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**Clinical study of Siddha drug for “Kumbavaatham”
(Periarthritis)**

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Abstract

The great sage *Yugi* mentioned in his text *Yugi vaithyachinthamani* classified vatha diseases into 80 types and *kumbavatham* is one among them that can be correlated with symptoms of Periarthritis of shoulder joint. Shoulder pain is the third most common musculoskeletal condition that has a life time prevalence of up to 70% and this seems to be increasing in incidences. prevalence of frozen shoulder is estimated to be 2%to5% in general population. Selected “*Rajaelathy chooranam*” (Internal medicine) and *Nathaichooriennai* (External medicine) along with *varmamtheraphy* for treating the disease with minimum cost effective. In this study, Very Good improvement were observed in 10% of cases with Varmam and 5% of cases without Varmam group, Good improvement were observed in 85% of cases with Varmam and 55% of cases without Varmam, Moderate improvement. observed in 35% of cases without Varmam group and 5% of cases in both the groups shows Mild improvement. The result of group A (with Varmam) is significant than group B (without Varmam). So, the Varmam therapy is beneficial in *Kumbavaatham* patients along with trial medicine. The outcome of this study was clinically observed by SPADI Score, which showed encouraging results of very good improvement in 3 patients (7.5%), good improvement in 28(70%) patients, moderate improvement in 7 Patients (17.5%) and mild improvement in 2 case (5%). Laboratory investigations were done for all the cases before and after treatment. There were no significant variations in hepatic, renal and other parameters before and after treatment. In this study, no adverse events were observed during the course of the treatment. At the time of discharge, all the patients were advised to attend Out-Patient Department of SirappuMaruthuvam of NIS for further follow-up treatment.

Keywords: Siddha drug, Internal medicine (*Rajaelathy chooranam*) and External medicine (*Nathai chooriennai*) kumbavaatham (periarthritis)

Introduction

A great deal of siddha medicine comes to us from the selfless work of untiring souls called Siddhars who preferred obscurity. They are the greatest scientists both material and spiritual of ancient period. The Siddhars sought to reveal the deepest truth of human physiology and health. These siddhars teachings were customarily passed on orally from teacher to student over decades. Siddha is not only a science of medicine but it includes several other disciplines like the *rasavatham* (alchemy), *kayakarpam* (rejuvenation), *yogam*, *panjapatchisastram*, *saram*, *varmam* etc.

The great sage *Yugi* mentioned in his text *Yugi vaithyachinthamani* classified vatha diseases into 80 types and *kumbavatham* is one among them that can be correlated with symptoms of Periarthritis of shoulder joint. Shoulder pain is the third most common musculoskeletal condition that has a life time prevalence of up to 70% and this seems to be increasing in incidences. prevalence of frozen shoulder is estimated to be 2%to5% in general population. People with diabetic mellitus are at greater risk of developing periarthritis with a prevalence of

10% to 12%, Periarthritis shoulder is defined as a clinical syndrome characterized by pain, restriction of both active and passive shoulder movements due to cause within the shoulder joint or remote. The patients have constant shoulder pain with restriction of movements and unable to do the daily routine activities.

The current clinical treatments mainly include administration of non-steroidal anti-inflammatory drugs, muscle relaxants, physiotherapy, analgesics, and so on. The treatment in other system does not give complete relief. The most optimal treatment has not yet been established. The visitation of *kumbavaatham* increases day by day at Ayothidhas Pandithar hospital and constant shoulder pain and restriction of movement are affecting the routine life, and this reaction made me to select this treatment protocol.

Hence, I had selected "*Rajaelathy chooranam*" (Internal medicine) and *Nathaichooriennai* (External medicine) along with *varmamtherapy* for treating the disease with minimum cost effective. The selected internal medicine is mentioned in the text *Kosayae Anuboga Vaithiya Brahmaragayasam 2nd* part and external medicine in the text *Sarabenthra Vaithiya Muraigal- Vatharogasigitchai*, the ingredients of internal drug *Milagu- Piper nigrum*, *Elam-Elattaria cadamomum*, *Kirambu- Syzygium aromaticum* have the anti-inflammatory, analgesic and anti-oxidant properties

Materials and Methods

Standard operating procedure:

Source of trial medicine:

The required raw drugs for the trial medicines will be purchased from a well reputed country raw drug shop then raw drugs will be authenticated by the department of Medicinal botany National Institute of Siddha. Authenticated raw drugs will be purified separately and then the trial drugs will be prepared as per the literature in Gunapadam Laboratory of National Institute of Siddha.

