A Preliminary trial on the effect of an indigenous medicine in the management of Rheumatoid arthritis.

By

Dr .R.Krishnakumar,

Senior physician,R&D

Vaidyaratnam oushadhasala

Thaikkattussery, Ollur, Thrissur

Under the supervision of :-

Dr. Jose Kurian MD(Ay) Reader (Govt. Ayurveda College, Trivandrum)

Dr. M.A. Shajahan Ph. D Lecturer (Govt. Ayurveda College, Trivandrum)

Dr. Joy Philip MD, MNAMS, PGDH, Professor (Govt. Medical College, Trivandrum)

Abstract

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Rheumatoid arthritis is a chronic symmetrical inflammatory poly arthritis which mainly affects the peripheral synovial joints, but is often associated with extra articular features. All the systems of medicine are facing difficulties in managing the disease and none of them could claim a complete mastery over the disease.

In the present study, an attempt to find out an effective remedy for Rheumatoid arthritis was done. The bark of Bodhivruksha (Ficus religiosa Linn.) and seeds of Chandrasoora (Lepidium sativum Linn) which were found effective in the management of the disease in the previous studies were successfully combined with the help of a pharmaceutical modification process viz, Bhavana (medicinal impregnation) told in Ayurvedic classics. This combination was selected for the present study.

The study design of the present study was randomised clinical trial. Fourty-five patients were selected according to the criteria. Selected patients were placed in three groups and were administered with the single drugs and the combined drug in appropriate dosage; for a period of 30 days. Assessments were done before and after the treatment. The results were analysed and found that the combination of the said single drugs, was statistically significant, and it was found superior in efficacy when compared with the individual usage of the single drugs. .

A Preliminary trial on the effect of an indigenous medicine in the management of Rheumatoid arthritis.

Ayurveda ,Indigenous science of life in India is on the way of globalization. The whole world is looking to Ayurveda as an alternative system of medicine . It is believed that Ayurvedic science is the outcome of thought, expressions and experiences of innumerable sages and traditional physicians , over thousands of years of its credit. But the important concepts presented by Ayurveda and the scientific view points propounded need contemporary rational consideration. The ethical concepts of Ayurveda need emphasis even now. Clinical researches play a vital role for attaining the above said things.

The doctrines of Ayurveda are based on the concepts of doshas, dhathus and malas. Since the imbalance of tridoshas namely Vatha, Pitha and Kapha are considered as the actual factors behind the pathology of the diseases, any disease process can be correlated with tridoshas. In this modern era, among so many other diseases Rheumatoid arthritis deserves special mention due to its intensity and chronicity. It is a chronic inflammatory disease which mainly affects the peripheral synovial joints, but often associated with extra articular features. The disease course varies from a self limiting poly arthritis to a severe destructive poly arthritis running a prolonged course with remissions and exacerbations. Among various joint disorders mentioned in Ayurveda, the disease Vathasonitham can be correlated to rheumatoid arthritis of modern medicine up to a certain limit. Many features of Vathasonitham resembles that of RA.

The modern medical system manage the disease with simple analgesics, NSAID, Chlorouine, Sulphasalizine, metharexate etc. This gives a sudden relief of symptoms, but may cause the . serious side effects, which include gastrointestinal disorders like gastric ulcers, gastritis, perforation etc., bone narrow suppression, peripheral neuropathy, renal failure etc. Like wise other systems like Homeopathy, Unani have also came with their own ideas, but none could claim a complete mastery over the disease.

All scientists working in the field of medicine are in search to find out a cheap and effective remedy for the management of the disease. In search of a powerful remedy, two individual drugs

which are found effective in some earlier studies are combined with the help of a pharmaceutical modification process told in Ayurveda, is thought of and selected for the present study.

Material & Methods

1. Materials

Drugs- The dried stem barks of Bodhivruksha and dried seeds of Chandrasoora were collected from the market and were botanically identified as dried barks of Ficus religiosa Linn of urticaceae family and dried seeds of Lepidium sativum Linn of Crucifereae family respectively.

