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The clinical efficacy of 'Kodasuri veeravaippu' (a sidha formulation) in patients affected by the disease "Keelvayu" (Arthritis)

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ABSTRACT

The present study deals with the clinical efficacy of Kodasuri veeravaippu, a sidha preparation, in the cure of Keelavayu or Arthritis. Both inpatients and out patients were treated with Kodasuri veeravaippu with a dose of 130 mg b. d with honey after food. The cure rate was observed for 15 days to a maximum of 40 days. The results were quite encouraging with 80 percent of patients giving promising positive cure with this drug. The results indicated the anti-inflammatory and analgesic efficacy of Kodasuri veeravaippu.

Key words: Kodasuri veeravaippu, Keelavayu, Arthritis, Anti-inflammatory, Analgesic,

INTRODUCTION

Arthritis or "Keelavayu" is a chronic disease of joints leading to swelling, pain and disability. It can be classified as osteoarthritis, cervical spondylosis, lumbar spondylosis and rheumatoid arthritis. Each type of disease has different etiology and could be caused by many factors, such food, type of profession, age, sex and other physiological parameters. In most of the cases this disease becomes chronic and crippling.

In sidha system of medicine Arthritis disease is known as "Keelavayu." In sidha and ayurvedic systems this disease is attributed to the defects in the vata or vayu attribute of the three life forces, namely Vata (Windy constitution), Pitta (Bilious constitution) and Kapha (Phelematic constitution).

In most forms of arthritis, the inflammation persists and damages the healthy tissues of the body. This may result in more inflammation and more damage. Osteoarthritis also known as degenerative arthritis or degenerative joint disease which results in mechanical abnormalities involving degradation of joints, including articular cartilage and subchondral bone.

Spondylosis is a specific form of arthritis, which attacks vertebrae and connecting bone, and ligament structures. The spines of majority of people above the age of 50 have certain degree of osteo arthritic changes.

Rheumatoid arthritis can be one of the most disabling types of arthritis. Its course varies, from a few symptoms to severe and painful deformities. Three times as many women as men are affected, usually at a fairly young age (between 25 and 50). The disease may come on slowly or appear suddenly. Rheumatoid arthritis typically affects the small finger joints, wrists, knees and toes. All joints of the body, however, are potential targets.

The treatment of any form of arthritis poses a big challenge to physicians around the world and a sure cure is still elusive to the rank and file of the medical community.

To date, the goal of treatment in rheumatoid arthritis is to reduce joint inflammation and pain, maximize joint function, and prevent joint destruction and deformity. Early medical intervention has been shown to be important in improving outcomes. Aggressive management can improve function, stop damage to joints as monitored on X-rays, and prevent work disability. Optimal treatment for the disease involves a combination of medications, rest, joint-strengthening exercises, joint protection, and patient (and family) education. Treatment is customized according to many factors such as disease activity, types of joints involved, general health, age, and patient occupation. Treatment is most successful when there is close cooperation between the doctor, patient, and family members.

Two classes of medications are used in treating rheumatoid arthritis: fast-acting "first-line drugs" and slow-acting "second-line drugs" (also referred to as Disease-Modifying Anti Rheumatic Drugs or DMARDs). The first-line drugs, such as aspirin and cortisone (corticosteroids), are used to reduce pain and inflammation. The slow-acting second-line drugs, such as methotrexate (Rheumatrex, Trexall), and hydroxychloroquine (Plaquenil), promote disease remission and prevent progressive joint destruction.

The degree of destructiveness of rheumatoid arthritis varies among affected individuals. Those with uncommon, less destructive forms of the disease or disease that has quieted after years of activity ("burned out" rheumatoid arthritis) can be managed with rest plus pain control and anti-inflammatory medications alone. In general, however, function is improved and disability and joint destruction are minimized when the condition is treated earlier with second-line drugs (disease-modifying anti rheumatic drugs), even within months of the diagnosis. Most people require more aggressive second-line drugs, such as methotrexate, in addition to anti-inflammatory agents. Sometimes these second-line drugs are used in combination. In some cases with severe joint deformity, surgery may be necessary.