Preparation of trial drugs

Internal Drug: Rajaelathy chooranam

Ingredients

- Elam (Fruit of *Elattaria cardomomum*)
- 64 Varaganeadai (269gm)
- Chukku (Rhizome of *Zingiber officinale*)
- 32 Varaganeadai (134.4gm)

- Koogaineer (Tuber of *Maranta arundinaceae*)
- 16 Varaganeadai (67.2gm)
- Thalissabathri (*Abies spectabilis*)
- 8 Varaganeadai (34gm)
- Serunaga poo (Flower of *Mesuna nagassarium*)
- 4 Varaganeadai (17gm)
- Milagu (Fruit of *Piper nigrum*)
- 2 Varaganeadai (8.4gm)
- Kirambu (Flower of *Syzygium aromaticum*)
- 1 Varaganeadai (4.2gm)
- Sugar - 1 ½ saer (420gm)

Purification of raw drugs:

Purification of Chukku: Soak in lime stone water and dry it in shade then peel off the outer layer [Ref: Sarakugalin Suthee Muraigal, Pg .6]

Purification of Milagu: Soak in butter milk for a period of 1 saamam (3 hours) then allow it to dry. [Ref: Sikicha Rathin Deepam Ennum Vaithiya Nool, Page 28]

Purification of Kirambu: Dry it in sunlight and fry. [Ref :Sarakugalin Suthee Muraigal Page : 6]

Purification of Thalissabathri: Dry it in sunlight.[Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool, Page 28]

Purification of Sirunagapoo: Dry it in sunlight.[Ref: Sikicha Rathina Deepam Ennum Vaishya Nool, Page 28]

Purification of Elam: Dry it in sunlight and fry. [Ref: Sarakugalin Suthee Muraigal, Page :6]

Purification of koogaikilangu : Dissolve in pure water for 7 times and filter it and dry it in sunlight. [Ref : Sikicha Rathina Deepam Ennum Vaithiya Nool.

External drug

Nathaichooriennai:

Ingredients:

- Nathaichooriveer (Root of *Spermacoce hispida*)
- 3palam (105gm)
- Vasampu (Rhizome of *Acorus calamus*)
- ¼ palam (12gm)
- Poondur (Bulb of *Allium sativum*)
- ¼ palam (8.75gm)
- Amanakkuennai (Oil of *Ricinus communis*)
- 1 padi (1.34litre)

Method of preparation:

Grind the raw drugs mix it with castor oil and heat it until attaining suitable consistency.

Drug storage:

The drug Rajaelathy Chooranam is stored in a clean glass jar and Nathai Choori Ennai is stored in a clean and dry narrow mouthed bottle.

Dispensing:

The Rajaelathi Chooranam will be given in packets and Nathaichooriennai will be given in bottles.

Varmam Points to be applied for the Patient:

KavuliKaalam
Vellaivarmam
Kaipujaporuthuvarmam

Clinical study

Study design:

Study type : An open clinical trail

Study place : OPD and IPD of
Ayothidoss Pandithar Hospital, National Institute of
Siddha, Tambaram Sanatorium, Chennai - 47.

Study period :18 Months

Sample size : 40 patients (Both IPD & OPD)

Subject Selection:

Patients reporting with symptoms of *Kumbavaatham* will be subjected to screening using screening proforma then they will be involved for the trial by fulfilling the inclusion criteria.

Inclusion Criteria:

Age: 20-60yrs, Sex: Both male and female, Pain and stiffness in shoulder region, Restricted movements of shoulder joint, Exacerbation of pain on movement

- Restricted movements of shoulder joint (abduction and external rotation)
- With or without pain radiating to upper arm
- Patients willing undergo radiological investigation and give blood samples for laboratory investigations
- Patient willing to sign the informed consent stating that he/she will consciously stick to the treatment but can opt out of the trial of his/her own conscious discretion.

Exclusion Criteria:

Diabetes Mellitus, Pregnancy and lactation, Cardiac disease, Septic arthritis, Malignant hypertension,

Gonococcal arthritis, Fracture and dislocations of shoulder joint, Cervical spondylosis, Any other chronic illness

Withdrawal Criteria:

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.