Preparation of drug for the 1st of group of Pts.

The dried stem bark of Ficus religiosa were cleaned, cut in to small pieces and made it in to a coarse powder. This was packed in small polythene dispensing packets of 48 gms each. The patients were advised to add 768 ml of water to the drug and reduce it in to 96 ml (1/8th time) by boiling in low flame. The principle followed for preparation of decoction was from the text sarangdhara samhitha and the metric equivalents adopted according to the Ay. Formulary of India.

Preparation of drug for the 2nd group of Patients

The dried seeds of Lepidium sativum Linn were properly cleaned and powdered well by using a micropulveriser to get fine powder of mesh size 120. This powder was made in to capsules of 500 mg using zero size capsules.

Preparation of drug for the 3rd group of Patients

This drug was prepared by Bhavana-a pharmaceutical modification process told in Ay. texts.

For Bhavana process the drugs are in 2 forms-powder and liquid. For the Bhavana of 1 kg of Lepidium powder 1 litre of Ficus decoction was required. For preparing the decoction 1 kg of coarsely powdered stem bark of Ficus was taken, 8 liters of water added and reduced to 1 liter by boiling in low flame.

Lepidium powder was spread on basins and the prepared decoction was added and mixed well in the first evening and kept over night. In the next morning, it was kept in sunlight covered with a white cloth. Process was repeated for seven consecutive days. At the end of 7th day, the mixture was ground well, spread in plantain leaves as then flakes were dried under sunlight. The dried flakes were collected and pulverised to get the fine powder (mesh size 120) of combined drug. Powder was made into capsules 500mg using zero size capsule.

Criteria for Selection of Pts.

Pts were selected from the O.P. dept of Dravyagunavijnanam Govt. Ay. College Hospital, Tvpm with suggested signs and symptoms of RA. (As per the revised criteria of ARA 1985). They were diagnosed on the basis of special performa prepared. Selection of pts was done at random from the age group of 16-65 yrs. Pts with others systemic diseases and with gross deformity were excluded from the study.

Clinical Study

Pts selected for the study were placed in to 3 groups on the basis of administration of the drug
Group I (Decoction of bark of Bodhivruksha)- 48 ml decoction twice daily.

Group II (Powdered Chandrasoora) – 2 capsules 6 hourly (8 Capsuls/day, 1 capsule 500 mg)

The drug was administered for a period of 30 days for all the patients in all the groups.

Dos & Don'ts

Pts were advised not to take cold food and regimes, day sleeping, violent exercises, excess sexual indulgences, excessive exposure to sunlight and reduce the use of sour, pungent and salty foods. Since the pts were from O.P.D to adherence to dos and don'ts instruction to them could not be assessed strictly.

Assessment Criteria

a) Symptoms-Subjective

1. Pain was recorded using Visual analogue rating scale.
2. Duration of morning stiffness.
3. Patients global assessment was recorded according to their statement such as very much worse, worse, status quo, better, very much better. All the assessments were done before and after the treatment.

b) Signs-Objective

1. Total no. of joints involved was recorded before and after the treatment.
2. Joint tenderness was recorded as absent, mild, moderate, severe or very severe.
3. Swelling on joints was recorded in cm before and after the treatment with the help of a measuring tape.

4. Hand grip strength of both hands was measured and recorded separately before and after the treatment by noting the rise in mercury level of sphygmomanometer, when the patient presses the inflated cuff.

5. Walking time-The time taken by the patient to cover a distance of 5m. with maximum possible speed was recorded as walking time before and after the treatment.

6. Physicians global assessment was recorded as very much worse, worse, status quo, betters, very much better before and after the treatment.

7. Haematological and bio chemical investigations such as Hb, TC, DC, E.S.R, RBS, Serum uric acid, Serum cholesterol, Serum R.A. factor etc and Routine urine examinations were carried out before and after the treatment.

