ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at: www.ijmacr.com

Volume – 2, Issue – 3, May - June - 2019, Page No. : 95 - 100

Safety and Comparative Open Clinical Study on "Ayavaththi Chooranam" And "Chiteramoola Ennai" Two Siddha Drugs in the Treatment of Lumbar Spondylosis

[1]A.Jenifer lancy,[2]N. J. Muthukumar,[3]Bernaitis L.

[1]Department of Sirappu Maruthuvam, Shantigiri Siddha Medical College, Pothencode, Kerala, India.

[2]Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai, India.

[3]Department of Microbiology, R.V.S Dental College and Hospital, Coimbatore, India.

Corresponding Author: A. Jenifer Lancy, Department of Sirappu Maruthuvam, Shantigiri Siddha Medical College, Pothencode, Kerala, India.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Siddha system of medicine is most ancient and spiritually enriched one. The drugs 'Ayavaththi Chooranam' as internal drug (Anupoga vaithya Navaneetham) and "Chiteramoola Ennai" **(**Sarabendirar Vaithya Muraigal - Vaatharoga chikichai) for external application to evaluate their efficacy in treating "Thandaga Vatham" (Lumbar Spondylosis). In recent research, it has been found that, kadukkai - Terminalia chebula, chukku – Zingiber officinale, Nilavagai – Cassia senna, were the drug of 'Ayavaththi chooranam' has, anti arthritic, anti - inflammatory properties.

Materials And Methods: The Study on Thandagavatham was carried out in the Department of Sirappu Maruthuvam, National Institute of Siddha over 12 months among 40 patients. On the first day of the treatment, Purgation will be given in the early morning with Agastiyar kulambu – 130 m.g o.d with ginger juice in empty stomach.Next day onwards the trial drug Ayavaththi chooranam, internally for 48 days and Chitermoola Ennai externally are given continuously for 48 days. OP patients are requested to visit the hospital once in 7days (FormIV). In each and every visit clinical assessment is done and prognosis is noted in the Prescribed Proforma. Under supervision of faulty members for IP Patients clinical assessment is done daily. 20 patients will be given Varmam treatment along with trial medicines and the remaining 20 will be given medicine only. If there is need of IP patients will be admitted in the ward for the clinical assessment. Laboratory investigations and Radiological investigations are done on the First day and the last day of the trial. At the end of the treatment, the patients were advised to visit the OPD for follow-up.

Results: Among the 40 cases, after the treatment the pain was reduced in 18 cases (45%), mild pain was present in 8 cases (20%), moderate pain was present in 9 cases (22.5%), severe pain was present in 5 cases (12.5%).

Conclusion: The clinical trial proves the efficacy of he trail drugs by reducing the clinical signs and symptoms like radiating pain, numbness, restricted movements and provides better improvement.

Keywords: Lumbar spondylosis, Low back pain, Siddha drugs, Ayavaththi Chooranam, Chiteramoola Ennai.

Introduction

Siddha system of medicine is most ancient and spiritually enriched one. Siddha system of Medicine, the tradition of

Tamil speaking world known for its proven ability in curing long standing diseases and their life threatening complications. Maintaining a perfect state of equilibrium of three basic humours by meant of the dietary habits, regular physical and mental activities. In normal healthy condition, the three humours exist with the ratio of 1:1/2:1/4 respectively. According to Siddha theory the root cause of any disease is alteration in the equilibrium of three humors ie. Vaatham, Piththam and Kabam[(1)].

In Siddha System of Medicine, the diseases of human beings are classified into 4448 types on the basis of Mukkutram theory.The five basic elements, namely Aagayam (Space), Vaayu (Air), Thee (Fire), Neer (Water), and Mann (Earth) are the building blocks of all the physical and subtle bodies existing in this whole universe. These are called as the 'panja Boothams' (Basic Elements) (or) 'Adippadai boothams. They could act only in co-ordination with other four elements. All the living creatures and the non-living things are made up of these five basic elements[(2)].

According to Saint Yugi, there are 80 types of Vaatha diseases. One among is Thandagavaatham. The symptoms are pain in the lower back region, spasm, numbness, radiating pain to both legs[(3)].

In Yugi as per the text the signs and symptoms of Thandaga vaatham may be correlated with the Lumbar Spondylosis in Modern science. According to it, Lumbar spondylosis is defined as a degenerative condition which affects the lower spine. In lumbar spondylosis the spine is compromised by a narrowing of the space between the vertebrae, causing a variety of health problems ranging from back pain to neurological issues. This condition is usually caused by trauma, obesity, spine undergoes changes as people grow older and many of these changes contribute to degeneration of the vertebrae[(4)].

