

A Clinical research of Siddha Drug “GLY CYN NEU” Ointment for AzhalVaatham (Neuropathy)

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Abstract: As a huge medical system in the World, herbal drugs are very effective for many diseases. However Diabetes Mellitus also control by herbal drugs even though not efficiency reducing the symptoms of Neuropathy. Therefore this research tries to correct that problem by poly herbal formula. In commonly patients are suffering from peripheral neuropathy caused by Diabetes Mellitus. We would like to do research in efficacy of ARUGANKATTAI PASTE (GLY CYN NEU Ointment) and Control Drug (placebo). Case control double blind clinical study measured to assess the effect of the treatment by significant relief of burning sensation within a month. The neuropathic symptoms; very mild grade 46.15% in Group-I (D.M.T), Marked improvement grade 15.38%, Moderate improvement grade 38.46% in Group-II (GlyCynNeu Ointment) and mild improvement 23.08%, very mild improvement 07.69% in Group-III in burning sensation than the Numbness, Numbness & Burning sensation (both). In statistically way, this research is qualitative analyses therefore compare with two and analyzed significant of each compares. However final identical results say: Comparing the control (Group-I), GlyCynNeu ointment (Group-II) was shown Significant ($p < 0.05$) reduction in symptoms of neuropathy. GlyCynNeu Ointment was significantly ($p < 0.05$) change symptoms of neuropathy within one month (4th Week) of treatment. Finally, concluded effectiveness of research drugs GLY CYN NEU Ointment significant most effective than Control Drug Group-III and Hospital Diabetic treatment (Group-I) for Diabetic Neuropathic symptoms. In neuropathic symptoms, BURNING SENSATION was highly notified changes like reducing within one a month than other symptoms.

Keywords: AzhalVaatham (Siddha Medical term), Neuropathy, Diabetes Mellitus (D.M), *Glycyrrhizaglabra*Linn, *Cynodondactylon* Linn.

1. Introduction

1.1 Background

Peripheral neuropathy is the term for damage to nerves of the peripheral nervous system which may be caused either by diseases or trauma to the nerve or the side-effects of systemic illness. The four cardinal patterns of peripheral neuropathy are polyneuropathy, mono-neuropathy, mononeuritis multiplex and autonomic neuropathy. The most common form is (symmetrical) peripheral polyneuropathy, which mainly affects the feet and legs. [6.1] This is known as AzhalVaatham in Siddha system of Medicine. [5]

Pathologically, diabetic neuropathy is a segmental degeneration of the peripheral nerve. Clinically, the condition is heralded by the onset of paraesthesia of limbs, fingers and toes; burning sensation of hands and feet; cramps and pains in the legs and muscles. [6.1]

In commonly patients are suffering from peripheral neuropathy caused by diabetes mellitus. [6.1] We would like to do research in efficacy of ARUGANKATTAI PASTE [1], [2] (GLY CYN NEU Ointment) and placebo. Case control clinical study measured to assess the effect of the treatment by significant relief of burning sensation within a month.

1.2 Research Problem

As a huge medical system, herbal drugs are very effective for many diseases. However Diabetes Mellitus also control by herbal drugs even though not efficiency reducing the symptoms of Neuropathy. Therefore this research tries to

correct that problem by poly herbal formula. This drug may more valuable product to the new generation.

1.3 Objectives

1.3.1 General Objective

To relief the Symptoms of Neuropathy in diabetic patients and give healthy life style.

1.3.2 Specific Objectives

- To introduce a new Siddha drug for Diabetic Neuropathy.
- To give a new look for herbal formula for Diabetic Neuropathy patient.

1.4 Hypothesis

The drug ARUGANKATTAI Paste – “GlyCynNeu Ointment” can reduce the Diabetic Neuropathic symptoms of hands & legs.

2. Materials and Methods (Methodology)

Type of Research: Double blind Case Control -Clinical Study.

Research area: Bandaranaike Memorial Ayurvedic Research Institute. (BMARI)

Research period: 02 months

Research Samples: 45 patients

2.1 Identification of Diabetic Neuropathy patients according to clinically diagnosis.

Parameters Measured: The parameters measured were both objective and subjective.

Subjective parameters included pain; burning sensation; numbness.

Objective parameters included assessment of pain appreciation- pinprick; assessment of light touch in upper and lower limbs; assessment of position sense; reflexes; trophic changes; shininess of the skin; ulcers; ability to walk; hyperhidrosis; blood pressure; urine analysis; and fasting blood sugars.

2.1.1 Inclusive Criteria

Patients were eligible if they were 18–65 years of age, had type 2 diabetes according to the known diabetic patients by past diagnostic medical report, were treated with diet, oral anti-diabetic agents and/or insulin, had stable glycemic control according to the investigator's judgment over 3 months before entry into the study, and had evidence of symptomatic symmetrical or Asymmetrical distal neuropathy.

