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A Randomised Clinical trial evaluating effectiveness of Guduchi and Shunthi kvatha in Amavata(Rheumatoid arthritis) in comparison with Indomethacin

Daneshwari S Kanashetti[1], Byadgi P S[*2], Dwivedi K N[1]

[1]Department of Dravyaguna, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, Uttar Pradesh, India
[2]Department of Vikriti Vigyan, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, Uttar Pradesh, India

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ABSTRACT

Indian Traditional system of medicine (Ayurveda) has played premier role in the management of crippling disease, Amavata is one among them. Amavata is a chronic disease caused by vitiation of Vata associated with Ama. The clinical presentation of Amavata closely mimic Rheumatoid arthritis in accordance with their similarities in clinical features like pain, swelling, stiffness, fever, general debility, fatigue, etc. Herbal drugs are becoming increasingly popular in managing chronic diseases because of its safety, long term usage with fewer side effects and multidimensional actions. Guduchi (Tinospora cordifolia (Willd.) Miers ex Hook.f. & thoms.) and Shunthi (Zingiber officinale Rosc.) are widely available economic drugs with effective pharmacological actions. Present clinical study is conducted on 3 groups with 27 patients in each group. Patients of group 1 were administered the test form i.e, Guduchi and Shunthi kvatha. Patients of group 2 were treated with standard drug Indomethacin 75 mg BD. Patients of group 3 were administered both with Guduchi & Shunthi kvatha and Indomethacin. The results were tabulated using statistical methods and compared between the groups. Change in subjective and objective parameters were observed at the end of treatment in each group. Subjective parameters like Pain, Angamarda, Aruchi, Trishna, Alasya, Gaurava, Jvara, Apaka and Shunata anganam were observed. Objective parameters like CBC, ESR, RA factor, CRP and collagen profile were carried out before and after treatment. Overall effectiveness in signs and symptoms was seen in the volunteers taking both trial and standard drug which signifies synergistic effect of both drugs help in resolution of Amavata better. Guduchi and Shunthi kvatha showed encouraging results but this must be taken for longer duration.

*Corresponding Author

Name: Byadgi P S
Phone:
Email: psbyadgi@gmail.com

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INTRODUCTION

The phantom notion of health of an individual fluctuates within a range, varying from optimum well-being to various degrees of dysfunction. The realignment from quality health to dysfunction is called disease. One such disease is Amavata and it is characteristically a chronic disorder chiefly associated with sandhishula, sandhishotha etc.

It is a challenging disease in terms of its management till date in spite of so much advancement in medical field and still there is ample scope to treat

the patients by using effective, cheap and adverse reaction free therapy by Ayurvedic Medicines. Amavata word is made from two words Ama and Vata. There are references of Ama and Vata right from veda. Literally in Sanskrit, term "Ama" denotes Apakva Annarasa which means unripe, immature or undigested food in liquid form (Chandra, 2008) leads to accumulation of Ama in the Amashaya. This 'Ama' is carried by 'Vayu' throughout the body and lodges in the joints and other Kapha sites (Khavaigunya).

Though Ama and Vata are the chief pathogenic factors, the disease involves the vitiation of Tridosha. Amavata affects both Abhyantara and Madhyama roga marga. Mandagni is a prerequisite factor for the initiation of the Samprapti of Amavata. Initially the Samprapti originates from the Annavaha Srotas (Abhyantara roga marga), then spreads to the Madhyama roga marga with special intimacy for Shlesmasthana, thus Amavata manifests as a systemic disease (Nidana, 2010).

In conventional system of medicine, symptoms of Amavata are correlated with Rheumatoid Arthritis (RA). Clinical study conducted by Dr.Neera Saini et al from department of Vikriti Vigyan clearly suggested the similar clinical presentation of Amavata with Rheumatoid Arthritis (Saini *et al.*, 2017). It is a chronic inflammatory disease of unknown aetiology marked by a symmetric, peripheral polyarthritis. It is the most common form of chronic inflammatory arthritis and often results in joint damage and physical disability. Because it is a systemic disease, RA may result in a variety of extra articular manifestations, including fatigue, subcutaneous nodules, lung involvement, pericarditis, peripheral neuropathy, vasculitis and hematologic abnormalities (Kasper *et al.*, 2015).