The collected data is conveniently segregated under 1. Demographic data and 2. Data related to response of treatment.

Statistical Analyis

The data collected were rendered into a master sheet and statistical tables were constructed. Demographical data were analysed by making tables and by computing percentage. In order to compare the three groups and to draw conclusions, the statistical constants like Arithmetic mean, Std deviation, percentage etc. were computed. The statistical hypothesis formulated was tested by using 'paired t test' to see the effectiveness after treatment. Similarly the improvement attained in different groups was tested with the help of student t test. The association between variables was tested by using chi-square test. For all the statistical computations statistical packages were applied.

Demographic Data

a) Distribution of pts by sex.

Table 1

Sex	Group							
	I		II		III		I+II+III	
	No	%	No.	%	No.	%	No.	%
Male	1	6.67	4	26.67	5	23.33	10	22.22
Female	14	93.33	11	73.23	10	66.67	35	77.78
Total	15	100	15	100	15	100	45	100

Out of 45 patients taken for the study 77.87% were females and males came only 10%. Groupwise also females dominate the picture. From the table I it is clear that the majority of pts included in the study were females considering the pts totally and group wise. The established clinical feature of RA are between 2 and 3 times more frequent in women than men.

b) Distribution by age

Table 2

Age	Group							
	I		II		III		I+II+III	
	No	%	No.	%	No.	%	No.	%
16-25	0	0	0	0	0	0	0	0
26-35	2	13.33	1	6.67	1	6.67	4	8.89
36-45	3	20	7	46.67	9	60	19	42.22
46-55	7	46.67	5	33.33	3	20	15	33.33
56-65	3	20	2	13.33	2	13.33	7	15.56
66-75	0	0	0	0	0	0	0	0
Total	15	100	15	100	15	100	45	100

In the present study majority of patients lie in the age group 36-45 years (42.22%) and next to it 46-55 years (33.33%), 56-65years (15.56%) 26-35 years (8.89%) Below 26 years and above 65 years these were no patients in any of the group. Even though the disease may begin at any age, the peak incidence is from 35-60 years. The present results almost coincide with this. Table 2 reveals the age wise distribution.

c) Distribution by diet (food pattern)

Table 3

Diet	Group							
	I		II		III		I+II+III	
	No	%	No.	%	No.	%	No.	%
Nonveg.	15	100	15	100	14	93.33	44	97.78
Veg	0	0	0	0	1	6.67	1	2.22
Total	15	100	0	0	15	100	45	100

It was very much interesting to note that 97.78% of patients included in the study were non vegetarians and vegetarians came only 2.22% . The group wise distribution also available in table 3. Generally non vegetarian food are hot spicy one. Ay. Consider these type of food which are predominantly lavana (salty), amla (sour), Katu (pungent), Kshara (alkaline), Ushna (hot) properties as one of the main etiological factor of the disease.

d. Distribution by nature of work.

The results exhibited in table 4 reveal that hard manual workers are lowest group included in the study. Housewives, office workers and moderate manual workers came in the order of

highest percentage group in the present study. This also coincide with the Ay. literatures which tells, people who are having a delicate constitution are more prone to this disease.

Table 4

Nature	Group							
	I		II		III		I+II+III	
	No	%	No.	%	No.	%	No.	%
Housewife	12	80	10	66.67	8	53.33	30	66.67
Off. work	0	0	2	13.33	4	26.67	6	13.33
Moderate	3	20	2	13.33	1	6.67	6	13.33
Hard	0	0	1	6.67	2	13.33	3	6.67

e. Distribution by chronicity of disease.

While considering the chronicity of disease, majority of patients come under 0-5yrs durations. The table 5 reveals that is the present study up to 20yrs.chronic patients were included in the study and there is no patients below 6 months duration. The disease is a chronic one as per the literature and the observation.

