



Research Article

**A CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF *KOKILAKSHADHI KWATHA* IN THE MANAGEMENT OF *VATAKANTAKA* (PLANTAR FASCIITIS)**

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**ABSTRACT**

Pain is a symptom which alters our day to day activities, affecting the quality of life. One among such pain is, pain in the heel, which causes difficulty in walking and in turn disturbs daily routines. Plantar fasciitis is most common cause of heel pain in adults. It is estimated that 1 in 10 people may experience inferior heel pain during their life time. Signs and symptoms of *Vatakantaka* resembles with Plantar fasciitis according to modern paralines.

Treatment Modalities according to modern science is NSAIDS, toe stretching, corticosteroid injections, extracorporeal shock wave therapy and surgical correction are the indicated treatments. Analgesics have been used in practice by modern practitioners to give immediate relief to patients from pain. And modern medicine has a huge number of the drug for pain management but they impact body with serious side effects. Therefore there is a large scope of finding a treatment for *Vatakantaka* So in this study *Kokilakshadi Kwatha* explained in *Yogaratanakara* is considered. The study is divided into four sections as Disease review, Drug review, Pharmaceutical study and clinical study.

**Methods:** The outcome of *Kokilakshadi kwatha* is evaluated clinically on minimum of 30 patients. *Kokilakshadi kwatha* was given for 21 days. The lab test and clinical analysis were done as per requirement for the assessment. Evaluation of parameters of the disease like Pain and Tenderness were done before treatment, after 11 days and after 21days.

**Results:** As a result, Out of 30 patients, highly significant results ( $p < 0.001$ ) were obtained with respect to pain (93.3%) and tenderness (60%).

**Conclusion:** *Kokilakshadi Kwatha* showed good results in reduction of signs and symptoms of *Vatakantaka*. The statistical analysis also supported this by concluding that the improvement after treatment is highly significant.

**INTRODUCTION**

Pain is most common reason which makes people seek medical help. Pain management is very important factor in clinical practice. Analgesics is used in practice by the modern physician from several years. Therefore there is a wide scope to find out a safest formulation from Ayurveda which will benefit the society.

*Vatakantaka* is the condition characterized by prickly kind of pain kind of pain at the heel of the foot. The earliest reference of it is available in *Sushruta Samhita* i.e., 1500 B.C. He explains as painful condition of heel due to placing foot in uneven surface. [1] In *Madhyama khanda* of *Bhavaprakasha*, *Lakshanas* and treatment of *Vatakantaka* is explained in *Vatavyadhyadhikara*. In treatment aspect he has mentioned *Dahana*, *Snehana*, *Upanahana* and usage of *Indravarunimula*, *Pippali* and *Guda* combined together internally.[2] *Lakshanas* and treatment of *Vatakantaka* are explained in *Vatavyadhy-adhikara* in *Poorvardha* of *Yogaratanakara*. [3] *Yogaratanakara* states a name as *Padakantaka* [4], which is pain on the soles because of placing foot on the uneven surface. When *Vata* gets localized in the ankle joint while placing the foot

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unevenly while walking or over exertion causes pain in the ankles. This is *Vatakantaka*. [5]

Plantar fasciitis affects individuals regardless of sex, age, ethnicity, or activity level. It is seen in physically active individuals such as runners and military personnel, but is also prevalent in the general population, particularly in women ages 40-60. [6] The *Nidanas* leading to *Vata prakopa* in the foot and results in heel pain.

Heel pain can be correlated to plantar fasciitis in modern science. It occurs from the inflammation of plantar aponeurosis at its attachment on the tuberosity of the calcaneum. The pain is first complained of in the early morning and gradually improves with activity. [7] The repetitive movement or running can cause injury to the fascia which in turn leads to inflammation. Plantar Fasciitis is considered an overuse injury and as such, the patient's history will typically reveal some combination of either extrinsic or intrinsic factors that contributed to the development of the injury. Extrinsic factors like moving on unyielding surfaces and improper or excessively worn foot wear. Intrinsic factors have included such elements as obesity, foot structure, reduced plantar flexion strength and reduced flexibility of the plantar flexor muscles. [8] Giving relief to patients from this condition stands as a challenge for clinicians.