Remissions and exacerbations are the hallmarks of Rheumatoid arthritis. As the exact etiopathogenesis of the disease is unknown till date, hence various theories have been put forth to explain the etiopathogenesis, autoimmune mechanism is one of them and is most commonly implicated. Acharya Chakradatta (Dwivedy, 2012) was the pioneer to describe the principle and line of treatment for the disease Amavata. Though there are various treatment options available for the management of Amavata, in the present study Guduchi and Shunthi kvatha is selected because of Ama and Vatahara property of both drugs, easy availability of the drug, cheap, free from adverse reactions associated with multi centric action. The present clinical study reveals the efficacy of Guduchi and Shunthi kvatha in comparison to Indomethacin in Amavata (RA).

Aim of study

To evaluate the effect of trial drug Guduchi and Shunthi kvatha in Amavata and compare the trial drug with the control group (Indomethacin).

MATERIALS AND METHODS

Type of study

Open label randomized clinical trial

Selection of patients

A total of 90 patients of Amavata were randomly selected for the present study, from the Dravyaguna OPD of Sir Sunder Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi. The case selection was done randomly of age (between 20-60 years), sex, occupation and socio-economic status. Both acute and chronic phase Amavata patients were selected for the study after fulfilling the diagnostic criteria (of Rheumatoid Arthritis in Modern Medicine(Table 2) and the clinical features of Amavata described in Madhava Nidana)(Table 1), inclusion criteria and exclusion criteria.

Study design

Present study is open labelled randomized controlled clinical trial.

Inclusion criteria

1. Adult subjects (both male and female) between 20 to 60 years presenting mild, moderate and severe degree presentation of Amavata.

2. Subjects pertaining to classical symptoms of Amavata.

3. Amavata of any dosha anubandha.

4. Patients having highly elevated Rheumatoid factor and C - reactive protein level.

5. Both seropositive and seronegative patients were included in this study.

Exclusion Criteria

1. Patients of below age 20 and above age 60 years.

2. Patients associated with severe joint deformities.

3. Patients associated with severe Ankylosed joints, Septic arthritis, Osteoarthritis and Gouty arthritis.

4. Rheumatoid arthritis associated with other systemic or metabolic disorders like Diabetes mellitus, Hypertension, Pulmonary tuberculosis etc.

5. Pregnant and lactating women.

Table 1 shows that The diagnosis was done on the basis of following symptoms as mentioned in Ayurvedic classics (Madhava Nidana by Madhavakara)

Table 1: Diagnostic Criteria of Amavata

S .NO	Symptoms
1	Alasya (lethargy)
2	Angamarda(body pains)
3	Apaka (indigestion)
4	Aruchi (anorexia)
5	Bahu mutratam (polyuria)
6	Gaurava (Heaviness)
7	Hridgraha (chest catch)
8	Kostha baddhata (constipation)
9	Nidra viparyaya (sleep disturbances)
10	Sandhi graham (morning stiffness)
11	Sparsha asahishnuta (tenderness)
12	Anga Shunata (Swelling of body)
13	Trishna (thirst)
14	Vrschcikadamshavat vedana (stinging pain)

Table 2: Diagnostic Criteria of Rheumatoid arthritis

S NO	Criteria
1	Morning stiffness- Stiffness in and around the joints lasting one hour before maximal improvement.
2	Arthritis of three or more joint area – At least three joint areas, observed by a physician, has soft tissue swelling or joint effusion, not just bony overgrowth. 14 possible joint areas involved are right or left PIP, MCP, wrist, elbow, knees and ankle and metatarsophalangeal joints.
3	Arthritis of hand joints- Arthritis of wrist, MCP joints or PIP joints.
4	Symmetrical Arthritis – simultaneous involvement of the same joint area on both side of body.
5	Rheumatoid Nodules- Subcutaneous nodules over the bony prominences, extensor surface, observed by a physician.
6	Serum Rheumatoid factor- Demonstration of abnormal amount of serum RA factor by any method for which the result has been positive.
7	Radiographic changes – Typical changes of RA on posteroanterior hand and wrist radiographs that must include erosions and bony decalcification localized in or most marked adjacent to the involved joints.