Tests and Assessments:

- A. Clinical assessment
- B. Laboratory Investigations
- C. Radiological investigations
- D. Siddha system examination

A. Clinical Assessment

Pain and stiffness in Shoulder joint, With or without radiation of pain to upper arm, Exacerbation of pain on movements, Restricted movements [abduction and external rotation]

B. Laboratory investigations:

Blood: H B, Total WBC Count, DC, Total RBC count, ESR (½ hr, 1hr), Blood sugar - Fasting, Post prandial, Serum cholesterol, uric acid, CRP, RA factor, ASO titre

Renal function tests:

Blood Urea, Serum Creatinine

Liver function tests:

Serum total bilirubin, Direct bilirubin & Indirect bilirubin, Serum Alkalinephosphatase, SGOT & SGPT

Urine:

Urine sugar – Fasting & Post prandial, Albumin, Deposits

C. Radiological investigation

X - Ray Shoulder joint: AP and Lateral View.

D. Siddha parameters:

Naadi, Sparisam, Naa, Niram, Mozhi, Vizhi, Malam, Moothiram

a. Neikkurib. NeerKuri:

Study enrollment:

Patients reporting at the OPD with the clinical symptoms of KUMBAVATHAM will be examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form V) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent would be obtained in writing from them in the consent form (Form VI).

Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma. Screening Form-I will be filled up: Form -II and Form - III will be used for recording the patient history, clinical examination of symptoms, signs and laboratory Investigation. If there is any abnormal Laboratory Reports obtained then excluded from the study.

Patients will be advised to take the trial drug and to follow the appropriate dietary advice. (Form -VIII)

Conduct of the study:

Purgation with Meganaatha Kuligai - 2 early morning with Hot Water will be given for balancing the deranged Mukuttram before starting the treatment. (Ref: *Siddha formulary of India. Part- I*)

Next day onwards the trial drug, RAJAEATHY CHOORANAM (Internal) and NATHAICHOORI ENNAI (external) are given continuously for 48 days. OPD patients are requested to visit the hospital once in 7 days. In each and every visit clinical assessment is done and prognosis is noted in the Prescribed Proforma. For IPD Patients clinical assessment is done daily. 20 patients will be given Varmam treatment along with trial medicines and the remaining 20 will be given medicine only. If there is need of IPD patients will be admitted in the ward for the clinical assessment. Laboratory investigations and Radiological investigations are done before and after the trial. At the end of the treatment, the patient will be advised to visit the OPD for follow-up. Defaulters will not be allowed to continue and be withdrawn (Form VII) from the study.

Data analysis:

After enrolling the patient for the study, a separate file for each and every patient will be opened and all forms will be kept in the file. Study No. and Patient No. will be written on the top of file for easy identification.

Whenever the patient visits OPD during the study period, the respective patient's file will be taken and necessary entries will be made at the assessment form or other suitable form. The screening forms will be filed separately. The data recordings will be monitored for completion and adverse event by HOD and pharmaco-vigilance committee. All forms will be further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased report.

Adverse effect/serious effect management

In this study, no adverse reactions were observed during the course of treatment.

Outcome:

Shoulder improvement assessed by following assessment:

Shoulder Pain and disability index (SPADI)

Source:

Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. *Arthritis Care Res.* 1991 Dec;4(4):143-9.

The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities. The pain dimension consists of five questions regarding the severity of an individual's pain. Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-extremity use. The SPADI takes 5 to 10 minutes for a patient to complete and is the only reliable and valid region-specific measure for the shoulder.

Scoring instructions

To answer the questions, patients place a mark on a 10cm visual analogue scale for each question. Verbal anchors for the pain dimension are 'no pain at all' and 'worst pain imaginable', and those for the functional activities are 'no difficulty' and 'so difficult it required help'. The scores from both dimensions are averaged to derive a total score.

Interpretation of scores

Total pain score: $\frac{\text{score}}{50} \times 100 = \%$ (Note: If a person does not answer all questions divide by the total possible score, e.g. if 1 question missed divide by 40)
Total disability score: $\frac{\text{score}}{80} \times 100 = \%$

(Note: If a person does not answer all questions divide by the total possible score, e.g. if 1 question missed divide by 70) Total Spade score: / 130 x 100 = %

(Note: If a person does not answer all questions divide by the total possible score, e.g. if 1 question missed divide by 120)The means of the two subscales are averaged to produce a total score ranging from 0 (best) to 100 (worst).Minimum Detectable Change (90% confidence) = 13 point (Change less than this may be attributable to measurement error) Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Outcome:

- Very good – 76-100% reduction of SPADI Score
- Good – 51-75% reduction in SPADI Score
- Moderate – 26-50% reduction in SPADI Score
- Mild – 0-25% SPADI Score