Plantar fasciitis is the most common cause of plantar heel pain, accounting for 80% of patients with symptoms. [9]

In modern science nonsteroidal anti-inflammatory drugs (NSAIDs), stretching, corticosteroid injections, extracorporeal shock wave therapy and surgical correction are the indicated treatments. [10] Analgesics have been used in practice by modern practitioners to give immediate relief to patients from pain.

## MATERIALS AND METHODS

### Source of data

#### 1. Literary Source

Significant data is collected from Ayurvedic classics, contemporary Ayurvedic literatures, modern texts and internet sources.

#### 2. Sample Source

Patient who fulfills the inclusion criteria will be randomly selected from OPD and IPD of Karnataka Ayurveda Medical College and Hospital and also from referral sources and special camps conducted for the purpose.

#### 3. Drug Source

Raw drugs will be procured from authentic sources and preparation of *Kwatha choorna* will be

carried out at the pharmacy attached to Karnataka Ayurveda Medical College, Mangaluru.

### *Kokilakshadhi Kwatha* [11]

#### Ingredients

#### *Kokilaksha and Guduchi*

Process of drug making-Take equal quantity of the above mentioned ingredients and coarsely powder it. Add 8 times of water and reduce to 1/4<sup>th</sup> by boiling under uniform heat.



#### Method of collection of data

##### a. Sample Size

A minimum of 30 patients fulfilling the diagnostic and inclusion criteria of either gender will be selected for the clinical study and will be administered *Kokilakshadi kwatha*.

##### b. Diagnostic Criteria

Patients presenting with the *Lakshanas* of *Vatakantaka* will be selected.

- *Thoda* (Pain in Plantar region of Foot)
- *Sparsha asahathwa* (Tenderness in Plantar region of foot)

##### c. Inclusion Criteria

- Age 30 – 60 years.
- Patients irrespective of Sex, Religion and Economic Status.
- Patients with symptoms of recent onset (Below 1 year)
- Patient with pain, Tenderness over medial aspect beneath the heel

##### d. Exclusion Criteria

- Patients having Chronic and Acute Systemic Diseases like Diabetes Mellitus, Tuberculosis.
- Pregnant and Lactating mother.
- Patients with Gout, sensory motor deficit due to nerve injury.
- Regional anatomical deformities like pes planus and pes cavus.

### Procedure and design of the study

Included patients will be treated as follows:

Sample size	30 Patients
Drug	Kokilakshadhi Kwatha
Dose	50 ml before breakfast and 50 ml before dinner

### Duration of study

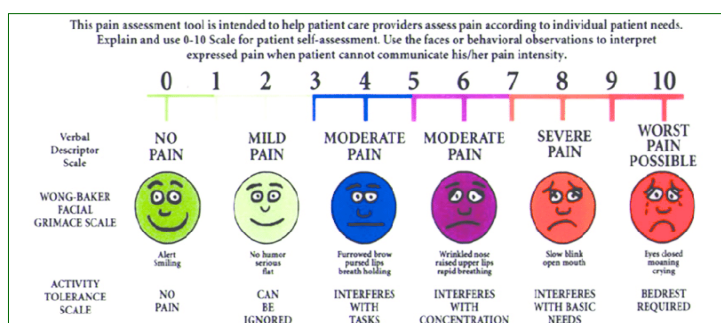
The total duration of the study will be 21 day of active intervention and periodic observation done once in a week during the intervention of drug.

### Assessment Criteria

It will be made on the basis of subjective and clinical objective parameters both before and after the treatment as per the clinical proforma.

