



AN OPEN LABEL CLINICAL STUDY TO EVALUATE EFFECT OF JUICE OF *TINOSPORA CORDIFOLIA* LINN. ON GROWTH OF CHILDREN

Patil Y. R.*

Dept. of Swasthavritta, Govt. Ayurved College, Nanded, M.S., India

Received on: 30/10/2011 Revised on: 21/12/2011 Accepted on: 18/01/2012

*Corresponding author

Dr. Patil Y. R., Associate Professor & Head of Department, Dept. of Swasthavritta, Government Ayurved College, Vazirabad road, Nanded, Maharashtra, India

ABSTRACT

Guduchi is being used as a rejuvenating herb in Ayurveda and other system of medicine since many decades. Guduchi is prescribed as a monoherbal as well as polyherbal formulation. The herb has free radical scavenging properties against reactive oxygen and nitrogen. Due to its Rasayana (free radical scavenging property) it was decided to evaluate efficacy of its juice in growth of children by comparing with standard growth charts developed by National centre for health statistics. 30 Children of age group 6 to 8 years were recruited in the trial. Children were assessed and evaluated on the basis of objective and subjective parameters at interval of 15 days for 3 months. Mean weight of children at baseline of study was 19.99 ± 1.59 kg and was increased moderately to 20.64 ± 1.57 kg (at 12th wk). Mean score of skin luster was 0.43 ± 0.5 and it was increased significantly to 1.17 ± 0.37 . Diet intake of these children at baseline was 0.467 ± 0.51 and in was increased significantly to 1.63 ± 0.48 . These findings suggest that juice of *Tinospora cordifolia* is an effective, safe, and herbal formulation for the children growth.

Keywords: Guduchi, *Tinospora cordifolia*, Child growth.

INTRODUCTION

Guduchi has been referred as a plant of rasayana, which is being used as a rejuvenating herb in Ayurveda and other system of medicine since many decades. Remarkable research work has been done on its immunomodulatory activity using various extracts of different parts¹. Guduchi's immunomodulatory property as an adjuvant therapy in diabetic patients with foot ulcers has been reported². The effect of alcoholic extract of whole plant on proliferation and myeloid differentiation of bone marrow haematopoietic precursor cells in mice bearing transplantable Dalton's lymphoma is being studied. The extract is found to influence the myeloid differentiation of bone marrow progenitor cells and the recruitment of macrophages in response to tumor growth in situ. The leaf extract have potential use as an immunoprophylactic to prevent diseases in finfish aquaculture³.

Guduchi is being prescribed as a monoherbal as well as polyherbal formulation. The effect of polyherbal formulation containing tinospora has been reported for cyclophosphamide induced genotoxicity in mice, favourable effect in patients with HIV infection and immunomodulatory activity.

The extract of tinospora modulates hepatoprotective and immunostimulatory function in carbon tetrachloride intoxicated mature rats. The whole and aqueous extracts are having significant adaptogenic activity on variety of biological, physical and chemical stressors on different animal models. Tinospora increases the activity of Kuffer cells in chronic liver disease model using carbon clearance test as parameter⁴.

The herb has free radical scavenging properties against reactive oxygen and nitrogen species as revealed by electron paramagnetic resonance spectroscopy⁵.

Objective

The primary objective of the study was to evaluate the efficacy of juice of *Tinospora* in growth of children above 80 to 90% of their expected weight at their age i.e. 6 to 8 yrs. by comparing with standard growth charts developed

by National centre for health statistics in collaboration with National centre for Chronic diseases and health promotion 2000.

MATERIALS AND METHOD

The study was an open-label, non-comparative, interventional, and exploratory clinical trial.

Plant Material

Fresh plants of *T. cordifolia* were collected from area adjacent to Nanded, Maharashtra. The plants were collected when they are fully mature condition especially at the time of flowering in the month of November. The plant material was authenticated in the Pharmacognosy Laboratory.

Processing of Guduchi Stem

The collected fresh stems of plants of *T. cordifolia* were cleaned thoroughly by removing outer flakes and washed with water. Then they were cut into smaller pieces and pounded to fine paste.

