

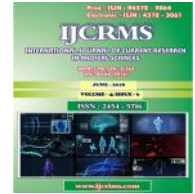


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Pilot Study on Efficacy Evaluation of Siddha Remedy Adathoda Cigarette in Reducing the Serum Nicotine Level for Tobacco Smoking De-Addiction

P.Kamalasoundaram^{*1}, T.Lakshmikantham², V.Banumathi³

^{1*}PG Scholar, Department of Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai 600047, Tamil Nadu, India.

²Lecturer, Department of Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai 600047, Tamil Nadu, India.

³Director, National Institute of Siddha, TambaramSanatorium, Chennai 600047, Tamil Nadu, India.

*Corresponding Author: **Dr.P.Kamalasoundaram**, PG Scholar, Department of Maruthuvam, National Institute of Siddha, TambaramSanatorium, Chennai 600047, Tamil Nadu, India.

E-mail: drkamala15@gmail.com

Abstract

Cigarette smoking remains the leading cause of death throughout the world, further it becomes the serious factor contributing premature death in the developing countries like India. Tobacco addiction involves the interplay of pharmacology, learned or conditioned factors, genetics, and social and environmental factors. The pharmacologic reasons for nicotine use are enhancement of mood, either directly or through relief of withdrawal symptoms, and augmentation of mental or physical functions. The major drawback of nicotine upon chronic usage causes anxiety and stress. Management of tobacco withdrawal becomes the major concern in subjects of de addiction program. Several methodologies have been adopted around the globe to manage the nicotine with symptoms of such as irritability, depressed mood, restlessness but most of them fail to provide successful relief. As an attempt of modern therapy with the conventional traditional siddha remedy. The present investigation aimed at supplementing the Adathoda cigarette (AC) mentioned in vedic literature Gunapadamporutpanbunool. Present pilot study was carried out in 10 male patients with three AC per day for the period of 2 months with decrement from regular nicotine cigarette (NC) usage starting from 75% at 1st week to 25% in the fourth week of the study. The results of the study have clearly projects that there was a significant decrease in the level of blood nicotine level in the subjects exposed to AC along with regular NC. Hence it was concluded based on the results of the study that the siddha remedy AC being an herbal moiety maybe considered as a drug of choice in tobacco withdrawal subjects.

Keywords: Tobacco withdrawal, Nicotine, Siddha remedy, Adathoda cigarette, Nicotine cigarette

1. Introduction

Tobacco use is associated with 5 million deaths per year worldwide and is considered as one of the leading causes of premature death. Comprehensive tobacco control programs can significantly reduce the prevalence of tobacco use. An important component of a comprehensive program is the provision of treatment for tobacco addiction. Treatment involves targeting multiple aspects of addiction including the underlying neurobiology and behavioral processes. Currently there are about 1.2 billion smokers in the world and half of these smokers today will die of smoking caused diseases. Smoking is responsible for 5 million deaths per year and if current patterns of smoking continue, it is projected to kill 10 million smokers per year in the year 2020. The prevalence varies a great deal, from less than 5% to over 55% in different countries.

Use of nicotine sustains tobacco addiction, which in turn causes devastating health problems, including heart disease, lung disease, and cancer, and increased susceptibility to a variety of infectious diseases. Smoking harms almost every organ of the body [1]. Quitting smoking at any age leads to significant reductions in the risks associated with it, and the vast majority of smokers in the United States indicate an interest in quitting [2]. Natural products still remain the most important source for discovery of new and potential drug molecules. Medicinal plants are important sources of practical drugs for people throughout the year. Nature acts as a prominent reservoir for new and novel therapeutics.

Adhatodavasica (L.)Nees (Acanthaceae), known commonly as Malabar nut tree, is a shrub growing throughout the Indian peninsula. *Adhatodavasica* Nees.leaf (*Vasaka*), is reported to be an expectorant [4], abortifacient [5], antimicrobial [6,7], antitussive and anticancer [8,9]. Important chemical constituents of leaf include pyrroloquinazoline alkaloids, vasicine, vasicol, adhatonine, vasicinone, vasicinol, vasicinolone [10]. Vasicine was reported to have bronchodilatory, respiratory stimulant and uterine stimulant effect [11]. Vasicinone was shown to have bronchodilatory, weak cardiac stimulant and

antianaphylactic action [12]. Still now there is no proper alternative therapy available for proper clinical management of tobacco withdrawal on de addiction subjects. Hence the current study has been undertaken to explore the alternate siddha remedy for tobacco de addiction in 10 patients as a pilot study.

2. Materials and Methods

2.1. Collection and Authentication of the Plant Material

The required raw drug *Justiciaadhatodalinn* (Adhatodai) Leaf were collected from kaveri farm virudhachalam. The raw drugs were b authenticated by the Asst. Professor Medicinal botany in NIS Chennai. The raw drug was purified and the medicine will be prepared as per SOP in Gunapadam laboratory of National Institute of siddha.

