

“Clinical assessment of the role of Moneta Wellness Noni in the management of Rheumatoid Arthritis (Amavata) ”

Abstract:

Thirty patients suffering from rheumatoid arthritis varying in duration from 5 months to 20 years were included in the study. Anywhere from 5 to 12 joints were involved. They were already on any one or more of the NSAIDs which brought about severe gastric distress and consequent non-compliance of drug intake. But they were asked to continue them along with Moneta wellness Noni 15 ml twice a day empty stomach in increasing dose. Significant reduction in constipation, pain intensity and morning stiffness was observed with Moneta wellness Noni. There was also improvement in grip strength. Reduction in diminished gastric irritation and better drug compliance.

INTRODUCTION

Rheumatoid arthritis is an autoimmune disease that causes chronic inflammation of the joints. Rheumatoid arthritis can affect persons of all ages. The cause is not known, but chronic inflammation of rheumatoid arthritis can cause permanent joint destruction and deformity. Damage to joints can occur early and does not correlate with symptoms. The prevalence of R.A. is estimated to be 1.2% out of 60% of the population having some form of Arthritis by the age of 60, being three times more common in women than in man. Rheumatoid arthritis is very common in India, particularly in Northern states like Punjab and Hariyana. Unlike osteoarthritis, rheumatoid arthritis affects younger people also; it has been seen that people between the ages of 20 to 50 years are susceptible to the disease.

The "rheumatoid factor" is an antibody blood test that can be found in 80% of patients with rheumatoid arthritis. Rheumatoid arthritis can also cause inflammation of the tissue around the joints, as well as in other organs in the body. Autoimmune diseases are illnesses that occur when the body tissues are mistakenly attacked by its own immune system. The immune system is a complex organization of cells and antibodies designed normally to "seek and

destroy" invaders of the body, particularly infections. Patients with autoimmune diseases have antibodies in their blood that target their own body tissues, where they can be associated with inflammation. Because it can affect multiple other organs of the body, rheumatoid arthritis is referred to as a systemic illness and is sometimes called rheumatoid disease.

While rheumatoid arthritis is a chronic illness, meaning it can last for years, patients may experience long periods without symptoms. Typically, however, rheumatoid arthritis is a progressive illness that has the potential to cause joint destruction and functional disability.

In modern medicines, early treatment of rheumatoid arthritis results in better outcomes. The treatment of rheumatoid arthritis optimally involves a combination of patient education, rest and exercise, joint protection, medications, and occasionally surgery. Medication such as aspirin and NSAIDs are used to reduce pain with inflammation in R.A. but these drugs are often associated with hazardous side effects such as G.I. bleeding, ulcers and abdominal pain to name few. However, there is no known cure for rheumatoid arthritis.

Scientists all over the world are looking in to *Ayurveda* for the treatment of rheumatoid arthritis. This only goes to show the effects of *Ayurvedic* medicines in the treatment. It can be co related with similar disease *Aamavata* described in *Ayurveda* classics. The detail description of *Aamavata* is available in medieval period classical text *Madhava Nidana*.

In Sanskrit, *Aama* means rheum, which is a fluid deposited in the cells as a result of improper digestion. When the *Vata Dosha* of the body is vitiated, then there is more circulation of *Aama* in the body. This *Aama* settles in the membrane surrounding the joints, leading to pains. This also explains the etymology of the Sanskrit name, *Aamavata*. The concept of *Ama* is prevailing since Vedic period. Reference about *Sandhi Vikriti* caused by *Sleshma Vikriti* is available in *Atharvaveda*. Pathogenesis of *Amavata* is initiated by *Ama*, occupying various *Sleshma sthanas*, mainly joints. *Amavata*, which involves

mainly the joints having characteristic symptoms like sotha, ruk, raga, sparsasahatva and juara has been equated with rheumatoid arthritis (RA).

Moneta wellness noni is a polyherbal formulation containing extracts of *Morinda cirifolia*, *Gold*, *Silver*, *Withania somnifera*, *Boerhaavia diffusa*, *Tinospora cordifolia*, *Tribulus terrestris* etc., and the present study was planned to evaluate the clinical efficacy and safety of Moneta wellness Noni in the management of Rheumatoid Arthritis.

AIMS AND OBJECTIVES:

- 1) To evaluate the efficacy of trial drug Wellness Noni in Rheumatoid Arthritis.
- 2) To find out whether the drug possesses any side effect or not.

MATERIALS AND METHODS:

Patients:

Patients of rheumatoid arthritis attending the Medical O.P.D. were selected for the present study.