Table 5

Chronicity (Years)	Group							
	I		II		III		I+II+III	
	No	%	No.	%	No.	%	No.	%
0-5	8	53.34	8	53.34	8	53.34	24	53.33
6-10	3	20	4	26.67	7	46.66	14	31.11
11-15	2	13.33	1	6.67	0	0	3	6.67
16-20	2	13.33	2	13.33	0	0	4	8.89

Data Related To Response Of Treatments

Pain

It is seen from the table 6 that the mean pain score before treatment was 7.3 is group I which has reduced to 6.3 after treatment .Similarly in group II, the initial score of 6.9 had attained a level of 4.9 after treatment. In case of group III reduction was so remarkable that it has come down to 3.9 after treatment from the before treatment value of 7.5. Invariably in all the 3 groups the reduction noted was highly statistically significant. A further comparison of the 3 groups is shown in table 7

Table 6

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	7.3 ± 1.3	6.3 ± 1.8	4.59	p<0.001
II	6.9 ± 0.9	4.9 ± 1.2	8.48	p<0.001
III	7.5 ± 0.9	3.9 ± 1.5	12	p<0.001

Table 7

Group	Reduction in Pain Score		t Value	p Value
	Mean	SD		
I	1.00	0.85 (0.71)	--	--
II	1.93	0.88 (0.78)	2.95	p<0.05
III	3.60	1.18 (1-4)	18.6	p<0.01

II Vs III t=4.38; df=28; p<0.01

The difference in the mean reduction pain score between the 3 groups was tested statistically and was highly significant between group I and group III and between group II and group III, the test was significant at 0.1% level. Thus it is established from the results that all the three treatment methods were effective in relieving pain. And further comparison revealed that the reduction in pain score in the combination drug group was more than 3 times higher compared to the Ficus group by placing lepidium group in second position.

Morning stiffness:

Table 8

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	2.67 ± 1.01	2.03 ± 0.91	11.44	p<0.001
II	2.50 ± 0.97	1.4 ± 0.74	9.04	p<0.001
III	4.67 ± 2.02	1.93 ± 1.33	8.3	p<0.001

While considering the morning stiffness scored before treatment, the mean score varied from 2.67, 2.5 and 4.67 in 3 groups respectively. After treatment stiffness score reduced to 2.03, 1.4 and 1.93. In all the groups reduction turned down to be highly statistically significant (P<0.001). In further comparison mean reduction was 0.77, 1.07 and 2.73 respectively in the 3 groups after treatment. Thus it is revealed although the 3 medicines are effective in reducing morning stiffness the combination drug is having very strong effect in reducing morning stiffness compared to the single drugs.

Table 9

Group	Reduction in MS Score		t Value	p Value
	Mean	SD		
I	0.772	0.26 (0.07)	--	--
II	1.070	0.46 (0.21)	2.19	p<0.05
III	2.73	1.28 (1.64)	5.8	p<0.001

II Vs III t=5.58; df=28; p<0.001

Joint Count:

Table 10

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	27.73 ± 8.09	24.07 ± 7.9	11.11	p<0.001
II	22.87 ± 3.64	17.4 ± 2.16	8.36	p<0.001
III	33.13 ± 7.02	25.8 ± 5.76	10.16	p<0.001

The mean joint count which was 27.73, 22.87 and 33.13 respectively in the 3 groups come down to 24.07,17.4 and 25.8 respectively. In all three groups reduction noted after treatment appeared to be highly statistically significant (P<0.001). In table 11 furthers comparison was done. The P value while comparing group I and II was P<0.05 and between group I and three was P<0.001.Thus it is reveled that the three treatment regimes were laving effectiveness in reducing the joint count. In combination group the reduction was 2 times higher compared to Ficus group and 1.33 times higher compared to lepidium group.

