

Comparative Clinical Evaluation Of Varma Therapy And Sagajarathi Kasayam With Manjal Kizhi Ottradam In The Management Of Kumbavatham: An Integrative Siddha Approach

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ABSTRACT

A clinical study was conducted on 40 patients diagnosed with Kumbavatham at the Postgraduate Department of Varma Maruthuvam, Government Siddha Medical College & Hospital, Palayamkottai. Diagnosis was established based on traditional Siddha texts and corroborated by modern investigations. The patients were equally divided into two groups. Group I received daily Varma point stimulation for 48 days, whereas Group II was administered SagajarathiKasayam (90 ml twice daily) along with daily external application of ManjalKizhiOttradam for the same duration. Throughout the treatment period, all patients adhered to a strict Pathiyam diet.

Comprehensive evaluations, including radiological examinations, routine laboratory investigations, and biochemical analyses of SagajarathiKudineer, were performed. Additionally, pharmacological studies demonstrated the anti-inflammatory and analgesic properties of the treatment, and both acute and sub-acute toxicity studies confirmed its safety for long-term use.

The study outcomes indicated significant clinical improvement in all cases, thereby demonstrating the effectiveness of integrating Siddha therapeutic principles with modern diagnostic methods in the management of Kumbavatham.

1. INTRODUCTION

In the Siddha system, Kumbavatham is correlated with Adhesive Capsulitis (Frozen Shoulder) in modern medicine, a painful inflammatory condition of the shoulder leading to fibrosis, stiffness, and restricted movement for over three months.

Siddha medicine, one of India's oldest healing systems, is rooted in Tamil traditions. It follows fundamental principles like Aimpootham (Five Elements), Mukkutram (Three Humors), and EnvakaiThervukal (Eight Methods of Examination) for diagnosis and treatment. Siddhar Thirumoolar emphasized his role in physical and psychological healing, disease prevention, and longevity.

Varmam, a vital part of Siddha medicine, is traditionally passed down through generations in Tamil Nadu. The Varma OdivuMurivu Sara Choothiram-1200 text highlights the significance of Vaci (Pranan) circulation in health. Improper vaci function leads to diseases, which can be treated by stimulating Varma points using various techniques such as Anukkal, Asaitthal, Thattal, and Thadaval.

This study explores the Siddha concept and treatment of Kumbavatham through two groups:

- Group I: Varma manipulation through external pressure on Varma points.
- Group II: SagajarathiKasayam (90ml twice daily) internally and ManjalKizhiOttradam externally.

A detailed analysis of these treatments forms the basis of this dissertation.

2. AIM AND OBJECTIVES

Aim

To compare the efficacy of Varma manipulation with *Sagajarathikasayam* (internal) and *ManjalKizhiottradam* (external) in the treatment of *Kumbavatham*.

Objectives

Primary objectives:

- ✓ To evaluate the clinical efficacy of *Varma* Manipulation on *KumbaVatham*.
- ✓ To evaluate the therapeutic efficacy of *Siddha* drugs *SagajarathiKasayam* (internal) *ottradam* (external) in the treatment of *Kumbavatham*.

Secondary objectives:

- ✓ To evaluate the Pharmacological activity, Anti inflammatory, Analgesic activity and biochemical analysis of the trial drug *SagajarathiKasayam*.
- ✓ To assess the quality of life by using EQ-5D scale.
- ✓ To assess the safety of the drug.

3. SIDDHA ASPECT

Kumbavatham

Clinical features :

According to **Kumbamuni Vatha Nithanam-800**, Kumbavatham is characterized by **shoulder pain and stiffness, loss of active and passive movement, excessive thirst, fatigue, burning sensation, heat intolerance, and increased bowel movements**.

Similarly, **Yugi Vaithiya Chinthamani-800** describes symptoms such as **pain in the shoulder joints and upper limbs, burning and tingling sensations in the cheeks and eyes, scalp twitching, lower abdominal pain, and glossitis (tongue inflammation)**.

Function of vatham

Table 3.1.1

Sl.No	VATHAM	GENERAL FEATURES	CHANGES IN KUMBAVATHAM
1.	Piranan	Responsible for respiration and digestion	Normal
2.	Abanan	Responsible for voiding of urine, stools, semen, menstrual flow.	Normal
3.	Udhanan	It is responsible for the reflex actions like vomiting, hiccough, cough ect.	Normal
4.	Viyanan	Found in extension and flexion of the parts of the body and helps in distribution of the nutrients to various parts of the body.	Affected
5.	Samanan	Transfers nutrients to each and every organ.	Affected
6.	Nagan	Helps in opening & closing of eyelids.	Normal
7.	Koornan	Responsible for vision, lacrimation and yawning.	Normal
8.	Kirugaran	Induces appetite and all secretions in the body including nasal secretion and sneezing.	Normal
9.	Thevathathan	Induces and stimulates a person to become alert, get anger to quarrel to sleep ect.	Affected