Lumbar spondylosis or degenerative arthritis is common lumbar spine due to excessive mobility in that area ofspine.In otherword it is a manifestation of the wear and tear process.Other predisposing factors can be old age,injury to the spine or any previous disease.

Many studies show that spondylosis is prevalent in about 80% of people over age 60 years. In one study, 10% of people in the 20-29 year age group has spondylosis.In a large population study conducted in the United Kingdom, patients over age 50 years showed spondylosis was prevalent in 84% of men and 74% of women subjects[(5)].

In this present study, the drugs 'Ayavaththi Chooranam' as internal drug (Anupoga vaithya Navaneetham) and "Chiteramoola Ennai" **(**Sarabendirar Vaithya Muraigal - Vaatharoga chikichai) for external application to evaluate their efficacy in treating "Thandaga Vatham" (Lumbar Spondylosis). In recent research, it has been found that, kadukkai - Terminalia chebula, chukku – Zingiber officinale, Nilavagai – Cassia senna, were the drug of 'Ayavaththi chooranam' has, anti arthritic, anti - inflammatory properties.

Materials And Methods

The Study on Thandagavatham was carried out in the Department of Sirappu Maruthuvam, National Institute of Siddha over 12 months among 40 patients[Out of 20 IP patients- 20 patients with trial medicine and the remaining 20 patients with Varmam along with trial medicine.

Patients reporting with symptoms of Thandaga vatham will be subjected to screening test using screening proforma then they enrolled for the trial. The inclusion criteria were Age : 20-65 yrs, Sex : Both male and female, Pain in lumbar region,Radiating pain to buttocks and lower limbs,Diffuse tenderness in lumbar region with limitation of movements,Stiffness of lumbar spine. Exclusion criteria were Cardiac diseases,Hypertension,Diabetes mellitus,Use of narcotic

drugs,Pregnancy and lactation. The patients were assessed for Clinical assessment ,Radiological investigations, Siddha system examination

Clinical Assesment: Pain in lumbar region,Radiating pain to back and lower limbs,Diffuse tenderness in lumbar region with limitation of movements,Stiffness of lumbar spine,Exacerbation of pain on movements,Pain increased on forward bending,Paraesthesia & sensory loss on affected area,Burning and tingling sensation in lower limbs. The Improvement assessed by Universal pain assessment scale[(6)].

Patients reporting at the OPD with the clinical symptoms of **Thandaga Vaatham** had examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled first informed(Form V) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent form got obtained from the patients (Form VI).

All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phone number etc were given, so as to report easily should any complication arises.Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma. Screening Form-I got filled up: Form –II and Form –III was used for recording the patient history, clinical examination of symptoms, signs and laboratory Investigation. If there is any abnormal Laboratory Reports obtained then excluded from the study. A patient was advised to take the trial drug and to follow the appropriate dietary advice. (Form -IX)

On the first day of the treatment, Purgation will be given in the early morning with Agastiyar kulambu – 130 m.g o.d with ginger juice in empty stomach

Next day onwards the trial drug Ayavaththi chooranam, Internally for 48 days and Chitermoola Ennai externally are given continuously for 48 days. OP patients are requested to visit the hospital once in 7days (FormIV). In each and every visit clinical assessment is done and prognosis is noted in the Prescribed Proformas. Under supervision of faulty members for IP Patients clinical assessment is done daily. 20 patients will be given Varmam treatment along with trial medicines and the remaining 20 will be given medicine only. If there is need of IP patients will be admitted in the ward for the clinical assessment. Laboratory investigations and Radiological investigations are done on the First day and the last day of the trial. At the end of the treatment, the patient were advised to visit the OPD for follow-up . No Defaulters withdrawn (Form VII) from the study.

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

Results

In this study, the disease was found to be higher in the age group of 41 – 50 years. Among the 40 patients selected, the disease was found to be female 18 (55%) and male 22 (45%).Among the 40 cases recruited,the prevalence of the disease seems to higher in Non vegetarian 36(90%)cases than in Vegetarian 4(10%) cases.

The chronicity of illness before recruitment for the study was more in 12(30%) cases who were between the time interval of two to five years.18 (45%) cases had chronicity

of 6 months to 1 year ,1(2.5%) had chronicity of 5 to 10 years, 9(22.5%) had chronicity of 1 to 2 years .

