minimize joint damage and improve or maintain the function and quality of life. Treatment includes analgesics, non-pharmacologic therapies, physical or occupational therapies, splints or joint assistive measures, patient education and support, weight loss, joint replacement and ultimately joint surgery.

In Ayurveda, arthritis is described as *sandhivata* and enlisted under *Vata* diseases. Various formulations and treatment modalities are used to cure *sandhivata*. Apart from the above listed measures, various toxic herbal drugs are also mentioned to have good medicinal values in this disease. Though the poison is harmful, dangerous and life threatening, they are vividly used therapeutically as they have quick distributing action (2). Hence, they are useful in acute conditions like joint pain.

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Gunja (Abrus precatorius), a *Vanaspatic Visha* (3) is described and classified as *Upavisha*. (4) In India, it is commonly known as *Ratti* or *Gunchi*. *Ratti* is referred to a single *Ratti* (120mg) seed. This seed was the standard weight in the ancient Indian system of measurement, because the seed is fairly constant in weight. It was used to measure gold and 1 *Tola* (11.6gm) = 1 *Masha*; (1 *Masha*=8 *Ratti*). It is called as *Kudri mani* in Tamil and *Guru ginja* in Telugu. It has been used even in Siddha medicine for centuries. The seeds are much valued in native jewelry for their bright coloration.

Two types, red and white *Gunja* are beneficial for many viz. cures diseases due to vitiation of *Vata* and *Pitta*, fever, dryness of mouth, giddiness, difficulty in breathing, thirst, excitement, diseases of eyes, improve sex vigor and bodily strength and is useful in pruritus, ulcer treatment, destruction of worms and similar parasites, nourishes hair and removes alopecia and other skin diseases (5) as well as *rakshograhavisha*. (6) It is indicated in atrophied ear lobule, dandruff, sciatica, erysepulous and few other dermatoses, blindness, diseases of head, dental caries, etc. (7) It is very much beneficial as anti-inflammatory, anti-microbial, anti-fertility, anti-tumor etc. A paste of *Gunja* seeds can be used as rubraficient in Sciatica, stiff shoulders, paralysis and other nervous and arthritic conditions. (8) In patients of arthritis, either steroids or non steroidal anti-inflammatory drugs (NSAID) are commonly used for quick relief. As the disease is a chronic, patients have to consume medicine for long term. Long term use of steroids is known to produce liver toxicity. Hence, a randomized clinical study was conducted to assess the efficacy of *Gunja beeja lepa* to manage the local inflammatory conditions of Arthritis in comparison with a standard anti-inflammatory Ayurvedic drug *Shunthi (Zingiber officinalis)* to provide a potent anti-inflammatory drug for the purpose of arthritis clinical practice.

Material and Methods

Materials:

- i.Red *Gunja (Abrus precatorius)* Linn) seeds
- ii.*Shunthi (Zingiber officinalis)* Linn)
- iii.Water
- iv.Measuring Tape
- v.Surface temperature measuring card
- vi.Universal Pain Assessment Scale.

Methods

After receiving approval from Institutional Ethics Committee Ref.No. DMIMS (DU)/IEC/2012-13/5 dated 24/12/2012, a standard comparative randomized controlled single blinded clinical study was conducted under the supervision of Professor and head, department of Panchakarma, M.G.A.C.H. & R.C. Salod (H), Wardha.

Patients ages 21-70 years, suffering from transient mono or bi-arthropathies of knee i.e. having history of pain and swelling of either one or both joints with unattended short duration of history were randomly selected from OPD and 128 patients were

screened. The patients were included in group A or group B by lottery method of randomization. Each group have 30 patients and the total number of included are 60 patients. Informed written consent was taken after due consultation with patients.

Patients below 20 and above 70 years of ages, patients with skin diseases or lesions over the knee or known allergic, pre diagnosed patients with conditions such as Rheumatoid arthritis, Gouty arthritis, Infective arthritis and Diabetic arthropathy, patients having any traumatic history along with local abrasion, erosion, cuts or laceration, patients associated with simple or compound fractures and pregnant and lactating women were excluded from the study.

Group A was treated with standard anti-inflammatory drug *Shunthi (Zingiber officinalis)* Linn) *churna lepa* and Group B was treated with Trial drug *Gunja (Abrus precatorius)* Linn) *churna lepa*.

Method of Preparation of study drug

Red coloured variety of *Gunja (Abrus precatorius)* seed was procured from local market and authenticated from HOD, Dravyaguna, M.G.A.C.H. & R.C. Salod (H), Wardha. Physical impurities were separated and fully developed, undamaged seeds were selected. The seed coat was removed after partial grinding and the seed was powdered till it becomes fine required for paste preparing. Fine powder of *Shunthi* was prepared simultaneously by grinding.

