

**A COMPARATIVE CLINICAL STUDY TO EVALUATE THE
EFFICACY OF *MARICHYADI CHURNA* AND SYRUP *DARVYADI* IN
TUNDIKERI ROGA (TONSILLITIS) IN CHILDREN**

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ABSTRACT

Introduction: Recurrent infections have adverse effects on normal growth and development of the children because of their vulnerable age group. One of them is tonsillitis which is a very common complaint in pediatric setups. There are about 7,455,494 cases of tonsillitis in India per year. If left untreated, it can lead to various complications like choking spells at night, acute otitis media, peritonsillar abscess, parapharyngeal abscess, tonsilloliths, rheumatic fever etc. The present study has been planned to evaluate and compare the efficacy of *Marichyadi churna* and Syrup *Darvyadi* in *Tundikeri Roga* (Tonsillitis) in children. **Aims & objectives:** To study and compare the efficacy and evaluate the safety of *Marichyadi Churna*

and Syrup *Darvyadi* in *Tundikeri Roga* (Tonsillitis) in children. **Materials & Methods:** The study was conducted over a period of 4 weeks on 45 patients aged between 5-15 years who were suffering from Tonsillitis and a case proforma was filled with the data obtained by interrogation, physical examination and collection of details of each child. **Results:** Excellent results were obtained when both the formulations i.e, *Marichyadi Churna* and Syrup *Darvyadi* were given simultaneously, moderate relief occurred in patients treated with Syrup *Darvyadi* and patients given *Marichyadi Churna* for local application depicted only mild relief in signs and symptoms of the disease. **Conclusion:** The study concludes that the relief occurred was best when both the formulations given simultaneously as compared to the individual therapies.

KEYWORDS: Tonsillitis, Tonsilloliths, Tundikeri, *Marichyadi Churna*, Syrup *Darvyadi*.

INTRODUCTION

Children are the supreme assets and their health determines the health of a nation. In today's era, they are the major consumers of health care. Protecting and promoting the health of children is an important goal in itself as they represent the future of the society. In India, about 35% of total population comprises of children below 15 years of age. They are not only large in number but also vulnerable to various health problems and considered as special risk group.

Tonsillitis which is a very common complaint found in pediatric setups. It is the inflammation of the tonsils, the two oval shaped pads on each side of oropharynx characterized by sore throat, fever, dysphagia, ear ache, malaise, loss of appetite, cough, halitosis. It can occur as acute or chronic. Refrigerated items, cold beverages, poor oral hygiene can make tonsillitis even worse. Affected children have serious setbacks like missing school days, economic burden of the treatment etc. Lower socio-economic group people are more prone as the immunity status is low in them.

In *Ayurveda*, it resembles with *Tundikeri Roga* on the basis of similarity of its clinical features described collectively under the *Mukharogas* caused by *Kapha Prakopa* and *Rakta Dushti* in *Talu* and *Kantha Pradesh*. The classification of *Mukha Rogas* on the basis of predominance of *Doshas* has been described in *Charak Samhita*. *Tundikeri Roga* has been enumerated under *Talugata Roga* in *Sushruta Samhita Nidana Sthana* whereas *Acharya Vagbhatta* has described it under *Kanthagata Rogas* in *Uttara Tantra*. Reoccurrence is common because the *Doshas* reside in their latent stage (predisposing stage) and give rise to the same disease when factors (aggravating factors) are favourable. *Kaphaj Prakruti* is predominant in children and in pathophysiology of *Tundikeri*, *Kapha* and *Rakta* are mainly involved, so this eventually adds up in making them more prone to this disease. Long term antibiotic courses are given to patients which render them immune compromised and resistant to many bacterial strains making the treatment ineffective in due course of time. About 2,00,000 tonsillectomies are performed in India per year⁷ that has many complications like dehydration, obstructive sleep apnea, infections etc. with no long-term benefits and even risk of recurrences after first year of surgery. Tonsils are the first barrier to pathogens and site of antibody production, their removal put a direct attack on respiratory and gastro-intestinal tracts.

Many effective remedies can be traced by unsheathed treasure of *Ayurveda* that can lessen the agony felt by the children suffering with *Tundikeri*. Currently in modern era, new avenues are being explored for better treatment yet the disease has not been dominated. Taking above mentioned facts in serious consideration and to provide children relief from uneasiness, frustration and pain, a sincere effort has been made in the present study entitled “A Comparative Clinical Study to Evaluate the Efficacy of *Marichyadi Churna* and Syrup *Darvyadi* in *Tundikeri Roga* (Tonsillitis) in Children.