Drug:

Moneta wellness Noni with Gold.

Dose:

In increasing dose:

Day 1, 2, 3: 5 ml b.i.d. twice, empty stomach

Day 4, 5, 6: 10 ml b.i.d. twice, empty stomach

Day 7 onwards: 15 ml b.i.d. twice, empty stomach

Duration:

Duration of the study was fixed as 60 days with weekly observation.

DIAGNOSTIC CRITERIA:

The patients were diagnosed on the basis of the signs and symptoms mentioned in different Ayurvedic texts with the cardinal symptoms as Sandhisoola, Sandhisotha, Sandhigraha, Sparsahatwa and Jvara. However, in addition, the revised criteria for the classification of Rheumatoid arthritis developed by the American College of Rheumatology were also considered.

The 1987 Revised Criteria for the classification of Rheumatoid

Arthritis:

(1) Guidelines for classification:

- (a) Four of seven criteria are required to classify a patient as having rheumatoid arthritis.
- (b) Patients with two or more clinical diagnosis are not excluded.

(2) Criteria:

- (a) Morning stiffness: Stiffness in and around the joints lasting 1 hour before maximal improvement.
 - (b) Arthritis of three or more joint areas: At least three joint areas, observed by a physician simultaneously, have soft tissue swelling or joint effusions, not just bony overgrowth. The 14 possible joint areas involved are right or left proximal interphalangeal, metacarpophalangeal, wrist, elbow, knee, ankle and metatarsophalangeal joints.
 - (c) Arthritis of hand joints: Arthritis of wrist, metacarpophalangeal joint, or proximal inter-phalangeal joint.
 - (d) Symmetric Arthritis: Simultaneous involvement of the same joint areas on both sides of the body.
 - (e) Rheumatoid nodules: Subcutaneous nodules over bony prominences, extensor surfaces, or juxtaarticular regions observed by physicians.
 - (f) Serum rheumatoid factor : Demonstration of abnormal amounts of serum rheumatoid factor by any method for which the result has been positive in less than 5 percent of normal control subjects.
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- (g) Radiographic changes: Typical changes of RA on posteroanterior hand and wrist radiographs which must include erosions or unequivocal bony decalcification localized in or most marked adjacent to the involved joints.

Criteria a-d must be present for at least 6 weeks. Criteria b-e must be observed by a physician.

Routine haematological, biochemical, stool and urine investigations were carried out before and after the drug treatment. Also, test for serum rheumatoid factor was carried out to support the clinical diagnosis wherever necessary.

CRITERIA FOR ASSESSMENT:

The observations regarding the signs and symptoms were assessed adopting suitable scoring pattern and recorded. Pathological and biochemical investigations were repeated after the treatment to note the improvement or for any marked changes which may come into picture in relation to the efficacy of the drug.

Scoring Pattern:

A.	<i>Sandhi shoola (Pain in the joints)</i>	SCORE
	No pain	0
	Mild pain	1
	Moderate pain but no difficulty in moving	2
	Moderate pain with difficulty in moving due to pain	3
	Much difficulty in moving the body parts	4
B.	<i>Sandhi Graha Stiffness of joints</i>	
	No stiffness	0
	0-10 minutes	1
	10-120 minutes	2
	2-8 hours	3
	More than 8 hours	4

C. Sparshasahatva - Tenderness in joints

No tenderness	0
Subjective experience of tenderness	1
Winching of face on pressure	2
Winching of face on pressure and withdrawal of The affected part	3
Resists touch	4

D. Shoth- Swelling in joints

No swelling	0
Slight swelling	1
Marked swelling	2
Enormous swelling	3

E. General symptoms

Presence of symptoms	2
Relief in symptoms	1
Absence of symptoms	0
No improvement in symptoms	2

Functional Assessment:

Functional assessment like walking time, grip strength, foot pressure and joint movement were not carried out as most of the patients were in the earlier stage of RA i.e. below 2 years of chronicity.

Statistical Analysis:

While carrying out statistical analysis, paired 't' test was employed. However, at last on comparing the effect of two groups unpaired 't' test was also employed.

CRITERIA TO ASSESS THE TOTAL EFFECT OF THERAPY:

The total effect of the therapy was assessed on the basis of following criteria:

Complete remission: 100% relief in signs and symptoms without any recurrence for a period of three months.



Markedly improved:	75% to 99% relief in symptoms without any relapse for a period of three months.
Moderately improved:	50% to 74% relief in signs and symptoms with or without any relapse for a period of three months.
Improved:	Less than 50% relief in signs and symptoms with or without relapse for a period of three months.
Not cured:	No relief in signs and symptoms.

