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Study of morbidity status in children and the effect of *Guduchi* Syrup as an Immunomodulator for lowering down the morbidity rate

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ABSTRACT

Introduction: Children are the most vulnerable group for illness, as their immune system is not fully developed. Frequent illnesses among children limit their growth and lead to improper development. Despite of high advancement in immunization to boost up the defence mechanism, the medical science is yet to reach a full proof mechanism against the virulent organisms. *Guduchi* (*Tinospora cordifolia* TC.), a well known *Rasayana* (Rejuvenation) in Ayurveda, is supposed to build up the *Dhatus* (tissues) in children and the immune system also. Further various clinical and experimental studies have proved immunomodulatory activity of *Guduchi* (TC). **Material and Methods:** Study was conducted on 100 children with frequent episodes of fever, diarrhea, respiratory and skin infections were divided into 2 groups. Group A children were administered Guduchi syrup and group B were administered placebo (sugar syrup) in doses of 1ml/kg/day in divided doses. Duration of trial was 90 days and follow up were done monthly. **Results and Discussion:** In group A where trial drug (*Guduchi* Syrup) was given, improvement in all morbidity scores were found highly significant except for Dyspnoea and Sore throat. In Dyspnoea and Sore throat significant results were found. In the present study, the trial drug *Guduchi* Syrup, decreased TLC, increased IgG level in children at a statistical highly significant level ($p<0.001$) and increased haemoglobin concentration at significant level ($p<0.01$) suggesting the effectiveness of the drug. In group B where placebo sugar syrup was given, insignificant result was observed. **Conclusion:** *Guduchi* (TC) works like an immunomodulator which lowered down the morbidity rate and therefore can be a simple and cost effective remedy to bring down the morbidity rate in children.

Key words: *Guduchi, Tinospora Cordifolia, Children, Immunomodulator, Morbidity.*

INTRODUCTION

Children are the most vulnerable group for illness, as their immune system is not fully developed. Frequent illnesses among children limit their growth and lead to improper development. Despite of high advancement in immunization to boost up the defense mechanism, the medical science is yet to reach a full proof mechanism against the virulent organism and some time we lose out in battle of survival. Therefore, by all means the children should be supported externally in order to prevent the infection and at the same time measures should be taken for the proper development of immune system. In this period, attempt should be made for prevention of disease and to enhance physical, mental and social well being of children. At this time if a method is developed or introduced from the treasure of Ayurveda, it will be a boon in the field of preventive paediatrics.

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According to Ayurveda immunity has been explained in terms of *Vyadhikshamatva* (Immunity).[1-3] According to Ayurveda, *Ojas* (vital factor) is considered as *Bala* (strength) or *Prakrita Kapha* attributed to immunity. Specific drug called *Rasayana* (rejuvenation) in Ayurveda are effective in diseases and promotion of health by improving immunity. *Ojas* (vital factor) plays an important role in maintaining the resistance power of the body and it is extract of all *Dhatu* (tissues). The *Rasayana* (rejuvenation) drugs are responsible to potentiate *Ojas* (vital factor), thereby increasing the immunity. *Guduchi* (*tinospora cordifolia* TC), an Ayurveda drug is having *Rasayana* (rejuvenation) property.[4] Also it possesses various therapeutic properties. Various clinical and experimental studies have also proved its immunomodulatory activity.

Materials and Methods

Study Type

Double Blind Randomized Controlled Trial.

Objectives of Study

1. To study the morbidity status in children.
2. To observe the immunomodulatory effect of *Guduchi* (*Tinospora Cordifolia*) Syrup.

Institutional Ethics Committee Clearance

Clinical study was approved by IEC, Order No.F10(5)/EC/2014/7220 Dated- 07/11/14.

CTRI Registration

CTRI/2017/11/010613 [Registered on: 23/11/2017] - Trial Registered Retrospectively

Selection of Cases

110 subjects were registered from villages of 10km periphery, from various schools by survey method and O.P.D/I.P.D. of Institute Hospital in Jaipur. Out of which 10 discontinued. Total 100 subjects completed the trial.

Inclusion Criteria

1. Children aged between 1 to 8 years of either sex.
2. Children with recurrent respiratory infections.
3. Children with recurrent G.I.T. diseases.
4. Children with other recurrent diseases.
5. Children with recurrent fever.

Exclusion Criteria

1. Children with severe diseases.
2. Children with chronic diseases.
3. Children with any genetic disorder.
4. Children having congenital anomalies.