2.1.2 Exclusive Criteria

Were the following:

1. Asymmetrical neuropathy of the trunk and proximal lower limbs,
2. Presence of foot ulcers,
3. Peripheral vascular disease (non-palpable foot pulses, intermittent claudication),
4. Myopathy,
5. Causes of neuropathy. Other than diabetes and significant neurological diseases,
6. Participation in a study of any investigational drug for neuropathy within the 3 months before the study,
7. Use of antioxidants or vitamin B within 1 month before the study,
8. Severe concomitant diseases, and
9. Pregnancy, lactation, or childbearing age without birth control devices.

3. Literature Review

2.1-Disease Review [6.1]

2.1.1 Siddha view of AzhalVaatham (Neuropathy)[5]

2.1.2 Modern view of Neuropathy [6.1]

2.2-Drug Review

2.2.1 GlycyrrhizaglabraLinn [3]

2.2.2 CynodondactylonLinn [3]

2.2.3 Coconut oil [3]

2.2.4 Bee's Wax [4]

- 1) Identify the treatment in Siddha Pharmacopoeia.
- 2) Making for sample and check the quality for phyto-chemicals and standardization.
- 3) Making the final product of the Siddha drug.
- 4) Clinical test for the drug from 45 patients in OPD (Out Patient Department) and wards and data collecting from a suitable Proforma.
- 5) Assessment Criteria

3.1 Final Assessment Criteria

- I. High Marked. (not cured)
- II. Marked improvement.
- III. Moderate improvement.
- IV. Mild improvement.
- V. Very mild.
- VI. Not improvement.
- VII. Aggressive.

6) Analysis of the data and making the thesis.

Qualitative Statistical analysis.

3.2 Drug preparation

We had prepared Research drug and control drug which as placebo.

3.2.1 Research drug

Ingredients:

Arugampul Cynodandactylon 20kg
Atimaduram Glycyrrhizaglabra 100g
Coconut Oil Cocosnucifera 2.5 bottle
Bee's Wax required amount.[1], [2]

Method of preparation

Pounded the Arugampul and took the juice. Added equal amount of oil into the juice and boiled them. At the boiling time put the Atimaduram powder into the oil. After that boiling oil container and took off from the fire. Filtered and added the Bee's wax into the oil which as an ointment stage. [1], [2]

Finally warm oil filled into the one ounce small plastic containers in equal amount (30ml). After that kept 30 minutes for become cool ointment. [1], [2]

3.2.2 Control drug

Ingredients:

Coconut Oil *Cocosnucifera* 2.5 bottles
Bee's Wax required amount.[4]

Method of preparation:

Put the Coconut oil into the vessel and heated. At the boiling time put the Bee's wax into the oil which as an ointment stage. Finally warm oil filled into the one ounce small plastic containers in equal amount (30ml). After that kept 30 minutes for become cool ointment. [4]Research and control drug final products are everything is similar (Labeling also) and non-identical.

3.3 Clinical Study

Clinical trial had done for research drug and Placebo to 45 patients in OPD (Out Patient Department) and wards. Data were collecting from a suitable Proforma.

Grouping the Samples:

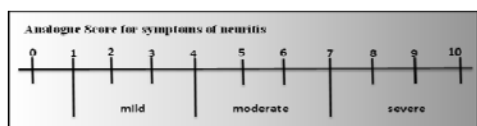
In this research, total sample divided into three (03) groups but all are same symptomatically Diabetic neuropathy condition. Those three groups are given below,

- Group I:** Diabetic neuropathy patients with Hospital internal treatment (DMT).(15 patients)
- Group II:** Diabetic neuropathy patients with Hospital internal treatment (DMT) and Research Drug (GlyCynNeu Ointment) external treatment.(15 patients)
- Group III:** Diabetic neuropathy patients with Hospital internal treatment (DMT) And Control drug treatment.(15 patients)

Hospital D.M.T is as follows:

Medicine	Dosage	Period of intake	Vehicle (Anupana)
ThiripalaQwatha	30 ml	Twice a day	-
ThiripalaChoorna	30 grains	Twice a day	With warm water
Somanatha Rasa	02 Tablets	Twice a day	juice of bitter gourd

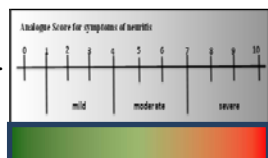
In our research Group-I, II & III:
 Initial - 15 samples
 Dis continue samples- 02 samples
 End of the research – only 13 samples



Final Assessments and Analogue Score



- 1-High Marked.(but not cure)
- 2-Marked improvement.
- 3-Moderate improvement.
- 4-Mild improvement.
- 5-Very mild.
- 6-Not improveent.