Table 2 shows that The 1987 revised criteria by American College of Rheumatology for diagnosis of Rheumatoid arthritis are (Arnett *et al.*, 1988).

Guidelines for Classification

1. Four of seven criteria are required to classify a patient as having Rheumatoid arthritis.
2. Patients with two or more clinical diagnoses are not excluded.
3. Criteria 1 and 4 must be present for at least 6 weeks. Criteria 2 and 5 must be observed by a physician.

Collection and Preparation of trial drug

The drug (Guduchi and Shunthi) administered to patients was purchased from authorised shop in Gola Deenanath market and also collected from vicinity of Varanasi. The sample was authenticated by Prof. K N Dwivedi, Head, Department of Dravyaguna, IMS, and BHU. The samples were kept in museum of department of Dravyaguna as a reference accession number DG/18-19/214, DG/18-19/215.

Both drugs (Guduchi and Shunthi) were dried in shade for two days and it was made into coarse powder in Ayurvedic pharmacy of Banaras Hindu University. Then it was packed with 400gm of drug in

Table 3: Following tabulation shows clinical assessment of each criteria with grading and score

Criteria	Symptoms	Grading	Score
Pain criteria	Severe (unable to do any work)	+++	3
	Moderate (continuous pain during movement)	++	2
	Mild (Pain precipitating with heavy work)	+	1
	No pain	0	0
Angamarda (Stiffness)	Stiffness lasting more than two hours	+++	3
	1-2 hour	++	2
	Less than 1hour	+	1
	No stiffness	0	0
Aruchi (Lack of eating desire)	Normal eating desire	0	0
	Mild	+	1
	Moderate	++	2
	Severe	+++	3
Trishna (Thirst)	Normally drink 2-3L/day	0	0
	More than3-4L/day	+	1
	More than 4L/day	++	2
Alasyam (Lethargy)	No	0	0
	Patient feels fatigue on mild work	+	1
	Moderate work	++	2
	Severe work	+++	3
Gauravam (feeling of heaviness)	No heaviness	0	0
	Local/part of the body	+	1
	Generalized heaviness	++	2
Jvara (Fever)	Normal (98-99F)	0	0
	Mild grade Fever (99-100F)	+	1
	Moderate grade fever(100-101F)	++	2
	High grade Fever (more than 101F)	+++	3
Apaka (Indigestion)	Normally digestion of food in 3yaam (9hours)	0	0
	In 3-4 yaam (9-12hr)	+	1
	In4-5 yaam (12-15hr)	++	2
	More than 5 yaam	+++	3
Shunata anganam (Swelling)	Normal /No swelling	0	0
	Felling of swelling	+	1
	Apparent swelling	++	2
	Huge swelling	+++	3

Table 4: Total effect of treatment Based on presence and absence of 8 symptoms initially and at 3^{rd} follow up the overall improvement is tabulated below

Improvement	Number of cases in which symptoms absent (%)		
	Group1	Group2	Group3
Mild improvement	3(11.11)	9(33.3)	2(7.40)
Moderate improvement	20(74.07)	17(62.96)	16(59.25)
Marked improvement	4(14.81)	1(3.70)	9(33.33)

each packet.

Selection of Dose and Dosage form

As per the reference Cakradatta Vatarakta cikitsa adhyaya, the churna or kvatha any one of the dosage form can be taken. Here kvatha form was taken because of enhanced efficacy and bioavailability as compared to churna. The dose of kvatha as per classical reference is 2 pala (nearly 96 ml) per day (Pandit, 2008). The patient was administered 45-50 ml twice a day. The patient was advised to prepare fresh kvatha every day with 50gm of coarse powder adding 4 parts of water, boil and reduced to $1/4^{th}$ part. Patient was instructed strictly to prepare fresh kvatha every day.

Randomization and treatment schedule

The total numbers of registered patients were 90, divided in 3 groups of 30 each –

1. Patients of group 1 administered the test form i.e, Guduchi and Shunthi kvatha.

2. Patients of group 2 were treated with Indomethacin 75 mg BD.

3. Patients of group 3 given both Guduchi & Shunthi kvatha and Indomethacin.

The total duration of treatment for this study was three months. Follow up was taken at an interval of each month with total of three follow ups. Patient was advised to consult in between for any reactions, side effects or complications. Out of 90 registered patients only 81 patients completed the total duration of trial with all 3 follow up studies. Results were calculated on 81 patients.