Discontinuation Criteria

1. Any acute or severe illness during the trial.
2. Parents not willing to continue the treatment.

Trial Drug (*Guduchi* Syrup)

The trial drug for the study was made up of *Guduchi (Tinospora cordifolia)*[5] and placebo was of sugar. It was prepared in the pharmacy of NIA Jaipur. Flavour was added in syrups in order to get similar appearance and taste.

Placebo: Sugar syrup

Dose and Duration

Guduchi Syrup was prescribed in doses according to body weight of children (1 ml/kg/day) for three months. A window period of ±3 days was given to allow for holidays and weekends. Follow-up were done monthly. Both the drug and placebo were prepared in the syrup form in order to enhance its palatability for easy administration in children.

Administration of Drug and Grouping

Study was completed on 100 patients, 50 in each group (A & B)

Group A: *Guduchi* syrup (N=50)

Group B: Placebo syrup (N=50)

Methods of Analysing Data

Observations documented during the study were analyzed and findings were evaluated by using statistical methods (student's t test) to establish the

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efficacy. Inter group comparison were evaluated by using Mann-Whitney U test.

Observations and Results

It was observed that out of 100 cases, maximum 86% cases suffered from recurrent episodes of cough, followed by 75% with recurrent running nose, 74% with recurrent fever, 70% with recurrent nasal obstruction and recurrent enlarged tonsils each. 55% children suffered from frequent episodes of diarrhea. (Table 1)

Table 1: Showing morbidity feature wise distribution of both groups.

SN	Morbidity Features (Recurrent)	Group A (n=50)		Group B (n=50)		Total (n=100)	
		No.	%	No.	%	No.	%
1.	Running nose	38	76	37	74	75	75
2.	Nasal obstruction	37	74	33	66	70	70
3.	Cough	45	90	41	82	86	86
4.	Sore throat	07	14	08	16	15	15
5	Enlarge tonsils	36	72	34	68	70	70
6.	Dyspnoea	02	04	03	06	05	05
7.	Diarrhoea	28	56	27	54	55	55
8.	Fever	40	80	34	68	74	74

Results

In group A where trial drug (*Gudichi* Syrup) was given, all scores were found Highly significant except for Dyspnoea and Sore throat. In Dyspnoea and Sore throat significant improvement were found. At the level of change in mass morbidity rate it was observed highly significant (BT - 10.54±3.08, AT- 7.99±2.16, n - 384, t value-6.278, p value < 0.001). In group B where placebo sugar syrup was given, insignificant result was observed. All scores were found insignificant. At the level of change in mass morbidity rate it was observed insignificant (BT - 10.61±3.06, AT - 10.46±2.93, n - 356, t value-0.3378, p value > 0.1). (Table 2) (Graph 1)

Graph 1: Showing Improvement in various morbidity features of group A and group B