In physical examination, all the tender and swollen joints were examined and counted. Local temperature at joints was assessed with surface temperature measuring card. Circumference of joints was measured with metal tape. Range of movement and stiffness was measured with Goniometry and pain was assessed with Universal pain assessment Scale.

Complete blood count, Erythrocyte Sedimentation Rate, Random Blood Sugar, C-Reactive Protein and Rheumatoid Arthritis test was conducted for each patient. Modified Disease activity score (DAS with 28 joints and three variables viz. tenderness, swelling and ESR) was calculated after physical and pathological examination as follows:

$$\text{DAS 28-3} = [0.56 \times \sqrt{(\text{TJC28})} + 0.28 \times \sqrt{(\text{SJC28})} + 0.70 \times \ln(\text{ESR})]1.08 + 0.16$$

Where, TJC28 -Tender Joint Count (Range 0-28), SJC28 -Swollen Joint Count (Range 0-28), ESR-Erythrocyte sedimentation rate

On the basis of score obtained, the condition of the patients was categorized as follows:

Level of Disease Activity:

- DAS 28 ≤ 3.2 – Low disease activity
- 3.2 > DAS 28 ≤ 5.1 – Moderate disease activity
- DAS 28 > 5.1 – High disease activity
- DAS 28 < 2.6 – Remission

Application of trial drug

A freshly prepared *Gunja beeja lepa* in water was applied with applicator on lower part of the leg of the patient and was kept for ten minutes to observe any sensitivity reaction. Once there was no sensitivity reaction, the lepa was applied gently and evenly over affected area only. It was then freely allowed to dry neither in sunlight nor in air from fan. After getting dried and becoming stiff, the lepa applied was allowed to wash with Luke warm water. The same procedure was adopted for both the groups (A and B) twice a day under supervision in IPD. The drug application period was 3 or 5 or 7 days on the basis of pain or swelling condition. If pain or swelling was not reduced after three days, *Lepa* application was continued for two more days. If pain or swelling was not reduced even

after fifth day, the application was continued for two more days. After seventh day, even though remains same the application was discontinued and listed as “No Response”. Thus, sets of 3, 5 and 7 days were observed, where the pain/swelling was the criteria to continue the drug application for both groups.

Statistical analysis

The results are presented as Mean± Standard Error of means (SEM) in each group. Statistical comparisons were performed by both paired, unpaired student's t test by using Sigma stat software (version 3.1) for both the experimental groups at p<0.05 (level of significance).

Observation and Results

Table No.1: Total Number of Patients in study

	Group A	Group B
Total patients enrolled	30	34
Adverse drug reaction	0	4

Table No.2: Distribution of Patients according to age and sex

Age group (yrs)	Group A		Group B	
	Male	Female	Male	Female
21-30	0	0	4	2
31-40	0	3	2	1
41-50	5	5	3	2
50-60	6	6	0	7
61-70	2	3	1	8
Total	13 (43.33%)	17 (56.66%)	10 (33.33%)	20 (66.66%)
Total	30		30	

Table No.3: Effect of *Shunthi Churna lepa* on Disease Activity Score (DAS) in Group A

DAS	Mean	SD	SEM	Mean difference	t value	p value
Before treatment	4.335	0.732	0.134	0.835	8.382	<0.001
After treatment	3.500	0.780	0.142			

Table No.4: Effect of *Gunja beeja lepa* on Disease Activity Score (DAS) in Group B

DAS	Mean	SD	SEM	Mean difference	t value	p value
Before treatment	4.339	0.850	0.155	1.510	13.437	<0.001
After treatment	2.829	0.880	0.161			

Table No.5: Comparison of Effect on Disease Activity Score (DAS) between both groups

DAS	Group	Mean	SD	SEM	Mean difference	t-value	p value
Before treatment	A	4.335	0.732	0.134	-0.00390	-0.0190	0.985
	B	4.339	0.850	0.155			
After treatment	A	3.500	0.780	0.142	0.671	3.127	0.003*
	B	2.829	0.880	0.161			

Table No.6: Overall effect of treatment in both groups

	Group A			Group B		
	Before Treatment	After Treatment	%	Before Treatment	After Treatment	%
Low DAS (<3.2)	2	6	20	5	9	30
Moderate DAS (< 5.1)	24	19	63.33	23	8	26.67
High DAS (> 5.1)	4	0	0	2	0	0
Remission (DAS < 2.6)	0	5	16.67	0	13	43.33

Discussion

Gunja (*Abrus precatorius* Linn) is an irritant vegetative poison. All the parts of *Gunja* are poisonous. But seeds are more poisonous which contain a variety of poisonous proteins. The most important one is Abrin, (9) which is highly toxic thermo labile protein (toxalbumin LD 50= 0.029 mg/kg body weight of mice) (10) present to the extent of 0.15 % in the seed. (11) Seeds are also used as *Vranaropana*, *vedanasthapana*, *keshavardhana*, etc. (12)

