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AN OPEN LABELLED PILOT STUDY ON THE EFFICACY OF SIDDHA FORMULATION SADHAKUPPAI CHOORANAM FOR THE TREATMENT OF KUDAL KIRUMI (ASCARIASIS)

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ABSTRACT

Intestinal worm infection is a common pediatric health problem causing morbidity and anguish. *Sadhakuppai Chooranam* is a traditional *Siddha* drug indicated for *Kudal kirumi* (Ascariasis) a common ailment among children. The current study was conducted among 40 pediatric patients (30 Out Patients and 10 In Patients) of the department of *Kuzhanthai Maruthuvam* at National institute of Siddha, Tambaram, Chennai. The trial drug *Sadhakuppai Chooranam* was given twice a day for 20 days and follow up was done once in 7 days. At each clinical visit clinical assessment was done and prognosis was noted. Laboratory investigations were done 0 day & 20th day of the trial, and the patients were followed up for another 2 months. The study data were circumspectly analyzed and are presented graphically in this work. The study results revealed that among the forty patients enrolled in the open labeled pilot study, 80% of them had very good prognosis with improvement in both clinical and laboratory parameters. Hence the trial drug *Sadhakuppai Chooranam* can be used clinically for the effective treatment of *Kudal kirumi* (Ascariasis).

KEYWORDS: *Sadhakuppai Chooranam*, *Siddha* medicine, Herbal medicine, Worm infestations, *Kudal kirumi*, Ascariasis.

INTRODUCTION

Intestinal worm infestation is a global health problem in widely prevalent in areas of poverty, unsafe water, poor sanitation and hygiene, especially among tropical and subtropical regions of the world.[1] Among the infections with Ascaris, Hook worm, Hymenolepis nana and trichuris trichura, Ascaris lumbricoides is the largest and most common intestinal nematode among the developing countries. The common symptoms associated with worm infestation

are vomiting, anorexia, constipation, pica, diarrhea, perianal pruritus, urticaria and loose stools.[2,3] Children are generally more heavily infested than adults due to promiscuous defecation by toddlers in vicinity and are more liable to undergo the pathologic consequences of these infestations.[4] Moreover, the menace of flies and insects, poor personal cleanliness, habitual bare foot walking, poor disposal of human excreta also contributes to the infectious sources.

It is estimated that 450 million are affected due to the intestinal infections among which the high risk morbidity was found to be among the pre-school and school aged Children. Helminths have also been linked with increased risk of nutritional anemias and protein energy malnutrition.[5,6] According to World health organization, Ascariasis contributes to 800-1000 million cases of intestinal infection.[7] Approximately 10,500 deaths per year are due to the complications of Asariasis. This intestinal infection is reported to be an important factor in causing vitamin A deficiency. Pohowalla (1959) also reported that vitamin A deficiency associated with malnutrition is often exaggerated by Ascariasis.[8]

With all these informations in the back drop the present study was undertaken at National Institute of *Siddha*, Department of *Kuzhanthai Maruthuvam* (Pediatrics), Tambaram where many of the patients who attend the Outpatient /In patient department are under poverty and low sanitation areas. The Siddha herbal formulation *Sadhakuppai Chooranam* along with preclinical supporting data for safety and efficacy was administered to the trial subjects and the results were recorded and analysed.

MATERIALS AND METHODS

An open labeled pilot study was conducted on the patients who attended outpatient department of *Kuzhanthai Maruthuvam* at National institute of *Siddha*, Tambaram, Chennai with a sample size of 40 patients for a period of 12 months during the year 2010-2011. The Protocol for the study was prepared and presented in the IEC & IAEC got approved (F.NO.NIS/6-20/Res/IEC/10-11). The methodology was strictly followed as per the Protocol.

The patients who were clinically diagnosed and confirmed for helminthic infection due to Ascariasis were enrolled. The diagnosis was based on strong clinical history, clinical presentation and examination findings. The inclusion criteria consisted of pediatric patients (3-12 years) belonging to both male and female sexes and presenting with any of the clinical features such as loss of appetite, History of passing worms in the stools, Presence of perianal

itching, Pain around the umbilicus, Teeth grinding during sleep (Bruxism), willing to give both blood and motion specimen for investigation, when required. Children below 3 yrs age, Patients not willing to give blood and motion sample for investigation, Enteric fever, Amoebiasis and other worm infestations were excluded from the study.

