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MULTICENTER TRIAL ON SCIATICA MANAGEMENT BY *NYCANTHUS ARBORTRISTIS* (*PARIJAT*)

Chawardol Seema Jain Sapan Akre Mrunal R.

Jupiter Ayurved Medical College, Nagpur

ABSTRACT

There are no as such drugs available for the treatment of Sciatica. Only analgesic in allopathic line of treatment is used to subside the pain. Or on contrary Physiotherapy treatment is used for early mobilization and decreasing pain. But in Ayurvedic treatment many drugs and procedures are mentioned in ancient texts which are followed by experts. From such text a drug *Nycanthes arbortristis*- Parijat is used in *Grudhrasi*-sciatica, which has dramatically results on patients. To prove that drug is efficient for treatment of sciatica a small trial for a short time has conducted by us at different clinics and places. This will be helpful for physician in treating the disease.

Keywords: Sciatica, *Nycanthus arbortristis*, anti inflammatory, SLR test, Herbal

INTRODUCTION

In the present age of pharmaceuticals various chemical has been employed for the effective management of disease. Due to their potential side effect researcher aimed on the effective herbal management of disease. Herbs have been always the main principle form of medicine since traditions in India and now a day it becomes most popular throughout the world. Herbal medicines are not only providing traditional and ethnic medicine but also promising for highly efficient novel bioactive molecules. Since ages, man has been dependent on nature for curing various body diseases. From ancient civilization various parts of different plants were used to eliminate pain, control suffering and counteract disease. Most of the drugs used in primitive medicine were obtained from plants and are the earliest and principle natural source of medicines. The plants used, as drugs are fairly innocuous and relatively free from toxic effects or were so toxic that lethal effects were well known. The nature has provided the storehouse of remedies to cure all ailments of mankind. There is no doubt that plants are a reservoir of potentially useful chemical compounds which serve as drugs, are provided newer leads and clues for modern drug design by synthesis.[1]

Nyctanthes arbortristis Linn. (Division: Magnoliophyta; Class: Magnoliopsida; Order: Lamiales; Family: *Oleaceae*), commonly known as Harsinger, Parijat or Night jasmine, is a well documented plant. It is a native of India, distributed wild in sub-Himalayan region and also found in Indian garden as ornamental plant. The indigenous people of Chittoor district Andhra Pradesh (India) widely use the whole plant for treatment of cancer, root for fever, sciatica, anorexia; bark as expectorant, Leaf for control fever, diabetes and as cholagogue, diapho-

retic and anthelmintic[2]. Various extracts of the plant is used to treat arthritis, malaria, intestinal worms, tonic, laxative, antitrypanosomal, anti-inflammatory and antioxidant activity[3]. Juice of the leaves is used as digestives, antidote to reptile venoms, mild bitter tonic, laxative, diaphoretic and diuretic[4,to 10]. The plants are very well known for their pharmacological properties science ancient age. Extensive works were carried out on plant of *Nyctanthes arbortristis* for their pharmacological properties[11]. Traditionally the powdered stem bark is given in rheumatic joint pain, in treatment of malaria and also used as an expectorant. The medicinal value is due to presence of potential phytochemical like nyctantic acid, friedelin, beta-sitosterol and oleanolic acid are present in leaves and responsible for antiviral activity,[12] polysaccharides, iridoid glycosides, phenypropanoid glycoside, β -sitosterol, β -amyrin, hentri-acontane, benzoic acid, glycosides, nyctanthoside-a iridoid, nyctanthic acid, Friedelin lupeol, oleanolic acid, 6ß-hydroxylonganin and iridoid glucosidesarborsides A, B and C, alkaloids, Phlobatanins, terpenoids and cardiac glycosidesn. Iridoid glucosides (arbortristosides- A (1), B (2), C (3), and 6- β hydroxyloganin show Anti-leishmanial activity.