Pharmacological properties of *Gunja* are *katu*, *tikta*, *kashaya rasa*; *katu vipaka* and *ushna virya*. It also possesses antitumor, anticancer, antispermatic, antifertility, CNS depressant and analgesic activity in rat. (13)

Externally, the seed extract is used in the treatment of ulcers and skin affections, anti-diarrheal and anti-helminthic activities. (14) 43 formulations are used as external applications for *kustha* (skin diseases), *krimi* (parasitic disease), *kandu* (itching), *arsha* (piles), *kasa* (cough), *indralupta* (alopecia), *apavahuka* (pain in arms), *gridhrasi*, *nasya*, *timiraroga* (eye disease), *nadivrana* (sinus ulcers), *shiroroga* (disease of the head), *gandamala* (chain of swelling), *karnapalivivardhana*, *andhatya* (blindness), *visarpa* (erysepelas), *dadru* (skin disease), *vicharchika* (one type of skin disease), *kaphaja galaganda* (goitre), etc. (15) It can cause redness with rash on skin as symptoms of local toxicity. If extract is administered in the skin, it may cause symptoms like viper snake bite and death within 24 hours. Internal consumption of *Gunja* seeds leads to symptoms like *vishuchika* (cholera). (16) *Tanduliyaka swarasa* (*Amaranthus spinosus* Linn) with sugar is described as an antidote for *Gunja* poisoning in Ayurveda. (17)

In the present study, disease activity score (DAS 28-3) was assessed before and after treatment in both the groups. In group A with standard drug, the intervention with *Shunthi churna lepa* was statistically significant ($p < 0.001$). All the patients required application of *lepa* for seven days duration.

In group B with trial drug, the intervention with *Gunja beeja lepa* was statistically significant ($p < 0.001$) and all the patients required application of *lepa* for seven days duration. But when the effect of both the groups were compared, it was found that intervention with *Gunja beeja lepa* was statistically significant ($p = 0.003$) in comparison with the intervention with *Shunthi churna lepa*. In group B, after treatment 9 patients (30%) had low disease activity score, 8 patients (26.67%) had moderate disease activity score, and 13 patients (43.33%) had remission. In group A, only 5 patients (16.67%) had complete remission. The disease activity score was only lowered in other patients of group A.

Reduction in pain and swelling at joint started from second day of application in patients with group B treated with *Gunja beeja lepa*, whereas it was started from day four to five in patients of group A. The result of the study indicates that *Gunja beeja lepa* is effective

in inflammatory conditions of arthritis in comparison with standard drug *Shunthi churna lepa*.

Even after negative sensitivity reaction in enrolled patients, four patients developed severe rash, itching, burning sensation and redness over the area where *Gunja beeja lepa* was applied. The intervention was stopped immediately to these four patients. These adverse effects were treated with application of coconut oil. The patients who had not responded to coconut oil, *Tanduliyaka swarasa* (*Amaranthus spinosus* Linn) was applied to the affected area and 10 ml BD given internally with sugar. Then the patients had relieved from these adverse effects within two days. Thereafter, they were withdrawn from the study. The reason found was the long term contact with the drug. In spite of proper instructions these patients had not washed the applied area after drying. In the present study, the adverse effects were manageable. Red variety of *Gunja* seeds was used without any *shodhana* as *shodhana* was not expected for external use. *Shodhita Gunja beeja* may not cause any adverse effect. Hence, a similar study can be conducted with red variety of *Gunja* with *shodhana* and white variety of *Gunja* with and without *shodhana* to avoid adverse effects.

During the intervention, most of the patients experienced some dragging sensation along the nerve root of the area of application. Then they were feeling better after each setting. *Ushna virya* property of *Gunja* may have reduced pain and swelling at the affected joint. *Visha dravya* have *laghu*, *ushna*, *tikshna*, *sookshma*, *ashukari* and *vyavayi* properties (18) with which they are readily absorbed in the body, spread quickly and show immediate effect causing decrease in inflammation and pain at the affected joint.

At the end of the 19th century, the extract of *Gunja* seeds was used therapeutically for its inflammatory properties, to treat various eye complaints including trachoma. But some cases of Abrin poisoning were also noted with local use. (19) It is observed from the reported cases that *Gunja* reduces inflammation in therapeutic dose and on the contrary in higher dose it causes inflammation.

Conclusion

Gunja Beeja lepa has been proved to be effective in comparison with standard anti-inflammatory Ayurvedic drug *Shunthi* in inflammatory conditions of either mono or bi Arthritis. But the local application should be restricted for limited time only to avoid adverse drug reaction. Similar study can be conducted with red variety of *Gunja* with *shodhana* and white variety of *Gunja* with and without *shodhana* to assess their efficacy without any adverse effects. As *Gunja* has been proved efficacious for external application in reducing pain and inflammation, the liniments or spray with the ingredients of *Gunja* may open new dimensions in sports medicine to relieve the pain and swelling instantly.

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