Parameters of assessments

All the patients were advised to consult every month during the 3 months. The effect of therapeutic regimen is assessed with the help of certain parameters stating the clinical, biochemical and immunological status of the disease. Follow up findings were compared with the initial observations and the data is subjected to the suitable statistical analysis.

Following parameters were selected as the criteria for assessing the improvement.

Clinical assessment of the disease

Clinical assessment of the disease its severity, extent and grades of inflammation was objectively done in terms of pain, swelling, temperature, deformity, general function capacity and stiffness of the joints (Table 3). The relative extent of all these criteria was recorded according to the rating scales in each patient at the initial stage and at subsequent follow ups.

Laboratory investigations were conducted before and after the treatment for objective assessment. All the routine laboratory investigations were done along with diagnostic parameters. Routine haematological investigations like Hb%, TLC, DLC. LFT, RFT, Serum uric acid, RBS were done to assess the general condition of patient and also to exclude the patients concurrently suffering from any infection or other abnormalities. Collagen profile and HLA B27 tests were carried out initially to exclude collagen disease.

Investigations carried out before and after treatment to rule out effect of therapy namely

1. Erythrocyte Sedimentation Rate (ESR),

Normal value: Female 0 to 20 mm/hr., Male 0 to 9 mm/hr.

2. C-Reactive Protein (C-RP titre), Normal value: <0.6 mg/dl

3. Rheumatoid factor (RA titre), Normal- < 20 IU/ml

Statistics applied

1. Comparison within the group was done by Friedman test.
2. Comparison between the groups was done using Chi square test.
3. Comparing mean was done using Paired T test.
4. Comparing mean between the groups using one way ANOVA and Post-Hoc test.

Observations

The data collected and compiled from this clinical trial were sorted out and processed further by subjection to varied statistical methods

Statistical observation confirms an incidence of disease and it is found notably higher in females than in males. The maximum number of patients registered in the present study belongs to the age group between 40- 60 years i.e. 74.1% followed by rare occurrence (7.4%) in 20-29 years of age group.

Greater number of patients were housewives (40.7%) followed by service (23.5%), business (19.8%), unemployed (8.6%) and agriculture (7.4%). Though this pattern of occupational incidence cannot be realistically generalized but notably high incidence of housewives contributes to the fact that "Nishcalatva" a sedentary mode of life style as one of the factors leading to Amavata. Apart from this nature of house hold work, vega dharana and irregular food habits may trigger the disease formation in females.

The groundwork revealed that maximum patients i.e. 54.3% were of Middle economic status, followed by 25.9%.of higher class, and 19.8% of the patients of poor class. Being the government hospital, majority of the patients approaching the hospital are of middle socio-economic class, this may be the reason of higher incidence of middle economic class patients in the present study. Among them 46 cases were from rural area and 35 cases were from urban area, indicating not much difference in area of occurrence of disease.

Personal history was assessed to inspect the association of Appetite, Sleep, Bowel habit and micturition in causation of disease. Equal percentage of patients show poor or moderate digestive power (45.7%) and very less percentage of patients nearly 9% showed normal appetite. In the same way bowel habit and micturition pattern of more than half patients was normal (>65%) followed by altered bowel and micturition habit. Among them 58% were habitual to pure vegetarian diet and 42% were habitual to both vegetarian & non-vegetarian diet. Amidst all the affected patients of Amavata around 70% suffer from disturbed or loss of sleep and only 30% people show normal sleep history. It reveals that aggravated Vata leads to Nidrahani.

Nearly 89% of cases had moderate to severe grade of pain in group 1 initially before treatment as compared to 93% in group 2 and 100% in group 3.

Nearly 70% of cases had 1-2 hour or >2-hour stiffness in group 1 initially before treatment as compared to 67% in group 2 and 81% in group 3.

71% of cases suffered from mild to moderate grade of anorexia (aruchi) in group 1 initially before treatment as compared to 74% in group 2 and 78% in group 3.

85% of cases feels fatigue (alasya) on mild to moderate work in group 1 & 2 initially before treatment as compared to nearly 92% in group 3.