Pharmacological activities and Medicinal use of *Nyctanthes arbortristis*

a. Hepatoprotective activity[13]

Ethanolic leaf extract of *Nyctanthes arbortristis* protect against carbon tetrachloride – induced hepatotoxicity in rat. For this investigation rats were pretreated with extract (1000mg/kg body weight/day, p.o. for 7 days) prior to the administration of a single dose of CC_{l4} (1.0ml/kg, s.c.). In study the leaf extract of *Nyctanthes arbortristis* and silymarin restored all serum and liver parameters which were altered by (CC_{l4}) from the normal level, also prevent loss of body weight, both candidate are also protected against (CC_{l4}) induced increase in liver weight and volume. These effects may be mediated by the antioxidant present in the plant.

b. Antihistaminic and antitryptaminergic activity[14, 15]

The aqueous soluble of the alcoholic extract of *Nyctanthes arbortristis* leaves (4.0 and 8.0g/kg oral) significantly protect against histamine aerosol - induced asphyxia (2% at 300 mm Hg) in guinea pigs. Arbortristosid A and arbortristosid C present in *Nyctanthes arbortristis* was reported to be antiallergic.

c. Antibacterial activity[16]

Methanolic and aqueous extract of the *Nyctanthes arbortristis* leaves were investigated for *in-vitro* bactericidal activities against *staphylococcus aureus, Bacillus subtilis, E. coli* and *Pseudomonas aeruginosa* by disk diffusion method. Both extracts were active against the bacteria except for *Pseudomonas aeruginosa* which was resistant to the aqueous extract. An earlier study tested the *in-vitro* antimicrobial and antifungal activity of stem bark chloroform, petroleum ether, and ethanolic extract of *Nyctanthes arbortristis* linn. by cup plate method angianst *Staphylococcus aureus,* Micrococcus luteus, *Bacillus subtilis, E. coli, Pseudomonas aeruginosa, Candida albicans* and *Aspergillus niger* using ciprofloxacin and flucanazole as a standard drug. The chloroform extract were found to be both antimicrobial and antifungal activity whereas the petroleum ether and ethanol extracts possess only antimicrobial activity.

d. Antiviral activity[17, 18]

The ethanolic extract, n-butanol fractions and two pure compounds, arbortristoside A and arbortristoside C, isoloated from the *Nyctanthes arbortristis* possess pronounced inhibitory activity against encephalomyocarditis virus (EMCV) and Semliki Forest Virus (SFV). The *in-vivo* ethanolic extract and the n-butanol fraction at daily doses of 125 mg/kg weight protected EMCV infected mice against SFV by 40 and 60% respectively.

e. Antifilarial activity[19]

The chloroform extract of the flowsers and a pure compound isolated from *Nyctanthes arbortristis* plant exhibit larvicidal activity against Culex quinquefasciatus say, a common filarial vector.

f. Antioxidant activity[20, 21]

The free radical scavenging potential of the different extracts of leaves of *Nyctanthes arbortristis* was evaluated in-vitro by employing diphenyl-picryl-hydrazy (DPPH) assay method. In this investigation the antioxidant which present in the plant extracts reacted with DPPH, which is a stable free radical and converted it to 1, 1-diphenyl -1, 2- picryl, hydrazine which was measured at 517 nm. The scavenging effect of plant extracts and standard (ascorbic acid and BHT) on the DPPH radical decreases in the following manner: Ascorbic acid > Butanol > Ethyl acetate > BHT > Pet ether, and it was found to be 93.88% for ascorbic acid at concentration of 10 mg, for BHT, Butanol, Ethyl acetate and Pet ether was found to be 97.42 %, 95.22%, 84.63% and 82.04% at concentration of 100 mg respectively. In this investigation different extract of *Nyctanthes arbortristis* leaves possess concentration dependant free radical scavenging activity.

g. Anti-nociceptive and antipyretic activity[23, 24,25]

The aqueous soluble fraction of ethanolic extract of the leaves exhibited significant aspirin-like antinociceptive activity which was evidenced by inhibition of acetic acid-induced writhing in albino mice but fails to elicit morophine-like analgesia which was tested via the rat tailflick and mouse tail-clip methods.