### Subjective parameters

- Pain



### Objective Parameters

- Tenderness

### Grading Scale for Tenderness

+1/4 T, or grade 1/4 tenderness	Tenderness with no physical response
+2/4 T, or grade 2/4 tenderness	Tenderness with grimace, wince, and/or flinch
+3/4 T, or grade 3/4 tenderness	Tenderness with withdrawal (positive jump sign)
+4/4 T, or grade 4/4 tenderness	Non-noxious stimuli (e.g., superficial palpation, gentle percussion) results in patient withdrawal or patient refusal to be palpated due to pain

### Laboratory Investigations

- X ray of foot Lateral view if required
- Serum Uric acid if required

### Assessment of results

- A detailed proforma will be prepared and assessment will be done on subjective and objective parameters during the study. The data obtained will be analyzed statistically by using suitable tests of significance.

### Analytical Study

### Results

**Table 1: Results of standardization parameters of of Kokilakshadi kwatha churna**

Parameter	Results n = 3%w/w (Avg ± SD)
Loss on drying	7.10 ± 0.00
Total Ash	8.11 ± 0.16
Acid Insoluble Ash	0.39 ± 0.01
Water soluble Ash	2.79 ± 0.01
Alcohol soluble extractive value	3.29 ± 0.01
Water soluble extractive value	15.08 ± 0.01

**Table 2: Results of preliminary phytochemical screening of Kokilakshadi kwatha churna**

Test	Inference
<b>Alkaloid</b>	-
<b>Steroid</b>	+
Carbohydrate	+
Tannin	+
Flavanoids	+
Saponins	-
Terpenoid	-
Coumarins	+
Phenols	-
Carboxylic acid	-
Amino acids	-
Resin	-
Quinone	-

(+) – Present; (-) – Negative

### Statistical Analysis

This study was carried out on 30 patients of *Vatakantaka*. Patients were treated with *Kokilakshadi kwatha* internally. For the assessment of effect of treatment subjective parameters like Pain, Tenderness is considered on before and after treatment. Normality of Variable (Pain, Tenderness) is checked using Shapiro Wilk Test  $p > 0.05$ . Hence using Non- Parametric Test. We have used Non Parametric test Wilcoxon Sign Rank test for pre and post comparison.

Friedman's Anova is used for Comparison of three time point's i.e. 0<sup>th</sup> day, 11<sup>th</sup> day and 21<sup>st</sup> day.

### Observations

Higher incidence of *Vatakantaka* was reported in age group of 40-49yrs. Out of 30 patients enrolled for the study 83.33% were females and 16.66% were males. 90% of patients belonged to Hindu religion. Out of total 30 patients 53.33% patients belonged to Middle class socio economic status. Out of total 30 patients 46.7% patients were Housewives in terms of occupation. 80% of patients were Non-vegetarians. Out of total 30 patients 70% patients were found as Moderate nature of work. Out of total 30 patients 73.33% patients were having pain with found Moderate exertion. Out of total 30 patients 53.33% patients were having chronicity of occurrence of symptoms between 1-6 months. 46.7% patients were having pain in right side.

### Distribution of Patients Based on Sex

**Table 3: Distribution of Patients According to Gender**

Gender	No of Patients	Percentage
Male	5	16.67
Female	25	83.33

Sex wise: Out of 30 patients 25 were female and 5 patients were male.

### According to Religion

Out of total 30 patients 90% of people were Hindu. Muslim were 6.66% and Christian were 3.33%. As given in the below table.

**Table 4: Distribution of Patients According to Religion**

Religion	No of Patients	Percentage
Hindu	27	90
Muslim	2	6.66
Christian	1	3.33

**According to Socio Economic Status**

In this study 53.33% patients were from middle class which was the largest class. 40% of people were from lower class and 6.66 % from higher class as shows in the below table.

**Table 5: Distribution of Patients According to Socio Economic Status**

Socio Economic Status	No of Patients	Percentage
Lower	12	40
Middle	16	53.33
High	2	6.66

**According to Occupational Status**

In this study the 46.7% of patients are house wife. 6.7% were Maid. 1% of people were clerk, Daily wage worker, Driver, Electrician, Factory worker, Fish Seller, Homemaker, LIC Agent, Nurse and Shopkeeper each.