4. DIAGNOSTIC METHODS ADOPTED IN SIDDHA SYSTEM OF MEDICINE

Pinyari Muraimai (Diagnostic Methods) in Siddha is based on four principles:

1. **PoriyalArithal** – Inspection using sensory organs
2. **PulanalArithal** – Examination through touch, auscultation, and palpation
3. **Vinathal** – Inquiry about symptoms from the patient or attendant
4. **EnvagaiThervu** – Eight diagnostic factors:

Neikuri Test: Urine is collected in the morning and examined by dropping gingelly oil into it, observing its behavior under direct sunlight to assess Dosha imbalance.

Character of different Neer:

Neikuri Interpretation:

- **Vatha Neer:** Oil spreads like a **snake**
- **Pitha Neer:** Oil forms a **ring**
- **Kapha Neer:** Oil stays like a **pearl**

Types of Kumbavatham (Symptoms):

1. **Ratha Kumba Vatham:**
 - Neck and upper limb pain, Body heaviness, Burning sensation in the eyes, Constipation.
2. **Vatha Kumba Vatham:**
 - Anorexia, Tingling and numbness in upper limbs, Tremors in upper limbs, Sleeplessness.
3. **Pitha Kumba Vatham:**
 - Neck stiffness, Deafness, Yawning and oversleeping, Head titubation, Difficulty using limbs.
4. **Sanni Kumba Vatham:**
 - Pain and swelling in neck, arms, and legs, Muscle weakness in hands, Vomiting and dizziness, Swelling all over the body.

5. TREATMENT

GROUP(I) VARMAMMANIPULATION:

Important Varma Points & Their Benefits

1. TisKbe;j Varma (KBR Varma)

- **Location:** 8 fingers from the base of the neck
- **Stimulation:** Light or deep pressure for 1-3 breaths
- **Benefits:** Relieves neck pain, stiffness, and nervous issues

2. Fhf;fl;il Varma (Throat Varma)

- **Location:** 8 fingers from the throat base
- **Stimulation:** Gentle or deep pressure for 30 breaths
- **Benefits:** Treats throat pain, voice issues, and neck tension

3. G[Varma (Chest Varma)

- **Location:** 10 fingers from the chest center
- **Stimulation:** Light pressure for 1-3 breaths
- **Benefits:** Helps with chest pain, breathing issues, and digestive problems

4. Iff;FoptHkk; (Shoulder Varma)

- **Location:** 9 fingers from the shoulder joint
- **Stimulation:** Light pressure for a few seconds

- **Benefits:** Relieves shoulder pain, arm numbness, and weakness

5. MirT Varma (Head Balance Varma)

- **Location:** 8 fingers from the head base
- **Stimulation:** Gentle pressure for 1-3 breaths
- **Benefits:** Treats dizziness, head tremors, and balance issues

6. Iff;G[g; nghUj;J Varma (Hand Varma)

- **Location:** 9 fingers from the wrist
- **Stimulation:** Light pressure for 1-3 breaths
- **Benefits:** Helps with hand pain, numbness, and circulation issues

7. Ga Nky; eLf;F Varma (Leg Varma)

- **Location:** 3 fingers from the ankle
- **Stimulation:** Light pressure for 1-3 breaths
- **Benefits:** Treats leg pain and circulation problems

6. GROUP II -INTERNAL MEDICINE : SAGAJARATHI KASAYAM

Rafunajp Varma (Vital Energy Point)

- **Location:** A key energy point in the body
- **Benefits:**
 - Balances energy flow, Enhances immunity and strength, Improves circulation and overall well-being, Helps with body pain and stiffness, Supports mental clarity and focus

7. METHOD OF PREPARATION

600 gm of Karunkurinjiver are cleaned into a coarse powder with 14.4 litre of water make a decoction about 5.76 litre. Then all the purified and powered raw drugs were added and make a decoction about 2.16 litre. Finally, intake the kudineer with the adjuvant (Maacheeni)

DOSE: 90ml (Twice a day) with Maacheeni (Melpodi)

DURATION: 48 days

8. EXTERNALMEDICINE: MANJALKIZHI OTTRADAM

METHOD OF PREPARATION:

Small cloth bags containing crushed raw drugs are soaked in warm neem oil and applied over the affected areas of the body as fomentation.