Anticholinesterase activity[26]

The aqueous extract of *Nyctanthes arbortristis* stimulated the activity of acetylcholinesterase in mice, it antagonize the inhibition of this enzyme by malathion.

h. Immunopotentiator activity[27]

The anti-immunosuppressive effect of an aqueous extract of *Nyctanthes arbortristis* was determined in three to four week old swiss albino mice (20-25g) which were exposed to the extract, malathion. *Nyctanthes arbortristis* leaf aqueous extract reverted humeral, non specific and cell - mediated immunological parameters to normalcy as the values of antibody titres of the non specific immune parameters and of cell mediated immune parameters were raised by extract. The T-cell number, Fc receptor bearing cell counts, complement receptor bearing Blymphocytes and IgG bearing B-cells of the extract-treated malathion mice were also increased towards normalcy while the phagocytic index was greater than in malathion mice not treated with the extract. The results showed that aqueous extract of leaf of *Nyctanthes arbortristis* showed immunopotentiator activity with the effective capacity for potentiating both humoral as well as cell mediated immune responses.

i. Sedative activity[28]

The sedative potential of a hot infusion of the flowers (3.7, 7.5, 12.5, 18.7 mg/kg, p.o.) were examined in rats using the rat hole-board test at 2 h post-dosing. In this test, each rat was placed at the center of the standard rat hole-board apparatus and observed for 7.5 min. The number of rears, number of head dips, cumulative time spent on head dips, and locomotory activity was monitored and the time spent per head dip computed. Male rats exhibited a dose-dependent conscious sedative activity (at 7.5 & 12.5 mg/kg, p.o.) while female rats remained unaffected.

j. Anti-inflammatory activity[22]

The water-soluble fraction of the ethanol extract elicited significant anti-inflammatory activity against acute inflammatory oedema produced in rats by different phlogistic agents, namely carrageenin, formalin, histamine, 5-hydroxytryptamine and hyaluronidase. The extract significantly reduced acute inflammatory swelling in the knee joint of rats induced by turpentine oil. The leaf and fruit extracts also showed anti-inflammatory action in the mouse model of arthritis which was elicited by immunological methods, namely, injections of Freund's complete adjuvant into the sub-planter surface of the right hind paw on days 0 and 12 and PPD-induced tuberculin reaction. In subacute models of carrageenin induced granuloma pouch and cotton pellet granuloma, rats were fed daily with the extract for 6 days from the day of pouch formation or for 5 days from the day of pellet implantation. Granulation tissue formations in both models were significantly inhibited by the extract. The ethanolic extract of the orange tubular calyx of N. arbor-tristis and the isolated carotenoid (200 mg/kg, i.p.) showed significant inhibition of carrragenan-induced rat paw edema when compared to the standard drug (diclofenac sodium) and untreated control.

Properties according *ayurved* pharmacopia

Rasa : Tikta, Katu
Guna : Lakhu
Virya : Ushna

Plant pacifies vitiated *vata, kapha,* inflammation, sciatica, dyspepsia, cough, asthma, constipation, hemorrhoids, baldness, premature graying of hair and pruritus. Useful part : Leaves, Flowers, Seeds.[29]

MATERIAL AND METHODS

Preparation of Tablet of *Nyctanthes arbortristis* Tablet of nycanthes was prepared by us in following steps:-

i. Leaves of nycanthes were grounded to form a fine paste.
ii. Paste and water added in proportion of 1:4 from which decoction was prepared.
iii. Decoction was concentrated to form a semisolid bolus.
iv. Tablet was prepared from this bolus, and dried under sunlight for 2-3 days.

OBJECTIVE

After studying the pharmacological and pharmacodynamical factors stated above, we carry a study to show the effectiveness of tablet prepared by decoction of nycanthes leaves[30] in treatment of sciatica. Patient was not informed about the drug, as it may inherit the trial by emotional involvement of the patient.

Clinical Trial: 20 patients were enrolled for the trial at different location in different out-patient department of physicians. Before enrollment of patient an evaluation was done to specify the sample size of patient. Patient will receive 500mg tablet in TDS form for 7

days to get result. The assessment was done on improvement in pain and SLR test with the help of suitable scoring method.

Type of research: The trial is single blinded- in which drug component is not known to patient but known to physician and all. It is multicenter trial conducted at 3 different clinics of Nagpur and umrer. Efficacy and potency of drug on sciatica disease will be proved by the trial.