AIMS AND OBJECTIVES

- ✚ To study the efficacy of both trial drugs in signs and symptoms of the disease.
- ✚ To compare the efficacy of both drugs.
- ✚ To evaluate the safety of both the drugs in children.

MATERIAL AND METHODS

For the present study, total 45 patients were registered from the Kaumarbhritya/Balrog OPD/IPD, R G G P G Ayurvedic College & Hospital, Paprola, randomly fulfilling the criteria of this study. A case proforma was filled with the data obtained by interrogation, physical examination and collection of details of each child.

Inclusion and Exclusion criteria

Inclusion criteria	Exclusion criteria
Age eligibility 5 to 15 years.	The patient who is suffering with any congenital, hereditary or acute systemic illness.
Gender eligibility – Both male and female.	Patients who do not fulfill the above-mentioned criteria.
Patients/ Parents who are willing to participate in the trial.	Patients who have developed complications of tonsillitis.
	Patients of unilateral tonsillar hypertrophy and tonsillar lymphoma.

Grouping of the patients: Study was conducted on 45 selected patients in three groups:

Group I: 15 patients were given *Marichyadi Churna* with *Saindhav* and honey for local application over tonsils.

Group II: Syrup *Darvyadi* was given orally to 15 patients of this group.

Group III: Both the trial drugs i.e *Marichyadi Churna* with *Saindhav* and honey for local application and Syrup *Darvyadi* orally were given simultaneously to 15 patients of this group.

Treatment Schedule

Particulars	Group I	Group II	Group III
Drug	<i>Marichyadi Churna</i>	Syrup <i>Darvyadi</i>	<i>Marichyadi Churna</i> +Syrup <i>Darvyadi</i>
Dosage	80mg/kg/day for local application (with <i>Saindhava</i> and honey) two times a day	0.5-1ml/kg/day in two-three divided doses	Same as for Group I and Group II
Duration	4 weeks	4 weeks	4 weeks

Follow-ups: 2 follow ups at 2nd week and at completion of trial.

Criteria of assessment for result: Done on the basis of various subjective and objective parameters before and after treatment.

Subjective Assessment: Scoring system was adopted for assessment of various subjective parameters and grading from zero to three, according to the severity was assigned as follows.

Sign and Symptoms	Score 0	Score 1	Score 2	Score 3
<i>Toda</i> (Pricking pain)	No pain	swallow saliva	swallow saliva with pain and difficulty	Unable to swallow saliva
<i>Daha</i> (Sore throat)	Pinkish mucosa	Visible engorged capillaries	Congested mucosa	Dark red and ironed mucosa
<i>Sthoolasotha</i> (Tonsillar hypertrophy)	Tonsils within tonsillar fossa	Tonsils outside the tonsillar fossa	Tonsils within 1 and 3	Tonsils obliterating whole of oral cavity (kissing type)
<i>Pichilta</i> (Sliminess)	Absent	Excessive salivation in oropharynx	Excessive salivation in oral cavity	Excessive salivation drooling outside the oral cavity
Cough	No cough at any time during tonsillitis	Cough on and off	Frequent cough	Painful and tiring cough
Foul breath	Absent	Only patient can feel him/her self	Examiner and family members can also feel	Surrounding person can also feel foul smell
Difficulty in Swallowing	Able to eat normally	Requires liquid with meals	Able to take only semisolid food	Able to take only liquids
Temperature	Normal	<100°F	101-104°F	>104°F
Tonsillar discharge	No discharge present	Few drops	Few drops to 1ml	>1ml
Snoring	Absent	Occasional snoring	Frequent snoring	One cannot share room or bed
Jugulodigastric lymphadenopathy	Not palpable	Size <5mm	6-10mm	>10mm

Objective Assessment

Laboratory investigations

- ✚ CBC (Hb, TLC)
- ✚ ESR
- ✚ LFT (SGOT, SGPT)
- ✚ RFT (S. Uric acid, S. Creatinine)

Statistical Analysis

The proposed research work was an open-label clinical trial. The results obtained from the clinical study were statistically analyzed in terms of Mean, Standard Deviation (SD) and Standard Error (SE), t value, P value and F values in **Paired t test** and **ANOVA test**, carried out at $p > 0.05$, $p < 0.05$, $p < 0.001$ and a significant level for each set of data. The obtained results were interpreted as follows.

