



ISSN 0975-413X
CODEN (USA): PCHHAX

Der Pharma Chemica, 2017, 9(12):50-54
(<http://www.derpharmachemica.com/archive.html>)

Rejuvenating Effect of *Nyctanthes arbor-tristis* (Pavalamalli) Ooral Kudineer (Leaf Decoction) in Patients with Vathasthambam (Chronic Sciatica): A Clinical Study Report

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ABSTRACT

Pain is a highly unpleasant sensation caused by illness or injury. Sciatica is a medical condition refers to intense pain emerging from deep nerve root that further radiates up to leg. Non-steroidal anti-inflammatory drugs (NSAIDs) have been used to manage musculoskeletal symptoms since antiquity. But the major crisis of using NSAIDs for long term results in stomach ulcer, hypertension, liver and kidney dysfunction. Herbs are considered to be safe alternative therapy for clinical management of sciatica as it has no side effects and provides convincing relief in patients. The plant *Nyctanthes arbor-tristis* commonly called as Pavalamalli in Tamil is known for its traditional analgesic and anti-inflammatory property for years together. Still now there is no proper clinical validation were done in subjects with clinical condition called Sciatica. Hence present investigation was adopted to establish the clinical therapeutic efficacy of the leaf decoction of *N. arbor-tristis* on subjects with varying degree of sciatica. A total of 10 patients of which 5 males and 5 females with persistent sciatica from 6 months to 3 years duration were included into the study and the subjects were treated with leaf decoction of *N. arbor-tristis* for the period of 30 days. The result of present clinical investigation has revealed that the leaf decoction of *N. arbor-tristis* has shown good improvement in 6 patients (60%), moderate improvement in 2 patients (20%), mild improvement in 1 patient (10%) and no improvement observed in 1 patient. Hence from the study it was concluded that the trial drug are therapeutically effective in clinical management of sciatica (Vathasthambam).

Keywords: Sciatica, Low back pain, *Nyctanthes arbor-tristis*, Clinical validation, Analgesic property

INTRODUCTION

Sciatica is medical condition associated with severe back pain radiated towards the leg. Due to recent advancement in the medical field most of the patients with sciatica has been exposed towards the attentive therapy in which very minor cases required surgery [1-3]. According to recent Dutch study nearly 70% of the subjects recovered from the indication after 3 months of the proper treatment [4-7]. Patients if not properly treated may emerge with indication even after 13 years as per the Finnish study [8]. Approximately 80% of surgically treated patients and 60% of non-surgically treated patients reported major improvement after 1 and 2 years of follow-up [9].

In comparison with the demography of this clinical indication females more often complied with this issue, whereas the success rate of recovery from sciatica after surgery seems to productively less in females when compare to males [10-12]. About 60% of patients reports back pain also reports leg pain [13-16]. Scientific evidence substantiate the clinical evidence of sciatica that reflect etiology of nerve root compression, disc bulging and other issues pertains to ligament, joint or intervertebral disc [17-20].

The use of herbal medicinal products and supplements has increased tremendously over the past three decades with not less than 80% of people worldwide relying on them for some part of primary healthcare [21]. By taking granted of all the advantages of herbal medicines in present days clinicians have concerned to recommend the use of natural remedies in case of failure and deleterious side effect caused due to allopathic drugs [22,23].

Nyctanthes arbor-tristis (Night-flowering Jasmine) belong to the family Oleaceae. It is commonly called as Pavalamalli in Tamil is a species of *Nyctanthes*, native to South Asia and Southeast Asia. Some of the ethnomedicinal uses of *N. arbor-tristis* include febrifuge, anti-inflammatory, antispasmodic, hypotensive, respiratory stimulant. Used for fevers, rheumatism, obstinate sciatica.