**Table 6: Distribution of Patients According to Occupational Status**

Occupation	No.of Patients	Percentage
Clerk	1	3.3
Daily wage worker	1	3.3
Driver	1	3.3
Electrician	1	3.3
factory worker	1	3.3
Fish Seller	1	3.3
Homemaker	1	3.3
House wife	14	46.7
LIC Agent	1	3.3
Maid	2	6.7
Nurse	1	3.3
shopkeeper	1	3.3

**According to Diet**

In this study vegetarians 20% were vegetarians and rest of the 80% are non-vegetarians as shown in the below picture.

**Table 7: Distribution of Patients According to Diet**

Nature of Diet	No of Patients	Percentage
Vegetarian	6	20
Non Vegetarian	24	80

**According to Nature of Work**

In this study 3.33% were having sedentary life, 70% were having moderate and 26.66% were doing the strenuous work as shown in the below picture.

**Table 8: Distribution of Patients According to Work**

Nature of Work	No of Patients	Percentage
Strenuous	8	26.66
Moderate	21	70
Sedentary	1	3.33

**According to Severity**

In this study 73.33% of people were having pain with Moderate exertion. 16.66% of People were having pain with Mild exertion sudden and 1%. Of People were having pain with severe exertion.

**Table 9: Distribution of Patients According to Severity**

Mode of Onset	No of Patients	Percentage
Severe Exertion	3	1
Moderate Exertion	22	73.33
Mild Exertion	5	16.66

**According to Chronicity**

In this study 53.33% of people were having 1 to 6 months of chronicity. 43.33% were having 6 to 12 month and 3.33% were having 1 month of chronicity.

**Table 10: Distribution According to Chronicity**

Chronicity	Frequency	Percent
1 month	1	3.3
1-6 months	16	53.33
6-12 months	13	43.33

**According to Side**

In this study 46.7% of people were having pain in both side. 36.7% were having pain in left side and 46.7% were having pain in right side.

**Table 11: Distribution According to Side**

Side	Frequency	Percent
Both	11	36.7
Left	5	16.7
Right	14	46.7

**Results**

This study was carried out on 30 patients of *Vatakantaka*. Patients were treated with *Kokilakshadi kwatha* internally. For the assessment of effect of treatment subjective parameters like Pain, Tenderness is considered on before and after treatment.

**Pain**

The symptom pain reduced and showed highly significant result. In before treatment assessment pain showed a Median score of 9. On the first assessment on 11<sup>th</sup> day the Median score of pain reduced to 5 with 80% improvement and on 21<sup>st</sup> day median score further reduced to 2 with 93.3%. The P value is <0.001 on the 21<sup>st</sup> day of treatment with extremely significant result.

**Tenderness**

Tenderness was reduced after the Treatment. In before treatment assessment tenderness showed a median score of 3. On the first assessment on 11<sup>th</sup> day the Median score of tenderness reduced to 2 with 40% improvement and on 21<sup>st</sup> day median score further reduced to 1 with 60% improvement. The P value is <0.001 on the 21<sup>st</sup> day of treatment with extremely significant result.

Hence it is observed that *Kokilakshadi kwatha* in plantar fasciitis showed highly significant result in reducing the signs and symptoms.

**Table 12: Comparison of Effect of *Kokilakshadi kwatha* on Pain in 3 time points**

Pain	Median	IQR=Q3-Q1	Chi-Sqaure	P-Value
0 <sup>th</sup> Day	9	1		
11 <sup>th</sup> Day	5	2	60.00	<0.001
21 <sup>st</sup> Day	2	1		

**Table 13: Comparison of Effect of *Kokilakshadi kwatha* on Tenderness in 3 time points**

Tenderness	Median	IQR=Q3-Q1	Chi-Sqaure	P-Value
0 <sup>th</sup> Day	3	0.25		
11 <sup>th</sup> Day	2	0	57.053	<0.001
21 <sup>st</sup> Day	1	0		

**Table 14: Comparison of Effect of Kokilakshadi kwatha on Pain before and After treatment**

Pain	Median	IQR=Q3-Q1	Z -Value	P-Value
0 <sup>th</sup> Day	9	1	-4.865	<0.001
21 <sup>st</sup> Day	2	1		

**Table 15: Comparison of Effect of Kokilakshadi kwatha on Tenderness before and After treatment**

Tenderness	Median	IQR=Q3-Q1	Z -Value	P-Value
0 <sup>th</sup> Day	3	0.25	-4.964	<0.001
21 <sup>st</sup> Day	1	0		

## DISCUSSION

Pain seems to be a serious matter for concern in Society. It is said to be the symptom present in all common and dreadful diseases.