2.1. Purification and Formulation

Adhatodai leaf with the specification of length of the leaf :8-10 cm, breath of the leaf :3-5 cm and weight of the leaf : 3-5gm were cleaned with wet cloth and dried in shadow , followed by this the mid vein were removed and the dries product were rolled cylindrically with the structure similar to conventional cigarette which is commonly called as Adhatodaisuruttu in Tamil the final rolled form of the leaf were allowed to shadow dry and then stored in clean and dry container for further usage.

2.2. Subject selection and Study design

Pilot study comprises of 10 subjects with the clinical Symptoms of tobacco smoking addiction age between 20 to 60 years. The entire study was conducted on Out-patient department of Ayothidass Pandithar Hospital (OPD), National Institute of Siddha, Tambaram Sanatorium, Chennai-47, Tamil Nadu, India. Institutional ethical committee clearance was obtained for this study with the total study period of 2 months.

2.3. Inclusion criteria

- Age: 20- 60 Years
- Sex: Male
- Patient Having The Symptoms of tobacco smoking addiction .
- Patient Willing To Undergo Routine Blood Investigation.
- Patient Willing To Participate In Trial And Signing In Consent Form.
- Existing Smokers

2.4. Exclusion Criteria

- Renal Disease
- Cardiac disease
- Lung disease such as COPD, Fibrosis, PTB etc.

2.5. Withdrawal criteria:

- Intolerance to the drug and development of adverse reactions during the drug trial.
- Poor patient compliance & defaulters
- Patients turned unwilling to continue in the course of clinical trial
- Patient will not take medication regularly

2.6. Diagnostics Methods

- 1.Clinical Assessment
- 2.Siddha Assessment
- 3.Routine Investigations
- 4.Special Investigation

2.7.1. Clinical assessment

- Nausea
- constipation
- Abdominal Pain
- Headache
- Dizziness
- Shaking and Tremors
- Seizures
- Dark Gums and Lips
- Chest Pain
- Numbness
- Cold fingers or toes
- Bad breath
- Confusion
- Anxiety
- Insomnia
- High Pulse Rate
- No Appetite
- Increased Blood Pressure
- Fatigue, And General Weakness.
- Central Nervous System Depression

2.7.2. Siddha Assessment

<ul style="list-style-type: none"> • Thinai (Living Place) Kurinchi (Hill Areas) Mullai (Forest) Marutham (Fertile Land) Neithal (Costal land) Paalai (Desert) 	<ul style="list-style-type: none"> • Paruvakaalam (Season): KaarKaalamKoothirKaalamMunpaniKaalamPinpaniKaalamElavenilKaalam MuthuvenilKaalam 	<ul style="list-style-type: none"> • Poripulankal: Mei (Skin) Vaai (Tongue) Kan (Eye) Mooku (Nose) Sevi (Ear)
<ul style="list-style-type: none"> • Gnanenthiriyam and Kanmenthiriyam: Vaai (Buccal Cavity) Kaal (Lower Limb) Kai (Upper Limb) Eruvaai (Anorectal Region) Karuvaai (Uro- Genital Region) 	<ul style="list-style-type: none"> • EzhuUdalKattugal: Saram Senneer Uoon Kozhuppu Enbu Moolai Sukkilam/Suronitham 	<ul style="list-style-type: none"> • EnnVagaiThervu(Eight Diagnostic Methods) Naadi Sparisam Naa Niram Mozhi Vizhi Malam Moothiram Neerkuri

2.7.3. Routine Investigations

<ul style="list-style-type: none"> • Hb (gms/dl) • PCV • MCV • MCHC • MCV • Bleeding Time • Clotting Time • Smear Study 	<ul style="list-style-type: none"> • Total RBC (million/Cu.mm) • Total WBC (cubic mm) • Differential Count : (%) <ul style="list-style-type: none"> Polymorphs Lymphocytes Monocytes Esinophils Basophils • ESR(mm/Hr) 	<ul style="list-style-type: none"> • Blood Sugar Level <ul style="list-style-type: none"> Fasting (mg/dl) Post Prandial (mg/dl) Random (mg/dl) ECG Lung X- ray. Lung Function Test
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2.8. Specific Investigations

Serum nicotine level

2.9. Treatment Schedule [13]

On the first day onwards the trial drug Adathodasurruttu was provided for 7 days. The trial drug given by the investigator in the OP Department of Maruthuvam, NIS, Chennai. The patients will be asked to have a regular treatment in the op department once in 7 days. In every visit the clinical assessment will be recorded in the prescribed proforma. Tapering method with decrement from regular nicotine cigarette (NC) usage starting from 75% at 1st week to 25% in the fourth week of the study. The recommended dosage of treatment schedule would be 3 cigarette per day. The laboratory investigation will be done before and after treatment and recorded in the prescribed format. At the end of the trial the patients advised to come for follow up for two months for observation.