Preparation of Juice of Tinospora (Guduchi Swarasa)

Ayurveda mentions some of plants which are always used in fresh. Guduchi is a plant which falls in this group. Stem from plants was cut in to small pieces, crushed and soaked in water. The soaked pulp was thoroughly mixed in water and the contents were then filtered through a muslin cloth to obtain the filtrate devoid of any solid content. The filtrate was the Swarasa of Guduchi⁶.

Dose: 20 ml per day (empty stomach in morning)

Anupana: Honey – 20 ml

Sample Size Calculation

Sample size calculation was based on the assumption that a sample size of 30 cases would provide a 90% power to detect mean change in frequency of growth per fortnight at 5% level of significance.

Institutional Ethics Committee Approval and Regulatory Compliance

Before the initiation of the study, the study protocol and related documents were reviewed and approved by

Institutional Ethics Committee at Govt. Ayurved College & Govt. Ayurved hospital, Nanded, Maharashtra. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics act, India, amended in 2005 and ICMR ethical guidelines for biomedical research on human participants 2006.

Patients Screening and Recruitment

Children (age group, 6 to 8 years) attending the Outpatient Clinic at Govt. Ayurved College & Govt. Ayurved hospital, Nanded, Maharashtra and meeting all the inclusion criteria were recruited in the trial. Precautions were taken not to recruit children from possible vulnerable groups.

Inclusion Criteria

1. Children having weight 80 – 90% of their expected weight at the age of 6 to 8 years given in 50th percentile as a median given in National Centre for health statistics in collaboration with CDC 2000 charts which is normal according to IAP (Indian academy of pediatrics)
 2. Children free from any systemic of surgical illness.
- Only those children whose parents were willing to give a written informed consent as well as follow the study procedures were included in the study.

Exclusion Criteria

1. Malnourished children of grade I to IV
2. Age below 6 years and 8 years.
3. Any medical emergencies or condition requiring surgical intervention
4. Children having complication during treatment and should be dropped out.

Study Procedure

Children were assessed and evaluated on the basis of objective and subjective parameters at interval of 15 days for 3 months.

1. **Objective parameters:** weight, height, chest circumference, head circumference, mid arm circumference
2. **Subjective parameters:** Diet intake, skin luster
3. **Investigations:** Hb%, TLC, DLC, ESR

Gradation of Subjective Parameters

Diet intake

- a. Child taking food in less quantity twice a day – 0

- b. Child taking food in moderate quantity twice a day – 1
- c. Child taking food in moderate quantity thrice a day – 2

Skin luster

- a. Dry – 0
- b. Some dryness – 1
- c. Normal – 2

Statistical Analysis

Statistical analysis of the study data was performed by an independent statistician using statistical software SPSS 10.0. Data describing quantitative measures were expressed as median or mean ± SD or SE or the mean with range. All P values are reported based on two-sided significance test and all the statistical tests were interpreted at 5% level of significance.

RESULT

Of the 41 screened children, eleven did not meet the inclusion criteria and hence were not included in the trial. Of 30 children included in the trial, 19 were male while 11 were female.

Thirty patients completed the study. No patient was dropped out or withdrawn due to the adverse event or an adverse reaction. Study treatment did not cause any significant change in vital signs like pulse rate, body temperature, respiratory rate, and the blood pressure.

Mean weight of children at baseline of study was 19.99 ± 1.59 kg and was increased moderately to 20.64 ± 1.57 kg (at 12th wk). The mean height of children at baseline of study was 102.95 ± 4.31 and it was increased moderately to 103.21 ± 4.28 (8th week) and 104.04 ± 4.23 (12th week). The mean head circumference of children at baseline of study was 49.97 ± 0.88 and was shown mild growth 50.18 ± 0.84 at end of 12th week. Chest circumference of these children shows mild growth from 58.71 ± 1.26 to 58.96 ± 1.22 at the end of 12th week. Also mid arm circumference of these children was increased from 16.87 ± 0.76 to 16.18 ± 0.76 at end of 12th week. At baseline, mean score of skin luster was 0.43 ± 0.5 and it was increased significantly to 1.17 ± 0.37. Diet intake of these children at baseline was 0.467 ± 0.51 and in was increased significantly to 1.63 ± 0.48 [Table 1]

