ISSN: 2395-6429

INTERNATIONAL JOURNAL OF CURRENT MEDICAL AND PHARMACEUTICAL RESEARCH

IJCMPR

Available Online at http://www.journalcmpr.com

DOI: http://dx.doi.org/10.24327/23956429.ijcmpr20170099

RESEARCH ARTICLE

# CLINICAL TRIAL OF THE EFFECTIVENESS CALAMUS ROTANG ON THE MANAGEMENT OF AZHAL KEELVAYU (OSTEOARTHRITIS OF KNEE)

**Dhashalini.T., Paheerathan.V*and Piratheep Kumar.R***

Intern medical officer, Bandaranayaka memorial Ayurvedic Research Institute Navinna, Sri Lanka.

**ARTICLE INFO**

***Article History:***

Received 24th March, 2017
Received in revised form 5th April, 2017
Accepted 11th May, 2017
Published online 28th June, 2017

***Key words:***

Azhal Keelvayu, Osteoarthritis, Calamus rotang

**ABSTRACT**

This is the single blind comparative clinical trial to determine the internal administration of rhizome of Calamus rotang powder in the management of Azhal Keelvayu. According to Siddha system Azhal Keelvayu is one of the 10 types of Keelvay which included under the Vatharogam. The sign and symptoms of Azhal Keelvayu similar to osteoarthritis of the knee joint. Further the study was investigated to determine the effectiveness of the drug with different dosage, the side effects and the associated factors between the Azhal Keelvayu. Thirty patients were selected and who were divided into three groups and named as Group A, B and C and the groups treated with 0.5g, 1g and 2g of Chooranam internally three times per day with lukewarm water for 40 days. Paired't' test was used to test the significance of treatment using before and after treatment. At the end of the treatment Calamus showed highly effective. Dose effectiveness as follows: 2g of Chooranam shows significant and markedly improvement on 20th and 40th day of treatment compare to 1g and 0.5g.1g shows markedly improvement on 20th and 40th day, the dose effectiveness comparably less than the 2g and more than the 0.5g. 0.5g shows moderately improvement on 20th and 40th day, the dose effectiveness comparably less than the dose of 2g and 1g.Symptoms were increased with particular foods and seasons and the side effect was comfortable in defecation. Based on the results it provides successful proof of the traditional literature about the Calamus rotang.



## INTRODUCTION

### *Study*

This is the single blind comparative clinical trial to determine the internal administration of *Calamus rotang powder* in the management of *Azhal Keelvayu*. Further the study to determine the effectiveness of the drug with different dosage on *Azhal Keelvayu*, and the associated factors between the *Azhal Keelvayu* and following, Seasonal variation, diet, physical act and Hereditary. The research focused on *Azhal Keelvayu* (knee osteoarthritis), with different dosage of *Calamus rotang* powder.

### *Azhal Keelvayu*

*Keelvayu* is one of the *Vatharogam* in *Siddha* comparable to Rheumatism in Allopathic Medicine (Supramaniyam, 1983) *Azhal Keelvayu* is one of the ten types of *Keelvayu*. According to the *Siddha* system diseases are said to be the result of derangement of one, two or all three *Humours* (*Valli, Azhal and Iyam*). Accumulation of *Valli Kutram* in *Poruthu* (Joints) is said to be *Keelvayu*. *Azhal Keelvayu* is common among elders and its signs and symptoms are akin to Osteoarthritis, such as swelling, pain in the knee joint, Crepitus during the flexion and restricted movement in the joints (Supramaniyam, 1983).

### *Calamus rotang*

**Figure 1** *Calamus rotang*

*Calamus rotang* widely known as *Pirapam Kizhangu*. The plant has the action of Expectorant and *Antivatha*. According to the literature review in *Siddha,* textbook stanza postulates that the plant *Calamus rotang* has potency to cure the *Vatha* disease. In medical system, *Azhal Keelvayu* is one of the *Vatha* disease (Murukesumuthaliyar, 2013).

***Background and Justification***

"தந்தரோ கத்தைத் தணியாத வாதத்தை
உந்துசூ லைப் பிடிப்பை யோட்டுங்காண்-வந்து
கரப்பு திறப்புமெனக் காட்டுகை மாதே!
பிரப்பங் கிழங்கதனைப் பேணு".
(Murukesumuthaliyar, 2013)

According to the above quotation *Pirapang kilangu* (*Calamus rotang)* cures diseases of tooth, *Valiperuku*, *Keelpidippu, Iya* disease & *Parisavatham.*

**Justification**

Several management plans are available for *Azhal Keelvayu* (osteoarthritis) in global wide with or without side effect. This study will provide an efficient herb of choice for development of drug of osteoarthritis.

***Objectives***

***General Objective***

To determine the effectiveness of Calamus rotang powder on Azhal Keelvayu**.**

***Specific objectives***

- To identified the effectiveness of *Calamus rotang* powder with different dosage.
- To determine the association between the *Azhal Keelvayu* and following factors: Diet, Physical activity, Seasonal variations, Hereditary.
- To identified the side effects of *Calamus rotang* powder.

## METHODOLOGY

This is the single blind comparative clinical trial study on *Azhal Keelvayu* patients, according to the inclusive criteria. Thepatients were selected at the Rural *Siddha Ayurvedic* Hospital, Kopalapuram, Trincomalee. The selected patients were treated with selected drug. The selected drug was administered for forty days with six intervention treatment arms.

***Study area***

This is an institutional based study; the study was conducted at the Rural *Siddha Ayurvedic* hospital in Kopalapuram, Trincomalee.

***Study unit***

Thirty (30) patients were selected for this study using systematic sampling method.
One of the first three patients was randomly selected for this study (*The random selection happened to be the first patient*). Thereafter every third patient was incorporated into the study. The patients were divided into three groups in the ratio of 1:1:1.

***Study duration***

This study was conducted from 05/06/ 2016 to 24/10/ 2016.

***Selection of AzhalKeelvayu patients***

According to the inclusive criteria, patients were selected for the study from outpatient department and indoor of Kopalapuram Rural *Siddha Ayurveda* Hospital. The purpose of trial was explained to the patients and consent has been obtained. The researcher interviewed all selected patients on their first visit to the OPD. The patients were subjected to a detailed clinical examination based on perform specially prepared for this study. Diagnosis was made based on history and clinical examination. Thirty (30) patients were selected within the study frame (September 2016 - October 2016) using inclusion/exclusion criteria. The first phase of screening procedure was done based on the sign and symptoms of *Azhal Keelvayu*. The purpose of the trial was explained to the patients those who volunteered signed informed consent to enrol in the trial.

***Inclusive criteria***

1. Patients of either gender belonging to the over 35 years of age group.
2. Diagnosis of *Azhal Keelvayu* patients based on typical history;

- Defect in both knee joint
- Swelling of both knees.
- Pain in both knees.
- Restricted movement of both knee joints.