MODERN ASPECT

PERIARTHRITIS/ FROZEN SHOULDER

Frozen shoulder (adhesive capsulitis) is a painful condition where the shoulder joint becomes stiff, inflamed, and difficult to move. It occurs when the shoulder joint capsule thickens and tightens, restricting motion. Pain and swelling reduce shoulder use, worsening stiffness and leading to a "frozen" state.

CALCIFIC PERIARTHRITIS:

Periarthritis, or calcific periarthritis, is a painful condition caused by calcium crystal buildup around joints or soft tissues. This leads to pain, swelling, and stiffness. While calcium is essential for bones and teeth, excess deposits can irritate tendons and muscles. It most commonly affects the shoulder but can also impact the hips, hands, and other joints.

ICD CLASSIFICATION

2023 ICD-10-CM Diagnosis Code M75.00

RISK FACTORS CAUSING FROZEN SHOULDER:

Age: Adults, most commonly between 40 and 60 years old.

Gender: More common in women than men.

HEALTH CONDITIONS CAUSING FROZEN SHOULDER:

Recent shoulder injury:

Any shoulder injury or surgery that results in the need to keep the shoulder from moving (i.e., by using a shoulder brace, sling, shoulder wrap, etc.). Examples include a [rotator cuff tear](#) and fractures of the shoulder blade, collarbone or upper arm.

Diabetes: Between 10 and 20 percent of individuals with [diabetes mellitus](#) develop frozen shoulder.

Other health diseases and conditions:

- [Stroke](#), [hypothyroidism](#) (underactive thyroid gland), [hyperthyroidism](#) (overactive thyroid gland), [Parkinson's disease](#), Heart disease.

SYMPTOMS AND CAUSES

Normally, the symptoms that are felt by the patients are as follows:

- └ tenderness in the affected joint
- └ pain that makes it difficult to move the affected joint or limb
- └ pain that is worse when you move the affected joint
- └ pain that gets worse at night
- └ pain that makes it difficult to sleep
- └ [reduced range of motion](#) (movement of the joint causes stiffness or severe pain)

Symptoms of frozen shoulder are divided into three stages:

- **The "freezing" stage:**In this stage, the shoulder becomes stiff and is painful to move. The pain slowly increases. It may worsen at night. Inability to move the shoulder increases. This stage lasts 6 weeks to 9 months.
- **The "frozen" stage:**In this stage, pain may lessen, but the shoulder remains stiff. This makes it more difficult to complete daily tasks and activities. This stage lasts 2 to 6 months.
- **The "thawing" (recovery) stage:**In this stage, pain lessens, and ability to move the shoulder slowly improves. Full or near full recovery occurs as normal strength and motion return. The stage lasts 6 months to 2 years.

DIAGNOSIS AND TESTS

Diagnosis includes symptom review, history, and physical examination to assess shoulder movement and range of motion. X-rays rule out other issues like arthritis, while MRI or ultrasound may be used if needed. Blood tests help identify underlying conditions.

MANAGEMENT AND TREATMENT

Treatment includes pain relief, hot/cold compresses, NSAIDs, physical therapy, home exercises, and TENS. If movement doesn't improve, options include manipulation under anesthesia or shoulder arthroscopy.

PREVENTION

The regular practice of shoulder exercise immediately after any shoulder injury can aid in the prevention of peri arthritis.

OUTLOOK / PROGNOSIS

Simple treatments, such as use of pain relievers and shoulder exercises, in combination with a [cortisone injection](#), are often enough to restore motion and function within a year or less. Even left completely untreated, range of motion and use of the shoulder continue to get better on their own, but often over a slower course of time. Full or nearly full recovery is seen after about two years.

9. MATERIALS & METHODS

The clinical study on kumbavatham was carried out in the post graduate Varma marutthuvam of government siddha medical collage, palyamkottai. In this study 40 patients (who are selected by inclusion and exclusion criteria) were treated as OP and IP patients

STUDY DESIGN AND CONDUCT OF STUDY:

STUDY TYPE :

AnopenlabelledNon-randomisedDoublearmPhase- II

Clinical Trial.

STUDY PLACE : OPD&IPD, Department of Varma Maruthuvam,
Govt. Siddha Medical College and Hospital, Palayamkottai.

STUDY PERIOD : 24 months

SAMPLE SIZE : 40 patients (OPD+IPD)

Selection of the patients:

Age : 20 years to 65 years

Sex : Male and female

Clinical Findings

The patients were selected on the basis of the following clinical findings

1. Pain and stiffness in Shoulder joint
2. Loss ROM both active and passive
3. Strong component of night pain
4. Pain with rapid or unguarded movement
5. Discomfort lying on the affected shoulder
6. Pain easily aggravated by movement

Shoulder Pain and Disability Index (SPADI)

Pain scale

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

• At its worst?														
• When lying on the involved side?														
• Reaching for something on a high shelf?														
• Touching the back of your neck?														
• Pushing with the involved arm?														