The use of these medicines is beset with the danger of undesirable side effects and also complete cure is elusive. Thus there a need to find out an alternative medicine which not only cures but also will have very less or no side effects. Ayurveda and Siddha systems of medicines are age old treatments for almost any type of disease. Many research articles and have proved the efficacy of ayurvedic drugs for the treatment of Rheumatoid arthritis [1, 2, 3, 4]. Chopra *et al*, 2012, have compared standardized ayurvedic formulations and hydrochloroquine sulphate (HCQS) in the treatment of Rheumatoid arthritis [5]. In one of our recent papers we have reported the efficacy of *Kodasuri veervaiippu* on Carrageenan induced paw edema and Cotton pellet induced granuloma in albino rats [6].

The present investigation reports the anti arthritic property of one sidha formulation, *Kudasuri Veervaiippu* (a formulation made up of many natural salts after a thorough processing).

'*Kodasuri veervaiippu*' is a unique formulation of siddhers. This medicine by its formulation possesses the greatness of '*Muppu*' by the combination of '*Thurusu guru*', '*Veera Muppu*', and '*Rasa guru*'. Specialty of the drug is its vast usage in the field of alchemy which turns *Thurusu* (copper sulphate) in to white form (*Thurusu guru*) which is used to make *rasa kattu*, *thalaga kattu* and so many chain process of alchemy. *Kodasuri veervaiippu* itself in *kattu* form of so many elements and minerals. '*Kodasuri veervaiippu*' is mentioned as red coloured '*sunnam*'. With its special formulation of mineral composition and form the *Kodasuri veervaiippu*' possesses multi pharmacological activities to cure all diseases.

Physio chemical analysis of the drug showed its potent ingredients such as mercury, copper, iron, sodium, potassium, chlorine, manganese and magnesium in the oxide forms play vital role in pharmoco therapeutic principle of the drug. These elements possess very good therapeutic value with major activities to cure all diseases mentioned in the literature. In the present study it was shown that this drug is anti inflammatory and analgesic and is a potential drug for arthritis.robial activity of this drug which associate to cure the disease '*keelvayu*' (arthritis).

MATERIALS AND METHODS

2. a. STUDY CENTRE- Arignar Anna Government Hospital of Indian medicine and Homeopathy, Arumbakkam, Chennai-106.

2. b. STUDY PARTICIPANTS

Both men and women and members of all the races and ethnic groups were eligible for this trial. Treatment was administered on an Inpatient / Outpatient basis. Sample size was 50 patients from outpatient and ten patients from inpatient ward. The patients were selected from the inpatient and outpatient wing of Arignar Anna Government Hospital of Indian medicine and Homeopathy, Chennai-106.

2 c. CRITERIA FOR INCLUSION

Patients with inflammatory disorder affected by the disease '*keelvayu*' with following symptoms were admitted for entry to the trial with the following criteria: Pain, swelling, stiffness, tenderness, crepitus on movement, limitation on movement, deformity, gait abnormality, inability to use limbs, cooperation of patients and knowledge of any previous treatment regime that the patient might have taken.

2 d. CRITERIA FOR EXCLUSION

Pregnant and lactating women, Age below 10 years and above 90 years, HIV patients, AIDS patients, Patient with Diabetes mellitus, the patient requires systemic steroid for the control of symptoms.

2 e. WITHDRAWAL CRITERIA

Patients were removed from study when any of the criteria mentioned herein were applicable: Disease progression, Deterioration of vital signs with cardiac, respiratory, hepatic, renal and CNS changes, Intercurrent illness that prevents further administration of treatment, Unacceptable adverse events, Patient decides to withdraw from the study or General or specific in the patient's condition render the patients unacceptable for the further treatment in the judgment of the investigator.

2 f. ROUTINE EXAMINATIONS AND ASSESSMENT

The clinical assessment was done initially at the end of 4 days, 7 days, 14 days and 21 days follow up.