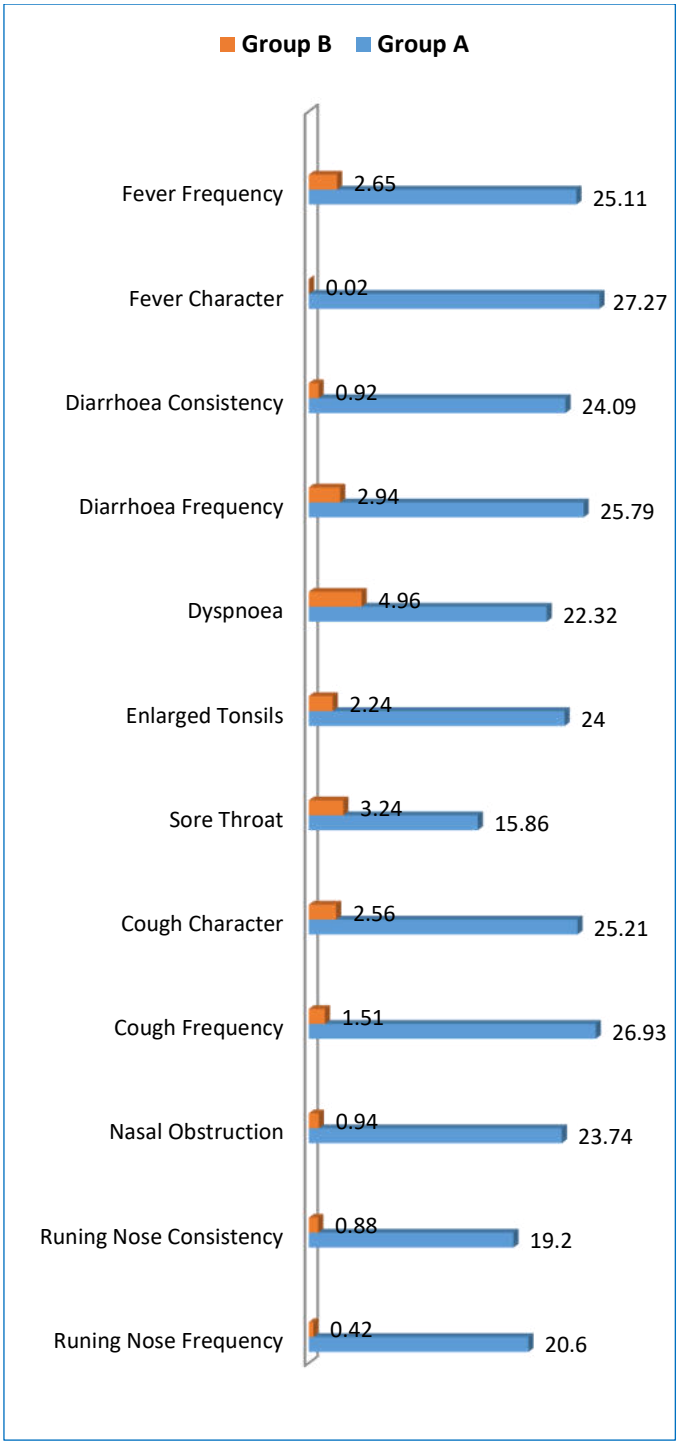

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Table 2: Showing Statistical Analysis of morbidity score in both groups.

Morbidity features	Group	BT Mean ± SD	AT Mean ± SD	t	p	Remark
Running Nose Frequency	A	12.47± 3.14	9.90 ±2.06	8.423	<0.001	HS
	B	11.71± 3.45	11.66±3.41	0.3262	>0.1	IS
Running Nose Consistency	A	11.61± 3.42	9.38±3.10	6.930	<0.001	HS
	B	11.25± 3.52	11.15±3.66	0.3697	>0.1	IS
Nasal Obstruction	A	9.39± 2.54	6.944±1.765	6.896	<0.001	HS
	B	9.54±2.54	9.63±2.73	0.8101	>0.1	IS
Cough Frequency	A	12.25± 3.72	8.95±3.05	13.89	<0.001	HS
	B	11.87± 3.64	11.69±3.54	1.164	>0.1	IS
Cough Character	A	11.5±3.09	8.60±2.51	11.47	<0.001	HS
	B	12.09± 3.13	11.78±3.16	1.576	>0.1	IS
Sore Throat	A	8.89± 2.30	7.48± 1.41	4.571	<0.01	S
	B	8.95± 2.72	8.66±2.45	1.826	>0.1	IS
Enlarged Tonsils	A	8.58± 1.90	6.52± 0.94	5.182	<0.001	HS
	B	9.82± 2.70	10.04±2.72	1.096	>0.1	IS
Dyspnoea	A	8.33± 2.09	6.46± 0.91	4.961	<0.01	S
	B	8.66 ±2.17	9.09±2.14	1.868	>0.1	IS
Diarrhoea Frequency	A	10.66± 2.84	7.91±2.15	7.838	<0.001	HS
	B	11.22± 2.96	10.89±3.09	1.239	>0.1	IS
Diarrhoea Consistency	A	10.75± 3.36	8.16±2.33	6.490	<0.001	HS
	B	9.75±2.93	9.66±2.88	0.4839	>0.1	IS
Fever Character	A	11.22± 3.02	8.08± 2.23	9.935	<0.001	HS
	B	11.94± 2.47	12.23±2.61	0.8435	>0.1	IS
Fever Frequency	A	10.83± 3.09	8.11± 2.35	9.410	<0.001	HS
	B	9.79± 2.09	10.05±2.41	0.8875	>0.1	IS

Statistical Analysis of Laboratory Investigations

Significant increase in IgG level was found in group A ($p<0.01$), highly significant improvement was observed in Hb% and TLC, Eosinophil and ESR reduced significantly ($p<0.01$), insignificant change was found in Neutrophil and Lymphocytes. (Table 3)

Table 3: Statistical analysis of investigation in group A

Investigation	BT Mean ± SD	AT Mean ± SD	Mean Diff.	t	p	Remark
IgG g/l	9.26 ± 3.3	11.35 ± 4.3	-2.09	2.137	<0.01	S
Hb gm%	12.06 ±0.96	13.27 ± 0.43	-1.21	7.328	<0.001	HS
TLC	10070 ± 1154	8370 ± 499.	1700 ± 655	6.044	<0.001	HS