3. Patients who were ambulant and required analgesic and/or NSAID.
4. Not satisfied with ongoing analgesic drugs and seeking a change.
5. Pain (visual analogue score VAS) in one or both knee joint while performing a weight bearing activity.

***Exclusive criteria***

1. *Azhal Keelvayu* in one knee joint.
2. Those with pain and swelling, other than the knee joint.
3. Patient with mild or severe pain and swelling.
4. Patients with severe pain and patients with incapacitation and bed ridden.
5. Women who were pregnant, lactating, and having child bearing potential and not following adequate contraceptive measures.
6. Patients with known contra indication to any of the investigational products and medicinal plants.
7. Those who had history of intra-articular knee injection (in particular corticosteroids and Hyaluronon equivalents) within the month preceding the study.
8. Those receiving treatment with anticoagulants, Hydantoin, Lithium, Steroids.
9. Those with history of active peptic ulcer at any time in the preceding six months or bleeding ulcer at any time in the past.
10. Those with evidence of severe unstable renal, hepatic, hemopoietic, and cardiac disorder as revealed by history and/or investigations.
11. Those with history of having received any investigational drug in the previous one month.
12. Patients taking antipyretics, analgesics, tranquilizers, hypnotics & excessive alcohol
13. Those unwilling to come for regular follow-up for the entire duration of the study and any patients considered not eligible according to the investigator's discretion.

***Withdrawals***

Patients could withdraw voluntarily or at the discretion of the researcher. Patients were not replaced and the new patients who were enrolled the next consecutive number. Efforts were made in each case to identify the reason for a failed follow-up visit and/or withdrawal.

***Assessment criteria***

Clinical evaluation was made at baseline and each week up to end of 6th week. The effectiveness of drug was evaluated by subjective and objective findings, Subjective and objective parameters:

***Section C: Physical function***

- ✓ Pain : — subjective
- ✓ Tenderness
- ✓ Warmness
- ✓ Swelling
- ✓ Range of movement — Objective
- ✓ Crepitus
- ✓ Six minutes walking distance
- ✓ WOMAC score
- ✓ Ligament injury

***Assessment of WOMAC score***

The index consists of 24 questions (5 pains, 2 stiffness, and 17 physical functions) and can be completed in less than 5 minutes. The WOMAC total score represents the sum of these three subscales to form a score ranging from zero (worst) to 96 (best). The raw scores are normalized by multiplying each score by 100/96 which produces a reported WOMAC score of between 0 (worst) to 100 (best). The WOMAC is a valid, reliable and sensitive instrument for the detection of clinically important changes in health status following a variety of interventions (Bellamy, 1998) (Bellamy, 1975).

***Section A: Pain***

Answer each question with an X in the appropriate box,base on fatigue or the amount of pain you experienced in your muscles. How much pain do you have?

| | None (0) | Mild (1) | Moderate(2) | Severe(3) | Extreme(4) |
|---|---|---|---|---|---|
| 1.walking on a flat surface | | | | | |
| 2.going up or down stairs | | | | | |
| 3.at night while in bed | | | | | |
| 4.sitting or lying | | | | | |
| 5.standing upright | | | | | |

***Section B: Stiffness***

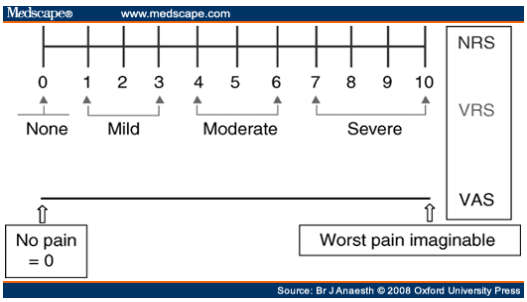
| | None (0) | Mild (1) | Moderate(2) | Severe(3) | Extreme(4) |
|---|---|---|---|---|---|
| 1.How severe is your pain after first awakening? | | | | | |
| 2.How severe has your stiffness been after sitting or lying down or while resting in the day? | | | | | |

***Section C: Physical function***

| | None (0) | Mild (1) | Moderate(2) | Severe(3) | Extreme(4) |
|---|---|---|---|---|---|
| 1.descending stairs | | | | | |
| 2.ascending stairs | | | | | |
| 3.rising from sitting | | | | | |
| 4.standing | | | | | |
| 5.bending to floor | | | | | |
| 6.walkkkking on flat surface | | | | | |
| 7.getting in/out of car | | | | | |
| 8.going shopping | | | | | |
| 9.putting on socks | | | | | |
| 10.lying in bed | | | | | |
| 11.taking off socks | | | | | |
| 12.rising from bed | | | | | |
| 13.getting in/out of bath | | | | | |
| 14.sitting | | | | | |
| 15.getting on/off toilet | | | | | |
| 16.heavy domestic duties | | | | | |
| 17.light domestic duties | | | | | |

***Assessment of Visual Analog Scale (VAS)***

The *Visual Analog Scale* (VAS) was designed as a rating scale to discriminate pain level. The respondent was asked to describe the severity of present pain, the least and most severe A total count was taken at all measurement points. Patients were offered a scale of 0 to 10, where 0 signifies no pain and 10 signifies the worst pain (Portenoy & Tanner., 1996) (Caffery and Pasero., 1999).




**0-1VAS Pain Measurement**

***Assessment of six minutes walking test***

The *6-Minute Walk Test* was used as a measure to determine the actual distance (measured in feet and inches) that a patient can walk in a 6-minute period. Patients are given the following instructions prior to walking on the well-marked, clear path: "The purpose of this test is to see how far you can walk in 6 minutes. Comfortably walk as rapidly as possible (Myles, 1999).

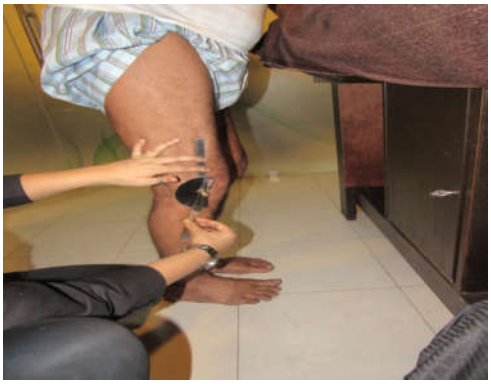
***Assessment of Clinical examination parameters***

*Clinical exam parameters* collected at baseline were frequency of pain, swelling, quality of pain, location of pain, range of

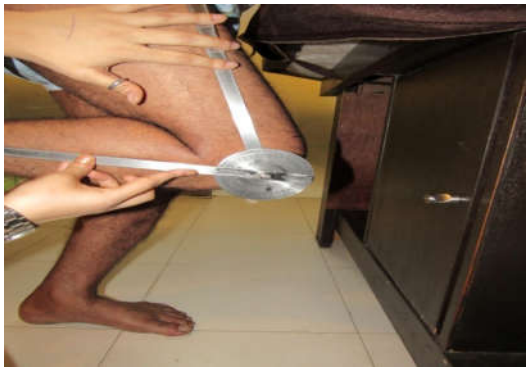
motion, crepitus, tenderness, warmness, erythematic, deformity, and ligament injury (Davis.,1992).