Table 11

Group	Mean	SD	Paired t value	p value
I	3.67	1.29 (1.67)	--	--
II	5.5	2.53 (6.41)	2.49	p<0.05
III	7.33	2.79 (7.81)	4.63	p<0.001

II Vs III t=1.81; df=28; p<0.001

Tenderness

From table 12 it is clear that in three groups the mean tenderness score reduced after treatment as follows 3.2 to 2.47, 3.13 to 1.6 and 4.2 to 1.8 respectively. The mean reduction in tenderness score was recorded as 2.4 in group III followed by 1.47 in group II and only 0.73 in group I (table13). Thus it is seen that there was three fold reduction in the tenderness score in combination drug group compared to the Ficus group and 1.6 times higher compared to the Lepidium group.

Table 12

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	3.2 ± 0.68	2.47 ± 0.83	6.21	p<0.001
II	3.13 ± 0.52	1.6 ± 0.63	11.03	p<0.001
III	4.2 ± 0.56	1.8 ± 0.68	14.72	p<0.001

Table 13

Group	Mean	SD	Paired t value	p value
I	0.73	0.46 (0.21)	--	--
II	1.47	0.52 (0.27)	4.14	p<0.001
III	2.4	0.63 (0.4)	8.38	p<0.001

II Vs III t=1.89; df=28; p<0.001

Swelling score

Table 14

Type	Mean Score		Paired t Value	pValue
	BT	AT		
Elbow – Right	26.47	25.2	4.2	p<0.01
Elbow – Left	25.87	24.47	5.5	p<0.01
Wrist – Right	18.07	16.93	5.27	p<0.01
Wrist – Left	17.8	16.93	2.8	p<0.05
Knee – Right	40.07	38.13	7.8	p<0.01
Knee – Left	39.27	37.8	7.13	p<0.01
Ankle – Right	23.93	22.13	6.87	p<0.01
Ankle - Left	23.77	22.4	4.14	p<0.01

In the present study, the extent of swelling was assessed by scoring techniques. The mean swelling score of both elbows, wrists, knees and ankles in groupI are recorded before and after treatment. The results in table14 reveals that invariably in all the different sites of assessment, there was reduction in mean swelling score which was found to be statistically significant. The same procedure repeated in group II and III . Results are shown in table15 and 16. Invariably in all the sites and sides, the reduction was highly statistically significant. Thus it is established that

there was significant reduction in swelling score in all the three groups irrespective of sites and sides.

Table 15

Type	Mean Score		Paired t Value	pValue
	BT	AT		
Elbow – Right	28.33	25.87	7.96	p<0.01
Elbow – Left	27.47	25.27	6.48	p<0.01
Wrist – Right	18.67	16.8	8.48	p<0.01
Wrist – Left	17.87	16.07	8.07	p<0.01
Knee – Right	40.40	38.3	6.89	p<0.01
Knee – Left	39.5	37.8	8.91	p<0.01
Ankle – Right	25.4	23	7.78	p<0.01
Ankle - Left	24.73	22.6	8.9	p<0.01

Table 16

Type	Mean Score		Paired t Value	pValue
	BT	AT		
Elbow – Right	25.87	22.2	9.24	p<0.001
Elbow – Left	26.6	22.67	15.49	p<0.001
Wrist – Right	19.6	16.10	8.83	p<0.001
Wrist – Left	19.4	16.07	6.29	p<0.001
Knee – Right	39.8	36.60	10.67	p<0.001
Knee – Left	39.4	36.53	10.62	p<0.001
Ankle – Right	25.07	22.50	9.62	p<0.001
Ankle - Left	24.53	21.53	8.88	p<0.001

Therefore computing the average swelling score by considering all the sites and sides together, performed further statistical analysis which is shown in table 17. In all the three groups, the reduction was statistically significant at a very high level. Then the reduction noted in 3 groups was further compared in table18. The mean reduction attained in group I after treatment was compared with group II and the student t test is happened to be insignificant ($p > 0.05$). At the same time the mean reduction in average swelling score in group III happened to be3.46 which was highly statistically significant compared to group I and II ($p < 0.05$). Thus it is revealed that the effect of Ficus and Lepidium in reducing the swelling is more or less similar. It is proved

beyond doubt that the combination drug had the maximum effect in reducing the swelling irrespective of sites and sides.