Sites of research

1. Dr. Mrunal Akre- 'SHANTIDATTA AYURSPA AND PHYSIOTHERAPY CENTER'- New Shukrawari Mahal Nagpur.
2. Dr. Rahul Wadaskar- 'SHRI SAMARTH CLINIC'- Koradi, Nagpur.
3. Dr. Vipul Gupta- 'GUPTA CLINIC' Market Road Umrer, Nagpur.

Criteria

I) Inclusion Criteria:-

i. Patient should be suffering from sciatica disease.

ii. No other disease should be associated with it.

iii. Patient should be 20-40 age group

iv. SLR should be 70^0 and below.

II) Exclusion Criteria:-

i. Patient having DM,CCF,HD or any other neurological disorder.

ii. Patient hypersensitive to drugs.

iii. Patient with gastric trouble.

Sampling

A.* Preparation of Tablet of *Nycanthes arbor tristis:-

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ii. Paste and water added in proportion of 1:4 from which decoction was prepared.

iii. Decoction was concentrated to form a semisolid bolus.

iv. Tablet was prepared from this bolus, and dried under sunlight for 2-3 days.

v. Prepared tablet packed in plastic container with cotton in it as moister absorbent.

vi. Each container contains 21 tablets in it.(as dose given 1 tab TDS)

vii. Plastic container labeled with date of manufacture and quantity of tablets.

Data Collection

I) **Primary collection of data:** Primarily data was collected from patient on a case report form. Bibliographic details and disease history was collected at opd by physician. A true copy of case report form retain at the site for future reference.

II) Secondary collection of data

After giving the drug patient asked to come for follow up at alternate days till the end of 7 days. At each visit changes in SLR test, Pain was noted by the physician in a chart. This was found helpful for tracking any AE, SAE or any symptom occurred in the patient.

III) Actual process

i. After enrollment of patient CRF was filled by physician in their own handwriting and in patients language.

ii. Patient was intimated about the follow up date and strictly asked to be present on the day.

iii. At each follow up data was collected and signed by the physician.

iv. After completion of visit a 15 days tracking of any unexpected events was done by physician.

v. By the end of 15^{th} day site was closed and further no change was declared to the data.

OBSERVATIONS

1. No AE/SAE seen

2. No drug allergy found

3. Drug tablet act equally on both the sexes

4. Tablet is useful in management of sciatica if use on regular basis

5. Drug was not given to children so no data available

6. Drug not given in condition like pregnancy/menstruation/gestation so no data available

7. Nycanthes also shown purgative effect, patient reported that there bowels get cleared by tablet; also they feel lightness in abdomen.

Result

Table 1: Effect of Tablet before Treatment (BT) and after Treatment (AT)

Parameter	Mean Score		Mean Difference	% of Relief
	B T	A T		
Pain	2.75	0.45	2.3	83.63
SLR Test	46.5	62	15.5	33.33

Table 2: Reduction in pain by Score

Pain Reduced by Score	No. of Patient	% of Relief
Pain Reduced by Score 4	2	10
Pain Reduced by Score 3	7	35
Pain Reduced by Score 2	7	35
Pain Reduced by Score 1	3	15
No Relief	1	5

Table 3: Improvement in SLR test

Improvement in Angle	No of Patient	% of Relief
Increased by 35^0 and above	0	0
Increased by 20^0 to 35^0	7	35
Increased by 5^0 to 19^0	11	55
Increased by 0 to 4^0	1	5
Decreased in angle	1	5

CONCLUSION

The above work cited in the article of phytochemicals and promising pharmacological activities are widely distributed in medicinal plant of *Nyctanthes arbortristis* and it revealed the importance of herbal and ayurvedic pathway for effective treatment of Sciatica diseases considering its tremendous potential pharmacological activities. The drug has proven its property in sciatica patients to decrease the pain of nerve compressed and to increase the SLR degree.

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CORRESPONDING AUTHOR
Dr. Sapan Jain
Dept. of Kayachikitsa,
Jupiter Ayurved Medical College, Nagpur
Email: sapanjain2008@rediffmail.com

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