- Highly significant $p < 0.001$
- Moderately significant $p < 0.01$
- Significant $p < 0.05$
- Insignificant $p > 0.05$

Overall results were categorized in terms of percentage relief in signs and symptoms as follows

Marked improvement (75%- 100% relief)
Moderate improvement (50% - 75% relief)
Mild improvement (25% - 50% relief)
No improvement (<25 % relief)

RESULTS

Assessment of the subjective parameters before and after treatment

Sign & symptoms	Group	Mean (BT-AT)		% Relief	SD+ ₋	SE	t value	P value
		BT	AT					
Toda	Gr I	2	1.41	29.1	0.36	0.09	3.92	0.002
	Gr II	1.66	0.66	60	0.53	0.13	7.24	<0.001
	Gr III	2.20	0.06	96.9	0.64	0.16	12.91	<0.001
Daha	Gr I	1.66	1.16	30	0.52	0.15	3.31	0.007
	Gr II	1.80	0.60	66.67	0.41	0.10	11.22	<0.001
	Gr III	1.73	0.13	94.1	0.50	0.13	12.22	<0.001
Sthoolasotha	Gr I	1.50	1.08	27.8	0.51	0.14	2.80	0.017
	Gr II	1.40	0.60	57	0.56	0.14	5.52	<0.001
	Gr III	1.67	0.13	92	0.51	0.13	11.5	<0.001
Pichilta	Gr I	0.66	0.41	37.4	0.45	0.13	1.91	0.082
	Gr II	0.53	0.33	40	0.41	0.10	1.87	0.082

	Gr III	0.80	0.13	83.7	0.72	0.18	3.56	0.003
Cough	Gr I	0.83	0.58	30	0.45	0.15	1.99	0.082
	Gr II	0.73	0.26	63.7	0.64	0.16	2.82	0.014
	Gr III	1	0.13	80	0.64	0.16	5.24	<0.001
Foul breath	Gr I	0.75	0.41	44.5	0.49	0.14	2.34	0.039
	Gr II	0.73	0.20	72.7	0.64	0.16	3.22	0.006
	Gr III	1.13	0	100	0.74	0.19	5.90	<0.001
Difficulty in Swallowing	Gr I	0.50	0.41	16.6	0.28	0.08	1.00	0.33
	Gr II	1.06	0.26	75	0.41	0.10	7.48	<0.001
	Gr III	1.26	0.13	94	0.99	0.25	4.43	<0.001
Fever	Gr I	0.83	0.08	29	0.45	0.13	1.91	0.082
	Gr II	0.26	0	100	0.45	0.11	2.25	0.041
	Gr III	0.4	0	100	0.50	0.13	3.05	0.009
Discharge	Gr I	0.41	0.08	80	0.49	0.14	2.34	0.039
	Gr II	0.80	0.20	75	0.82	0.21	2.80	0.014
	Gr III	1.0	0	100	0.84	0.21	4.58	<0.001
Jugulodigastric Lymphadenopathy	Gr I	0.75	0.58	22.2	0.38	0.11	1.48	0.166
	Gr II	0.80	0.33	58.3	0.51	0.13	3.50	0.004
	Gr III	0.73	0.13	85	0.50	0.13	4.58	<0.001
Snoring	Gr I	0.16	0.16	0	0	0	0	1
	Gr II	0.26	0.0	100	0.59	0.15	1.74	0.04
	Gr III	0.46	0.0	100	0.74	0.19	2.43	0.0029

Intergroup comparison of sign and symptoms

Sign & symptoms	Mean diff (BT-AT)			SST	MST	F value	P value by ANOVA
	Grp I	Grp II	Grp III				
Toda	0.58	1	2.2	32.37	0.325	30.3	<0.001
Daha	0.5	1.2	1.6	17.13	0.23	17.65	<0.001
Sthoolasotha	0.4	0.8	1.13	14.6	0.28	6.26	0.004
Pichilta	0.25	0.2	0.6	13.3	0.30	2.26	0.117
Cough	0.25	0.46	0.86	16.3	0.35	3.75	0.03
Foul breath	0.3	0.5	1.13	21.3	0.413	6.3	0.004
Dysphagia	0.08	0.8	1.13	24.5	0.43	8.6	<0.001
Fever	0.25	0.26	0.4	8.9	0.2	0.44	0.642
Discharge	0.3	0.6	0.1	25.6	0.5	2.92	0.065
Jugulodigastric lymphadenopathy	0.16	0.46	0.6	10.3	0.23	2.86	0.069
Snoring	0.0	0.26	0.46	14.07	0.325	2.17	0.128

Assessment of lab investigations (Before & after treatment)