Disability scale

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

• Washing your hair?														
• Washing your back?														
• Putting on an undershirt or jumper?														
• Putting on a shirt that buttons down the front?														
• Putting on your pants?														

• Placing an object on a high shelf?																			
• Carrying a heavy object of 10 pounds (4.5 kilograms)																			
• Removing something from your back pocket?																			

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, eg. 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, eg. if 1 question missed divide by 70)

Total Spadi score: $\frac{\text{score}}{130} \times 100 = \%$

(Note: If a person does not answer all questions divide by the total possible score, eg. 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 points

CRITERIA FOR INCLUSION:

1. **Age:** Between 20 Yrs - 65 Yrs
2. **Sex:** Both male and female
3. Pain Shoulder joints
4. Stiffness or heaviness of shoulder muscle
5. Idiopathic cause
6. History of Diabetes mellitus
7. Patient who are willing for admission and stay in IPD or willing to attend OPD.
8. Patient willing to sign Informed consent document.

CRITERIA FOR EXCLUSION:

9. History of Trauma of shoulder joint/surgery
10. Hyperthyroidism and Hypothyroidism
11. Cardiovascular disease
12. Tuberculosis
13. Parkinson's Disease
14. AC Arthritis
15. Congenital anomalies
16. Pregnant women and Lactating mothers
17. Patients with any other serious systemic illness
18. Patient who are having the skin disease

WITHDRAWAL CRITERIA:

19. Intolerance to the drug and development of adverse reactions during drug trial.
20. Poor patient compliance & defaulters.

21. Patient turned unwilling to continue in the course of clinical trial.
22. Occurrence of any serious illness during the course of study.
23. If patients had fever during Varmam therapy.

BLOOD:

Total WBC Count, Differential WBC Count (Neutrophils, Lymphocytes, Eosinophils, Monocytes, Basophils), Haemoglobin, ESR, Blood sugar (Random, Fasting, Postprandial), Blood Urea, Serum Creatinine, Serum Cholesterol URINE: Albumin, Sugar, Deposits

RADIOLOGICAL INVESTIGATIONS:

X-Ray of the Shoulder joint (AP view)

MRI

INVESTIGATIONS BASED ON SIDDHA SYSTEM

Envagai Thervu, Udal Thathukkal, Vinathal, Poriyaal Arithal, Pulanal Arithal, Neerkuri, Neikuri

ETHICAL REVIEW:

The study was conducted in accordance with the ethical principles that are consistent with GCP guidelines and obtained prior approvals before start of the trial from the IEC Committee of GSMCH, Palayamkottai (GSMC—IEC-VIII-2021-Br.VIII/34-.13.08.2021) and IEAC of Arulmigu Kalasalingam College of Pharmacy, Krishnankovil. (AKCP/IAEC/64/22-23). The trial was applied and approved by the CTRI (CTRI/2022/04/053153)

OBSERVATION AND RESULT

The analysis of the patients helps in understanding the condition of the patients on admission and also in deriving the success/failure of the treatment. The forty patients in the study were analysed on the basis of multiple standards and the results have been demonstrated in this chapter.

1. Age	7. History Of Other Illness	13. Blood Reports
2. Sex	8. Kalam	14. Blood Glucose
3. Type Of Work	9. Thegi	15. Blood Cholesterol
4. Income Based	10. Uadal Uyir Thathu	16. Side Affected
5. Duration Of Illness	11. Nadi	17. Number Days Taken For Pain Reduction
6. Nilam	12. Neikuri	18. Range Of Movement

AGE WISE CLASSIFICATION:

The age of the patients help one to understand the other illnesses that may appear during the same period. It also helps to get a clear view on the impact of one disease on the other.