Table 17

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	26.91 ± 1.79	25.5 ± 1.92	4.73	p<0.01
II	27.80 ± 1.40	25.72 ± 1.7	7.7	p<0.001
III	27.53 ± 1.2	24.28 ± 1.3	9.6	p<0.001

Table 18

Comparison

Group	Mean	SD	Paired t value	p value
I	1.41	1.15 (1.33)	--	--
II	2.08	1.03 (1.07)	1.675	p>0.05
III	3.46	1.41 (1.99)	4.36	p<0.001

Grip strength

Table 19

Gr. (Rt. H)	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	50.70 ± 31.5	63.73 ± 35.65	3.84	p<0.01
II	78.00 ± 34.42	89.00 ± 36.74	8.54	p<0.001
III	56.33 ± 32	78.33 ±31.38	9.2	p<0.001
Gr. (Rt. H)	BT	AT	t Value	pValue
I	57.53 ± 35.90	70.4 ± 40.6	3.28	p<0.01
II	78.33 ± 43.33	92.53 ± 46.62	10.58	p<0.001
III	54.87 ± 26.50	80.00 ± 27	9.41	p<0.001

It is attempted in table19 to compare the mean grip strength before and after the treatment. It is clear from the table that the increase in grip strength in all the groups found to be significant irrespective of right or left side. Since all three groups are statistically significant the data were further analysed to compare the increase in mean grip strength. Then it is really remarkable to note that except in case of group III, the mean increase happened to be insignificant statistically.

Thus it is showed that even in the case of grip strength, the combination drug happened to be superior than the other two treatment methods.

Table 20

Group	Mean	SD	Paired t value	p value
I Right	12.40	12.5 (156.5)	--	--
Left	12.87	12.87 (230.0)	--	--
II Right	14.00	6.32 (40)	0.44	p>0.05
Left	15.87	5.82 (33.84)	0.72	p>0.05
III Right	22	9.6 (92.1)	2.36	p<0.05
Left	25.10	10.33 (106.7)	2.58	p<0.05

II Vs III Right t=2.69; df=28; p<0.05

II Vs III Left t=3.01; df=28; p<0.05

Walking time

Table 21

Group	Mean ± SD		Paired t Value	pValue
	BT	AT		
I	17.87 ± 5.11	14.67 ±5.18	8.7	p<0.01
II	15.13 ± 2.7	11.93 ± 2.4	10.32	p<0.001
III	16.67 ±2.8	10.67 ± 2.26	11.22	p<0.001

In this present study, the changes that occurred after the treatment in the mean walking time was also assessed and compared. From table 21, it is clear that in all the 3 groups, the improvement noted after treatment was found to be highly statistically significant. The mean reduction in walking time attained in three different groups was further compared. The student test showed that the maximum reduction noted in group 3 was highly statistically significant (p<0.001) comparing to group 2 and group 1.

Table 22

Group	Mean	SD	Paired t value	p value
I	3.2	1.42 (2.03)	--	--
II	3.2	1.21 (1.46)	--	--
III	6	2.07 (4.29)	4.31	p<0.001

II Vs III t=4.52; df=28; p<0.001

Haematological findings.

Effects were made to compare the haematological findings before and after the treatment . As per table 23, in group 1, Hb% increased 12.52 % from 11.74%. Similarly mean E.S.R level reduced to 31.8 mm/ hr from 38.73. These changes found to be statistically significant ($P<0.05$). In the case of cholesterol there was a slight decline (from 189.4 to 184.73 mg %), but was not significant statistically. The mean serum uric acid and RBS also revealed no appreciable difference after the treatment and not statistically significant ($p> 0.05$) Thus it was found that Ficus drug is effective increasing Hb level and decreasing E.S.R level. But in the case of cholesterol, S. uric acid and RBS no appreciable difference after treatment is found.