Adverse events All adverse events reported or observed by patients were recorded with information about the severity, date of onset, duration and action taken regarding the study drug. Relation of adverse events to study medication was predefined as “*Unrelated*” (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug), “*Possible*” (follows a known response pattern to the suspected drug, but could have been produced by the patient’s clinical state or other modes of therapy administered to the patient), and “*Probable*” (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient’s clinical state). Patients were allowed to voluntarily withdraw from the study, if they had experienced serious discomfort during the study or sustained serious clinical events requiring specific treatment. For patients withdrawing from the study, efforts were made to ascertain the reason for dropout. Non-compliance (defined as failure to take less than 80% of the medication) was not regarded as treatment failure, and reasons for non-compliance were noted.

OBSERVATIONS

In the present study, total 30 patients of Amavata were registered, out of which 5 patients discontinued the treatment before completion of the course against the medical advise. The clinical observations of the 25 patients completed the duration of treatment are presented hereunder:

Cardinal symptoms observed in 30 patients of Rheumatoid Arthritis i.e.

Aamavata

Cardinal symptoms	No. of pts.	%
Sandhisoola	25	100.00
Sandhisotha	24	93.33
Sandhigraha	25	100.00
Sparsasahatva	25	100.00
Prasaranakuncane Vedana	25	100.00
Jvara	06	20.00

General symptoms observed in 30 patients of Rheumatoid Arthritis

i.e.Amavata

General symptoms	No. of pts.	%
Agnimandya	24	80.00
Anaha	06	20.00
Angamarda	27	90.00
Antrakujana	02	13.33
Aruci	16	53.33
Bahumutrata	03	20.00
Bhrama	00	00
Cchardi	04	13.33
Daurbalya	24	80.00
Gaurava	09	30.00
Kandu	04	13.33
Kuksisoola	04	13.33
Nidralpata	04	13.33
Shrama	02	6.67
Vibandha	08	26.67

Chronicity wise distribution of 30 patients of Rheumatoid Arthritis i.e.

Amavata

Chronicity (yrs)	No. of pts.	%
<1	12	40.00
1-2	04	13.33
2-3	08	26.67
>3	06	20.00

Joint involvement observed in 15 patients of Amavata

Joints	No. of pts.	%
Upper extremities :		
DIP	06	20.00
PIP	22	73.33
MCP	26	86.67
Wrist	26	86.67
Elbow	20	66.67
Shoulder	22	73.33
Lower extremities :		
PIP	10	33.33
MTP	20	66.67
Ankle	20	66.67
Knee	24	80.00
Hip	04	13.33
Temporomandibular	00	00
Cervical vertebral	12	30.00
Sternoclavicular	00	00

**Rheumatoid factor wise distribution of 30 patients of Rheumatoid
Arthritis i.e. Amavata**

RA factor	No. of pts.	%
Positive	18	60.00
Negative	12	40.00

RESULTS:

**Effect cardinal symptoms of Rheumatoid Arthritis i.e. Amavata in 16
patients**

Symptom	Mean ± SEM		% Relief	Mean ± SEM
	BT	AT		BT-AT
Sandhishoola	2.15 ± 0.06	0.04 ± 0.05	56.28	1.21 ± 0.05 ***
Sandhishotha	1.73 ± 0.1	0.80 ± 0.11	53.76	0.92 ± 0.08 ***
Sandhigraha	1.85 ± 0.03	0.94 ± 0.02	49.19	0.91 ± 0.03 ***
Sparshasahatva	1.90 ± 0.05	0.97 ± 0.05	48.95	0.93 ± 0.06 ***

*** p<0.001

Table shows that 56.28% relief in sandhishoola, 53.76% relief in sandhishotha, 49.19% relief in sandhigraha and 48.95% relief in sparshasahatva were observed. All the above observations were statistically highly significant.

Effect on general symptoms:



General Symptoms	BT	AT	% Relief
Agnimandya	1.86 ± 0.14	0.86 ± 0.26	53.76
Anaha	1.67 ± 0.33	0.67 ± 0.33	
Angamarda	1.86 ± 0.13	0.63 ± 0.26	66.13
Aruchi	1.83 ± 0.17	0.67 ± 0.33	63.39
Autrakujana	2.0 ± 0.0	1.0 ± 0.0	50.00
Bahumutrata	2.0 ± 0.0	1.33 ± 0.33	33.5
Cchardi	2.0 ± 0.0	1.0 ± 0.0	50.00
Daurbalya	1.86 ± 0.13	0.5 ± 0.27	73.12
Gaurava	2.0 ± 0.0	1.0 ± 0.0	50.00
Hrillasa	2.0 ± 0.0	0.5 ± 0.5	75.00
Kandu	2.0 ± 0.0	1.0 ± 0.0	50.00
Kuksishoola	2.0 ± 0.0	0.5 ± 0.5	75.00
Vibandha	2.0 ± 0.0	0.75 ± 0.25	82.5