2 g. TRIAL DRUG: '*KODASURI VEERAVAIPPU*' and the dosage was 130 mg b.d with honey after food.

2 h. DURATION OF TRIAL: Study period: 3 days to 7 days with 15 days follow up.

Total duration: 40 days if necessary.

2 i. TREATMENT PLAN**i. a. DIET RESTRICTION AND MEDICAL ADVISE**

The patients were instructed to follow fat free, salt free and easily digestible foods, to avoid cold damp climate, to take rest and not to do hard physical work.

The clinical improvement was observed and recorded daily in the Proforma of the case sheet.

2 j. CLASSIFICATION OF RESULTS

Good Response: Relief of symptoms above 75% and Parameter findings towards normality.

Fair Response: 50% to 75% relief in symptoms and significant improvement in laboratory parameters.

Poor Response: 25% to 49% relief in symptoms and minimal improvement in laboratory parameters.

No Response: No relief in symptoms and so significant improvement in laboratory parameters.

2 k. FOLLOW UP

Assessment was taken for every three days before and after treatment during the period of clinical assessment and laboratory investigations were also carried out.

RESULTS**3 a. Case assessment in out-patient ward**

'*Kodasuri veeravaippu*' was given 130 mg bid with honey to the 50 patients in Arignar Anna Siddha Hospital, Chennai 106.

Among 50 patients treated in outpatient wing 80 % were scored good response, and 20 % got fair response to the medicine.

In total 50 patients 60 % were affected by Osteoarthritis out of which 80 % were responded well and 20 % responded fair.

32 % of patients were affected by lumbar spondylosis, among them 31 % were responded fairly.

8 % of patients belongs to cervical spondylosis, 100 % were responded well.

52 % of patients were noticed pain reduction in 3 days, 32 % in 4 days, 12 % in 5 days, 4% were noticed their pain reduction in 6 days.

36 % of patients registered their reduced inflammation in 4 days, 32 % in 5 days, 12 % in 6 days, 10 % in 3 days, 8 % in 7 days and 2 % were noticed their inflammation reduction in 8 days (Figure 1, 2, 3).

Thus it was clear that 'Kodasuri veeravaippu' shows excellent therapeutic value in treating 'keelvayu' (Arthritis).

