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Study on efficacy of *Siddha* drugs (CL and CEN) in rheumatoid arthritis

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Siddha system, a traditional Indian Systems of Medicine, noticed much of the musculo-skeletal disorders, termed as *Vatha* diseases, under which joint diseases were put as *Keel vayu. Vali azhal keelvayu* is one among the types of *keel vayu*. In ancient *Siddha* texts, various causative factors, clinical features as well as the treatment methodology for the disease *vali azhal keelvayu* were broadly explained. This condition was well correlated with the disease rheumatoid arthritis, for which there is no curative drugs. So, two polyherbal *Siddha* drugs (for internal and external use), were tried in a clinical trial as well as pharmacological, biochemical analysis in order to prove the efficacy of these drugs in rheumatoid arthritis, which revealed a positive answer.

Keywords: rheumatoid arthritis, *Siddha* drugs

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Rheumatoid arthritis (RA) is a chronic multi-system disease that affects joints connective tissue, muscles, tendon and fibrous tissue, which is basically an inflammatory joint disease, primarily characterized by a symmetrical, poly arthritis affecting 3% of total population in 25 -50 yrs of age. Females are more affected than males (3:1). Generally considered as systemic disease, but in early stages it is only an articular disease characterized by inflammation, edema of synovium with increased vascularisation and pannus formation. This is followed by destruction of cartilage by pannus, distension of joint capsule, destruction of bony joint margin and sub chondral bone leading to joint damage resulting in deformity, fibrous ankylosis and eventual bony ankylosis of joints. There is not a total curative therapy for the disease. The disease mentioned in *Siddha* literature as *Vali azhal keelvayu* and a study about the efficacy of polyherbal *Siddha* drugs, i.e CL (internal), C EN (External) on rheumatoid arthritis was carried out by conducting a clinical trial as well as pharmacological and biochemical analysis carried out at Government Siddha Medical College, Palayamkottai, Tamil Nadu during 2002-2004 at PG Department of Special Medicine[1].

Methodology

For the clinical study 20 patients suffering from rheumatoid arthritis were selected by adopting a criterion as laid down by American Rheumatologist Association. The Criteria for inclusion were morning stiffness of minimum 1 hr duration, arthritis of 3 or more joints, arthritis of hand joints, symmetric arthritis, rheumatoid nodules, serum rheumatoid factor, and radiological changes pertaining to rheumatoid arthritis. Patients with four or more of the above features were included for the clinical trial. Exclusion criteria included CVS: pericarditis, myocarditis, endocarditis, valvular heart diseases; RS: pleurisy, pleural effusion, interstitial fibrosis, rheumatoid arthritis nodules, bronchiolitis; GIT: severe acid peptic disease, H/o GIT bleeding; renal: amyloidosis, renal tubular acidosis, renal insufficiency- drug induced; neurological : Nerve entrapment syndrome like Carpal tunnel syndrome; eye : Keratoconjuntivitis, scleritis, episclertis; deformities: joints with permanent deformities; surgical : those underwent orthopaedic surgeries on the affected joints; and pregnant and lactating women. Selected 20 cases (Male 11, Female 9) at varied age group were admitted as in patients at Govwernment Siddha Medical College Hospital, Palayamkottai for about 3-7 weeks (Tables 1-2). After necessary ethical clearances and written consent, patients were enrolled for treatment. All the 20 cases were subjected to the following investigations: blood (routine tests – TC, DC, ESR, Hb, sugar, urea and total cholesterol, and rheumatoid arthritis factor); urine (routine albumin, sugar, deposits, bile salts, and bile pigments); radiology (X- ray of the affected joints). The selected

20 cases were given with polyherbal *Siddha* drugs: CL - 5 gm bid (internal) and CEN (external). As per the investigation results, all the cases had positive RA factor, Low Hb, increased ESR and radiological changes pertaining to RA in the affected joints before treatment. After the therapy with trial drugs, lab investigation was repeated.

Table 1 Case history charts (Age distribution)

Age (in yrs)	No of cases	%
21-30	2	10%
31-40	4	20%
41-50	3	15%
51-60	7	35%
61 and above	4	20%
Total	20	100%

Table 2 Sex distribution

Sex	No of cases (out of 20)	%
Male	11	55%
Female	9	45%
Total	20	100%

Results and discussion

Positive markers for an effective drug in RA, i.e reduction of ESR was achieved in 16 cases (80%), increase in Hb% was achieved in 18 cases (90%), reduction in soft tissue swelling of X-ray was achieved in 14 cases (70%), and relief from clinical signs and symptoms was achieved in 17 cases (85%). Observation made during the study showed that the trial medicines were clinically effective in RA (Tables 3-4). Further, the potency of the drugs were studied by pharmacological, and biochemical analysis of the drugs. Biochemical analysis of the internal drug CL revealed that it has Ca, ferrous ion, unsaturated compound, reducing sugar in trace amount and amino acids. Pharmacological study revealed that the trial drugs have acute antiinflammatory, antipyretic, and analgesic activities.