Among the 40 patients recruited, 33 cases (82.5%) and 7 cases (17.5) not under go any treatments. In naadi Vaatha piththa naadi was found in 22 cases (55%), Piththa vaatha naadi was found in 8 cases (20%), Piththa kaba naadi was found in 2 cases (5%), Kaba piththa naadi was found in 8 cases (20%). Malam was affected in 4(10%) of the cases due to constipation. Naa, vizhi, Sparisam, Mozhi, Malam, Moothiram ar not affected. Among 40 cases, all of them had lumbar pain (100%), 35 cases (87.5%) had radiating pain to back and lower limbs, 7 cases (17.5%) had diffuse tenderness in lumbar region with limitation of movements, 12 cases (30%) had stiffness in lumbar spine, 37 cases (92.5%) had exacerbation of pain on movements, 26 cases (65%) had numbness and paraesthesia.

Among the 40 cases, after the treatment the pain was reduced in 18 cases (45%), mild pain was present in 8 cases (20%), moderate pain was present in 9 cases (22.5%), severe pain was present in 5 cases (12.5%).

Table:1 Restricted Movement Assessment Scale:

Grading	Before Treatment		After Treatment	
	Number of Patients	Percentage %	Number of Patients	Percentage %
GRADE I	6	15	15	37.5
GRADE II	21	52.5	18	45
GRADE III	13	32.5	7	17.5
GRADE IV	-	-	-	-
TOTAL	40	100	40	100

After the treatment among 40 patients restriction was reduced in 13 cases (32.5%), mild restriction was found in 19 cases (47.5%), moderate restriction was found in 8 cases (20%).

Among the 20 cases, after the treatment the pain was reduced in 20 cases (50%), mild pain was present in 8 cases (30%) and moderate pain was present in 8case (20%). It was observed that there was reduction in 67%of pain after treatment.There is significant difference between before and after treatment on pain score – $t=13.02, p<0.0001$.

Discussion

The retrospective review of the disease Thandaga vaatham mentioned in Siddha literatures begins from the correlation of it to signs and symptoms of the disease lumbar spondylosis.

The drugs which possess anti-vaatha property as mentioned in Siddha literature were selected and the trial drugs were prepared by the Author in the Gunapadam practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal Botany Department under the supervision of the members of the teaching faculty and guided by the Head of the Department of Sirappu Maruthuvam of the National Institute of Siddha, Chennai - 47.

40 patients of both genders were recruited for this study. Among 40 patients, 20 In-patients were treated with Varmam treatment along with the trial drugs, remaining 20 patients trial Medicine only.

The treatment was aimed to normalizing the deranged Thodams and providing relief from symptoms. Before treatment the patients were advised to take Agasthiyar kuzhambu- 130 mg with ginger juice in early morning for purgation empty stomach. The patient was advised to take rest without internal medicine and other activities on that day.

The patients were treated with trial drugs Ayavaththi Chooranam twice a day with honey and Chiteramoola Ennai external for 48 days. Patients were instructed to take the Medicines regularly advised to follow pathiyam (avoid

tamarind, tubers, etc) and advised to avoid weight bearing, and prolonged sitting. Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 48 days and the clinical assessment was done under the supervision of the faculty on 0th day, 8th day, 15th day, 22th day , 29th day, 36th day, 43th day and 49th day.

For In-Patients the drugs were given for 48 days and the clinical assessment was done daily. 20 In-Patients were given varmam treatment along with their trial drugs. The results were compared at the end of the study. For In-Patients, who are not in a situation to stay in the hospital for a long time, were advised to attend the Out-Patient Department of Sirappu Maruthuvam for further follow-up[7].

After the treatment, the patients were advised to visit the Out-Patient ward of Department of Sirappu Maruthuvam for another 2 months for follow-up.

Among the 40 cases 22 (55%) were males and 18 (45%) were females. In this study majority affected sex is male (55%)[8]. The one of the common cause for this may be depletion of calcium from their body and heavy works. From history taking these were concluded as the reasons for male predominance[9].

This study shows that the highest age distribution of Thandagavatham is between 41-50years of age. Most of the patients under this analysis were predominantly of Raso gunam assessed from interrogation and other observations[10]. In this study, the majority of cases 47.5 were reported during Pinpani kalam and Munpani kalam. Remaining 2 (5%) cases were reported during Koothir kaalam[11].

Most of the patients 36 (90%) were non vegetarians. Non vegetarian diet may be the cause for deposition of fat in adipose tissue and there by promoting obesity. This alters the weight transferring mechanism in lumbar vertebra, causing this disease[12].

In Vatham Viyanan and Samanan vayus were affected in all 40 cases. Abanan was affected in 4 cases, and Devathathan in 8 cases.