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	.0	57				
Neutrophil	52.10± 10.19	51.65± 11.17	0.45	0.3800	>0. 1	IS
Lymphocyte	40.30 ± 9.90	40.35 ± 9.06	-0.05	0.0596	>0. 1	IS
Eosinophil	1.80 ± 0.76	1.35 ± 0.81	0.45	2.015	<0.01	S
ESR	11.50 ± 8.03	9.55 ± 6.36	1.95	1.903	<0.01	S

In group B, insignificant change was observed in IgG, TLC, Neutrophil, Lymphocytes count and ESR (p>0.1). Significant gain was observed in Hb% and Eosinophil. (Table 4)

Table 4: Statistical analysis of investigation in group B

Investigation	BT Mean ± SD	AT Mean ± SD	Mean diff.	t	p	Remark
IgG g/l	8.05 ± 3.12	8.47 ± 3.49	-0.4155	0.6300	>0.1	IS
Hb gm%	11.96 ± 1.09	12.04 ± 1.01	-0.080	1.633	<0.01	S
TLC	10250 ±866.03	10170± 828.51	80± 38	0.2985	>0.1	IS
Neutrophil	54.90 ± 9.44	53.95 ± 10.04	0.950	1.078	>0.1	IS
Lymphocyte	39.90 ±11.0	40.05 ±	-0.15	0.1302	>0.1	IS
	5	10.98	0			
Eosinophil	1.850 ± 0.98	2.15 ±0.81	-0.30	1.552	<0.01	S
ESR	10.90 ±9.30	10.85 ± 7.59	0.050	0.1022	>0.1	IS

Intergroup Comparison

In intergroup comparison highly significant gain was seen in group A over group B at the level of (P<0.001) for runing nose, nasal obstruction, cough frequency, enlarge tonsils, dirrhoea and fever. Whereas for cough character, sore throat and dyspnea, significant (P<0.01) advantage was observed in group A over group B.

Discussion

In group A where trial drug (*Guduchi* Syrup) was given, improvement in all morbidity scores were found highly significant except for Dyspnoea and Sore throat. In Dyspnoea and Sore throat significant results were found. In the present study, the trial drug *Guduchi* Syrup, decreased TLC, increased IgG level in children at a statistical highly significant level (p<0.001) and increased haemoglobin concentration at significant level (p<0.01) suggesting the effectiveness of the drug. In group B where placebo sugar syrup was given, insignificant result was observed. Improvements in all scores were found insignificant in group B. Intergroup comparison revealed significant gain in group A (trial drug) over group B (Placebo) in all morbidity scores.

Ayurveda has a unique concept of increasing *Bala*/*Vyadhikshamatva* (Immunity) with the help of various *Rasayana* (rejuvenation) drugs, which are responsible for production of best qualities of *Dhatus* (tissues) and their essence *Ojas* (vital factor) or *Bala* (strength). The *Rasayana* (rejuvenation) property of *Guduchi* (*tinospora cordifolia*) is able to increase the *Bala* (strength) in children and hence the *Vyadhikshamatva.* In any infection, *Jwara* (fever) is a common symptom. The *Jwaraghna* (antipyretic) property of *Guduchi* (*Tinospora cordifolia*) lower down

