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ORIGINAL RESEARCH ARTICLE

Evalution of Parangipattai Rasayanam (Internal) and Lasunathy Thylam (External) Drugs Choices for Preclinical and Clinical Studies on the Kumbavaatham (Periarthritis Shoulder)

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ABSTRACT

The principle aim of this research is to evaluate the safety and therapeutic efficacy of the Siddha polyherbal formulation Parangipattai Rasayanam (internal) and Lasunathy Thylam (external)**.** The objectives and motivations are (i) Botanical identification and authentication of the trial drug (ii) Prepare the trial drug Parangipattai Rasayanam as per Siddha literature and analysis of qualitative and quantitative constituents present in the trial drug, (iii) to establish the toxicological profile by performing acute oral toxicity studies and sub acute toxicity studies on mice and rats following WHO guidelines, (iv) to Study the Safety and efficacy of the test drug through an open clinical trial, (v) Analyze the prevalence of Kumbavaatham among the society through Age, Sex, Occupation, Distribution etc.

Key words: Parangipattai Rasayanam, Lasunathy Thylam, Kumbavaatham.

INTRODUCTION

Health of an individual is assessed by the way a person who leads his life. This means not only the physical activities of a person but also the mental makeup. In recent times due to life style modifications, lot of dreadful changes have started occurring in an individual's physical and mental health which can cause hindrance to the progress of a person's day to day activities [1]. The Siddha system can provide longevity, even immortality to the society through yoga and medicines prepared from meticulously processed minerals, herbal extracts and their rejuvenating compositions. Siddhar Yugi Munivar in his Yugivaithiya Chinthamani - 800 described about 80 types of Vaatha diseases. KumbaVaatham is one among them. As per his poem symptoms of kumba vaatham are pain in the shoulders, arms, burning sensation in the eyes, benumbed feeling in the neck and giddiness, Dizziness [2, 3]. These symptoms may be correlated with that of periarthiritis shoulder in modern science. The main symptoms of the Periarthritis shoulder are acute shoulder pain, restricted movements in upper limb, loss of abduction and forward flexion followed by stiffness of the shoulder joint [4]. The estimated prevalence of frozen shoulder is 2%–3% in the general population and 5%–6% in patients evaluated by shoulder surgeons. Age incidence ranges from 40 to 70 year; predominantly females are affected [5]. Surgery is one of the treatment options for periarthritis shoulder in Allopathic system. So the people are in search for a treatment which is free from side effects and can cure the disease. The Internal drug Parangipattai rasayanam is an herbal preparation. It won't cause any side effects. Most of the drugs in lasunathy thylam which is used for external application have Anti –Vaatha property **[Anti-inflammatory and anti-nociceptive activities of drugs**] [6-10]. So a preclinical and clinical study on the kumbavaatham (periarthritis shoulder) and the drug of choice is Parangipattai Rasayanam [11] (internal) and Lasunathy Thylam [12] (external) has been framed to find out the efficacy of the internal and external medicines in the treatment of Kumbavaatham (periarthritis shoulder).

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MATERIALS AND METHODS

Clinical Features:

Table 1: Clinical Features

Clinical Features	No. of Patients	Percentage
Pain in Shoulder	40	100.00%
Swelling in Shoulder	4	10.00%
Benumbed feeling of Shoulder joints	39	97.50%
Restricted movements	40	100.00%
Minimal tenderness	40	100%

Inference

All 40 patients had pain in shoulder, 39 have benumbed feeling and only 4 had swelling in shoulder.

Prognosis:

Table 2: Prognosis

Clinical Features	No. of Patients		No. of Patients Recovered	Percentage of Patients Recovered
	Pre Treatment	Post Treatment		
Pain in Shoulder	40	4	36	90.00%
Swelling in Shoulder	4	0	4	100.00%
Benumbed feeling of Shoulder joints	39	0	39	100.00%
Restricted movements	40	1	39	97.50%
Minimal tenderness	40	0	40	100.00%
Early Morning Stiffness	26	1	25	96.15%

Inference

Among 40 patients 36 got relieved from pain and all 40 patients got relieved from minimal tenderness in shoulder, all 4 got relieved from swelling in shoulder joint, all 39 got relieved from benumbed feeling and 39 got relieved from restricted movements.

RESULTS

Statistical Analysis

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired‘t’ test was performed for determining the significance between before and after treatment.