In Pitham Saathaga pitham was affected in all the 40 cases. Ranjaga pitham was affected in 3 cases. In Kabam Santhigam was affected in all the 40 cases. All cases were observed and examined by the eight clinical parameters of Siddha system. Naadi (Pulse reading) was observed in all 40 patients. 22 cases had Vaatha piththam, 8 cases had Piththa vatham, 2 cases had Piththa kabam and 8 cases had Kaba piththam naadi. In Malam 4 cases (10%) had constipation.

The urine of all the patients was in Elamanjal niram (Pale yellow coloured urine)[13]. In Neikkuri (Oil on urine sign) examination, oil spreads slowly in 18 cases indicates vitiation of vatham in the Thandaga vatham patients, in 12 cases it appeared like pearl and in rest of the 10 cases oil acquired a ring form. This reveals that most of the cases has derangement in vatham. In Seven Udal kattugal Enbu and Saaram were affected in all 40 cases (100%), Senneer was affected in 4 cases (10%), Oon was affected in 10 cases (4%) and Kozhuppu was affected in 37 cases (92.5%).

In Kanmenthiriangal Kaal was affected in 40 cases (100%), Kai was affected in 2 cases (5%) and Eruvai was affected in 4 cases (10%).

In clinical features Pain in the lumbar region was present in all the 40 cases (100%). Radiating pain to the buttocks and lower limbs was present in 35 cases (87.5%). 7 cases (17.5%) had diffuse tenderness in lumbar region with limitation of movements[14]. The other important features were stiffness of lumbar region in 12 cases (30%). Exacerbation of pain on movements in 37 cases (92.5%), Numbness and paraesthesia in 26 cases (65%).

Already it was explained that aging is the most common cause for Thandagavatham. Apart from that, increased

household works, Obesity and menopause are the other precipitating factors.

Household work accounts for the highest number (47.5%) of cases. More weight bearing, improper posture of spine, laxity of lumbar vertebral column during delivery also produces the impact[15].

Laboratory investigation of blood and urine were done for all 40 cases.There were no significant changes in blood and urine parameters before and after treatment.

The radiographic studies of the cases showed narrowed joint space and presence of osteophytes. The trial drug showed improvement in prognosis of the disease clinically [16].

On the basis of curative effect of the trial drugs, Good improvement was assessed in 20 Patients (50%), Moderate improvement was assessed in 8 patients (20%), Mild improvement in 8 patients (20%) and No improvement was assessed in 12 patients (30%).

20 IP patients are given Varmam treatment along with the trial drug. The remaining 20 0P patients received only trial medicines. The results are compared at the end of the study. Patients treated with Varmam showed better result than the without Varmam, since there is marked reduction in the Pain of Thandagavatham in this clinical trial[17].

The mean pain score before treatment is 5.075, after treatment it is reduced to 1.95. Hence this study reveals Patients treated with trial drugs and varmam showed good enhancement when compared to those who were treated only with trial drugs. The acute toxicity study was conducted for the trial drug Ayavaththi Chooranam in National Institute of Siddha and it showed no abnormal results. Hence the safety of the trial drug was also proved.

References

1. Patharthagunavilakkam,C.Kannusamy Pillai,1st Edition 2009
2. AgathiyarkanmagaandamGowmathinool,S.P.Ramachandran,1st Edition 1995.
3. Praanaratchamirthasindhu,R.C.Mohan , 2nd Edition 2002
4. Essential orthopaedics by J.Maheswari .
5. Text Davidson's priniciples and practice of medicine.-chirstober,haslet..
6. Book of orthopedics and traumatology – John Ebnezar
7. Text book of orthopedics and trauma – Kulkarni
8. Handbook of medicinal botany-pg no-119
9. Colour atlas of medicinal plants-edwin jarald,sheeja pg no:19
10. The Wealth Of India Vol.2 National Institute Of Science Communication And Information Resources Dr.K.Skrishnan Marg Csir- Pg No:18
11. Indian Herbal Pharmacopoeia, P – 424
12. Indian Materiamedica,K.M.Nadkarnivol I,Ii,2nd Reprint Of 3rd Revised And Enlarged Edition 2005.
13. T.V.Sambasivam Pillai,Tamil,English Dictionary Of Medicine,Chemistry,Botany,Alliedscience,Vol I,V,Iv(Parti)
14. P.J.Mehta's Practical Medicine,18th Edition 2007.
15. Text Book Of Orthopaedics And Traumatology ,Prof.Mayilvahanan Natarajan,6th Edition
16. Harrison's Principles Of Internal Medicine,Vol Ii,17th Edition.
17. Development Of Standard Siddha Terminologies, National Institute Of Siddha.