Several investigations have been carried out on phytoconstituents of extracts of leaves, stem bark, seeds, roots, and flowers of *N. arbor-tristis* have been taken up, but leaves of *N. arbor-tristis* have been widely reported to contain nyctanthine, an alkaloid, ascorbic acid, tannic acid, mannitol, methyl salicylate, carotene, etc. [24-26]. Further presence of iridoids glycoside and flavonoid and have also been reported in the leaves of *N. arbor-tristis* [27].

Other than this there is an evidence reveals the present of myristic acid, linoleic acid, stearic acid, oleic acid and salicylic acid [28,29]. Investigation of stem of *N. arbor-tristis* reveals the presence of naringenin-4-o- β -glucopyranosyl-a-xylopyranoside and β -sitosterol [30]. As per the recent literature review it was evident that bark of this plant contains a glycoside, alkaloids and tannins [31]. *N. arbor-tristis* is bestowed with numerous pharmacological activities which include antipyretic, analgesic, anti-inflammatory, anti-anemic, hepatoprotective, tranquilizing, hypnotic, anticonvulsant, local anesthetic, antihistaminic, antioxidant, antispermatic, antibacterial, antifungal, antiviral, antimalarial, antitrypanosomal, anti-amoebic, anthelmintic, leishmanicidal and anticancer [32-34].

As per the literature review it was evident that still now there is no proper clinical validation of *N. arbor-tristis* for sciatica in diseased subjects. Hence the present investigation was pursued to establish the proper clinical evidence based data with respect to rejuvenating potential of leaf decoction of *N. arbor-tristis* against persistent sciatica.

MATERIALS AND METHODS

Preparation of paste of *Nyctanthes arbor-tristis* decoction

Fresh leaves of *Nyctanthes arbor-tristis* were collected and the herb was identified by the botanist. 2 g of *N. arbor-tristis* leaf was soaked in purified hot water and the decoction of 60 ml was advised to be taken in both morning and evening. The method of preparation was advised to all the subjects who included in the study.

Study design

An open-labelled clinical observational study on exploratory study with baseline as control was chosen for the individualized in-depth evaluation. Protocol, Case Record Form (CRF) and the author obtained approval from Director, NIS for conducting the study as Director being member secretary of Institute Wide No: -NIS/6-2/Res/Research/14-15 of National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India, for the period of September 2014 to march 2015.

Selection criteria

Patients visiting the In Patient Ward of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai-47, with age between 20-50 years of both gender, presenting complaints of low back pain, radiating pain starting from the lumbar region towards, the foot with non-involvement of urinary bladder and rectum were included in to study. Patients with duration of the disease more than 3 years, monoplegia, paraplegia, hip joint arthritis, crippling conditions of radiculopathy and patients with concomitant other Vertebral/Spinal pathology (i.e., T.B Spine), pelvic pathology were excluded.

Drug administration

Each subject was provided with 60 ml of *N. arbor-tristis* Ooral kudineer (leaf decoction) 60 ml morning and evening for the period of 30 days. Patients were monitored for clinical improvement and other compliance.

Pre study assessment

Duration of illness

Out of 10 patients it was observed that 40% of the patient is suffering with sciatica since last 6 months, 30% of them with the complication from 6 months to 1 year, 20% of them suffers from illness 1-2 years and 10% of them with illness from 2-3 years.

Category of Gunam

Based on the nature of the character, the patients were categorized in to Sathuvam (0%), Rasatham (40%) and Thamatham (60%).

Precipitating factors

Out of 10 patients it was evident through history that for 30% of the patient the precipitating factor was increased household works, for 50% of the patient it was occupation related, obesity is the factor for 20% of patients and for 10% of the patient Menopause was the precipitating factor.

Pain assessment criteria

Pain assessment scale were utilized for assessment of efficacy of the trial drug by using universal pain assessment scale starting from 0-no pain, 1-3 mild pain, 4-6 moderate pain, 7-10 severe pain [35].

Straight Leg Raising Test (SLRT)

SLRT is widely used in clinical practice. In the present investigation patients were subjected to SLR test and their degree of movement in angle were analyzed to interpret the efficacy of the treatment [36].