Table 1: Results showing changes observed in children per visit in weight, height, head circumference, chest circumference, mid arm circumference, skin luster & diet intake

Duration in days	Mean weight gain of children per visit	Mean height of children per visit	Mean head circumference of children per visit	Mean chest circumference of children per visit	Mean mid arm circumference of children per visit	Improvement of skin luster of children per visit	Improvement in diet intake of children per visit
0 days	19.99						
15 days	19.99 ± 1.594	102.95 ± 4.31	49.97 ± 0.88	58.71 ± 1.26	15.87 ± 0.76	0.43 ± 0.5	0.467 ± 0.51
30 days	20.11 ± 1.606	103.21 ± 4.29	49.99 ± 0.83	58.73 ± 1.27	15.93 ± 0.76	0.47 ± 0.51	0.633 ± 0.49
45 days	20.26 ± 1.584	103.51 ± 4.28	50.04 ± 0.86	58.81 ± 1.27	16.00 ± 0.77	0.57 ± 0.5	0.767 ± 0.57
60 days	20.42 ± 1.588	103.78 ± 4.27	50.11 ± 0.85	58.87 ± 1.25	16.07 ± 0.76	0.83 ± 0.38	1.233 ± 0.63
75 days	20.54 ± 1.599	104.04 ± 4.27	50.15 ± 0.85	58.94 ± 1.25	16.11 ± 0.77	1.13 ± 0.43	1.533 ± 0.51
90 days	20.64 ± 1.574	104.27 ± 4.23	50.18 ± 0.84	58.96 ± 1.22	16.19 ± 0.76	1.17 ± 0.37	1.633 ± 0.48

DISCUSSION

This study confirms the beneficial effect of juice of *Tinospora cordifolia* in growth of children. The mean weight & height gain significantly increased (P<0.05). The increase in mean head circumference at end of study (i.e., on day 120) was not statistically significant, but the mean score was higher than that of baseline value and was

clinically significant (P<0.05). There was statistically significant improvement in mean chest, mid arm circumference, skin luster and food intake after 12 weeks of treatment.

The present investigation was an open-label, uncontrolled, and pilot study and was performed to gather the preliminary reports on efficacy of ayurvedic formulation.

A randomized, double blind, comparative clinical study of juice of *Tinospora* with placebo or other conventional formulations in larger population may endorse the findings of the current study.

CONCLUSION

An Ayurvedic medicine juice of *Tinospora cordifolia* is significantly effective on growth of children. 12 weeks of treatment with the drug also show improvement in height, weight & hematological values.

These findings suggest that juice of *Tinospora cordifolia* is an effective, safe, and herbal formulation for the children growth. Further comparative, double blind studies with large sample size would be able to confirm the above findings.

REFERENCES

1. Misra B, *Bhava Prakash Nighantu*, Vol. 1, (Hindi commentary by K C Chuneekar), (Chowkhamba Vidya Bhavan, Varanasi), 1969;269
2. Rege NN, Dahanukar SA, Thatte UM. Adaptogenic properties of six Rasayana herbs used in Ayurvedic medicine. *Phytotherapy Research*, 1999;13: 275-91.
3. Thatte UM, Dahanukar SA. Comparative study of immunomodulating activity of Indian Medicinal plants, lithium carbonate and glucan. *Methods and findings in experimental and clinical pharmacology* 1988; 10 (10): 639-44.
4. Sharma V, Pandey D, Protective Role of *Tinospora Cordifolia* against Lead-induced Hepatotoxicity. *Tox Inter.* 2010;17(1):12-17
5. Mathew S, Kuttan G. Antioxidant activity of *Tinospora cordifolia* and its usefulness in the amelioration of cyclophosphamide induced toxicity. *Journal of Experimental and Clinical Cancer Research* 1997; 16: 407-11

Source of support: Nil, Conflict of interest: None Declared