4. Result and Discussion

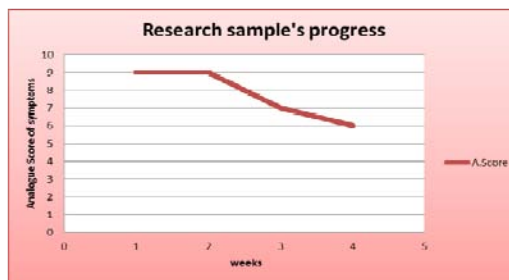
Phyto-Chemical analysis Report of the Research Drug

Organoleptic Characteristics:
 Colour – Green
 Odour – Coconut Oil smell.
 Taste – Sweet

Physico-Chemical Specifications:

- Specific gravity – 0.9200
- Loss on drying – 0.07%
- Acid Value – 1.24
- Saponification value – 274.22

Reported from: Research & Quality Assurance Laboratory, BMARI, Nawinna.



Each sample progress chart in every Week

4.1 Final Assessment of hospital D.M treatment on the clinical symptoms of Diabetic Neuropathy (Group I)

End of the research (after 04 Weeks) effect of the Group- I; burning sensation in very mild level and only 06 samples, numbness in very mild level – 03, not improvement-01 and Burning sensation & Numbness in Very mild-01 sample, not improvement-02 samples.

End of the research (after 04 Weeks) effect of the Group- I; burning sensation in very mild level and only 46.15%, numbness in very mild level – 23.08%, not improvement-07.69% and Burning sensation & Numbness in Very mild-07.69%, not improvement-15.38%.

4.2 Final Assessment of “GlyCynNeu” Ointment treatment on the clinical symptoms of Diabetic Neuropathy (Group II)

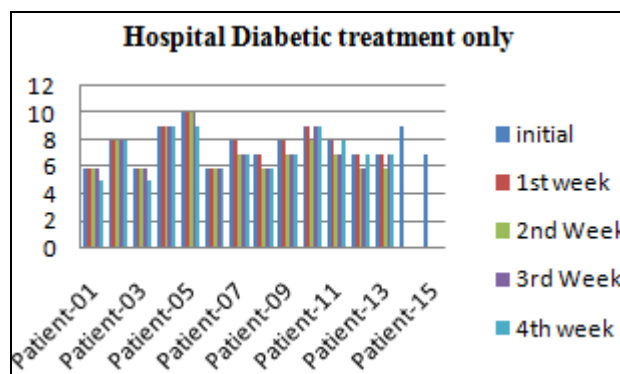
End of the research (after 04 Weeks) effect of the Group- II, burning sensation in marked improvement – 15.38% ,and moderate improvement – 38.46%, numbness in marked improvement– 07.69%, moderate improvement-15.38% and Burning sensation & Numbness in marked improvement-07.69%, moderate improvement-15.38%.

4.3 Final Assessment of Drug Group-III treatment on the clinical symptoms of Diabetic Neuropathy (Group III)

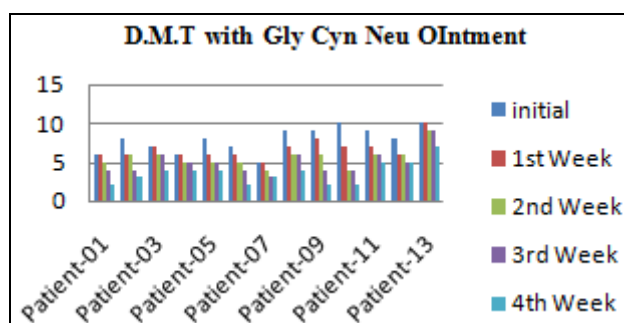
End of the research (after 04 Weeks) effect of the Group- III, burning sensation in mild level-23.08% and very mild improvement 07.69%, numbness in mild level – 23.08%, very mild improvement-38.46% and Burning sensation & Numbness in mild level-07.69%.

5. Charts in Data Analyzing

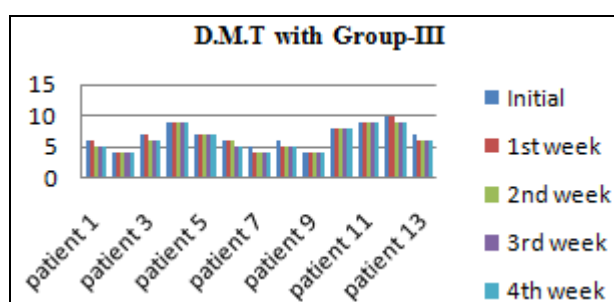
5.1 Progress of the symptoms with treatment of sample group I, II& III:



Progress of the Neuropathic Symptoms with research drug and controls in 04 weeks in Sample Group-I (initial visit, 1st week, 2nd Week, 3rd Week and 4th Week).