RESULTS

Result analysis on functional ability gradation scale of subjects after administration of trial drug

Movement assessment is considered to be the good indication for reduction in pain and social wellbeing of the subjects. Assessments were carried out by using the following grades. Grade I-Fit for all activities and doing their work without support, Grade II-Mild pain and reduction of movements, Grade III-Pain and moderate reduction of movements, Grade IV-Severe pain, Grade V-No movement. At the end of the trial period it was observed that out of 10 subjects included in the study nearly 40% of the patients falls on grade I and other 40% of them falls on grade II, 10% falls on grade III where as 10% falls on grade IV, as described in Table 1.

Result analysis on pain assessment scale of subjects after administration of trial drug

After administration of trial drug for stipulated period of time the pain assessment scale of the subjects were classified in to mild, moderate and severe. In which nearly 40% of the case falls on mild category (scale 1-3), 60% of the subjects falls on moderate pain category with scale ranges from 4-6 and 10% of the subjects falls on severe pain category with scale ranges from 7-10, as described in Table 2.

Table 1: Effect of *Nyctanthes arbor-tristis* (Pavalamalli) leaf decoction on functional ability of the patients

GRADE	Before treatment		After treatment	
	Number of patients affected	Percentage %	Number of patients recovered	Percentage %
Grade I	4	40%	4	100%
Grade II	4	40%	4	100%
Grade III	1	10%	1	100%
Grade IV	1	10%	0	0%
Total	10	100%	9	90%

Table 2: Effect of *Nyctanthes arbor-tristis* (Pavalamalli) leaf decoction on pain assessment scale of the patients

Pain assessment	Before treatment		After treatment	
	Number of affected patients	Percentage %	Number of recovered patients	Percentage %
No pain (0)	-	-	-	-
Mild (1-3)	3	30%	3	100%
Moderate (4-6)	5	50%	5	100%
Severe (7-10)	2	20%	1	10%
Total	10	100%	9	90%

Result analysis on SLRT interpretation of subjects before and after administration of trial drug

Before treatment about 30% of the patient observed and the category of movement 20 degree and 70% of the patient were under the category of 30 degree. Whereas after treatment the about 20% of the patient were under the category of 20 degree, 40% of the patient were under the category of 30 degree, 20% of the patient were under the category of 70 degree and remaining 20% of the patient were under the category of 90 degree, It shows a good sign of indication in treatment, as described in Table 3.

Table 3: SLRT Assessment on patient treated with *Nyctanthes arbor-tristis* (Pavalamalli) leaf decoction

SLRT interpretation in degree angle	Percentage category before treatment	Percentage category after treatment
20°	30%	20%
30°	70%	40%
70°	0%	20%
90°	0%	20%

Overall assessment

The overall assessment of the study reveals that about 60% of the patients shown Good improvement, 20% of the patients shown moderate improvement, 10% of them shown mild improvement and 10% of them shown no improvement, as described in Table 4.

DISCUSSION

Medicinal plants, used in siddha and other traditional systems of medicine, have been of continuous interest as a potential resource of chemical scaffolds for new anti-sciatica drugs. In recent time's use of herbal medicines were consistently increases but still now there is no proper documentation were made with respect to the biological significance of most of the herbal drugs [37].

According to recent review it requires highly skilled factorial prediction to exactly locate the profound disability in patients seeks primary care for treatment of sciatica [38]. Most often symptoms such as anxiety and depression were comorbid with pain associates sciatica persist up to 3 y follow-up study [39].

After administration of trial drug for stipulated period of time the pain assessment scale of the subjects was categorized in to mild, moderate and severe. In which nearly 40% of the case falls on mild category (Scales 1-3), 60% of the subjects falls on moderate pain category with scale ranges from 4-6 and 10% of the subjects falls on severe pain category with scale ranges from 7-10.