Name of The Drug : Adathoda cigarette (AC)
 Dosage : 3 cigarette / day
 Tapering method : 1st week-Reduce the No of cigarette into ¾ from those the patient already use
 2nd week-2/4.
 week -1/4
 4th week – 1 or 2 only weekly once.
 Indication : Tobacco Smoking
 De-Addiction .
 Book ref : Gunapaadam

-porutpanbunool-

Mooligaivaguppu

Author Name : VaithiyaRathinam
 K.S

MurugaesaMudhaliyar

Edition : 2nd Edition 2008

2.10. Statistical analysis

Data's will be analyzed using data software under the guidance of SRO (stat), NIS. The level of significance will be 0.05 descriptive analysis will be made and necessary tables/graphs generated to understand the profile of the patients included in the study. Student 't' test and chi-square test are proposed to be performed for quantitative and qualitative data.

3. Results

Result analysis of the present study has revealed that patients presented with the symptoms of tobacco withdrawal was concomitantly administered with siddha remedy AC at the dose of three per day with the continuous decrement of conventional nicotine based cigarette. At the end of the trial period subjects were screened for serum nicotine level. The data have shown that there was significant decrease in the level of serum nicotine level before and after treatment with AC. Before treatment the highest serum nicotine level was found to be 220.2 ng/ml treatment with AC has shown significant decrease in the level of serum nicotine at the level of 16.41 ng/ml. As shown in table 1

Table 1: Serum Nicotine level of subjects treated with Adathoda cigarette before and after treatment

Subject No	Before Treatment Nicotine level in ng/ml	After Treatment Nicotine level in ng/ml
1.	170.18	24.8
2.	193.42	16.41
3.	107.66	46.24
4.	121.84	32.1
5.	220.20	20.14
6.	180.14	18.17
7.	140.16	25.13
8.	190.41	58.02
9.	117.28	31.16
10.	144.1	40.24

4. Discussion

The risk of tobacco dependence increases when smoking begins early [14]. Studies of the developing brain in animals suggest that nicotine can induce permanent changes that lead to addiction. Brain changes in adolescent rats exposed to nicotine are greater than those in exposed adult rats. Adolescent rats that have been exposed to nicotine have higher rates of nicotine self-administration as adults, which is consistent with the idea that early exposure to nicotine increases the severity of dependence [15,16]

Nicotine acts on nicotinic cholinergic receptors, triggering the release of neurotransmitters that produce psychoactive effects that are rewarding. With repeated exposure, tolerance develops to many of the effects of nicotine, thereby reducing its primary reinforcing effects and inducing physical dependence (i.e., withdrawal symptoms in the absence of nicotine). Smoking behavior is influenced by pharmacologic feedback and by environmental factors such as smoking cues, friends who smoke, stress, and product advertising. Levels of nicotine in the body in relation to a particular level of nicotine intake from smoking are modulated by the rate of nicotine metabolism, which occurs in the liver largely by means of the enzyme CYP2A6. Other

factors that influence smoking behavior include age, sex, genetics, mental illness, and substance abuse.

Nicotine withdrawal causes anxiety and stress, both of which are powerful incentives to take up smoking again [17]. Cessation of smoking causes the emergence of withdrawal symptoms: irritability, depressed mood, restlessness, and anxiety [18]. The intensity of these mood disturbances is similar to that found in psychiatric outpatients [19]. Result analysis of the present study has revealed that patients presented with the symptoms of tobacco withdrawal was concomitantly administered with siddha remedy AC at the dose of three per day with the continuous decrement of conventional nicotine based cigarette. At the end of the trial period subjects were screened for serum nicotine level. The data have shown that there was significant decrease in the level of serum nicotine level before and after treatment with AC. Before treatment the highest serum nicotine level was found to be 220.2 ng/ml treatment with AC has shown significant decrease in the level of serum nicotine at the level of 16.41 ng/ml. The additional benefits offered by AC are its tendency to cause broncho dilation which aids in COPD patients to respire at the maximum comfort.

5. Conclusion

Nicotine withdrawal symptoms such as anxiety, stress and depression offers greater physical and mental discomfort in subjects under tobacco de addiction program. Hence there is a need of the hours of research pertains to alternate therapy in particular form siddha origin which can able to manage such symptoms are at greater demand. In the present study treatment with AC has greatly reduced the serum nicotine level in the subjects underwent treatment. Hence it was concluded from the results that the siddha remedy AC can be used as an alternate strategy in managing the clinical signs of the patients under tobacco de addiction program.

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