29.6%, 25.9% and 14.8% cases were found to have local part heaviness (gauravata) respectively in group 1,2 & 3 whereas 51.9%, 48.1% and 74.1% have generalised swelling in group 1, 2 & 3 respectively.

Nearly 59% of recorded to have mild to moderate grade fever(jvara) in group 1 & 2 initially before treatment as compared to nearly 74% in group 3.

52% patients in group 1, 44% in group 2, 63% in group 3 show improper digestion (apaka).

51.9%, 66.7% and 74.1% cases in group 1, 2 & 3 respectively show apparent swelling (anga shunata).

RESULTS AND DISCUSSION

Effect of therapy on subjective parameters

In group 1, highly significant results (p<001) in subjective parameters like Pain (66.7%), Angamarda(66.7%), Aruchi(93%), Alasya (81.5%), Gauravata(92.6%), Jvara(100%), Apaka(92.6%), Shunata anganam(88.9%).

In group 2, highly significant results (p<001) in subjective parameters like Pain (96.3%), Angamarda(66.7%), Aruchi(81.5%), Alasya(55.6%), Gauravata(88.9%), Jvara(92.6%), Apaka(51.9%), Shunata anganam (88.9%).

In group 3, highly significant results (p<001) in subjective parameters like Pain (88.9%), Angamarda (88.9%), Aruchi(85.2%), Alasya (81.5%), Gauravata(51.9%), Jvara(96.3%), Apaka(92.6%), Shunata anganam (85.2%).

Intergroup comparison between group 1, 2 and 3

The intergroup comparison of pain grade was highly statistically significant at 1^{st} 2^{nd} and 3^{rd} follow up. Absence of pain was higher in group 2 as compared to group 1 &3 at each follow up.

The intergroup comparison of Angamarda was statistically significant at 2^{nd} follow up. Absence of Angamarda was higher in group 3 as compared to group 1 & 2 at each follow up.

The intergroup comparison of Aruchi was not statistically significant at 1^{st} 2^{nd} and 3^{rd} follow up. Absence of symptom was higher in group 1 as compared to group 2 &3 at each follow up.

The intergroup comparison of Alasya was statistically significant at 1^{st} and 3^{rd} follow up. Absence of symptom was higher in group 3 as compared to group 1&2 at each follow up.

The intergroup comparison of Gauravata was statistically significant at 3^{rd} follow up. Absence of symptom was higher in group 1 as compared to group 2&3 at each follow up.

The intergroup comparison of Jvara was not statistically significant. Absence of symptom was higher in group 1 as compared to group 2&3 at each follow up.

The intergroup comparison of Apaka was statistically significant at 3^{rd} follow up. Absence of symptom was higher in group 1 and 3 as compared to group 2 at each follow up.

The intergroup comparison of Shunata anganam was not statistically significant at all follow ups.

Effect of therapy on objective parameters

In group 1, mean decrease in Erythrocyte Sedimentation Rate (ESR) is highly significant (p<0.001) about 8.148 $\pm$ 3.371, Mean decrease in Rheumatoid Arthritis (RA) factor is 11.029 $\pm$ 14.075. Mean decrease in C-reactive protein is 12.778 (Table 1).

In group 2, mean decrease in ESR is highly significant (p<0.001) about 10.370 $\pm$ 7.923, Mean decrease in RA factor is 12.673 $\pm$ 7.202. Mean decrease in C-reactive protein is 18.593 $\pm$ 9.208 (Table 1).

In group 3, mean decrease in ESR is highly significant (p<0.001) about 16.519 $\pm$ 7.536, Mean decrease in RA factor is 16.632 $\pm$ 7.210. Mean decrease in C-reactive protein is 20.407 $\pm$ 8.116 (Table 4).

The intergroup comparison of mean ESR and RA factor was not statistically significant before treatment and after treatment. The mean uric acid value was in normal range before treatment and after treatment however mean decrease after treatment was 2.248 in group 1 similarly, 1.070 & 2.544 in group 2 and 3 respectively which were highly significant.

There was significant difference between the groups in results of Pain, Angamarda (2^{nd} follow up), Alasya (1^{st} & 3^{rd} follow up), Gauravata (3^{rd} follow up) and Apaka (3^{rd} follow up).