Table 3: Stastical Analysis

	Mean	Std Deviation	Significant
Before	5.58	1.318	**p<0.001**
After	0.33	0.694	

Inference

The Mean ± Standard Deviation of pain score at before and after treatment were 5.58 ± 1.318 and 0.33 ± 0.694 respectively which is statistically **highly significant (p<0.001).**

DISCUSSION

Kumbavaatham has increased in incidence now days due to various life style modifications. Severity of the disease attracts the attention of physicians to implement various therapies. Numerous medicines have been tried previously for treating this condition. Taking into account the indication of trial drugs in sastric texts and pharmacological activities of ingredients, they were chosen for study.

The internal medicine Parangipattai Rasayanam was analyzed methodically. Biochemical and pharmacological analysis were done. Acute and subacute toxicity studies were carried out to confirm the safety of the drug. The biochemical markers of liver and kidney function tests did not show evidence of liver and kidney toxicity. There was no significant change in biochemical parameters like blood cholesterol, blood sugar. No significant changes in body weight, food, water intake were observed in drug treated animals when compared to controls.

The treatment was aimed to normalize the deranged kuttram and to provide relief from the symptoms. Before treatment the patients were advised to take Agasthiyar Kuzhambu-130 mgs with zinger juice, during early morning for purgation followed by rest on that day. The next day onwards treatment with the trial drug **parangipattai rasayanam (**internal**) 6gm twice**

daily for 24 days with milk and lasunathy Thylam (external) **50ml for external application.**

During treatment, the patients were advised to follow pathiyam (diet restrictions). 40 patients were admitted for trial, among whom 30 were out-patients and 10 were in-patients. Progress of the patients was documented regularly. Various criteria like gender predominance, incidence of the disease with respect to the age, kaalam (seasonal variation) and diet were assessed. Clinical manifestation and assessment of the improvement in the prognosis of the disease with trial drugs were taken into account for evaluating the efficacy of trial drugs. The study reveals highest range of occurrence of disease between the age of 36 – 45 and 46-55 among 40 patients. It is due to the degenerative changes in this age group. Among the 40 patients, home makers were in higher percentage (57.5%), persons in cooly 22.5% occupation is followed by mechanics 7.5%, engineers (5%), tailors (5%). drivers (2.5%), Heavy house-hold works act as an aggravating factor in home makers

Females are affected more than males among study sample (60%).This may be due to increased work load and deficiency state of nutrients. Among 40 patients, 2 patients (5%) were Vegetarians and 38 patients (95%) were Non-vegetarians.Among 40 patients, 31 patients (77.50%) have Thontha udal, 6 patients (15%) have Pitha udal and 3 patients (7.5%) have Kaba udal. On considering the socio-economic status, 57.5% subjects of study sample were from lower income group, 35% were from middle income group and the remaining 7.5% were from high income group. 73% of patients were reported from Neithal nilam, 23% of patients were reported from Marutham nilam and 3% were from Kurinji and Mullainilam. Highest occurrence 60% was reported in Ilavenil kaalm and 40% was reported during mudhuvenil kaalam. According to Siddha literature, the Vaatha kuttram attains thannilai valarchi (mild derangement) during Mudhuvenil kaalam. Among 40 patients, coating in tongue is seen in 12 patients, Pallor is seen in 2 patients and 26 patients have normal tongue. After treatment all the patients have normal tongue. Before treatment, 3 patients told their malam is seen as constipation, 3 patients told as stool bulk and another 3 patients as consistent. After treatment, normal Malam is seen in all the patients. Viyanan and Samanan vayus (pain and restricted movents in the shoulder joints) were affected in all the 40 patients. Abana vayu was affected (constipation) in 3 patients and koorman (dull vision) in 3, devaathathan (sleeplessness) in 1 patient. In Pitham, anarpitham (loss of appetite) was affected in 1 patient and Sathaga pitham (cant do day today activitys) in 40 patients. In Kabam, Santhigam (shoulder joint) was affected in all the 40 patients and this would have resulted in the joint involvement.

Enbu thathu was affected in all the 40 patients (100%) It is due to the involvement of clenoid cavity of scapula and humerus. Saaram (general tiredness) was affected in 2 patients (50%), Seneer (pallor) in 2 subjects (50%), Oon (spasmodic pain) and kozhupu (restricted movements in shoulder joints) in 40 patients (100%).Naadi nadai (Pulse reading) was examined in all the patients. 62.5% patients had vaatha pitha naadi and 17.5% subjects had pithavaatha naadi, 10% kabavaatham and pitham 7%, kabapitham 2.5%. Among 40 patients, abnormal Niram (yellow colour) is seen in 15 patients and abnormal Manam (odur) is seen in 4 patients. After treatment, Niram and Manam have become normal in all the patients who were affected. In Neikkuri Examination (Oil on urine sign), serpentine fashion was seen in 27.5% subjects and pearl fashion was seen in 72.5% patients

Among 40 patients of the trial 100% patients were reported with pain in the shoulder joints and restricted movements and Minimal tenderness and 97.5% of patients reported benumbed feeling of Shoulder joints and 10% reported Swelling in the Shoulder joints. All the 40 cases, (100%) were found to posses Rasatha gunam.