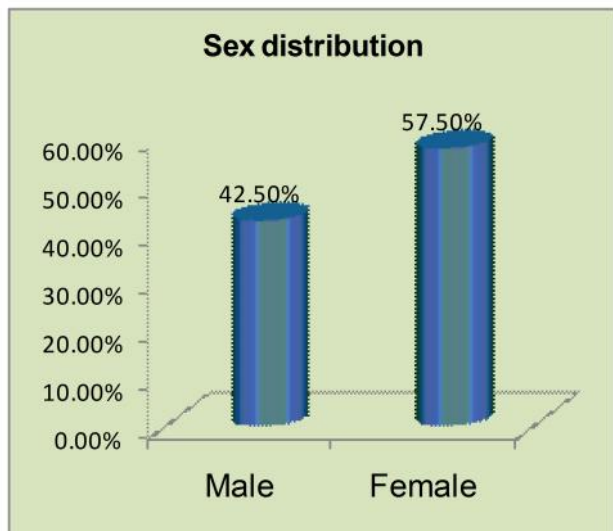
Observations and Results

The trial drug *Rajaelathy chooranam*(Internal) and *Nathaichooriennai* (External) were given to 40 patients for 48 days.

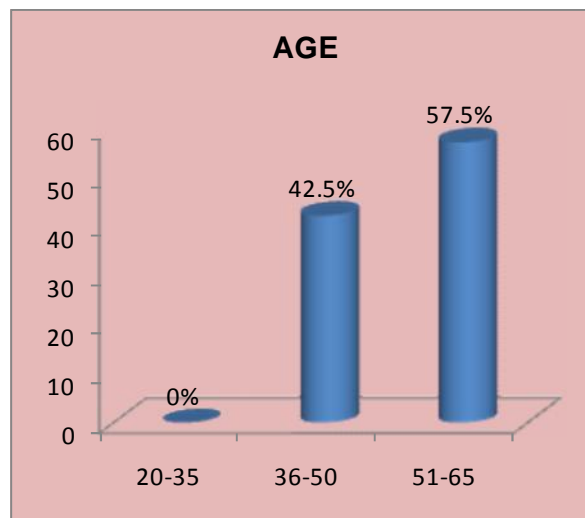
Observation:

The trial drug *Rajaelathy chooranam* (Internal) and *Nathaichooriennai* (External) were given to 40 patients for 48 days. Very Good improvement was observed in 3 patients (7.5%), Good improvement was observed in 28 patients (70%), moderate improvement in 7 patients (17.5%), and mild improvement in 2 (5%) cases.

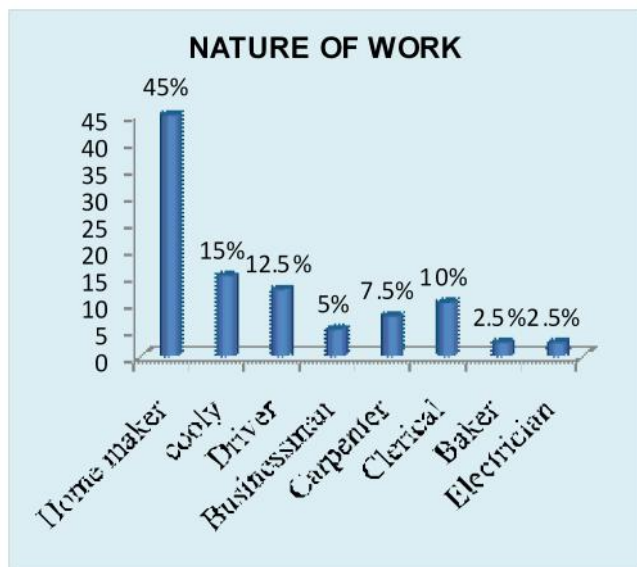
1. Sex distribution:



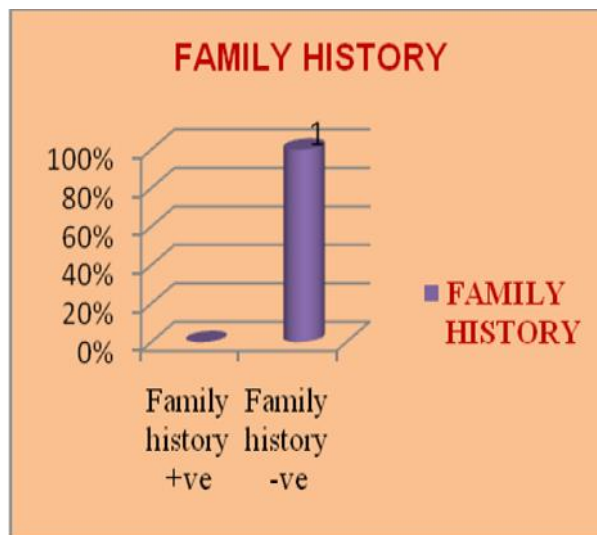
2. Age distribution:



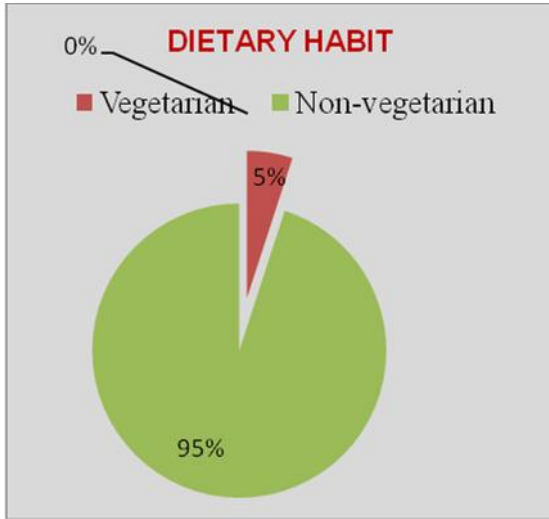
3. Occupational status:



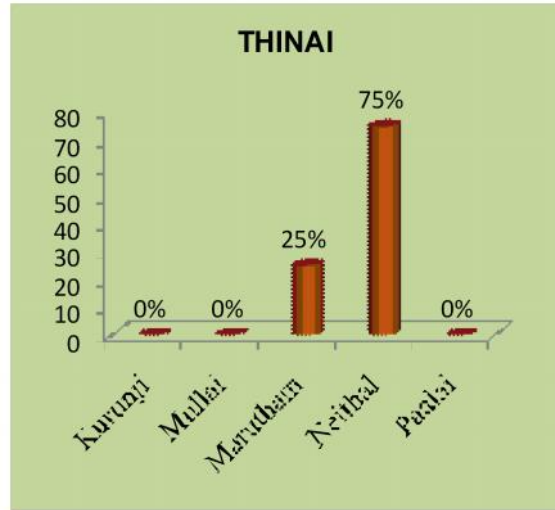
4. Family history;



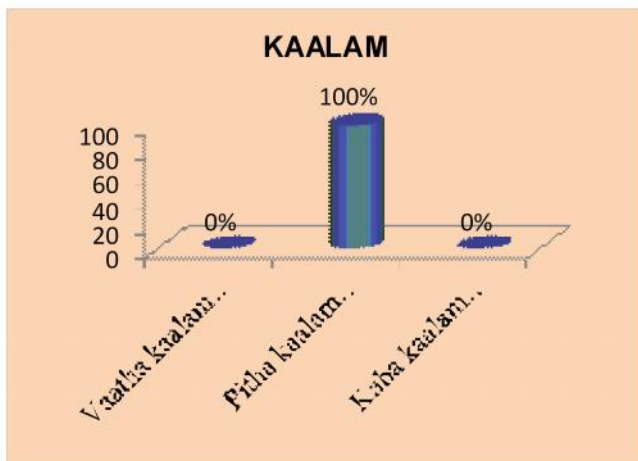
5. Dietary habits:



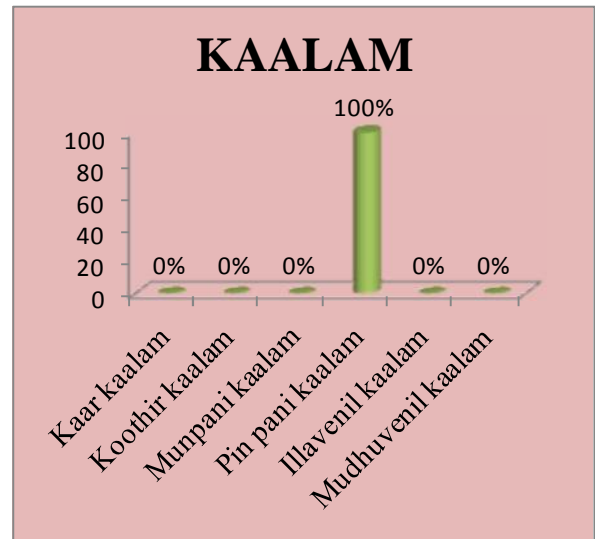
6.Thinai distribution:



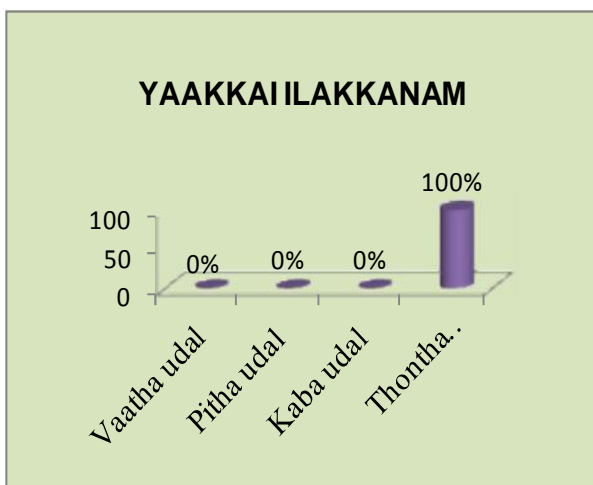
7. Kaalam distribution (According to age)



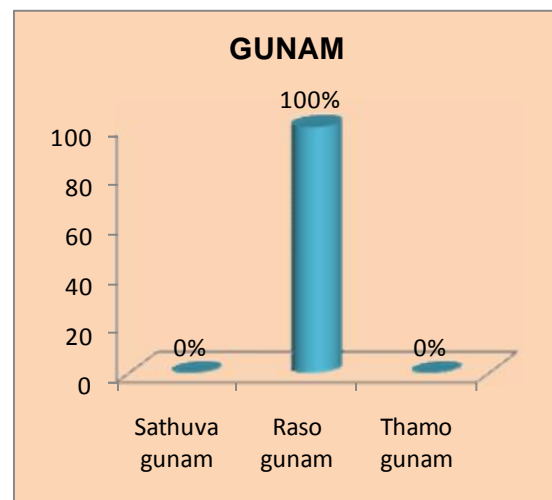
Kaalam distribution:



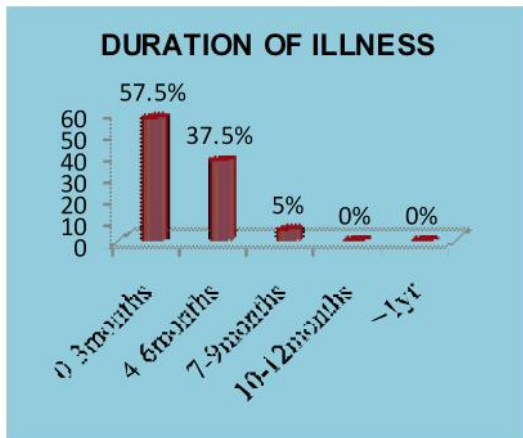
8. Yaakkailakkanam (Physical constituents)



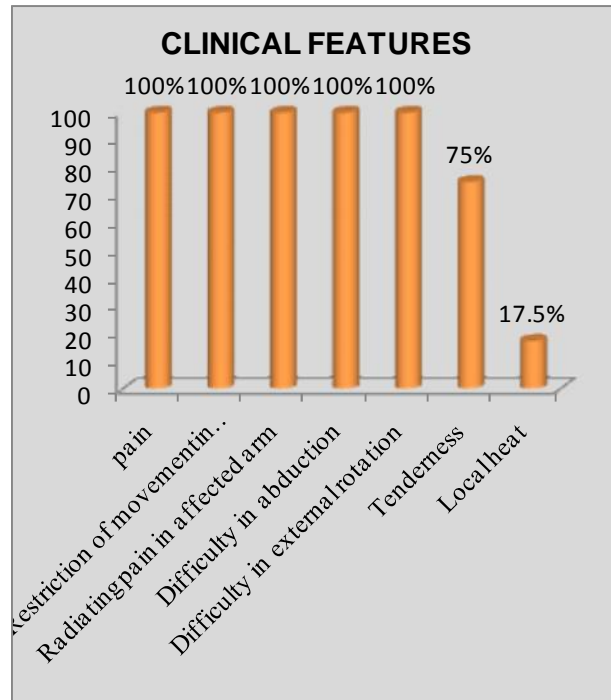
9. Gunam (Quality and Character)