***Method to measurement of range of movement***

Range of movement measured with Goniometer. The angles of flexion and extension of Knee joints were measured. Goniometer is a device used to measure joint angles or range of movement. It is ideal for quick, simple, and accurate measurement of joint movement in multiple planes.



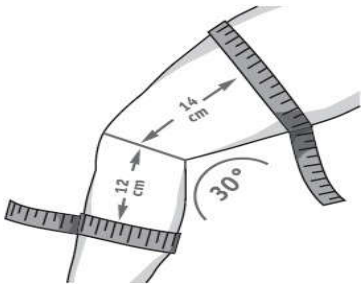
**0-1** Measurement of knee extension



**0-2** Measurement of knee flexion

***Method to measure swelling of the knee***

Swelling of knee joint measured with measurering tap. The measurement to be taken 3inches above the knee cap or 14 cm above from the mid of knee joint. The second measurement 2 inches below the knee cap or 12 cm apart from the mid of the knee joint.




**0-3** Method to measure knee swelling

***Examination for tenderness***

It was scored depending on the patient's reaction to firm pressure of the joint between finger and thumb in supine position.

***Examination for Crepitus***

Knee crepitus is the medical term used to describe the sound and/or sensation of crunching as the knee joint bends back and forth. The sound of knee crepitus may be quite soft, but the crunching sensation is often palpable. It can be felt by placing the hand on the knee while flexing and extending the joint.

***Examination for warmness***

It was detected by feeling the joint with dorsum of the hand in supine position and scored.

3.7.10. Examination for defected ligements of knee joint

Knee joint delaminated for medial collateral, lateral collateral, anterior, posterior cruciate ligaments and meniscus to detect the injury of ligaments.

***Collection of plant material***

The plant *Calamus rotang* rhizomes were collected from the various places of local area of Trincomalee and Jaffna, during the month of January. The plant was identified and authenticated by Dr. (Ms).V.Paheerathan.

***Preparation of testing drug***

The plant rhizome was collected and cleaned. Then dried under the shade at ambient temperature and crushed well sieved to get the fine powder.

***Treatment procedures***

Selected patients (30 patients) were divided into 3 groups Ten (10) for each group. The groups were treated as following manner of *Calamus rotang* powder with lukewarm water, orally, thrice a day for 40 days.

| Group | Dose |
|---|---|
| Group A | 0.5g |
| Group B | 1g |
| Group C | 2g |

***Adverse effects***

*Patients were specifically questioned as per a predetermined list of common symptoms as drowsiness, Fever, flatulence, vomiting, nausea, headache, heart burn, palpitation, constipation, diarrhea, comfortable in defecation, Burning sensation, tremor, based on researcher's experiences in clinical practice and mentioned in literatures.*

## Result And Interpretation

Clinical assessment was made on the basis of changes in the signs and symptoms before and after the treatment. Evaluation visits were made at baseline and each week up to 6$^{th}$ week. Effect of treatment was evaluated on the basis of changes in the signs and symptoms after the treatment. Clinical examination parameters were analysed by score as difference between the visits on first day of the treatment, middle part of the treatment (20$^{th}$ day) and end of the treatment (40$^{th}$ day).

The clinical efficacy of the drug was analysed statistically on all the symptoms mentioned in the assessment criteria. Initially, the variation and significance of effect seen within the 30 patients were calculated by paired **t test**. The difference of individual score SD was calculated with Standard Error in Mean (SEM). These data are shown as Mean ± SEM. Then, to more specifically quantify the percentage of improvement in each patient, this was also calculated using the formula (BT – AT) × 100/BT. On the basis of grading pattern as well as percentage relief, patient was classified under the five categories.

1. Complete remission:- 100% relief in signs and symptoms

2. Markedly improved: - Patients showing improvement between 50-99%
3. Moderately improved : - Improvement between 49-26%
4. Mildly changed:- Less than 25% relief
5. Unchanged:- No improvement

***Data analysis***

The data was analysed using the Statistical Package for Social Sciences (SPSS) version 20. Dependent variables and independent variables were used.

***Descriptive statistics/ Univariate analysis***

Descriptive statistics/ univariate analysis of data were performed to identify the main characteristics of the research variables.

***Paired-Samples T Test***

The Paired-Samples T Test procedure compares the means of two variables for a single group. The procedure computes the differences between values of the two variables for each case and tests whether the average differs from 0.Confidence Interval- By default; a 99% confidence interval for the difference in means is displayed. Enter a value between 1 and 99 to request a different confidence level. Missing Values- When test several variables and data are missing for one or more variables, can tell the procedure which cases to include (or exclude): Exclude cases analysis by analysis. Each t test uses all cases that have valid data for the tested pair of variables. Sample sizes may vary from test to test. Exclude cases list wise. Each t test uses only cases that have valid data for all pairs of tested variables. The sample size is constant across test.

***Limitation of the study***

- This study had been conducted as a preliminary study.
- The sample size is very less (30)
- Follow up has made only 40 days.

## RESULT AND DISCUSSION

***Age***

Maximum number of patients 9(9:30%) was in age groups of above 60 years, followed by 7(7:23.3%) in the age group of 50-54 years, 5(5:16.7%) was in age group of 45-49years, and 4(4:13. %) in the group of 55-59 years. It may be deduced that symptoms of *Azhal Keelvayu* starts after the 4$^{th}$decade. In *Azhal Keelvayu*, *Azhal and Váta Dosahs* are mainly involved. According to the Siddha principles, *Azhal and Váta dosahs* fluctuates in mid and last thirty three year division of one life span. *Keelvayu* is prevalent in 80% of the population above the age of 40 years of both sexes (Vasudeva, 2004). One's vocation may influence the causation of this condition**.**

**Occupation**

Maximum number of patients 12(40%) were housewives, followed by 8(8:26.7%) were hotel workers, about 5(5:16.7%) were farmers and 4(4:13.3%) were fisher man. This supports the fact that physical exertion plays is an important role in the development of pathology in the weight bearing joint to produce *Azhal Keelvayu*. Ganten berg in a survey of a large series of cases found that there was high incidence of joint disorders in miners followed by factory workers (Jaffe, 1975).This study also shows that housewives, hotel workers, fisher man and farmers are more prone to get *Azhal Keelvayu.*

***Aggravating factors of Azhal Keelvayu***

***Types of food***

Maximum number of patients 26(86.7%) showed increase in symptoms on consumption of ash plantain followed in the descending order by 25(25:83.3%). Of ash pumpkin, 23(23:76.7%) for breadfruit and curd, and 22(22:73.3%) for pumpkin, snake gourd, potato, mutton 21(21:70%), cold water 19(19:63.3%), sweet potato, beef 18(18:60). These foods play an important role in the aggravation of *Vatha*. Vitiation of *Valli* and *Azhal* are the main causes for the development of *Azhal Keelvayu*. When *Vayu* is in vitiated condition if diets, which stimulate the Azhal (Pitham), are taken *Azhal Keelvayu* occurs (Kuppusamy Muthaliyar, 1936). Hence, according to the Siddha philosophy these foods are restricted during the treatment period (*Pathium*). This data supports the data in the literature.