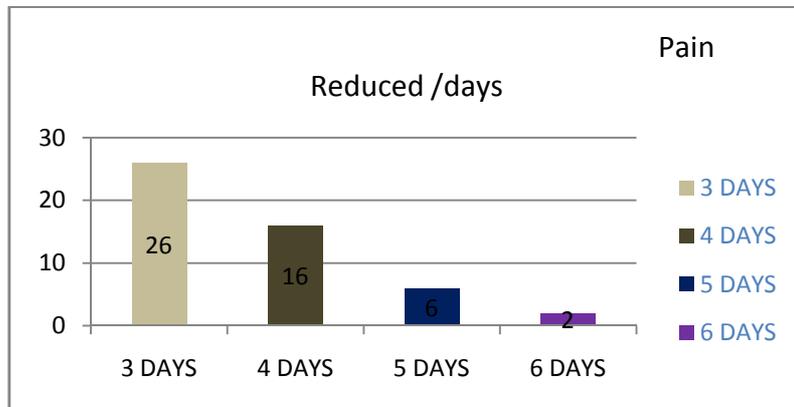


Figure 1. Bar diagram for outpatient treatment showing pain reduction in days

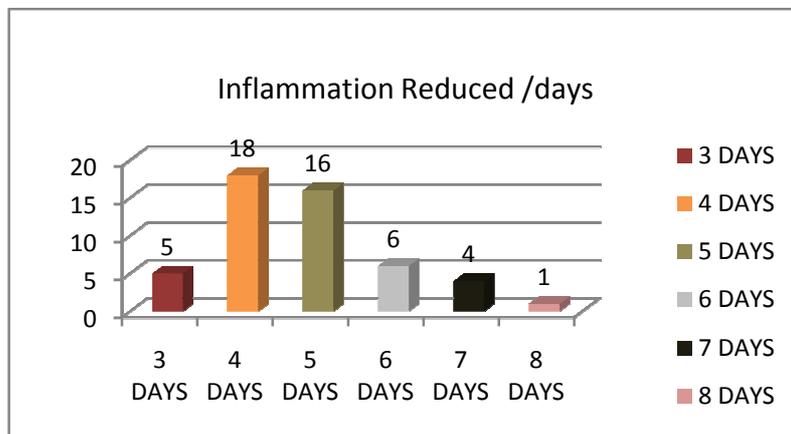


Figure 2. Showing the reduction of inflammation among patients in days

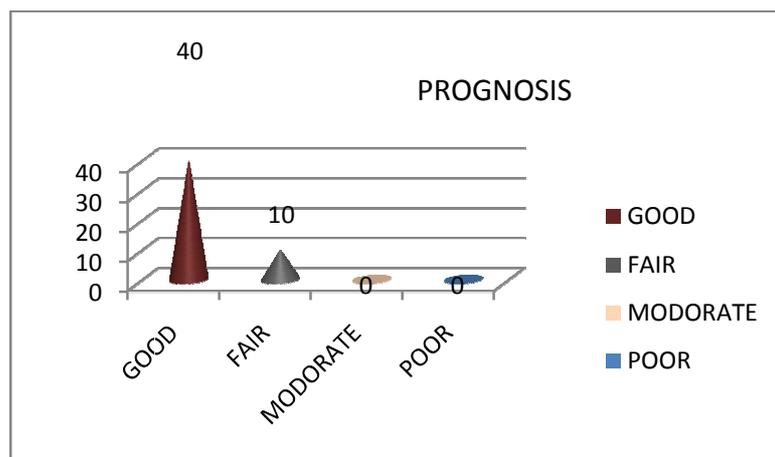


Figure 3. Prognosis of outpatients treated with Kodasuri veeravaippu

Table No 1. Clinical assessment of 'Kodasuri veeravaippu' on the disease 'Keelvayu' – Inpatient treatment

No	Ip. number	Age/ sex	Date of Admission	Date of Discharge	Diagnosis	Duration/ Days	Symptoms relieved/days		Investigation				Result
							Pain	Inflam-Mation	Before treatment		After treatment		
									Blood	x-ray	Blood	x-ray	
1	5743/5014	60 Male	22.10.10	27.10.10 Improved Discharge.	Osteo- arthritis	6	3	6	ESR 24-48 mm	Pettallo-Femoral Joint space reduced	ESR 10-20 mm	Affected Joint space improved	Fair
2	3611/9419	25 Female	01.11.10	06.11.10 Discharged At request.	Rheumatoid Arthritis	6	5	6	ESR 35-70 Mm R.A-factor positive	Inter arterial space reduced	ESR 12-24 mm	Sign reduced	Modo- rate
3	3068/6443	38 Female	22.01.10	27.01.10 Improved Discharge	Cervical spondylo- Sis	6	2	5	ESR 23-46 mm	C ₅ -C ₆ space reduced	ESR 9-18 mm	Improved	Good
4	3423/9764	62 Male	24.02.10	29.02.10 Improved Discharge	Cervical spondylo- Sis	5	3	4	ESR 20-40 mm	C ₅ -C ₆ space reduced	ESR 9-18 mm	Improved	Good
5	-3517/3610	50 Male	06.03.10	12.03.10 Improved Discharge	Osteo- arthritis	7	3	6	ESR 35-70 mm	Pettallo-Femoral Joint space reduced	ESR 12-24 mm	Affected Joint space improved	Good
6	3517/3600	65 Female	06.03.10	11.03.10 Improved Discharge	Cervical spondylosis	5	3	3	ESR 38-61 mm	C ₄ -C ₅ space reduced	ESR 12-24	Improved	Good
7	4021/2502	30 Male	27.04.10	01.05.10 Improved Discharge	Lumbar Spondylosis	5	3	4	ESR 40-80 mm	L ₄ -L ₅ space reduced	ESR 10-20	Improved	Good
8	4247/9420	56 Female	17.05.10	24.05.10 Improved Discharge	Osteo- arthritis	8	3	6	ESR 24-48 mm	Pettallo-Femoral Joint space reduced	ESR 08-16 mm	Affected Joint space improved	Good
9	5551/8389	38 female	05.10.10	09.10.10 Discharged At request	Lumbar Spondylosis	5	3	4	ESR 35-60 mm	L ₄ -L ₅ space reduced	ESR 14-28 mm	Improved	Good
10	4144/5619	39 Male	06.05.10	11.05.10 Improved Discharge	Osteo- arthritis	6	3	5	ESR 15-30 mm	Femoral space reduced	ESR 12-24 mm	Joint space Improved	Good