The age wise classification of patients is given in Table 5.1.1

TABLE 5.1.1 AGE WISE CLASSIFICATION

PATIENT'S AGE	GROUP I	GROUP II
35-40	0	3
41-45	3	1
46-50	5	3

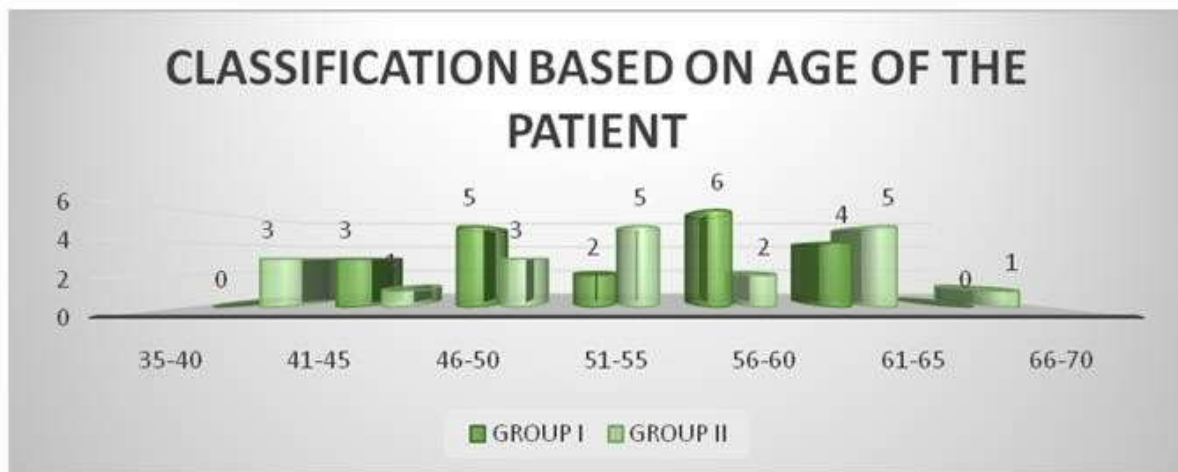
51-55	2	5
56-60	6	2
61-65	4	5
66-70	0	1
TOTAL	20	20

Source: Primary Data

The period from 33-66 years has been stated as the *Pitha Kaalam*, according to *Siddha* texts. Most of the cases admitted to the trial were also from the same age group. Of this, the age group 56-65 recorded the maximum cases (97.5 per cent), showing that near retirement, the transition from working to sedentary lifestyle made the patients prone to *Kumbavatham Noi*.

The age wise classification of the patients is depicted pictorially in Fig 5.1.1

FIG 5.1.1 AGE WISE CLASSIFICATION



SEX WISE CLASSIFICATION

The sex wise classification of the patients helps the scholar to analyse the prevalence of the disease between the sexes.

TABLE 5.1.2 SEX WISE CLASSIFICATION

PATIENT'S SEX	GROUP I	GROUP II
MALE	11	8
FEMALE	9	12
TOTAL	20	20

Source: Primary Data

The data given in Table 5.1.2 makes one to understand that the incidence of *Kumbavatham Noi* is almost equal in both sexes, ie between men and women. This is further elaborated via Fig 5.1.2

CLASSIFICATION BASED ON THE GENDER

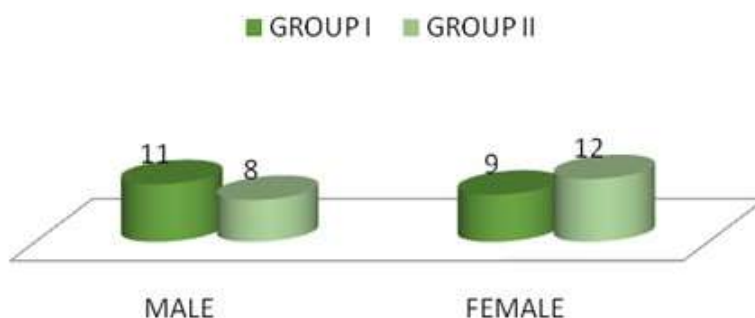


FIG 5.1.2 SEX WISE CLASSIFICATION

TYPE OF WORK

The type of work that a person does is mostly the route of origin of the disease. This is because, most diseases occur due to the change in the lifestyle of the patient due to his/ her work burden. The grouping of patients on the basis of their work is given in Table 5.1.3

TABLE 5.1.3 TYPE OF WORK

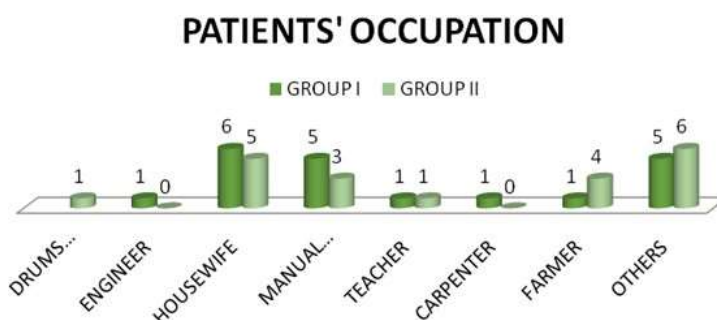
OCCUPATION	GROUP I	GROUP II
DRUMS PLAYER	0	1
ENGINEER	1	0
HOUSEWIFE	6	5
MANUAL LABOUR	5	3
TEACHER	1	1
CARPENTER	1	0
FARMER	1	4
OTHERS	5	6
TOTAL	20	20

Source: Primary Data

Table 5.1.3 shows that patients who were involved in work that were sedentary (Eg: typist, driver, etc) and the patients who were in work that made them use their hands for prolonged periods (teacher, farmer, etc) were mostly suffering from *Kumbavatham Noi*. These work conditions produce a derangement in the *Mukkuttram* of the patient, leading to the onset of the disease.