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the temperature.[6] In the condition of recurrent diarrhea *Guduchi* (*Tinospora cordifolia*) had shown very good results, this might be due to its *Sangrahika* property[7] (retention property). The antidiarrheal activity of *T. cordifolia* extracts is supported by various studies. A study evaluated antidiarrheal activity by castor oil and magnesium sulfate-induced diarrhea using parameters such as onset of diarrhea, number of wet stools, total number of stool and weight of total number of stools. *Tinospora cordifolia* extracts were more efficacious in reducing number of total stools in both the models of diarrhea and showed a dose-dependent antidiarrheal effect.[8] The fresh juice of the stem is used as *Medhya Rasayana* (intellect promoting) and is also a content of *Chyawanprasha* (rejuvenating agent/drug), which is indicated in *Kasa-Swasa* (cough and asthma), *Balanama angavardhna* (increasing growth in children).[9] The drug *Guduchi* has *Rasayana Prabhava* (rejuveniting properties). The *Rasayana* drugs are supposed to increase all the *Sharira Dhatu (body tissues)*, both qualitatively and quantitatively. These drugs also improves the quality of *Rasadhatu* and thereby the entire status of the body. The immuomodulatory property of *Tinospora cordifolia* is well documented.[10-12] Active compounds 11-hydroxymustakone, N-methyl-2-pyrrolidone, N-formylannonain, cordifolioside A, magno orine, tinocordiside and syringin has been reported to have potential immunomodulatory and cytotoxic effects.[13] They have been reported to function by boosting the phagocytic activity of macrophages, production of reactive oxygen species (ROS) in human neutrophil cells, enhancement in nitric oxide (NO) production by stimulation of splenocytes and macrophages indicative of anti-tumor effects.[14] Aqueous *Tinospora* extracts has been also reported to influence the cytokine production, mitogenicity, stimulation and activation of immune effector cells.[15] In mice, *Tinospora cordifolia* extracts has been shown to result in up-regulation of IL-6 cytokine, resulting in acute reactions to injury, inflammation, activation of cytotoxic T cells, and B cell differentiation. Active compounds in aqueous extracts like alkaloids, di-terpenoid lactones, glycosides, steroids, sesquiterpenoid, phenolics, aliphatic compounds or polysaccharides in experimental rat model have been reported for their cytotoxic action. Dry stem crude extracts of Tinospora cordifolia with a polyclonal B cell mitogen, G1-4A on binding to macrophages have been reported to enhance immune response in mice by inducing secretion of IL-1, together with activation of macrophages. Reports on *Tinospora cordifolia* in prevention of oxidative damage also exist.[16] The (1,4)-alpha-d-glucan (alpha-d-glucan), derived *Tinospora cordifolia* have been shown to activate human lymphocytes with downstream synthesis of the pro and anti-inflammatory cytokines, in vitro.[17] Synergistic effects of compounds in the immunomodulatory activity of *Tinospora cordifolia* are reported. The compound *Tinospora cordifolia*-1, *Tinospora cordifolia*-2, *Tinospora cordifolia* 4 to 7 exhibits enhancement of IgG antibodies. *Tinospora cordifolia* 4 and *Tinospora cordifolia* 6 are more active in enhancing the immunoglobins. *Tinospora cordifolia* 7 has highest immunopotentiating actvity. It is seen that the active principles caused a significant enhancement of phagocytosis. *Tinospora cordifolia* 4 doesn't have any action on phagocytosis.[18] *Guduchi*, in Ayurveda is also a well known *Rasayana* (immune-potentiating agent) drug.[19] A novel polysaccharide from the *T. Cordifolia* (alpha D glucan) has shown immune stimulating properties by virtue of its activation of lymphocyte specially NK cells; activation of compliment system and stimulation of ThI pathway associated cytokine profile.[20] In a study seven immune-modulatory active compound belonging to different classes has been isolated and they exhibited significant immune-modulatory activity with an increase in % phagocytosis.[21] Another study documented lymphoproliferative and macrophage activating properties of immune-modulatory protein (Im P) in *Guduchi* stem.[22] Studies also report that the active principles from *T. cordifolia* enhance host immune system by increasing immunoglobulin and blood leukocyte levels and by the stimulation of stem cell proliferation. It has the ability to reduce solid tumour volume by 58.8%, which is comparable to cyclophosphamide, a known chemotherapeutic agent.[23,24] In a study, after oral administration of *T. cordifolia* alcoholic extract (100 mg/kg, p. o) there was

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increase in foot pad thickness which indicates immunomodulatory effects of *T. cordifolia* as compared to vehicle and cyclophosphamide treated groups. Also significant increase in the WBC counts and bone marrow cells indicate stimulatory effect on haeomopoetic system. In zinc sulphate turbidity test *T. cordifolia* treated rats serum showed the more turbidity (cloudy) which indicate the increase in the immunoglobulin level as compared to vehicle, SRBC sensitized and cyclophosphamide treated group.[25,26] One more study reported that, pretreatment with *Tinospora cordifolia* or gentamicin reduced mortality in mice injected with 1 x 10(8) E. coli intraperitoneally from 100% in controls to 17.8% and 11.1% respectively. Further, there was significant improvement in bacterial clearance as well as improved phagocytic and intracellular bactericidal capacities of neutrophils in the *Tinospora cordifolia* treated group. In the gentamicin treated mice although bacterial clearance was rapid, polymorph phagocytosis was depressed, but *Tinospora cordifolia* did not possess in vitro bactericidal activity.[27]

CONCLUSION

Present research reveals that *Guduchi* (*Tinospora cordifolia*) works like an immunomodulator which decreased/lowered down the morbidity rate in children. Post treatment follow up showed sustained effect of the trial drug. Therefore *Guduchi* (*Tinospora cordifolia*) can be a simple and cost effective remedy to bring down the morbidity rate in children. No adverse effects of the trial drug were observed during the present study.

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