3 b. Case assessment in in-patient ward

10 patients affected by 'keelvayu' were admitted in In-patient ward of Government Arignar- Anna Siddha hospital, Chennai-106.

4 patients were diagnosed as affected by Osteo arthritis, 2 patients were affected by cervical- spondylosis, 3 patients were affected by Lumbar spondylosis and 1 patient was affected by Rheumatoid arthritis.

Out of 10 patients 8 patients responded well. (Table 1, Figure 4, 5)

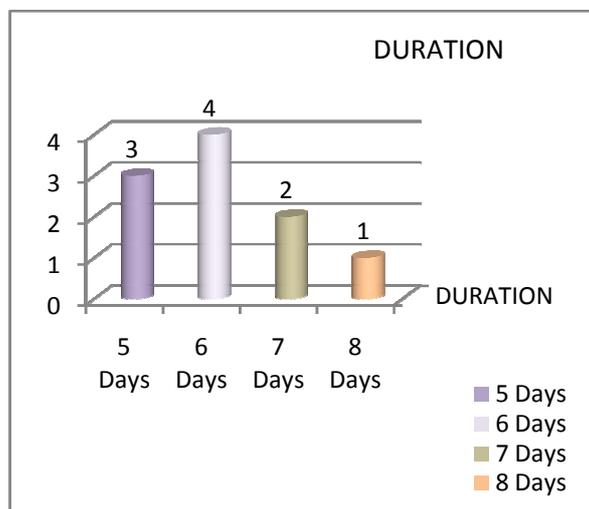


Figure 4 Bar diagram of inpatients improvement

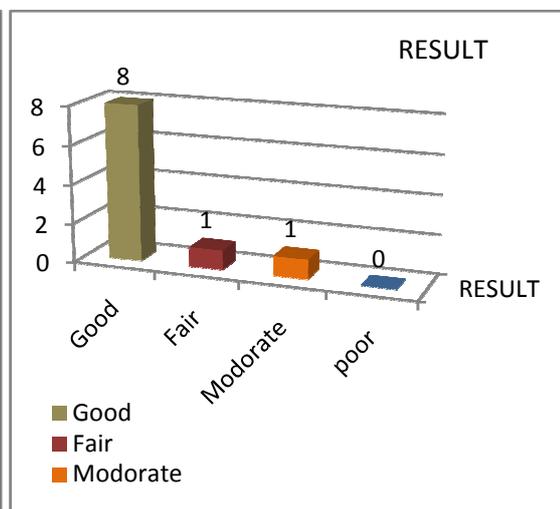


Figure 5 Bar diagram representing the cure results

Screening of the anti inflammatory activity and efficacy of 'kodasuri veeravaippu' in treating the disease *keelvayu* (arthritis) was carried over through relevant preclinical and clinical parameters. Results of such test and trials reveal the safety and potentiality of the test drug 'kodasuri veeravaippu'. Toxicological studies revealed that L.D₅₀ of 'kodasuri veeravaippu' is 130 mg/kg and E.D₅₀ of 'kodasuri veeravaippu' is 13 mg / kg.