The classification of the patients on the basis of their working style is given in Fig 5.1.3

TYPE OF WORK



INCOME BASED CLASSIFICATION OF THE PATIENTS:

As said earlier, it is mostly the people who use their hands for prolonged periods that suffer from the disease. On the same accord, one could understand that the people from the low income categories are easily affected by the disease, as understood from table 5.1.4

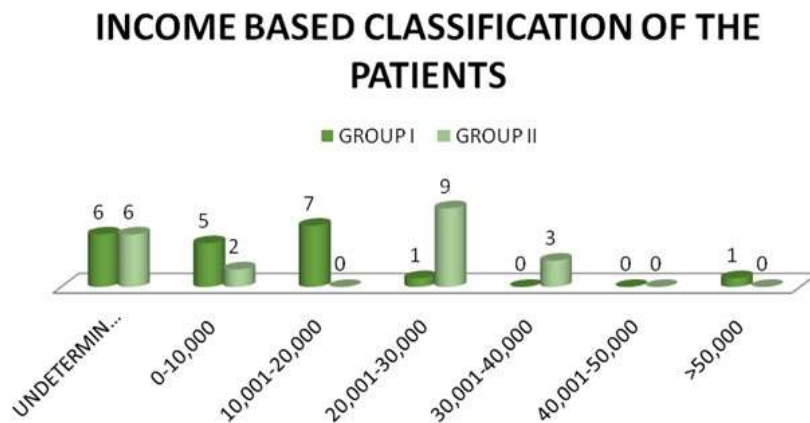
TABLE 5.1.4 INCOME BASED CLASSIFICATION OF THE PATIENTS:

INCOME (Rs)	GROUP I	GROUP II
UNDETERMINED	6	6
0-10, 000	5	2
10,001-20,000	7	0
20,001-30,000	1	9
30,001-40,000	0	3
40,001-50,000	0	0
>50,000	1	0
TOTAL	20	20

Source: Primary Data

The above study consisted 65 % from low calss, 35 % from middle class .

The same could be interpreted pictorially from Fig 5.1.4.

FIG 5.1.4 INCOME BASED CLASSIFICATION OF THE PATIENTS:**DURATION OF ILLNESS**

The duration of illness helps the scholar to understand the increase in complications with its duration. The time period from which the admitted *Kumbavatham Noi* patients were suffering from the disease is shown in Table 5.1.5

TABLE 5.1.5 DURATION OF ILLNESS

DURATION OF ILLNESS	GROUP I	PERCENT	GROUP II	PERCENT	TOTAL	PERCENT
<6 MONTHS	2	10	8	40	10	25
6 MONTHS- 1 YEAR	5	25	5	25	10	25
2 YEARS	2	10	2	10	4	10
3 YEARS	4	20	1	5	5	12.5
4 YEARS	0	0	0	0	0	0
5 YEARS	0	0	1	5	1	2.5
6 YEARS	1	5	1	5	2	5

7 YEARS	1	5	0	0	1	2.5
8 YEARS	1	5	0	0	1	2.5
10 YEARS	0	0	1	5	1	2.5
11 YEARS	1	5	0	0	1	2.5
12 YEARS	2	10	1	5	3	7.5
13 YEARS	1	5	0	0	1	2.5
TOTAL	20	100	20	100	40	100

Source: Primary Data

From Table 4.5, it is clear that most of the patients sort Siddha treatment within one year (50 per cent). This shows that the patients were well aware of the risk of the disease and were willing to take up treatment soon.

The data in Table 5.1.5 is represented pictorially through Fig 5.1.5

BIO CHMICAL ANALYSIS OF SIDDHA POLY HERBAL DRUG SAGAJARATHI KASAYAM

PREPARATION OF THE EXTRACT :

5 gms of the drug was weighed accurately and placed in a 250 ml clean beaker then 50 ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100 ml volumetric flask and then it is made to 100ml with distilled water. This fluid is taken for analysis.