Before treatment, Mei (warmth in shoulder joints) was affected in 12 patients, vai (carries teeth) was affected in 3 patients and kann (dull vision) was affected in 3 patients. After treatment all the patients affected by Mei (warmth in shoulder joints) was relieved. But patients who were affected by vai and kann remain affected. Kai was affected in all the 40 patients, and all the cases were relieved from the symptoms after treatment. Kaal was affected in 2 patients, and the symptoms were relieved after treatment. Eruvai was affected in 3 patients, and the symptoms were relieved after treatment. Vai was affected in 2 patients, no one got relieved from symptoms after treatment. Among 40 patients, Vignanamaya kosam is affected (pain and restricted movements in

shoulder joints) in all the 40(100%) patients. After treatment, 8 (20%) patients were affected by Vignanamaya kosam. Remaining 32 (80%) patients were relieved. Laboratory investigation of blood and urine were done for all 40 subjects prior to and after trial. There were significant changes in ESR and Hb parameters. Pre-treatment and post-treatment results of Liver function tests and renal function tests were normal. The radiographic studies of the subjects showed presence of osteophytic changes. The trial drug showed reduction in clinical signs and symptoms rather than any changes in radiographic studies. After treatment, 90% patients recovered from pain in the shoulder joints and 97.5% recovered from restricted movements and 100% recovered from Minimal tenderness and benumbed feeling of Shoulder joints and Swelling in the Shoulder joints.

Outcome measures

Primary outcome observations

Nature of pain (pain assessment scale-Annexure i)

Among 40 cases, As per the numerical Pain assessment scale,

In 32 (80%) cases there was no pain after treatment.

In 8 (20%) cases there was mild pain after treatment.

Improvement in pain assessment per patient

Among them, 40 cases have shown reduction in pain after the completion of treatment. Hence

The range of improvement varies as stated below

8 (20%) cases had improved 2 grades after treatment.

32(80%) cases had improved 1 grade after treatment

Secondary outcome observations

i. Clinical symptoms

Observation with reference to clinical symptoms

a. Pain:

Among the total number of 40 cases,

- In 32 (80%) cases there was complete relief of pain.
- In 8 (20%) of cases there was reduction in pain.

b. Aggravating factor on movements

Among the 40 cases, 40 (100%) cases were pain aggravating on movements before treatment.

But in 40 (100%) cases there was no pain aggravating on movements after treatment.

c. Releiving factor – during rest

Among the 40 cases, 17 cases were pain relieved during rest and 23 cases were no pain relieved during rest before treatment

- In 38 (95%) cases were pain relieved during rest after treatment.
- In 2 (5%) cases were no pain relieved during rest after treatment

d. Restriction of shoulder joints

Among the 40 cases, 29 cases were partial restriction movement in the shoulder joints present and 11 cases were fully restriction movement in the shoulder joints present before treatment

But

1. In 39 (97.5%) cases were no restricted movement in the shoulder joints after treatment
2. In 1 (2.5%) cases were partial restricted movement in the shoulder joints present after treatment

ii. Statistical analysis

a. Pain assessment scale before and after treatment

Bio statistical analysis

The clinical trials of the drug PARANGIPATTAI RASAYANAM (Internal) and LASUNATHY THYLAM (External) are differentiated in terms of percentages. The effectiveness of the drug is assessed by using paired comparison test (paired t test). The responses (intensity of pain) of the patients to the drug are analyzed.

Assessment of the effectiveness of drug

The effectiveness of the drug was assessed by the relief of the patients from pain, and which is measured using a standard pain scale.