Objective parameters assay has also been undertaken to witness the effect of trial drug. Mean decrease in ESR after treatment was 8.148, 10.370 & 16.519 in group 1, 2 and 3 respectively. Mean decrease in RA factor after treatment was 11.029, 12.673 & 16.632 in group 1, 2 and 3 respectively.

The mean uric acid value was in normal range before treatment and after treatment. However, the mean reduced after treatment was around 1.5-3. Mean decrease of C-reactive protein in group 1 after treatment was 12.778 similarly, 18.593 & 20.407 in group 2 and 3 respectively. All the data expound significant outcome after treatment. Above observations signifies better improvement in subjects of group 3 taking both trial and standard drug.

On interpreting both subjective and objective parameters, trial drug shows better results in subjective parameters but objective parameters did not vary much. Standard drug shows better results via objective parameters.

Literary review of ayurvedic classics conclude that both drugs possess multidimensional properties that help in subsiding or preventing the severity of Amavata. The probable mode of action may be assessed based on rasa panchaka. Guduchi is having Katu, Tikta, Kashaya rasa and Ushna virya, it does Ama pachana. It also acts as Agni dipaka, Amahara and Vatahara. Shunthi having the property of agneya guna helps in pachana of ama. It possesses Laghu guna, Ushna virya and Madhura vipaka thus helps in alleviating Vata. Because of having Ushna virya both drugs enter sukshma srotas and helps to remove ama out of srotas and clear them for smooth functioning of Vata thus srotorodha janita Vata prakopa is pacified. Both drugs act as kaphahara, as adhisthana of Amavata is shleshmasthana so they help in subside the disease process. Based on current research Guduchi has been proved to possess antirheumatic, anti-inflammatory and immunomodulatory properties (Manjrekar *et al.*, 2000).

The anti-inflammatory effect of Tinospora cordifolia extract was mediated via reduction of the pro-inflammatory cytokines such as: IL-1β, TNF-α, IL-6, and IL-17; the frequency of IL-17-producing T cells; and the production of chemokines such as RANTES. Furthermore, its limited bone damage by shifting the balance of mediators of bone remodelling (e.g., receptor activator of nuclear factor-kB ligand [RANKL] and MMP-9) in favour of anti-osteoclastic activity (Sannegowda *et al.*, 2015).

Shunthi is beneficial in rheumatic and musculoskeletal disorders (Sharma and Denis, 2000). It acts as anti-inflammatory agent by producing inhibitory effect on prostaglandin synthesis and leukotriene biosynthesis (Kiuchi *et al.*, 1992). The activity of *Zingiber officinale* as an anti-inflammatory agent was investigated by Thomson and his group in rats. Experimental rats were treated with aqueous extract of *Zingiber officinale* either orally or intraperitoneally daily for 4 weeks. Though at low dose ginger did not reduce prostaglandin E2 concentrations, at high doses it significantly lowered PGE2 levels. Therefore, ginger could reduce inflammation associated with RA (Thomson *et al.*, 2002). Ginger shows potential analgesic and anti-inflammatory activity which can be applied to reduce pain and inflammation arising from arthritis (Ojewole, 2006).

Above researches substantiate the effect of Guduchi and Shunthi Kvatha in Amavata.

CONCLUSIONS

Amavata is chronic in nature and described as krichrasadhya vyadhi. The condition of exaggerated state of disease is said as pravruddha Amavata. Vitiation of Ama and Vata are essential entities in causing Amavata. The exact etiology of the disease remains unknown, but the pathognomic cause like Ama is believed to act as autoantigen, which triggers the immunological reaction in genetically suscepti-

ble individuals.

Guduchi and Shunthi kvatha are almost equally effective like Standard group of Indomethacin in majority of the symptoms. Overall effectiveness in signs and symptoms were seen in the volunteers taking both trial and standard drug which concluded synergistic effect of both drugs help in resolution of Amavata better. If the disease is genetic and autoimmune in origin, the complete remission is not possible. But Ayurvedic management can help to decrease the symptoms of Amavata. The specific Ayurvedic line of management and drugs helps in modifying the immune response to autoantigens. At the same time the drugs are safe and can be given for longer duration without any adverse effects. As a whole, Guduchi and Shunthi kvatha showed encouraging results but this has to be taken for longer duration.

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