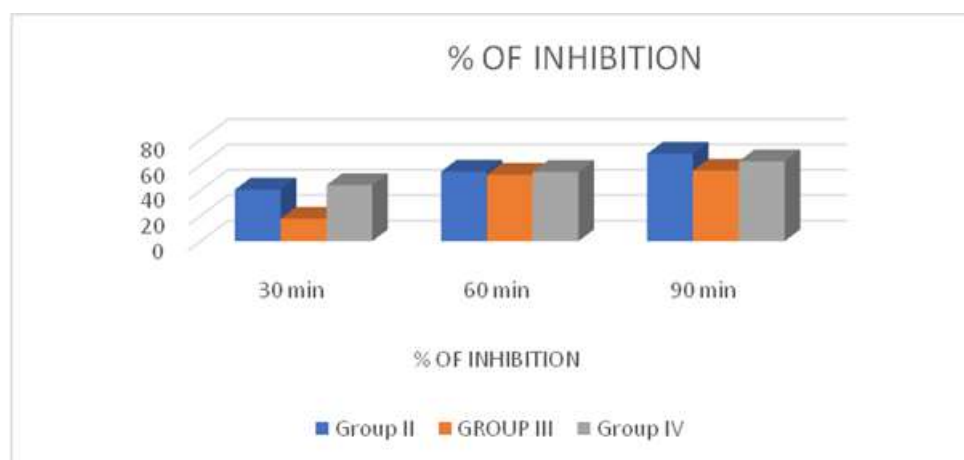
EVALUATION OF ANALGESIC ACTIVITY OF SIDDHA FORMULATION SAGAJARATHI KUDINEER IN ANIMAL MODELS

ANALGESIC ACTIVITY

Hot plate method (Annexure IV) table 5.2.3.1

The drug were found to exhibit a dose dependent increase in latency time when compared with control. At 90 minutes, the percent inhibition of two different doses (200 and 400 mg/kg body weight) was 55.59% & 63.04% respectively.

The results of the effect of SagajarathiKasayamon pain induced by hot plate method are given in Table 1. As pentazocine, SagajarathiKasayam200 and SagajarathiKasayam400 significantly increased percentage of reaction time with dose dependent response.



Discussion

The hot plate test showed that SagajarathiKasayam (100 and 200 mg/kg) significantly increased latency time (~60 min), indicating analgesic effects. The 400 mg/kg dose exhibited the highest analgesic activity, surpassing Pentazocine.

Conclusion In conclusion, results showed Sagajarathikasayam has significant analgesic properties. This study results confirmed the validity of traditional indications of Sagajarathikasayam in pain conditions.

TOXICITY STUDY OF SIDDHA FORMULATION SAGAJARATHI KUDINEER

TOXICITY STUDIES

Effect of acute Toxicity Study (14 Days) of SAGAJARATHI KASAYAM

Table no – 5.2.4.1 Physical and behavioral examinations.

Group no.	Dose(mg/kg)	Observation sign	No. of animal affected.
Group-I	5mg/kg	Normal	0 of 3
Group-II	50mg/kg	Normal	0 of 3
Group-III	300mg/kg	Normal	0 of 3
Group-IV	2000mg/kg	Normal	0 of 3

Statistical analysis (one-way ANOVA, Dennett's test, n=3) showed no significant changes ($p>0.05$) in physical or behavioral toxicity signs at SAGAJARATHI KASAYAM doses of 5mg/kg, 50mg/kg, 300mg/kg, and 2000mg/kg in rats.

Table no-5.2.4.2 Home cage activity

Functional and Behavioural observation	Observation	5mg/kg Group (G-I)	50mg/kg (G-II)	300mg/kg (G-III)	2000mg/kg (G-IV)
		Female n=3	Female n=3	Female n=3	Female n=3
Body position	Normal	3	3	3	3
Respiration	Normal	3	3	3	3
Clonic involuntary Movement	Normal	3	3	3	3
Tonic involuntary Movement	Normal	3	3	3	3
Palpebral closure	Normal	3	3	3	3
ApproKPh response	Normal	3	3	3	3
Touch response	Normal	3	3	3	3
Pinna reflex	Normal	3	3	3	3
Tail pinch response	Normal	3	3	3	3

Statistical analysis (one-way ANOVA, Dennett's test, n=6) showed no significant changes ($p>0.05$) in home cage activity or toxicity signs at SAGAJARATHI KASAYAM doses of 5mg/kg, 50mg/kg, 300mg/kg, and 2000mg/kg in rats.

Table no-5.2.4.3 Hand held observation

Functional and Behavioral observation	Observation	Control	5 mg/ kg (G-I)	50 mg/kg (G-II)	300mg/kg (G-III)	2000mg/kg (G-IV)
		Female n=3	Female n=3	Female n=3	Female n=3	Female n=3
Reactivity	Normal	3	3	3	3	3
Handling	Normal	3	3	3	3	3
Palpebral closure	Normal	3	3	3	3	3
Lacrimation	Normal	3	3	3	3	3

Salivation	Normal	3	3	3	3	3
Piloerection	Normal	3	3	3	3	3
Pupillary reflex	Normal	3	3	3	3	3
Abdominal tone	Normal	3	3	3	3	3
Limb tone	Normal	3	3	3	3	3

Statistical analysis (one-way ANOVA, Dennett's test, n=6) showed no significant toxicity (nsp>0.05). SAGAJARATHI KASAYAM at doses of 5mg/kg, 50mg/kg, 300mg/kg, and 2000mg/kg caused no observable toxic effects in rats.