Conduct of the study

The trial drug "*Sadhakuppai Chooranam*" was given continuously for 20 days and follow up was done once in 7 days. At each clinical visit clinical assessment was done and prognosis was noted. For IP patients the drug was provided daily and prognosis was noted. Laboratory investigations were done 0 day & 20th day of the trial. Even after the end of the treatment, the patients were followed up for another 2 months.

Method of collection of data

The diagnosis of Ascariasis was made based on the stool examination. Other laboratory parameters such as complete blood count (CBC) were also, performed and recorded in the proforma. The proforma of clinical trial was filled on the bases of clinical evaluation and prognosis was recorded for all the patients at every follow up visit. Follow up in each case was planned for a minimum 2 months. During the follow up each case was evaluated according to the scoring criteria, which includes the intensity of the symptoms before and after treatment.

Preparation of Trial Drug

Sadhakuppai Chooranam

The following ingredients of Sadhakuppai Chooranam (Anethum graveolens), Seeragam (Cuminum cyminum), Peruncheeragam (Pimpinella anisum), Karuncheeragam (Nigella sativa), Elam (Elettaria cardamomum), Lavangapattai (Cinnamomum verum) Athimadhuram (Glycyrrhiza glabra), Kothumalli(Coriandrum sativum), Lavangam (Syzygium aromaticum) and Cheenakarkandu *(White sugar candy)* were purified according to literature and dried in the proper sunlight. All the dried drugs (except White sugar candy) were powdered and then finally it was mixed with sugar candy. Then it was filtered with a mesh cloth and stored in a air tight bottles. The final product was further placed on the cloth tied on top of a vessel containing milk for purification of Chooranam and was steamed until the milk dried. The purified powder was taken and then dried.[9]

The above drug was given 500mg twice daily for Children 3 – 7 years and 1gram twice daily for Children 8 – 12 years for a period of 20 days.

Figure 1: Sadhakuppai Chooranam.

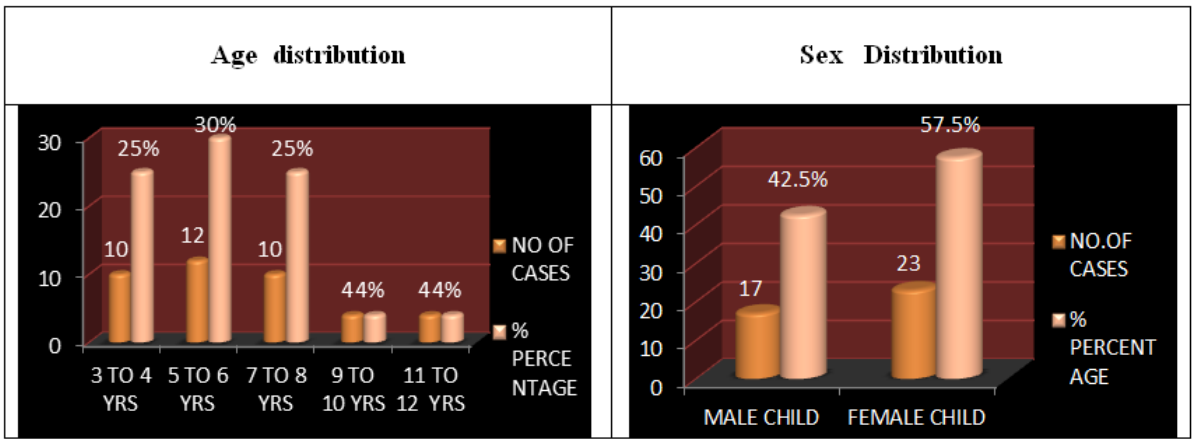

Figure 2: Distribution of Age and Sex.