Table 3 Case history chart

In-Patient No	WBC Total Count Cu. mm	Differential Count P%	L%	E%	P%	L%	E%	ESR 1 hr	ESR ½hR	ESR 1 hr	URINE ANALYSIS Alb	Sug	Dep	Alb	Sug	Dep	Xray
BT AT	BT AT	BT AT	BT AT	BT AT	BT AT												
777	7200	7400	55	40	5	53	43	4	30	55	12	24	88	90	NIL	NIL	NIL
871	9000	9100	60	36	4	58	30	4	14	28	7	15	72	86	NIL	NIL	NIL
992	8200	8800	63	33	4	60	36	4	15	30	8	18	65	84	NIL	NIL	NIL
1142	9000	9200	58	40	2	60	38	2	8	20	6	14	70	81	NIL	NIL	NIL
1173	9600	9700	58	24	8	59	23	8	15	35	4	18	72	86	NIL	NIL	NIL
1176	9800	9400	54	40	6	55	38	7	6	12	4	10	70	85	NIL	NIL	1-2PC
1177	8200	8400	70	26	4	65	31	4	40	70	18	34	72	80	NIL	NIL	NIL
1198	8500	8700	62	32	6	62	32	6	24	46	8	21	74	89	NIL	NIL	NIL
1257	9500	9100	58	30	12	62	29	9	07	15	5	12	74	86	NIL	NIL	NIL
1302	9200	8700	64	28	8	65	29	6	30	60	12	20	72	87	NIL	NIL	NIL
1314	7200	8100	60	38	2	61	30	9	30	70	10	18	60	83	NIL	NIL	NIL
1370	8600	8700	70	25	5	64	31	5	20	45	10	22	54	80	NIL	NIL	NIL
1402	8400	8100	58	38	4	60	38	2	24	36	8	16	72	80	NIL	NIL	NIL
1472	9000	8300	54	38	8	50	44	6	30	60	10	22	78	80	NIL	NIL	NIL
1434	8200	8400	64	34	2	60	38	2	28	54	12	20	74	79	NIL	NIL	NIL
1505	9000	8900	65	30	5	62	37	1	8	15	4	8	57	80	NIL	NIL	1-2EC
1548	8600	8800	54	40	6	59	34	7	55	100	20	40	72	74	NIL	NIL	NIL
1555	9200	8100	55	40	5	53	42	5	25	47	8	14	70	79	NIL	NIL	NIL
1609	9200	7800	64	28	8	60	32	8	15	25	4	10	72	81	NIL	NIL	NIL
1624	6500	7100	60	38	2	58	40	2	50	100	14	28	68	88	NIL	NIL	NIL

Table 4 Case history chart

In – patient No Age & sex	Date of admission Date of	discharge No of days treated	Drugs given Investigation blood sugar	mg% (PP) Serum cholesterol	mg% Blood urea mg%	RA factor
777 55/M	17.04.2003 25.02.2003	35	CLL 5mg bid (Int) CEN(Ext)	120	194 31	Positive
871 45/M	28.04.2003 15.05.2003	17	-do-	130	174 34	-do
992 41/M	13.05.2003 21.06.2003	39	-do-	124	182 27	-do
1142 70/M	03.06.2003 16.06.2003	13	-do-	142	198 36	-do
1173 75/M	07.06.2003 20.06.2003	13	-do-	146	204 33	-do
1176 62/M	09.06.2003 08.07.2003	29	-do-	128	178 37	-do
1177 52/M	09.06.2003 24.07.2003	45	-do-	110	198 17	-do
1198 60/F	11.06.2003 05.07.2003	24	-do-	148	210 27	-do
1257 60/M	17.06.2003 11.07.2003	24	-do-	110	178 23	-do
1302 40/F	20.06.2003 02.08.2003	43	-do-	140	168 17	-do
1314 49/F	23.06.2003 20.07.2003	27	-do-	130	202 37	-do
1370 25/M	30.06.2003 05.08.2003	37	-do-	142	186 31	-do
1402 55/F	03.07.2003 21.07.2003	18	-do-	136	190 29	-do
1472 57/F	07.07.2003 23.07.2003	16	-do-	144	204 34	-do
1434 35/F	07.08.2003					

20.07.2003 12 -do- 134 173 33 -do 1505 60/F 17.07.2003 26.08.2003 40 -do- 120 188 29 -do 1548 40/F 21.07.2003 25.08.2003 35 -do- 120 174 20 -do 1555 65/M 22.07.2003 04.08.2003 13 -do- 130 183 27 -do 1609 33/F 28.07.2003 02.08.2003 05 -do- 128 198 34 -do 1624 25/F 30.07.2003 27.08.2003 29 -do- 130 168 17 -do-

Conclusion

From the clinical trial study, efficacy results were found good in 85% of cases. No adverse effects were noticed during the treatment period. Further follow up of the cases showed good recovery and fine improvement in the general well being as they could carry out their day to day activities. The trial drugs have acute antiinflammatory, antipyretic, and analgesic actions. Preparation of both the polyherbal *Siddha* drugs is simple. The treatment with the trial drugs for rheumatoid arthritis was found to be effective.

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