***Heredity***

Maximum number of patients (12:40%) had family history of *Azhal Keelvayu*, followed by 8(8:26.7%) patients without family history of *Azhal Keelvayu*. Heredity plays an important role in the development of *Azhal Keelvayu*. The above data is supported by literature survey.

***Seasonal Variation***

Maximum number of patients 26(26:86.7%) had increase in symptoms during the season *Kuthirkalam* (October-November), followed by 24(24:80%) patients during the season *Karkalam* (August-September), 22(73%) of patients during the season *Muthuvenilkalam* (June- July) and 6(6:20%) of patients during the season *Munpanikalam* (December-January) and *Pinpanikalam*(February-March). According to the Siddha principals, accumulation (*Thanilai valarchi)* of *Váta* and *Azhal* is during the season *Muthuvenilkalam* and *Karkalam*. Provocation (*Vetrunilai valarchi)* is during the season *Karkalam* and *Kuthirkalam*. Normalcy (*Thanillai)* is during the season *Kuthirkalam* and *Munpanikalam* (Shanmugavelu, 2003).This study shows that aggravation of symptoms of *Azhal Keelvayu* during the season *Kuthirkalam*, which is the provocation period of *Azhal*. Next to *Kuthirkalam* aggravation of symptoms was during the season *Karkalam* which is the provocation period of *Váta* and accumulation period of *Azhal.* Next to *Karkalam* aggravation of symptoms during the season *Muthuvenilkalam,* this is the accumulation period of *Vatha*. *Munpanikalam* is the cold and rainy season. *Seetha* (cold) aggravates *Vatha.*A seasonal variation is mentioned as causative factors for *Vatharogam* in the texts and has been confirmed in this study.

***Past history of trauma***

Maximum number of patients (18:60%) had trauma in knee joint in the past Trauma directly damages the knee joints. Trauma mentioned as a risk factor for *Vatharogam* in the texts and is confirmed in this study**.**

***Menopause***

The maximum number of female patients (56.25%) had reached menopause. During the menopausal period, the deficiency of female hormone (Oestrogen) leads to increase the calcium absorption from the bones which causes calcium deficiency and the bones become weak leading to joint problem (Akhtar, 2010).

### *Effect of drug on pain*

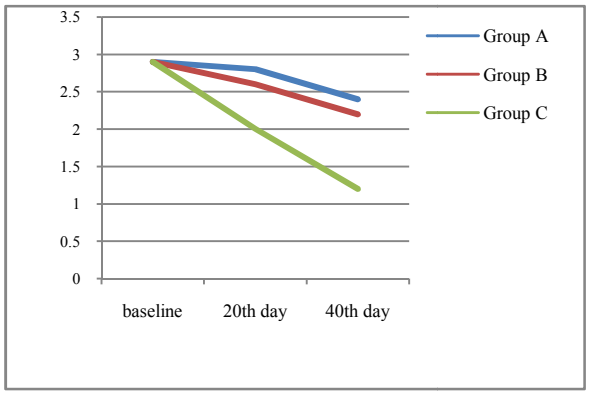



**Figure 4-4** effect on pain

**Table 4-1** Result of significance for pain

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed) P |
|---|---|---|---|---|---|---|
| Group A | 20th day | 1.00000 | .94281 | .29814 | 3.354 | .008 |
| | 40th day | 1.80000 | .63246 | .20000 | 9.000 | .000 |
| Group B | 20th day | .225 | .423 | .067 | 3.365 | .002 |
| | 40th day | .675 | .474 | .075 | 9.000 | .000 |
| Group C | 20th day | .90000 | .56765 | .17951 | 5.014 | .001 |
| | 40th day | 1.60000 | .84327 | .26667 | 6.000 | .000 |

In total, all the groups showed significant improvement. Treatment with 2g (Group C) showed high significant improvement over treatment with 1g (Group B) and Group C (0.5g).

### *Effect of drug in swelling*

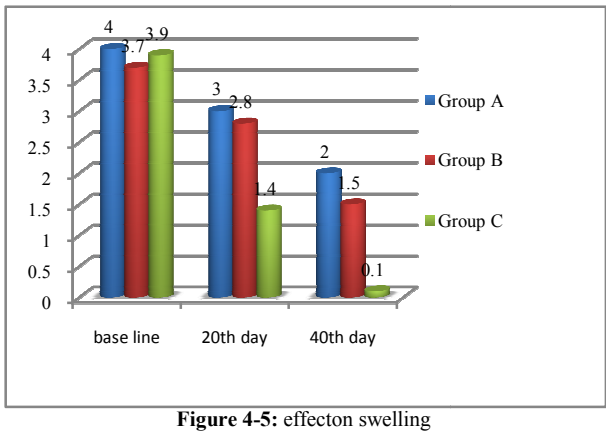



**Figure 4-5:** effecton swelling

**Table 4-2** Result of significance for swelling

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|
| Group A | 20th day | 1.07500 | .41679 | .06590 | 16.312 | .000 |
| | 40th day | 2.12500 | .79057 | .12500 | 17.000 | .000 |
| Group B | 20th day | .90000 | .31623 | .10000 | 9.000 | .000 |
| | 40th day | 2.20000 | .78881 | .24944 | 8.820 | .000 |
| Group C | 20th day | 2.50000 | .97183 | .30732 | 8.135 | .000 |
| | 40th day | 3.60000 | .84327 | .26667 | 13.500 | .000 |

In total, all three groups showed significant result in reduction in swelling. It clearly showed that the drug was effective on swelling with different doses.

### *Effect of drug in range of movement extension*

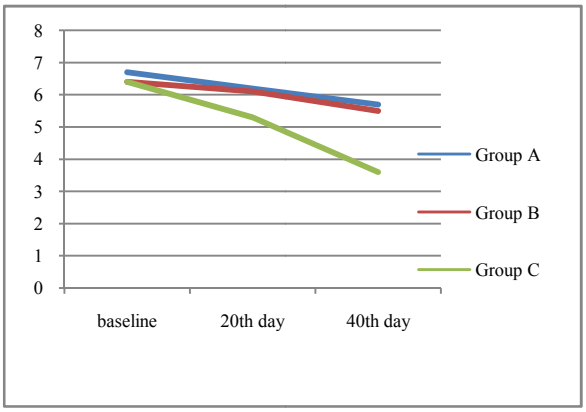



**Figure 4-6** effect on extension

In total, all the groups showed significant result in improvement in defect in restricted movement of extension. It clearly showed that the drug was effective on restricted joint movement extension on the dose of 2g, 1gand 0.5g. However, more relief with the dose of 2g.