RESULTS AND DISCUSSION

Forty patients with a diagnosis of Ascariasis were included in this study. After the administration of *Sadhakuppai Chooranam* for a period of 20 days, the patients were followed up for a period of 2 months.

In this study maximum prevalence of 5-6 years (12 cases-30%) followed by 25% (10 cases) in the age group of 3-4 years and 7-8 years. The minimum prevalence is found in 9-10 and 11-12 years (4.4%) years of age. Among the affected subjects 57.5% (23 cases) were females and 42.5% (17 cases) were males. 60% of them belonged to low socio economic status. In the following figures comparative data of each variable is represented graphically.

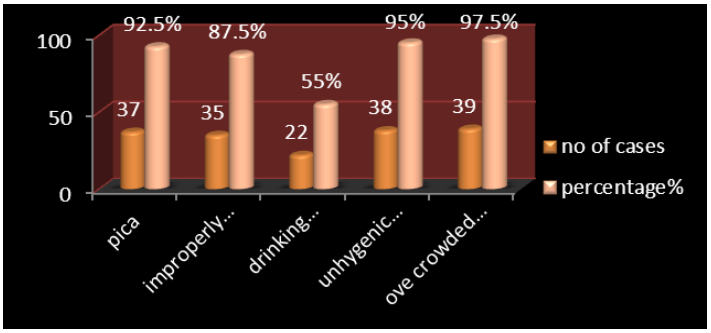

Figure 3: Etiologic Factors.

Among the enrolled subjects 97.5% (39 cases) belonged to overcrowded area and 95%(38 cases) were from unhygienic location. The other etiologic factors such as pica , improper diet and unsafe drinking water contributed 92.5%, 87.5% and 55% of the cases with intestinal infection. Since the conditions of poor sanitation are related with the maintenance of infection cycle of Ascariasis, the disease is found to be more prevalent in such areas.

The outcome assessment of the clinical features of the enrolled subjects suggested significant improvement in appetite (34 out of 38 patients), reduction of umbilical pain in 30 out of 34 patients. All 22 patients who had perianal itching were relieved completely. The prognosis based on stool examination indicated that 80% (32 cases) had good prognosis with absence of Ascaris ova and cyst and 20% (8 cases)had poor prognosis due to the presence of Ascaris ova and cyst.

The laboratory parameter Hemoglobin count (Hb) showed a mean value of 10.050gm/dl before treatment and the mean Hb increased to 10.260 after treatment with *Sadhakuppai Chooranam* for a period of 20 days. Though the result was not found to be statistically significant (two-tailed P value equals 0.4700), the presence of ferrous iron in the formulation as indicated by the previous preclinical study confirms that the herbal formulation would be beneficial when used for a longer period.

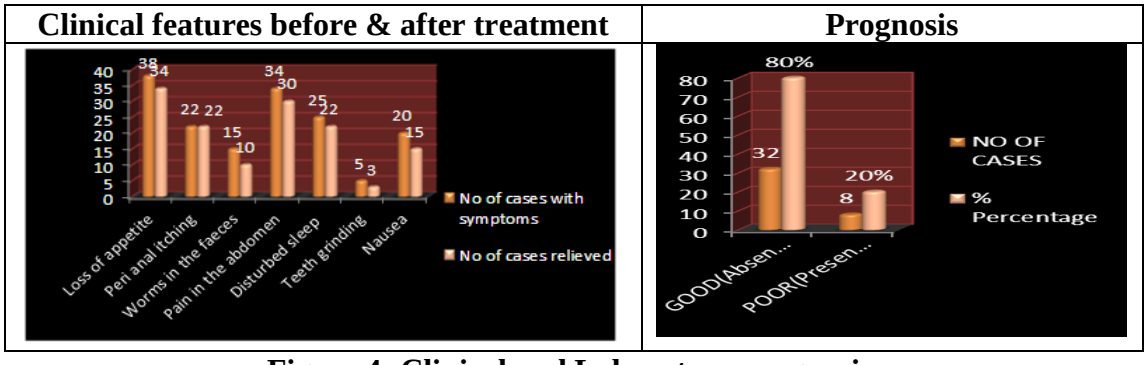

Figure 4: Clinical and Laboratory prognosis.