Table 23

HF	Mean ± SD		Paired t Value	pValue
	BT	AT		
Hb	11.74 ± 1.03	12.52 ± 0.81	2.95	p<0.05
ESR	38.73 ± 27.7	31.8 ± 24.18	2.83	p<0.05
Chol.	189.4 ± 18.6	184.73 ± 20.13	1.16	p<0.05
SUA	4.38 ± 0.72	4.64 ± 0.77	1.3	p<0.05
RBS	111.00 ± 28.3	104.6 ± 21.00	1.65`	p<0.05

As per table 24 , in Lepidium group, E S R and cholesterol shares significant reduction after treatment.($P<0.05$). In the case of HB, S. uric acid and RBS, no significant change was noticed. ($P>0.05$ in all cases).

Table 24

HF	Mean ± SD		Paired t Value	pValue
	BT	AT		
Hb	11.95 ± 1.78	12.35 ± 1.24	1.04	p>0.05
ESR	35.33 ± 22.26	20.67 ± 16.63	4.74	p<0.05
Chol.	202.67 ± 28.2	186.5 ± 35.5	2.88	p<0.05
SUA	4.94 ± 1.41	4.65 ± 0.95	1.27	p>0.05
RBS	100 ± 21.8	101.67 ± 32.7	0.24	p>0.05

In the case of combination drug (table25) the reduction in ESR was highly statistically significant. ($P<0.001$) and in the case of Hb level it was significant at 5% level . In the case of cholesterol the numerical reduction noticed after treatment happened to be insignificant

statistically (P> 0.05) . This may be probably due to the increased standard deviation noted before treatment. In the case of S.uric acid and RBS also, the results were statistically insignificant. (P >0.05)

Table 25

HF	Mean ± SD		Paired t Value	pValue
	BT	AT		
Hb	10.94 ± 1.8	11.27 ± 1.23	2.14	p<0.05
ESR	59.8 ± 37.83	35.27 ± 35.3	5.66	p<0.05
Chol.	200.6 ± 44.1	189.3 ± 23.3	0.98	p>0.05
SUA	4.91 ± 1.88	4.8 ± 1.86	0.63	p>0.05
RBS	101.4 ± 14.1	97.53 ± 18.99	0.83	p>0.05

While considering the haematological findings of group I, II & III there was significant reduction in E.S.R in all the 3 groups, the mean reduction noted was further compared is table 26. This revealed that the reduction in E.S.R level in combination drug group was three times higher compared to Ficus group and 1.5 times higher compared to Lepidium group.

Table 26

Group	Mean	SD	Paired t value	p value
I	6.93	9.47 (89.64)	--	--
II	14.67	11.96 (143)	1.965	p<0.05
III	24.67	16.9 (285)	3.550	p<0.05

II Vs III t=1.87; df=28; p<0.05

The results from the present study revealed that statistically there is no significance between R.A factor and type of treatment. But in the case of the combination drug therapy , a non statistical /improvement was noticed in the case of RA factor(table 27).

Table 27

Group	BT		AT	
	No	%	No	%
I	4	27	4	27
II	3	20	3	20
III	9	60	6	40

$x^2 = 0.27$; df=2 p>0.05

Conclusion

It is proved conclusively that the combination drug made from stem bark of Ficus religiosa and seeds of Lepidium sativum is significantly effective in the management of RA and the drug is more effective than the said single drugs.

Recommendations for further Study

Since this was a preliminary study larger follow-ups were not done due to lack of time . Study included three groups and the sample selected for each group was small. The combination drug showed excellent results within the short period itself. Hence long term benefits of the drug may be studied .Due to limited study period , follow up studies were not done in the present study. Since the disease exhibits exacerbation and remission a long term follow up study may be conducted to establish efficacy of the drug.

Even though the sample size was small the drug showed statistically significant results. Study may be conducted on large samples to establish the efficacy thoroughly.