### *Effect of drug on range of movement flexion*

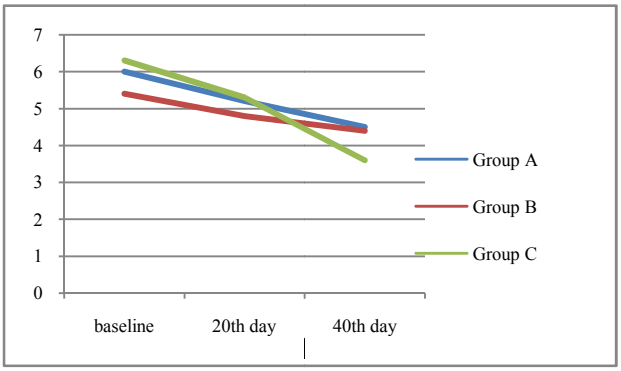



**Figure 4-7** effect on flexion

**Table 4-3** Result of significance for range of movement

| Group | | Treatment period | Mean | Std. Deviation | Std. Error Mean | Paired "t" | Sig. (2-tailed) P |
|---|---|---|---|---|---|---|---|
| Group A | extension | 20th day | .50000 | .52705 | .16667 | 3.000 | .015 |
| | | 40th day | 1.20000 | .78881 | .24944 | 4.811 | .001 |
| | Flexion | 20th day | .80000 | .63246 | .20000 | 4.000 | .003 |
| | | 40th day | 1.50000 | .84984 | .26874 | 5.582 | .000 |
| Group B | extension | 20th day | .32500 | .61550 | .09732 | 3.340 | .002 |
| | | 40th day | .90000 | .98189 | .15525 | 5.797 | .000 |
| | Flexion | 20th day | .67500 | .91672 | .14495 | 4.657 | .001 |
| | | 40th day | 1.02500 | .86194 | .13629 | 7.521 | .000 |
| Group C | extension | 20th day | 1.10000 | .73786 | .23333 | 4.714 | .001 |
| | | 40th day | 2.80000 | .78881 | .24944 | 11.225 | .000 |
| | Flexion | 20th day | 1.00000 | .66667 | .21082 | 4.743 | .000 |
| | | 40th day | 2.70000 | .94868 | .30000 | 9.000 | .000 |

In total, all the groups showed significant result in improvement in defect in restricted movement of flexion. It clearly showed that the drug was effective on restricted joint movement flexion on the dose of 2g, 1g and 0.5g. But more relief with the dose of 2g compare with other groups.

***Effect of drug with tenderness***

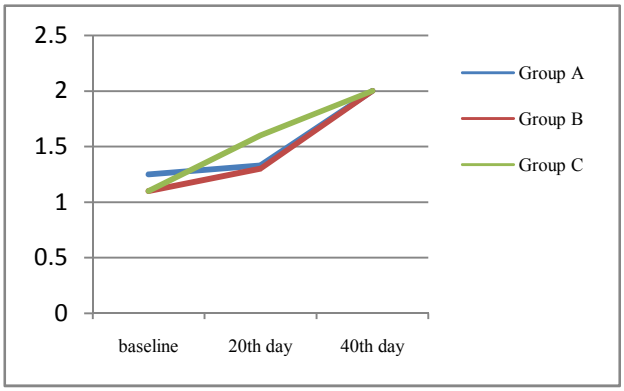



**Figure 4-9** effect on tenderness

**Table 4-4** Result of significance for tenderness

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|
| Group A | 20th day | -.075 | .764 | .121 | -.621 | .538 |
| | 40th day | -.750 | .439 | .069 | -10.817 | .000 |
| Group B | 20th day | -.20000 | .63246 | .20000 | -1.000 | .343 |
| | 40th day | -.90000 | .31623 | .10000 | -9.000 | .000 |
| Group C | 20th day | -.50000 | .52705 | .16667 | -3.000 | .015 |
| | 40th day | -.90000 | .31623 | .10000 | -9.000 | .000 |

In total, all the groups showed significant result in improvement in tenderness at 40th day. It clearly showed that the drug was effective on tenderness the dose of 2g, 1g and 0.5g. However, more relief with the dose of 2g compare with other groups.

***Effect of drug on crepitus***

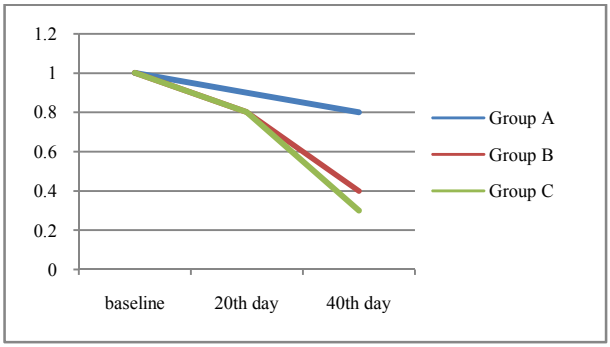



**Figure 4-10** effect on crepitus

**Table 4-5** Result of significance for crepitus

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|
| Group A | 20th day | -.100 | .304 | .048 | -2.082 | .044 |
| | 40th day | -.100 | .304 | .048 | -2.082 | .044 |
| Group B | 20th day | -.20000 | .42164 | .13333 | -1.500 | .168 |
| | 40th day | -.60000 | .51640 | .16330 | -3.674 | .005 |
| Group C | 20th day | -.20000 | .42164 | .13333 | -1.500 | .168 |
| | 40th day | -.70000 | .48305 | .15275 | -4.583 | .001 |

In total, two groups B and C showed significant result in improvement in crepitus on 40th day of treatment. It clearly showed that the drug was effective on crepitus on the dose of 2g and 1g with 40 day of treatment period but less effectiveness with in Group A.

***Effect of drug on warmness***

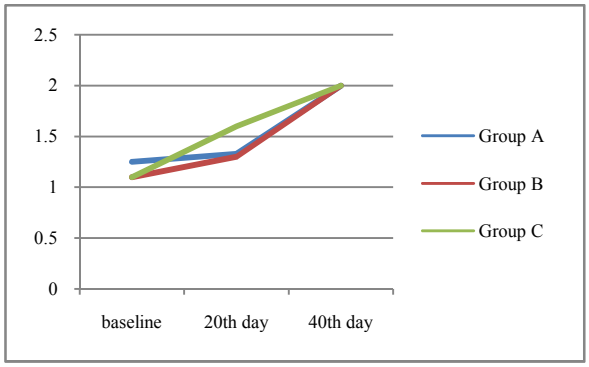



**Figure 4-11** effect on warmness

**Table 4-6** Result of significance for warmness

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed) P |
|---|---|---|---|---|---|---|
| Group A | 20th day | -.075 | .764 | .121 | -.621 | .538 |
| | 40th day | -.750 | .439 | .069 | -10.817 | .000 |
| Group B | 20th day | -.20000 | .63246 | .20000 | -1.000 | .343 |
| | 40th day | -.90000 | .31623 | .10000 | -9.000 | .000 |
| Group C | 20th day | -.50000 | .52705 | .16667 | -3.000 | .015 |
| | 40th day | -.90000 | .31623 | .10000 | -9.000 | .000 |

In total, all the groups showed significant result in improvement in warmness in 40th day. It clearly showed that the drug was effective on warmness on the dose of 2g, 1g and 0.5g after 40 day of treatment but more relief with group B and C compare with Group A.