In addition to ferrous iron, the qualitative phytochemical test of water extract revealed that formulation contains calcium, sulphate, starch, phosphate, tannin amino acids, proteins and trace amount of alkaloids. ICP-OES analysis of Sadhakuppai Chooranam showed that all the heavy metals Mercury, Arsenic, Cadmium and Zinc were below the detectable limits. Hence this Siddha formulation is considered to be safe without any heavy metals. The invitro anthelmintic activity showed a dose dependent activity (90mg, 180 mg) against the adult nematode Ascaris lumbricoids and the exposure of test drug Sadhakuppai Chooranam 180mg showed early paralysis than the standard drug Piperazine citrate at 8.05±1.6 followed by mortality of parasites at 50.33±3.1.[10]

Intestinal worm infestation with the commonest nematode Ascariasis is a matter of serious concern especially in overcrowded and poor sanitation areas of Tamil Nadu. Moreover the migration of large masses of floating population to cities greatly favours the transmission of parasitic infection resulting in high endemicity. The association of malnutrition and worm infestation is a very well-known feature. Many workers have suggested that presently, the control of these nematodes relies largely on the conventional anthelmintics, However widespread use of anthelmintics result in resistance to many of these drugs. Therefore, there is a need to find new natural drugs that are safe to ensure sustained and effective treatment. Since the origin of many effective drugs is found in the traditional literature[11] hence, the present clinical study was performed using Sadhakuppai Chooranam a polyherbal formulation indicated in Siddha literature for worm infestation among children.

CONCLUSION

This preliminary clinical study results revealed that among the forty patients enrolled in the open labeled pilot study, 80% of them had very good prognosis with improvement in both clinical and laboratory parameters after consuming the drug for 20 days, twice daily. The above clinical study results reveal that the drug *Sadhakuppai Chooranam* can be effectively used for the treatment of Ascariasis (*Kudal kirumi*). Though traditional classical formulations surpass toxicity studies, further clinical studies on larger populations and reverse pharmacological studies on its acute and long term toxicity may be essential to re assure its safety in pediatric usage.

REFERENCES

1. Hemant Kumar, Brig, Kalpana Jain, and Rahul Jain, Maj. A study of prevalence of intestinal worm infestation and efficacy of anthelminthic drugs. Med J Armed Forces India, 2014; 70(2): 144–148.
2. Suresh K Kumbhar, Renuka S. Ashtekar, Satish D Ashtekar, Bidkar. Study of epidemiological and clinical profile of worm infestation among preschool age children attending Anganwadi of urban and rural areasof Sangli district. International Medical Journal, May 2016; 3(5): 2348-1897, 495-500.
3. Talib V.H., Hasija B.D. Silas C, Cough A. Incidence of helminthiais and protozoal infections in hospital population of Delhi. The Clinician, 1980; 44: 178- 187.
4. BansalMangala P. Sengupta S. R. Deshpande M.S. Incidence of helminthic infestation in Aurangabad. The clinician, 1975; 39: 61 – 64.
5. Bethony J, Brooker S, Albonico M et al. Soil-transmitted helminth infections: ascariasis, trichuriasis, and hookworm. Lancet, 2006; 367: 1521-1532.
6. Amare M,Solomon G, Tesfaye K. Prevalence of intestinal parasitic infections among urban dwellers in Southwest Ethiopia. Ethiop J Health Dev, 2007; 21(1): 12-17.
7. UNICEF. The Prescriber, May 1993; 1-8.
8. Pohowalla J. N. and Singh S.D. Worm infestation in infants and children of preschool age in Indore. Indian Journal of. Pediatrics, 1959; 26: 459-65.
9. Arangarajan S. Agathiar Attavanai Vagadam, 1st Edn, Saraswathy Mahal Library publisher, 1991.
10. R. Savitha, Qualitative phytochemical analysis and pharmacological action of siddha formulation Sadhakuppai Chooranam. WJPR, 6(5): 691-699.
11. Ravindra G Mali and Anita A Mehta. A Review on Anthelmintic Plants. Natural Product Radiance, 2008; 7(5): 466-475.