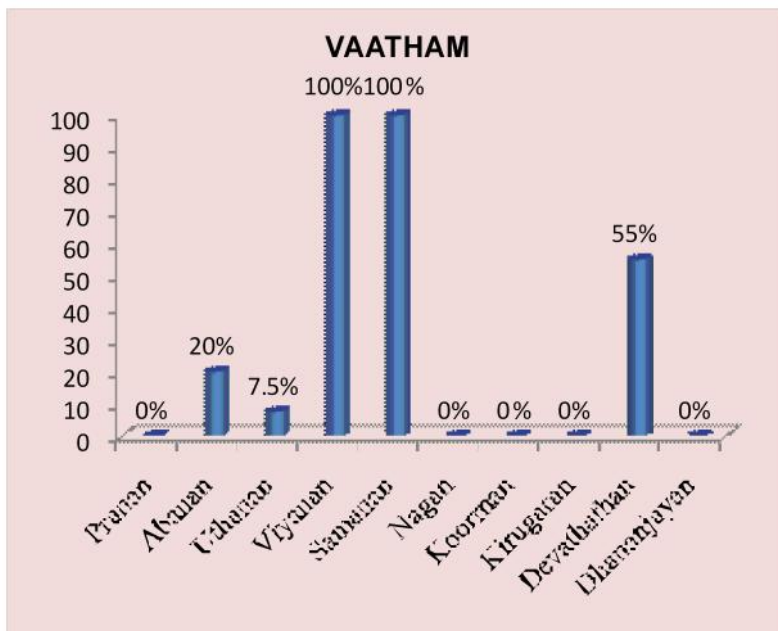
10. Duration of illness:



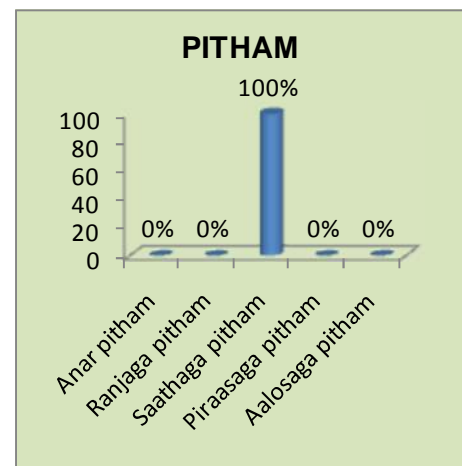
11. Clinical features:



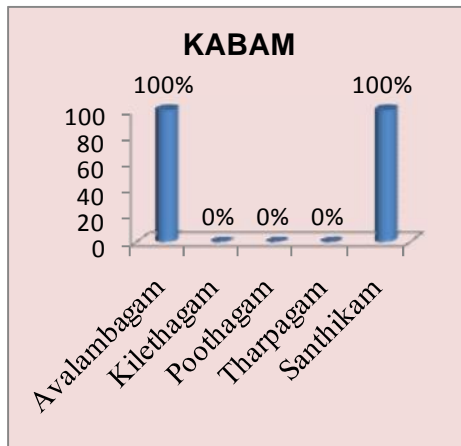
12. Distribution of Mukkutram - Vaatham:



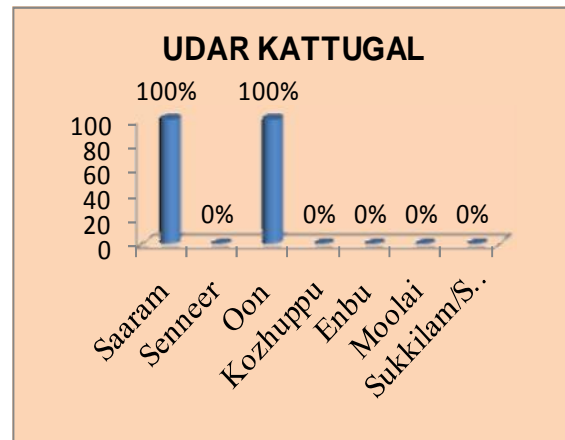
Pitham:



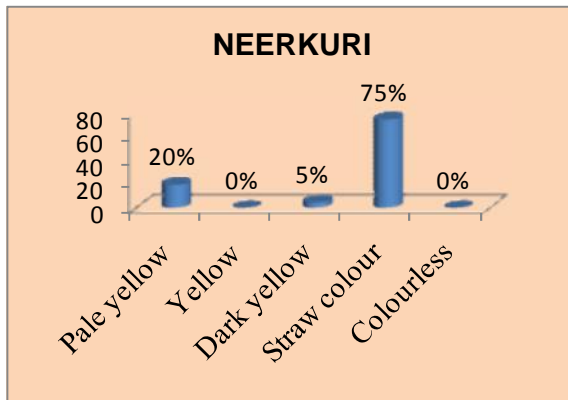
Kabam:



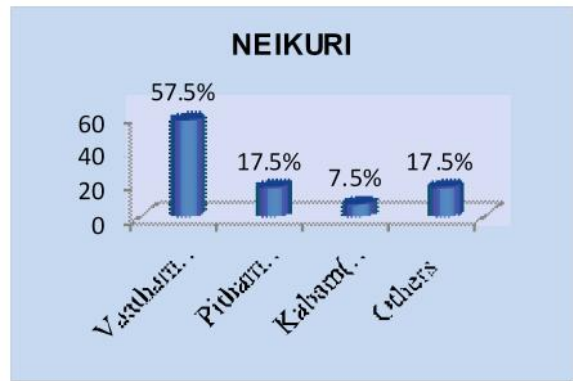
13. Udarkattugal:



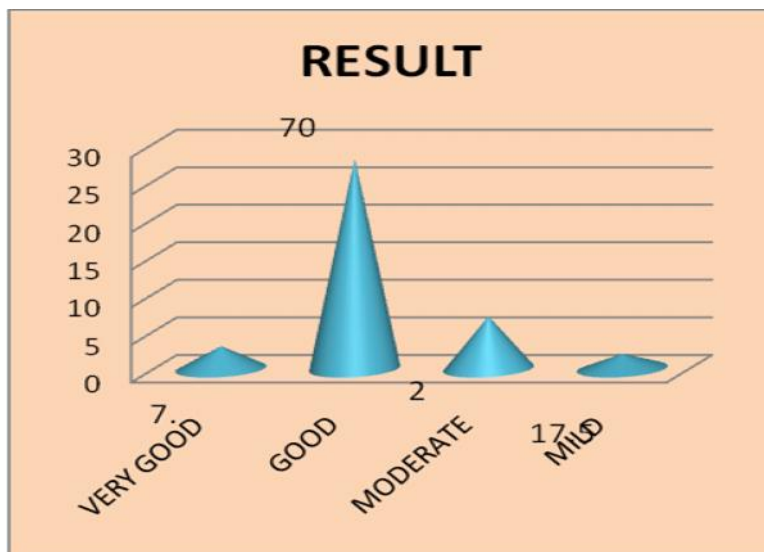
14. Neerkuri Reference:



15. Neikuri Reference



Results



Discussion and Conclusion

Periarthritis (*Kumbavatham*) is one of the Painful and Disabling disorders of unclear cause in shoulder capsule the connective tissue surrounding the glenohumeral joint of the shoulder. People who suffer from periarthritis usually experience severe pain and sleep disturbances, they have extreme difficulty concentrating, working or performing daily activities for extend period of time. The condition tends to be self-limiting and usually resolves over time without surgery.

In Siddha System, it is necessary to bring the vitiated humours to equilibrium. Hence before the treatment *Meganatha kuzhigai-2* pills with warm water was given for *Viresanam*(Purgation) in the early morning to normalize the vitiated humours. During the treatment, the patients were advised to follow *pathiyam* (Dietary regimen).

Internal Drug: *Rajaelathy chooranam*- 1gm two times per day with water.

External Drug: *Nathaichooriennai* for external application.

Duration of Drug: 48 days

40 patients of both genders were recruited for this study. Among the 40 patients, 22 (55%) patients were females and 18(45%) patients were males. Generally, this condition is more common in females, this study also concludes the same. Among 40 patients, 17 (42.5%) patients between 36-50 and years, 23 (57.5%) patients between 51 and 65 years. *Kumbavaatham* commonly occurs between the age of 20-60 years. The majority of patients in this study were Homemakers 18(45%), Cooly 6(15%) and Driver 5 (12.5%). Businessman 2 (5%), Carpenter 3(7.5%), Clerical 4(10%), Baker 1 (2.5%) Electrician 1 (2.5%). The majority of patients in this study were Non-vegetarian (95%) remaining (5%) patients were vegetarian. 100% of the patients showed negative family history In this present study, among 40 patients' considerable numbers of patients were reported from *Neithal* (30patients) and *Marutham* (10 patients) All the 40 patients were in pithakaalam (34-66yrs)Among40 patients 23 patients (57.5%) were affected in durations of 0-3months, 15(37.5%) patients were affected by the illness from 4-6 months, 2 (5%) were affected by the illness from 7-9 months. Out of 40 patients all (100%) had clinical features of pain and restriction of movements, radiating pain in affected arm, difficulty in Abduction and External rotation and Tenderness was noted in 30 (75%) patients, Local heat was noted in 7(17.5%) patients. In this study, Very Good improvement were observed in 10% of cases with Varmam and 5% of cases without Varmam group, Good improvement were observed in 85% of

cases with Varmam and 55% of cases without Varmam, Moderate improvement observed in 35% of cases without Varmam group and 5% of cases in both the groups shows Mild improvement. The result of group A (with Varmam) is significant than group B (without Varmam). So, the Varmam therapy is beneficial in *Kumbavaatham* patients along with trial medicine.

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