	Groups	Mean (BT-AT)		SD+-	SE+-	t	P value
		BT	AT				
Hb	I	11.5	11.6	1.08	0.3	-0.29	0.77
	II	11.4	11.5	0.89	0.23	-0.3	0.75
	III	11.6	11.9	0.52	0.13	-1.7	0.10
TLC	I	7.04	7.11	1.013	0.292	-0.25	0.802
	II	8.86	8.5	1.91	0.49	0.59	0.563
	III	7.3	7.19	0.44	0.11	1.62	0.126

ESR	I	12.2	8.5	8.3	2.39	1.52	0.154
	II	8.33	9.13	4.2	1.09	0.73	0.476
	III	10.8	7.4	4.54	1.17	2.89	0.012
SGOT	I	32.3	31.7	4.05	1.17	0.49	0.628
	II	28.3	27.3	8.93	2.30	0.43	0.671
	III	33.2	31.7	15.8	4.09	0.35	0.726
SGPT	I	25.08	24	10.9	3.14	0.34	0.737
	II	15	18.6	5.66	1.46	-2.50	0.025
	III	22.2	19.5	7.99	2.06	1.29	0.217
S. Uric acid	I	5.09	5.30	1.45	0.42	-0.49	0.630
	II	0.64	0.72	1.65	0.427	0.71	0.484
	III	4.88	4.66	1.00	0.26	0.84	0.412
S. Creatinine	I	0.67	0.77	0.176	0.05	-1.97	0.074
	II	0.64	0.72	0.179	0.04	-1.58	0.135
	III	0.70	0.69	0.23	0.06	0.22	0.827

DISCUSSION

- ✚ Excellent results were observed in Group III with complete relief in symptoms of foul breath, fever, discharge and snoring while marked relief was present in other symptoms of *Toda*, *Daha*, *Sthoola Sotha*, *Pichilta*, Cough, Dysphagia and Jugulodigastric lymphadenopathy with statistically highly significant results.
- ✚ The results obtained were satisfactory in Group II with moderate relief in *Toda*, *Daha*, *Sthoola Sotha*, *Pichilta*, cough, foul-breath, dysphagia, discharge and jugulodigastric lymphadenopathy. However, 100% relief was obtained in symptoms of Fever and Snoring with statistically significant differences after treatment.
- ✚ Group I depicted only mild relief in symptoms of *Toda*, *Daha*, *Sthoola Sotha*, *Pichilta*, cough, foul breath, dysphagia, fever and jugulodigastric lymph nodes with no relief in symptom of snoring at all after the intervention.
- ✚ In intergroup comparison, significant improvement in Group III and Group II over Group I was observed in all the subjective assessment parameters.
- ✚ Differences in mean values of the objective parameters like Hb, TLC, ESR, SGOT, SGPT, S. Uric acid, S. Creatinine before and after treatment were not significant to exclude the possibility of by-chance occurrence with statistically insignificant results.
- ✚ Therefore, the present study reveals that the results obtained when both the formulations i.e. *Marichyadi Churna* for local application over tonsils (with *Saindhava* and honey) and Syrup *Darvyadi* were given simultaneously in Group III patients were most satisfactory with statistically highly significant p values ($p < 0.001$) than individual therapies of Group I and Group II.

CONCLUSION

- ✚ Tonsillitis is a very common and frequent presenting complaint in childhood period as their immune system is in developing stage and they are constantly exposed to germs from their peers.
- ✚ It is a subject of great concern to the parents because beside the agony of physical symptoms like pain, sore throat, dysphagia, it also affects their normal growth and development. This is because the resultant reduced dietary intake causes inadequate nutrition in their budding stage when it is most required.
- ✚ *Ayurvedic* remedies are effective in reducing the morbidity pattern of children suffering from tonsillitis whether it comes to alleviating the symptoms of involved site like enlarged size, pricking pain, sore throat, dysphagia or mitigating the associated features like cough, halitosis, fever, snoring and jugulodigastric lymphadenopathy.
- ✚ The formulations selected for the study i.e *Marichyadi Churna* for local application over tonsils and Syrup *Darvyadi* orally possess excellent *Kapha-Pitta-Raktahara Doshakarma* with *Katu, Tikta, Kashaya Rasa, Laghu, Ruksha, Teekshna Guna, Ushna Veerya, Katu Vipaka* properties which are against *Kapha-Raktaja* nature of *Tundikeri*.
- ✚ The constituent herbs of both the formulations are collectively known to have anti-inflammatory, anti-microbial, immunomodulatory, analgesic, anti-pyretic and hepatoprotective effects based on pharmacological evidence-based studies which aids in breaking the pathogenesis of the disease.

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