Table no-5.2.4.4Mortality

Group no	Dose no(mg/kg)	Mortality
Group-I	5(mg/kg)	0 of 3
Group-II	50(mg/kg)	0 of 3
Group-III	300(mg/kg)	0 of 3
Group-IV	2000(mg/kg)	0 of 3

Statistical analysis using one-way ANOVA followed by Dennett's test (n=6) showed no significant toxicity (nsp>0.05). Acute toxicity study confirmed that SAGAJARATHI KASAYAM at 2000 mg/kg caused no drug-related toxicity or mortality, establishing the NOAEL at 2000 mg/kg.

Discussion

All animals in control and treated groups survived the 28-day dosing period with normal body weight gain, food, and water intake. Hematological and biochemical tests showed no significant changes, confirming no impact on bone marrow, spleen, liver, or kidney functions. Organ weights remained comparable to controls, ensuring the safety of SAGAJARATHI KASAYAM.

10. CONCLUSION

Acute and subacute toxicity studies in Wistar albino rats (OECD 423) showed no mortality. A 28-day subacute test found no significant changes in biochemical or hematological profiles, confirming the safety of SAGAJARATHI KASAYAM for long-term use.

11. DISCUSSION

Study Summary on Kumbavatham Noi (Based on Yugi Vaithiya Chinthamani-800 &Kumbamuni Vatha Nithanam-800)

A total of 40 cases were studied. Diagnosis was made using *Envagaithervugal* (Siddha method) and confirmed with modern investigations. Two treatment groups were used:

- **Group I** – Varma point stimulation
- **Group II** – *SagajarathiKasayam* (internal) and *ManjalKizhiOttradam* (external)

Clinical Findings:

1. **Age Distribution:**97.5% were aged 56–65, indicating susceptibility near retirement age due to sedentary lifestyle.
2. **Sex:**Equal incidence among men and women.
3. **Occupation:**Sedentary jobs (e.g., typist, driver) and work involving repetitive hand use (e.g., housewives, farmers) were commonly affected.
4. **Income:**Higher incidence among low-income groups.
5. **Duration of Illness:**50% sought Siddha treatment within a year of onset.
6. **Region (Nilam):**75% were from *Marutham Nilam* regions.

7. **Comorbidities:** 6 patients also had hypertension.

Pre-clinical & Pharmacological Studies on *SagajarathiKasayam*

- **Biochemical Analysis:** Contained calcium, sulphate, chloride, starch, ferrous iron, tannic acid, reducing sugars, amino acids, and unsaturated compounds.
- **Pharmacological Properties:** Exhibited anti-inflammatory and analgesic effects.
- **Toxicity:** No significant changes in biochemical/hematological profiles, indicating it is safe for long-term use

12. SUMMARY

A clinical study on 40 cases of Kumbavatham was conducted at the Postgraduate Department of Varma Maruthuvam, Government Siddha Medical College & Hospital, Palayamkottai. Diagnosis was based on Siddha texts and supported by modern investigations.

Patients were treated with **SagajarathiKasayam** (90 ml twice daily for 48 days) and **ManjalKizhiOttadam** (external application for Group II). Group I received **Varma point stimulation** once daily for 48 days. A strict **Pathiyam diet** was followed.

Biochemical analysis of **SagajarathiKudineer**, along with **anti-inflammatory, analgesic, acute, and sub-acute toxicity studies**, was performed. Radiological and routine lab investigations were conducted. Significant clinical improvement was observed in all cases.

13. CONCLUSION

A total of **40 patients** (20 in Group I and 20 in Group II) were selected for this dissertation study. Group I patients received **stimulation of Varma points** once daily for 48 days, while Group II patients were treated with **SagajarathiKasayam** (90 ml twice daily) along with **ManjalKizhiOttadam**, which was externally applied once a day.

The treatment approach combined Siddha principles with modern diagnostic methods, ensuring a **comprehensive evaluation** of Kumbavatham. A **strict Pathiyam diet** was followed throughout the study period. Biochemical analysis of **SagajarathiKudineer**, along with **anti-inflammatory, analgesic, and toxicity studies**, was conducted. Radiological and routine laboratory investigations were performed for each case. The study demonstrated **significant clinical improvement** in all patients.

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