Progress of the Neuropathic Symptoms with research drug and controls in 04 weeks in Sample Group-II (initial visit, 1st week, 2nd Week, 3rd Week and 4th Week)



Progress of the Neuropathic Symptoms with research drug and controls in 04 weeks in Sample Group-III (initial visit, 1st week, 2nd Week, 3rd Week and 4th Week)

5.2 Statistical Analysis

This research can analysis with QUALITATIVE STATISTICAL ANALYSIS not quantitative analysis therefore we analyzed symptoms in grading level not measurable therefore we used in qualitative way. We used Minitab 14 as statistical package. In a qualitative test or research **Wilcoxon rank sum test (Mann-Whitney Test)** is used to compare two independent samples.^[6,2]

6. Neuropathic Symptoms

6.1 Group-I & Group-II 4th Week (AFTER treatment) level of the samples.

The test is significant at 0.0001 (adjusted for ties)

- Comparing the control (Group-I), GlyCynNeu Ointment (Group-II) was shown Significant ($p < 0.05$) reduction in symptoms of neuropathy.
- One month (4th Week) of treatment with GlyCynNeu Ointment significantly ($p < 0.05$) change symptoms of neuropathy with the control group (group-I).

6.2 Group-I & Group-III End of the research (4th Week level) of the samples.

The test is significant at 0.0602 (adjusted for ties)

- Comparing the control (Group-I), Drug Group-III(Group-II) was shown not Significant ($p > 0.05$) reduction in symptoms of neuropathy.
- One month (4th Week) of treatment with Drug Group-III not significantly ($p > 0.05$) change symptoms of neuropathy with the control group (group-I).

6.3 Group-II& Group-III End of the research (4th Week level) of the samples.

The test is significant at 0.0018 (adjusted for ties)

- Comparing the control (Group-I), GlyCynNeuOintment (Group-III) was shown Significant ($p < 0.05$) reduction in symptoms of neuropathy.
- One month (4th Week) of treatment with GlyCynNeu Ointment significantly ($p < 0.05$) change symptoms of neuropathy with the control group (group-III).

7. Burning Sensation

Group-I & Group-II End of the research (4th Week level) of the samples. *The test is significant at 0.0012 (adjusted for ties)*

- Comparing the control (Group-I), GlyCynNeuOintment (Group-II) was shown Significant ($p < 0.05$) reduction in burning sensation.
- One month (4th Week) of treatment with GlyCynNeu Ointment significantly ($p < 0.05$) change symptoms of neuropathy with the control group (group-I).

8. Discussion and Conclusion

This research is clinical control study and also double blind clinical assessment and qualitative analysis research. Selection of samples and same time preparation of our new research drug is initial works. There after data collections and observation of the progress of the effect of the research drug. Finally was analyzed by the tables, charts and statistical way. According to tables, charts and statistical result; Each every table explained various angle of collection of the data and observations with sum of numbers and percentage level. In final analysis, according to the neuropathic symptoms; burning sensation- very mild grade 46.15% in Group-I (D.M.T), Marked improvement grade 15.38%, Moderate improvement grade 38.46% in Group-II (GlyCynNeu Ointment) and mild improvement 23.08%, very mild improvement 07.69% in Group-III than the Numbness, Numbness & Burning sensation.

Charts were used two types because Bar charts are using for analysis with initial stage to end stage and Pie charts were used to indicate percentage clearly. In statistically way, this research is qualitative analyses therefore compare with two and analyzed significant of each compares. However finally we got identical result.

- In statistical results say, Comparing the control (Group-I), GlyCynNeu Ointment (Group-II) was shown Significant ($p < 0.05$) reduction in symptoms of neuropathy.
- GlyCynNeu Ointment was significantly ($p < 0.05$) change symptoms of neuropathy within one month (4th Week) of treatment.

Finally, we concluded effectiveness of our research drugs **GLY CYN NEU Ointment** most effective than **Drug Group-III and Hospital Diabetic treatment (Group-I)** for **Diabetic Neuropathic symptoms**. In neuropathic symptoms, **BURNING SENSATION** was highly notified changes like reducing within one a month than other symptoms.

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Author Profile



Dr. S. R. Pholtan Rajeev received the B.S.M.S. (Bachelor of Siddha Medicine and Surgery) degree with Class in medical field from University of Jaffna in 2011 and completed internship training registration at SLAMC in 2012, respectively. During internship period, he had done clinical research in Bandaraneika Memorial Ayurvedic Research Institute (BMARI), Sri Lanka. He already published student research works in monographs of Medicinal plants in under graduate period.