INFERENCE: The test drug is is **highly statistically significant ($p<0.001$)** and hence effective in reducing the pain

b. Erythrocyte sedimentation rate (ESR)

Though there was improvement in 22 patients (55%), there was no significant increase after the treatment statistically

Summary

The aim of the study is to evaluate the safety and efficacy of trial drug for Kumbavaatham. Institutional Ethical Committee (IEC) of National Institute of Siddha (NIS) had given approval to

the project entitled Safety and Efficacy of parangipattai rasayanam (internal), lasunathy Thylam (external) in KumbaVaatham. **Approved IEC No:NIS/IEC/2011/3/08 - 24/12/2011**. Institutional Animal Ethical Committee (IAEC) had approved for animal study. **Approved IAEC No: 1248/ac/09/CPCSEA/4-08/2011 - 20/12/2011.** The raw drugs were authenticated by the concerned department and the trial drug was prepared by the investigator in the Gunapadam lab of National Institute of Siddha as per the Standard Operating Procedure mentioned in the protocol. The medicine was then subjected to pre clinical toxicity studies (Acute and long term toxicity studies) as per the protocol and the safety of the drug was ensured.

The qualitative and quantitative bio chemical studies were done at the bio chemistry lab of National Institute of Siddha Chennai respectively. For the clinical study 40 cases were selected based on the Inclusion criteria and Exclusion criteria, Out of 40 cases, 30 cases were treated in OPD and 10 cases were treated in IPD of Ayothidass Pandithar Hospital, National Institute of Siddha, Chennai-47. Clinical diagnosis of kumbaVaatham was done by Siddha and Modern methodologies. Informed Consent was obtained from the Patients before starting the treatment. Investigations were carried out before and after the treatment. The day before starting the trial drug treatment Agasthiyar Kuzhambu - 130 mgs with zinger juice, during early morning for purgation followed by rest on that day, was given to correct the elevated kuttrams. The clinical trial was conducted in 40 patients of kumbavaatham the drug **PARANGIPATTAI RASAYANAM (**internal**) 6gm twice daily for 24 days with milk and LASUNATHY THYLAM** (external) **50ml for external appication**. Diet restriction was strictly followed during the period of drug administration as well as re dieting period (Diet free of salt, tamarind etc) is noted in the form IV D (Dietary advice form). Clinical assessments were made daily in the IPD cases and 12 days once in OPD cases and observation were noted in the concerned forms. During the study period there was no adverse drug reactions occur. Among 40 cases, 90% patients recovered from pain in the shoulder joints and 97.5% recovered from restricted movements and 100% recovered from Minimal tenderness and benumbed feeling of Shoulder joints and Swelling in the Shoulder joints.

The results of the study reveal the fact that these medicines are efficacious in reducing pain, benumbed fleeing and restriction of movements in kumbavaatham. As per the Siddha Literature and modern science reviews and research articles, the ingredients of the trial drugs were found to have the property of controlling the Vaatha diseases, some drugs exhibited anti inflammatory and analgesic action owing to the disease manifestations. In case of Clinical Lab parameters there was reduction in ESR which showed the therapeutic effect of the drug in controlling the disease to a greater extent. Qualitative analysis reveals parangipattai rasayanam contains, nitrates, sulfates, tanic acid, Iron, Calcium, unsaturated compounds. Statistical analysis showed significant reduction in pain scale before and after the treatment **(p<0.001)**. Oral toxicity studies conducted ensured the safety usage of the drug to animals up to a maximum dose of 1800 mg/animal.

CONCLUSION

Siddha literature is treasured with numerous formulations of medicines for various disease conditions. This study was done with the sastric medicines **parangipattai rasayanam (internal) and lasunathy Thylam** (external). These are indicated for vaatha diseases in the texts. Among 40 cases, 90% patients recovered from pain in the shoulder joints and 97.5% recovered from restricted movements and 100% recovered from Minimal tenderness and benumbed feeling of Shoulder joints and Swelling in the Shoulder joints. The results of the study reveal the fact that these medicines are efficacious in reducing pain, benumbed fleeing and restriction of movements in kumbavaatham. The safety studies (the acute toxicity and subacute toxicity) studies conducted revealed that the trial drug was safe even at higher dosage of 1800 mg/animal. There were no abnormalities found in histopathological examination .Hence it can be reasonably assumed that the drug is safe for human.

Statistical analysis showed significant reduction in pain scale before and after the treatment **(p<0.001)**. There was a reduction in the elevated lab parameters ESR after the treatment revealing the contol of the disease. There were no adverse reactions complained during the trial. Because of the encouraging clinical outcome, the study may be further carried out with the same drug in a large number of cases. Thus it is concluded the medicines **parangipattai rasayanam (internal)**

and lasunathy Thylam (**external**) reducing pain, benumbed fleeing and restriction of movements in kumbavaatham.

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