It can be observed from the table that in general symptoms found in the patients, 70-75% relief in daurbalya, hrillasa, and kuksisoola; 60-70% relief in angamarda, aruci, vibandha; 50-60% relief in agnimandya, echardi, kandu, antrakujana and gaurava; 33.5% relief in bahumutrata and no relief in shrama was observed.

Overall effect of Moneta wellness Noni :

Grade	No. of patients	Percentage
No cure	0	0
Improved	7	23.33
Moderately improved	15	50.00
Markedly improved	8	26.66
Completely cured	0	00

Table shows that with Wellness Noni with Gold, 50% of patients were moderately improved, 25% of patients were markedly improved, 12.5% of

each patients had no cure or completely cured and no patients had improved effect on the disease Amavata.

DISCUSSION:

In rheumatoid arthritis, which is a chronic and progressive ailment, the aim of therapy is mainly conservative – to conserve the function, to arrest or retard degeneration and destruction of joints and, above all, to bring symptomatic relief to the patient. The advent of newer non-steroidal anti-inflammatory drugs and third generation antirheumatic agents indicates that the ideal drug is not yet available. The use of a drug ought to be measured against parameters like efficacy, tolerance, incidence of side effects, safety during prolonged use and the cost factor. In ayurveda there is very detailed description about Rheumatoid arthritis or "Ama vata". It has been described as

" Sa Kashtaha Sarvarogaanaam yadaa prakupito Bhavet |
Hastha paada shiro gulpha trika jaanu uru sandhishu ||
Karoti sarujam shopham yatra doshaha prapadyate |
Sa desho rujate atyatham vyavidha iva vrishchkaihi || "

This means " If the disease "ama vata" (rheumatoid arthritis) becomes chronic the joints (sandhi) of hands (Hastha), feet (paada) , ankles and elbow (gulpha) , low back (trika) , The toxin ama is carried by imbalanced vata (one of the three energetic forces) and reaches the kapha (one of the three energetic forces) dominated places like joints, stomach , chest , brain etc. This toxin becomes sticky due to imbalanced doshas and blocks the vital channels which nourish the body. The sticky toxin ama not only affects the joints but also spreads all over the body . The channels (channels like arteries, intercellular spaces , pores in cells etc are called srotas) which allow nutrients to flow through and nourish body tissues , cells get partially blocked. This leads to a decreased supply of nutrients to body tissues and cells . Thus the immunity of the body gets lowered , the appetite reduces , the body becomes weak due to insufficient nourishment of body tissues.

The ama which gets harbored in joints acts like a foreign substance and triggers the immune system. This leads to inflammation of linings of joints.

Moneta wellness noni with gold is a poly herbal formulations containing anti oxidants like Morinda Citrifolia, Tinospora cordifolia, Gold etc. which are well proven immuno modulators.

Recent studies have shown that Gold compounds accumulate slowly in the body and, over time, reduce inflammation, especially related to rheumatoid arthritis, inflammatory bowel disease, psoriatic arthritis, membranous nephritis, lupus erythematosus and, infrequently, juvenile rheumatoid arthritis (JRA).

The exact mechanism is not known but it is believed that it merely inhibit the function of the various components of the immune response associated with Rheumatoid Arthritis, rather than acting in a disease curing fashion. It is thought that gold affects the entire immune response (phagocytes, leukocytes, T-Cells...) and reduce its potency and limit its oxidizing nature, ending the cycle of joint inflammation and erosion.

Moneta wellness Noni has been shown to have a marked and prolonged beneficial effect on Rheumatoid arthritis thereby indicating action on the autoimmune mechanism. More work to elucidate the mode of action of this useful remedy is necessary. Its main advantage seems to be its action coupled with a lack of side or toxic effects which makes prolonged treatment safe.

CONCLUSION: It can therefore be concluded from the observations in 30 cases that Wellness Noni with gold can be a good adjuvant to the existing therapy with anti-inflammatory agents. No side effects were observed after treatment per se. As the search for an ideal chemical compound is still going on, In view of these results it would be worthwhile to give a trial to Wellness Noni with gold to achieve better control of rheumatoid arthritis with no side effects.

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