***Effect of drug on defected ligaments of knee joint***

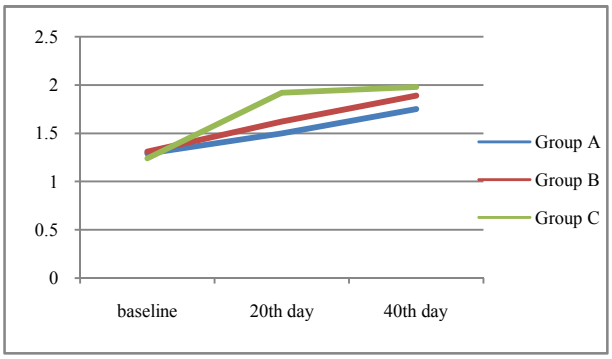



**Figure 4-12** effect on ligament

**Table 4-7** Result of significance for ligament healing

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|
| Group A | 20th day | .05000 | .16499 | .05217 | .958 | .363 |
| | 40th day | -.60000 | .29059 | .09189 | -6.529 | .000 |
| Group B | 20th day | -.31250 | .35532 | .05618 | -5.562 | .000 |
| | 40th day | -.57500 | .33108 | .05235 | -10.984 | .000 |
| Group C | 20th day | -.68000 | .35214 | .11136 | -6.107 | .000 |
| | 40th day | -.72000 | .31198 | .09866 | -7.298 | .000 |

In total, all the groups showed significant result improvement in defected ligament. It clearly showed that the drug was effective on defected ligament on the dose of 2g, 1g and 0.5g. Only 0.5g was effective after the treatment 40 days of treatment.

***Effect of WOMAC score on test drug with dosage***

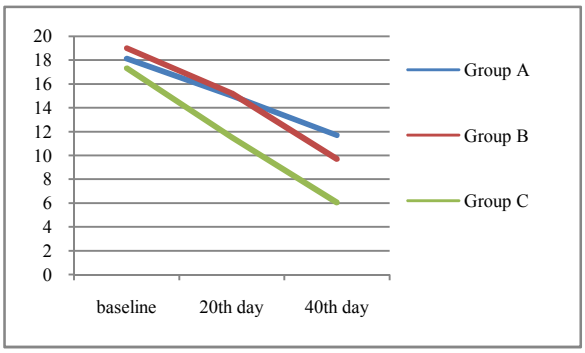



**Figure 4-13** effect on WOMAC score

**Table 4-8** Result of significance for WOMAC score

| Group | | Treatment period | Mean | Std. Deviation | Std. Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|---|
| Group A | Pain | 20th day | .400 | .516 | .163 | 2.449 | .037 |
| | | 40th day | 1.200 | .632 | .200 | 6.000 | .000 |
| | stiffness | 20th day | .175 | .385 | .061 | 2.876 | .006 |
| | | 40th day | .725 | .452 | .071 | 10.140 | .000 |
| | Physical function | 20th day | .800 | .789 | .249 | 3.207 | .011 |
| | | 40th day | 2.200 | .919 | .291 | 7.571 | .000 |
| Group B | Pain | 20th day | .125 | .335 | .053 | 2.360 | .023 |
| | | 40th day | .800 | .405 | .064 | 12.490 | .000 |
| | stiffness | 20th day | 1.000 | .667 | .211 | 4.743 | .001 |
| | | 40th day | 1.800 | .919 | .291 | 6.194 | .000 |
| | Physical function | 20th day | .325 | .474 | .075 | 4.333 | .000 |
| | | 40th day | .800 | .911 | .144 | 5.551 | .000 |
| Group C | Pain | 20th day | 1.100 | .738 | .233 | 4.714 | .001 |
| | | 40th day | 2.000 | .667 | .211 | 9.487 | .000 |
| | stiffness | 20th day | 1.000 | .667 | .211 | 4.743 | .001 |
| | | 40th day | 1.900 | .738 | .233 | 8.143 | .000 |
| | Physical function | 20th day | 1.100 | .738 | .233 | 4.714 | .001 |
| | | 40th day | 2.200 | 1.135 | .359 | 6.128 | .000 |

In total, all three groups showed significant result in reduction in WOMAC score. Anyhow Group C showed high effectiveness in deduction of symptoms such as pain, stiffness and physical function compare with Group A and B.

***Effect of drug on six minutes walking distance***

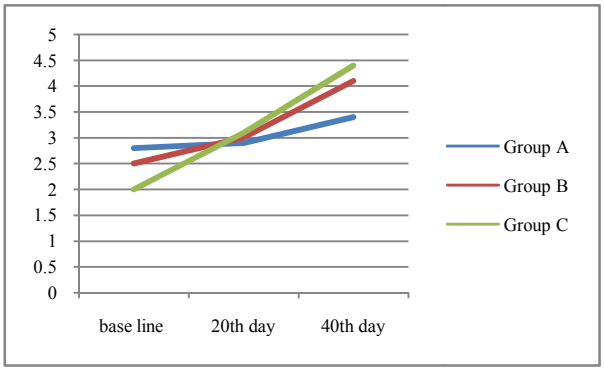



**Figure 4-14**effect on six minutes walking distance

**Table 4-9** Result of significance for six minutes walking test

| Group | Treatment period | Mean | Std. Deviation | Std.Error Mean | Paired "t" | Sig. (2-tailed)P |
|---|---|---|---|---|---|---|
| Group A | 20th day | .125 | .335 | .053 | 2.360 | .023 |
| | 40th day | -.475 | .506 | .080 | -5.940 | .000 |
| Group B | 20th day | -.600 | .516 | .163 | -3.674 | .005 |
| | 40th day | -2.000 | .943 | .298 | -6.708 | .000 |
| Group C | 20th day | -1.100 | .568 | .180 | -6.128 | .000 |
| | 40th day | -2.400 | .516 | .163 | -14.697 | .000 |

In total, all the groups showed significant result in improvement in six minutes walking distance. It clearly showed that the drug was effective on six minutes walking distance on the dose of 2g, 1g and 0.5g on 20th day. Group A showed significant after 40th day of treatment.