Acute and chronic toxicity of the drug showed normal values of haematological parameters, Autonomic and CNS activity, biological activity and histopathological results of liver, lungs, kidney and spleen.

DISCUSSION

The cure or remedy for this difficult disease could be achieved by age old system of Ayurveda and Sidha. The use of herbs and other natural products proved to be very effective in control and cure of this crippling disease. Mahapatra, 2013 has described in a review article about a unique study conducted by allopathic physicians in which a total of 290 patients were enrolled and Ayurvedic physicians administered individualized treatment, closely adhering to principles set forth in classical Ayurvedic texts. The duration of treatment varied from 1 to 6 months and results showed statistically significant improvement in all parameters from admission to discharge. The results indicated that classical Ayurvedic treatment was effective in this first cohort of patients who completed treatment. Although there was no control group, the results were positive enough to warrant further study of classical Ayurvedic treatment for RA as controlled trials [7].

Medicinal herbs have been reported to be of great importance in the cure of RA.

The anti-inflammatory and free radical scavenging activity of *Ricinus communis* was observed by Ilavarasan *et al*, 2006 [8]. Another medicinal plant *Commiphora mukul* was effective in osteoarthritis of the knee [9]. The combination of *Boswellia serrata* and *Acacia catechu* was reported to be very effective on arthritis [10]. Anti-arthritic and anti-oxidant activity of leaves of *Alstonia scholaris* was reported by Sinnathambi *et al*, 2011[11]. Other reports of plant extracts and parts used for arthritis treatment include those of *Aristolocia bracteata* extracts, ethanolic leaf extract of *Cratogeomys haliacabum* Linn, keaqrt wood of *Cedrus deodar* (Roxb.), hydroalcoholic extract of *Lawsonia innermis*, chemical constituents of *Leonitis nepetefolia*, root extracts of *Withania somnifera* [12, 13, 14, 15, 16, 17, 18]. Tarannum *et al*, 2013 have described the curative effects of a polyherbal formulation prepared by Unani medicinal plants on knee osteoarthritis [19].

The present investigation however does not study the plants and their role in RA treatment. The study concentrates on the curative role of one sidha formulation, namely, Kodasuri Veervaiuppu on RA. This medicinal formulation is prepared with various natural salts after thorough cleaning and processing. The efficacy of this Sidha preparation was studied on patients with arthritis and the results were very encouraging. The reports of the use of natural salts for curative purposes are scanty.

Physio chemical analysis of the drug showed its potent ingredients such as Mercury, Copper, Iron, Sodium, Potassium, Chlorine, Manganese and Magnesium in the oxide form which play vital role in pharmoco therapeutic principle of the drug. These elements possess very good therapeutic value with major activities to cure all diseases mentioned in the literature. Through the present study the anti inflammatory and analgesic properties of this drug was established which is potent drug for the cure of disease 'keelvayu' (arthritis).

Toxicological studies made, explain the safe angle of the drug with its prescribed amount of elements like mercury within the ppm level. Normal histopathological and haematological results both in animal and human, explain the effective pharmacokinetic and pharmacodynamic properties of the drug.

CONCLUSION

'Kodasuri veeravaippu' is a unique formula of siddha medicine propounded by 'Yuhimuni' in his work 'Yuhimuni Vatha kaviyam' an excellent treatise of siddhers alchemy. For a disease like 'keelvayu' (arthritis) with its variety and variance of sign and symptoms, finding single medicine for therapy is challenging. The efficacy of 'kodasuri veeravaippu' proves to be one of that kind.

Physio chemical analysis shows oxide form of elements in nano particle level of varying sizes enriches the therapeutic efficacy and safety of the drug.

'Kodasuri veeravaippu' is economically cheap drug. The drug is effective in short duration of treatment in very little amount of dose are other advantages.

'Kodasuri veeravaippu' a great formulation of alchemy is proved as an effective and safety medicine with its anti inflammatory activity in treating the disease 'keelvayu'.

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