Heel pain is the one of the most common problem in which most of the population is suffering.

It especially seen in Middle class, heavy workers, Teachers, Police and Athletes. Even though the pain usually will not be very severe in nature, it affects the daily routine. So here is an attempt to try the efficacy of *Kokilakshadi kwatha* in the management of *Vatakantaka*.

*Guduchi* and *Kokilaksha* due to its *Tridosahara* property and *Vata Pitta hara* property respectively acts on the causative *Dosha* and *Dushya* i.e., *Vata* and *Rakta*. It pacifies the vitiated *Pitta dosha* which is dominant in the pathogenesis of *Vatakantaka* along with *Vata dosha*. Due to repeated *Abhighata* there will be Inflammation occurring in the part which can be considered as *Pitta* and along with that there will be *Vata dhushti*. Since *Pitta* and *Rakta* has *Ashraya ashrayi sambanda*, it indirectly vitiates the *Rakta dhatu* as well.

*Rasa* of *Kokilaksha* being *Madhura* and *Amla* pacifies *Vata dosa* and that of *Guduchi* being *Tikta* and *Kashaya* pacifies *Pitta dosa*. *Tikta rasa* also does *Srothoshodaka*.

*Snigda Guna* of *Kokilaksha* helps in Pacifying *Vata*. *Sheeta Virya* of *Kokilaksha* acts as *Pitta shamaka* whereas *Ushna virya* of *Guduchi* acts as *Vatashamaka*.

*Madhura Vipaka* in both the drugs is *Pittashamaka* at the end of digestion which therefore is *Rakta dhusti hara* as well.

*Madhura, Guru* and *Snigda guna* is *Mutrala* which will help in relieving the *Shotha* happening in the Pathogenesis. And *Kokilaksha* has told to be having *Shotohara karma*.

Steroids, Flavanoids, Courmarins, Tanins etc. present in *Kokilaksha* acts as anti-inflammatory and Analgesics.

The aqueous extract of *Tinospora cardifolia* has a significant anti-inflammatory activity. *Tinospora cardifolia* have active principles which have potent anti-inflammatory and anti-arthritis activity. This effect is also considered to be due to inhibition of C3 convertase and serine protease, which indicates that

inhibition of serine protease in general may be involved in anti-inflammatory activity. When C3 convertase is inhibited, pro inflammatory anaphylactic peptides are also released with the result that no inflammation is observed.

*Kokilaksha* possess significant analgesic, anti-inflammatory & diuretic properties. Thus acts in reversing the pathogenesis.

## CONCLUSION

*Vatakantaka* is painful disease of heel which is mainly caused by improper placing of foot. According to modern science plantar fasciitis is considered to be common cause for heel pain. *Vata* and *Rakta* are the important factors in pathogenesis of the disease. *Poorvarooopa* of the plantar fasciitis is considered to be common cause for heel pain. *Vata* disease is not mentioned in classics, and *Lakshanas* in milder state can be considered as *Poorvarooopa*. Some of the *Lakshanas* of *Vatakantaka* is similar to plantar fasciitis.

So this clinical study is carried out to evaluate effectiveness of *Kokilakshadi kwatha* in the management of *Vatakantaka*.

*Kokilakshadi kwatha* was taken as trial drug for the study. Effect of formulation on both sign and symptom was considered and critically analyzed. The results thus obtained were subjected to statistical techniques. *Kokilakshadi Kwatha* showed good results in reduction of signs and symptoms of *Vatakantaka*. The statistical analysis also supported this by concluding that the improvement after treatment is highly significant.

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