***Overall therapeutic effect with dosage***

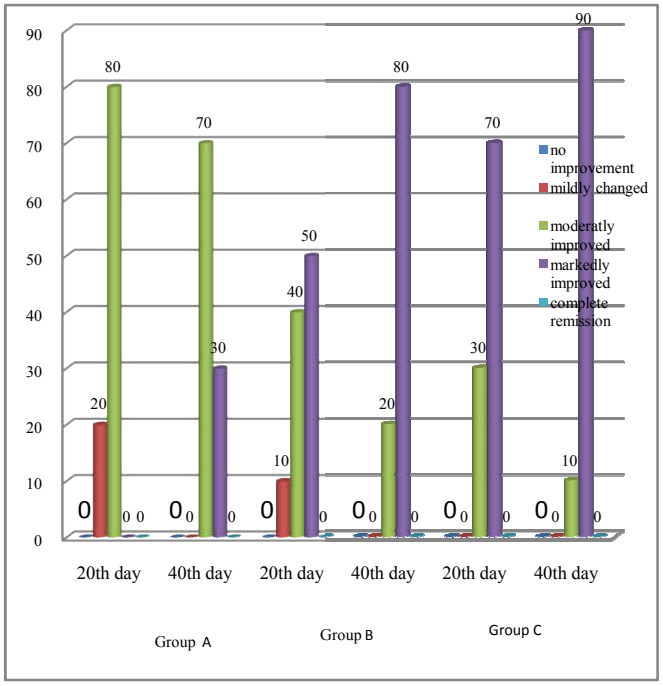



**Figure 4-15** overall therapeutic effect

In summary, based on the research with these results, it can concluded that 2g and 1g of *Calamus rotang Chooranam* have potency to cure the *Azhal Keelvayu* and serve all the needs, which are required for the treatment of *Azhal Keelvayu*.

***Side effects of test drug***

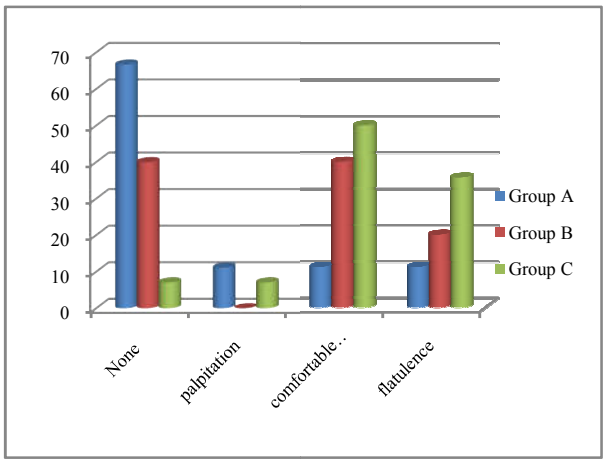



**Figure 4-16** side effect

In total side effect were increasing with the dose of the drug, however the evacuation of stool and flatulence were more common side effect of this study. Constipation is a common problem among the elders and this drug is effective in *Azhal Keelvayu* as well as in constipation. Therefore, the side effect of the drug showed beneficial effect on elder and who had constipation.

## CONCLUSION AND RECOMMENDATION

## CONCLUSION

***Based on results and the findings of this study, the following conclusion can arrived at;***

1. *Calamus rotang Chooranam* can used as a highly effective internal administrative medicine for *Azhal Keelvayu.* Dose effectiveness of *Calamus rotang Chooranam* as follows:

I. 2g of *Chooranam* of *Calamus rotang* (Group C) shows significant (<0.01) and markedly improvement on 20th and 40th day of treatment compare to 1g and 0.5g (Group A and Group B).

II. 1g of *Chooranam* of *Calamus rotang* shows markedly improvement on 20th and 40th day, the dose effectiveness comparably less than the 2g and more than the 0.5g.

III. 0.5g of *Chooranam* of *Calamus rotang* shows moderately improvement on 20th and 40th day of treatment the dose effectiveness comparably less than the dose of 2g and 1g.

2. It provides the successful proof of the traditional literature about *Calamus rotang.*
3. This study confirms the aggravating and etiological factors mentioned in the texts (Kuppusamymuthaliyar, 1936), Supramaniyam (1983), (Shanmugavelu 2003) and (Arunachalam, 2004) for *Azhal Keekvayu*.
4. No severe side effect was detected although it shows comfortable in evacuation of stool, which consider as a beneficial effect of *Calamus rotang Chooranam*.

***Recommendation***

*Chooranam* of *Calamus rotang* is a single herbal preparation even though it shows effective improvement in *Azhal Keelvayu*. This provides a base for further research especially on the phytochemical analysis.

Further research should be continuing in experimental study on *Calamus rotang* for *Azhal Keelvayu.*

## References


1. Abhinov.T, V. (2014). Protective effect of methanolic extract of rhizome Calamus rotang linn on carbon tetra chloride induced hepatotoxicity in rat. *Journal of chemical and pharmaceutical sciences*3(2) 974 -2115.
2. Amit Gupta, S. R., & Chaphalkar. (2015). Rapid Detection Of Immunosuppressive Activity Of Aqueous Extract Ofcalamus Rotang Using flow cytometry. *Journal of Medicinal Chemistry and Drug Discovery* , 2(1) 01-08.
3. Amit Gupta, J. P. (2016). Evaluation Of Antibacterial Activity Of Medicinal Of plants against pseudomonas fluorescens and bacillus subtilis. *World journal of pharmaceutical and medical research* , 2(4),142-145.
4. Aparna Shil, M. K. (2012). In vitro antioxidant activity of the methanolic extracts of leaf and fruit of calamus rotang linn. *J.Expt.Biosci* , 3(2):33-36.
5. Altman RD, Alarcon GS, Appelrouth D, Bloch D, Borenstein D, Brandt K et al,(1991) the American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip, Arthritis Rhum ;3(4):505-14.
6. Balgojevic M, Jinks C, Jeffery A,Jordan KP.,(2010) Risk factor for onset of Osteoarthritis of the knee in older adults: a systematic oeviea and meta-analysis. Osteoarthritis and cartilage.1 (8): 24-33.
7. Bellamy N,Buchanan WW, Goldsmith Ch, Campbell J, Stitt LW,(1988), Validation study of WOMAC: a health status instrument for measuring clinical important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee, *J Rheumatol* :1(5):1833-40.
8. Bellamy N.(1995) WOMAC osteoarthritis user's guide. London, Ontario, Canada: Victoria Hospital.
9. Brain R. Walker, Nicki R, C. B. (2014). *Davidson's principal and practice of Medicine.* 22nd edition, London, England: Churchi Living Stone Elsevier.
10. Chaphalkar, A. G. (2015). Immunosuppressive activity of crude saponins from the leaves of Calotropis gigantea Calamus roteng and Artocarpus integrifolia. *International Journal of Pharma Sciences and Research (IJPSR)* , 526-531.
11. Corjena Cheung, J. B. (2014). Yoga for managing knee osteoarthritis in older women: a pilot randomized controlled trial. *journal of inflammation*
12. Creamer P, Flores R, Hochberg MC. (1998). Management of osteoarthritis in older adults *Clin Geriatr Me*d; 14(3):435-54.
13. Davis MA, Ettinger WH, Neuhaus JM, Barclay JD, Segal MR.(1992) correlates of knee pain among United States adults with and without radiographic knee osteoarthritis. *J Rheumatol*; 19(1):1943-9.
14. Eichenseer C, W. J. (2010 Jan). Biomorphous porous hydroxyapatite-ceramics from rattan (Calamus Rotang). *J Mater Sci Mater Med.* , 21(1):131-7.
15. Farhana Alam Ripa, P. R. (2015). CNS depressant, analgesic and anti-inflammatory activities of methanolic seed extract of Calamus rotang Linn. fruits in rat . *Journal of Pharmacognosy and Phytochemistry* , 3(5): 121-125.
16. Felson DT, Lorence RC, Dieppe PA,Hirsch R, Helmick CG, Jordan JM. (1990) Osteoarthritis, new in size: The disease and risk factors. Ann: Intern. Med. 200,635-646.
17. Gupta, A., & Chaphalkar, S. R. (2016). Assessment of immunomodulatory activity of aqueous extract of Calamus rotang. *Journal of Phytomedicine*.
18. *http://www.augustayurveda.com.* (n.d.).
19. http://www.botnical.com
20. http://www.nischennai.org (2014).
21. http://www.naturalstandard.com.
22. http://www.Siddha ayurveda altimate well-being. (2014)
23. Hannan MT, Anderson JJ, Pincus T, Felson DT (1992). Educational attainment and osteoarthritis – differential association with radiographic changes and symptom reporting. *J Clin Epidermiol* 1992; 4(5):139-47.
24. Jayaweera, D. (1998). *Medicinal plants (Indigenous and Exotic) used in Ceylon. part 4.* Colombo: The National Science Council of Srilanka.
25. Kandaswamy Pillai, (1979).N. History of Siddha Medicine. Madras.
26. Kenneth G. (2008): *Asceticism and healing in ancient India*. 1991; rpt. Motilal Banarsidass, Delhi.