Table 4: Overall assessment scale on treatment with *Nyctanthes arbor-tristis* (Pavalamalli) leaf decoction in sciatica

Result	Number of patients	Percentage (%)
Good improvement	6	60%
Moderate improvement	2	20%
Mild improvement	1	10%
No improvement	1	10%
Total	10	100%

At the end of the clinical trial period it was witnessed that out of 10 subjects included in the trial nearly 40% of the patients falls on grade I and other 40 % of them falls on grade II, 10% falls on grade III where as 10% falls on grade IV. In a randomized study on early surgery versus prolonged conservative treatment for sciatica, female sex was found to be a strong predictor of an unsatisfactory outcome in both groups [40]. The clinical evaluation of a patient with radicular pain / sciatica includes adequate history and clinical examination. SLRT is one of the most common tests used in clinical practice. However together with other clinical signs used in practice for evaluation of a patient with lumbar radiculopathy, it was found to be of limited utility when used in isolation, and with low reproducibility when used in general practice [41,42].

Before treatment about 30% of the patient observed and the category of movement 20 degree and 70% of the patient were under the category of 30 degree. Whereas after treatment the about 20% of the patient were under the category of 20 degree, 40% of the patient were under the category of 30 degree, 20% of the patient were under the category of 70 degree and remaining 20% of the patient were under the category of 90 degree, It shows a good sign of indication in treatment.

Assessment on prognosis basis after treatment it was observed that nearly 90% of the patients explore pain in lumbar region, whereas before treatment it was 100%, there was about 10% reduction were observed in lumbar pain complication. Before treatment about 70% of the patient reported with the radiating pain complication whereas after treatment it was 50%, there was about 20% reduction in complication were observed. Before treatment about 70% of the patients have reported with increased pain intensity on forward bending. Whereas after treatment it was 60%, there was about 10% reduction in complication was observed. Before treatment about 90% of the patients have reported with exacerbation of pain on movements. Whereas after treatment it was 60%, there was about 30% reduction in complication was observed. Before treatment about 50% of the patients observed with Stiffness of lumbar spine this figure remain same even after administration of trial drug. Before treatment about 60% of the patients were observed with tenderness whereas after treatment it was 50%, there was about 10% reduction in complication were observed. Before treatment about 80% of the patients were observed with Paraesthesia and sensory loss in affected area whereas after treatment it was 70%, there was about 10% reduction in complication were observed, as shown in Table 5.

Table 5: Prognosis Assessment on patient treated with *Nyctanthes arbor-tristis* (Pavalamalli) leaf decoction

Symptoms	Complaints before treatment	Recovered after treatment
Pain in lumbar region	10	9
Radiating pain to buttocks and lower limbs	7	5
Tenderness	6	5
Stiffness of lumbar spine	5	5
Exacerbation of pain on movements	9	6
Pain increased on forward bending	7	6
Paraesthesia and sensory loss in affected area	8	7

In the present clinical investigation we revealed the features of 10 primary care patients seeking care for symptoms of back and leg pain including sciatica. The major strength of this present clinical study is the high response rate and the use of complimentary herbal supplement for the clinical management of sciatica. Outcome of the study was precisely measured with highly sensitive measures like pain assessment and gradation scale.

CONCLUSION

Few investigations exist which describe the features and clinical course of the full spectrum of patients seeking care for their low back and leg pain/sciatica. Number of studies focus on patients with back pain alone, include mixed populations with back and leg pain (without differentiating between them), or are alarmed with describing the characteristics of highly selected populations from tertiary care settings (including surgical candidates). Robust evidence regarding the epidemiology of low back related leg pain (including sciatica) is lacking from primary care, the setting where the majority of these patients will present and be managed.

The result of present clinical investigation has revealed that the leaf decoction of *Nyctanthes arbor-tristis* has shown good improvement in 6 patients (60%), moderate improvement in 2 patients (20%), mild improvement in 1 patient (10%) and no improvement observed in 1 patient. Hence from the study it was concluded that the trial drug was therapeutically effective in clinical management of sciatica (Vathasthambam).

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