27. Kirtikar, K.R., Basu, B.D., 1987. Indian medicinal plants. 2nd edition. Dehradun: International Book Distributors.
28. Kuppusamymuthaliar, K.N., (2007) Siddha maruthuvam(pothu), 8th edition., Chennai: inthiyamaruthuvam homeopathythurai
29. Lad, Vasant. (1998). Textbookof Ayurveda, volume 2: A complete guide to clinical assessment. *The Ayurvedic press,* 2(4) 30,235,242-279.
30. McCaffery M, Pasero C. (1999) *Pain: Clinical Manual,* St. Louis, 1999, P. 16. RK Portenoy & RM Tanner, *Pain Management: Theory and Practice* 1996 by Oxford University Press, Inc.
31. Meenan RF, Gertman PM, Mason JH (1980), Measuring health status in arthritis:the arthritis impact measurement scales. *Arthritis Rheum*: (23):146-52.
32. Menkes, CJ. Radiographic criteria for classification of osteoarthritis. *J Rheumatol.*, (1991); 18 (27)18:13-5.
33. Mishra LC, Singh BB, Dagenais S. (2001) Healthcare and Disease Management in Ayurveda; 7(2):44-50.
34. Murugesamuthaliyar.K.S (2013). *siddha Materia Medica (Plant division).* Chennai, India: Indian Maruthueam, Homeopathy thurai.
35. Myles PS, Troedel S., (1999). Boquest M, Reeves M. The pain visual analog scale: is it linear or nonlinear? [See comments]. *Anesth Analg*. 1999;89:1517-20
36. Narayanaswami, V., (1975):.*Introduction to the Siddha system of medicine*. Pandit S.S. Anandam Research Institute of Siddha Medicine, Madras,1-5
37. Pole, Sebestain. (2006). Ayurvedic Medicine. The Principles of Traditional practice. Churchill Livingston Elsevior, 51-52.
38. Ramaswamy, H. N. (2003). Contributions to the Study of microsporogenesis in calamus L.(Arecaceae). 180-193.
39. Ramanathan. P, (2002). *Mooligai seyal thokuppu Action of herbs*, Ezhalai Mahathma Atchagam.
40. Saraswathy A, a. V. (2012, december). *idma-assn.org.* Retrieved november 26, 2012, from india-drugs.
41. Scott JC, Hochberg MC.,(1993) Arthritic and other musculoskeletal diseases. In Brownson RC, Remington PL, Davis JR, eds. chronic diseas epidemiology and control. Washington, D.C.: American Public Health Association, 1993.
42. Shanmugavelu, M., (2010). Noi naadal Noi muthal naadal Thirattu.part1, 8th ed., Chennai: Inthiya maruththuvam homeopathy thurai, pp. 21-25,245.
43. Shanmugavelu, M., (2010) Noinaadal Noimuthalnaadal Thirattu.part 2, 8thed. Chennai: inthiyamaruththuvam homeopathy thurai. 2(8).
44. Sharma, R, Dash, B., (2001).Charaka Samhita, Varanasi, India:Chukhambha Sanskrit Series Office
45. Singh BB, Mishra LC, Kohlbeck F, Aquilina N., (2001) Usefulness of Guggul for Osteoarthritis of the Knee: An Experimental Case Study. Alter There; 7(2):114-120.
46. Supramaniyam,S.V Madhavan, (1983). Keelvayu (arthritis) A detailed study. In: Supramaniyam, V (eds), Heritage of Tamil Siddha Medicine, Madrass 600113: Internal Institute of Tamil studies, Pp 227-332.
47. Subbarayappa, B.V., (1971). Chemical practices and alchemy. In: Bose DM. Sen SN, Subbarayappa BV, editors. A Concise History of Science in India, New Delhi: Indian National Science Academy. p. 315-35.
48. Subramaniam, S.V & Madhavan V.R., (1984). *Heritage of the Tamils. Siddha Medicine*. International Institute of Tamil Studies, Madras.
49. Supramaniyan,V., (2007). Siddha maruthuvam (vatham thodarpana noikal), 2nd ed., Chennai: Tamil valarchi kalaham, pavai printers pvt ltd, 4(2).
50. Uththamarayan.K.T, (2009). *Siddhar Aruwai Maruthuwam* (Vol. 5). Chennai 600106: India Maruthuwam, Homeopathy thurai.
51. Uthamaroyan, C.S,. A Compedium of Docrine, 2005. *Govt. of Tamilnadu. Department of Indian and Homoeopathy. Chennai-106, pp362.*
52. Uthamaroyan C,S., (1992) .Thotra Kirama Araiachium Siddha Maruthuva Varalarum. Chennai: Tamilnadu Govt. Siddha Medical Board.
53. Vasudhevasasthri.K. (1998). *Sararabenthira vaithiya muraikal, vatha roga sikitchai.* Sarasuwathy mahal library.
54. Yugimamunivar. (1998). *Yugi vaithiya chindamani.* chennai 600106: Indian medicine - hormiopathy.
55. www.dsir.gov.in


*******