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Clinical efficacy of oral *pippalyadi churna* in comparison with *gandhak rasayana* in *Gilayu* w.r.t. acute tonsillitis: A Comparative Study

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Abstract

Ayurveda is one of the most ancient systems of life, health and cure, deals with both the preventative and curative aspects of life in a more comprehensive way. The increasing refractory nature of infection caused by recently appearing drug resistance bacteria is a particular major clinical problem and to overcome above limitations and side effects it becomes necessary to elucidate another safe, economical cheap, therapy to treat tonsillitis and give better results, so a lot of can be done to support and attain tonsil health, naturally through the traditional medicine. Ayurvedic literature shows that Gilayu is having kaphaj dominant entity and this kapha dosha vitiates the rakta dhatu mainly in the oral cavity as the seat of disease. In the management of gilayu, sushruta advised bhedan shastrakarma, while vagbhata and chakradatta advised use of bitter, pungent taste drugs with hot potencies. So, in this study, tikta rasapradhan drugs in compound formulation of pippalyadi churna as trial group chikitsa (30 patients) were selected and gandhak rasayan as control group (30 patients) were selected. Aim- To study clinical efficacy of oral pippalyadi churna in comparison with gandhak rasayana in Gilayu w.r.t. Acute tonsillitis. Objectives-• To assess the effect of compound formulation of oral pippalyadi churna for in gilayu w.r.t. acute tonsillitis• To assess the effect of gandhak rasayana in gilayu w.r.t. acute tonsillitis. • Comparison in between oral pippalyadi churna in comparison with gandhak rasayana gilayu w.r.t. acute tonsillitis. This was Comparative, open, randomized, clinical study study. The effect of study shows that oral pippalyadi churna provided better relief comparative to gandhak rasayan in the management of gilayu w.s.r to acute tonsillitis.

Keywords: Acute tonsillitis, Gilayu, Pippalyadi churna, Gandhak rasayana

1. Introduction

Everybody is desirous for rising higher than his present position for reaching acme of progress. In the struggle for survival man has to neglect his own health care, as he has to face effect of polluted environment, host factors low immunity, indiscriminate, use of antibiotics, ecological consideration, faulty dietary habit which contribute to variety of throat problem where tonsil is common site of affection that give rise to "Acute Tonsillitis" i.e., inflammatory condition of the tonsils which is associated with sore throat, fever, dysphagia [1].

Different medical faculties with various therapies have tried in this disease with limited success or time bound relief. ENT specialist recommended tonsillectomy for recurrent attach of tonsillitis but it has less detrimental effect on the local IgA response in the nasopharyngeal fluid.

The increasing refractory nature of infection caused by recently appearing drug resistance bacteria is a particular major clinical problem and to overcome above limitations and side effects it becomes necessary to elucidate another safe, economical cheap, therapy to treat tonsillitis and give better results, so a lot of can be done to support and attain tonsil health, naturally through the traditional medicine.

Ayurveda is one of the most ancient systems of life, health and cure, deals with both the preventative and curative aspects of life in a more comprehensive way.

Acharya Sushruta has described disease Gilayu as mainly *kapha raktai* disease [2].

Acharya Sushruta advised surgical management in tonsillitis [3], while acharya Vagbhata advised conservative treatment on tonsillitis which mainly includes bitter, pungent taste drugs pacifying blood and having hot in potency, having subtle nature. According to *vagbhatacharya*, the substance that taste *katu* are valuable in the treatment of *gilayu*, because these are having *deepana*, *pachan* as well as it vitiates aggravated kapha and purify blood [4].

Acharya Chakradatta has explained *pippalyadi Churna* in *kantharoga*, *galrog* chikitsa (disease of throat) which mainly contain *pippali*, *pippalimula*, *chavya*, *chitrak*, *nagar*, *sarjikakshar* each in equal quantity ^[5]. Due their penetrating power, hot in potency it pacifies aggravated kapha vata dosha. It also having antibacterial, antiviral, antifungal, antipyretic and anti-inflammatory action.

Palatine tonsils are the "first line of defense" as they have a pivotal role in immunological detection of airborne and ingested antigens like bacteria and viruses ^[6]. They fight off illness and infection. These special functions give a special honor to tonsils to be known as "Guards of oral cavity". The entire lymphatic system of the body functions like this. The inflammatory condition of the tonsils is known as tonsillitis. The commonest cause of tonsillitis is infection of tonsils by microorganism. Environmental factors that may trigger an attack are exposure to cold, weather, damp climate or change of weather. Infection can easily catch in schools, parks, theaters etc by patients who are prone to tonsillitis.

All signs and symptoms of tonsillitis truly evident in *Gilayu Vyadhi*, as described by Sushruta ^[7]. As tonsils are vital to the body and so it need to be saved because we called it as protective glands. The role of tonsils is immune competence is become extremely important. Culture and sensitivity of throat swab of patients was done and it observed that Pippalyadi Churna has antimicrobial property. It is mainly active against staphylococcus aureus and Streptococci pneumonae.

So, to evaluate an economic alternative form of treatment in modern era which can be used without compromising tonsillar health and without the risk of side effects. Considering all these needs it has been described to contribute little effort to manage this problem so the "To study the efficacy of oral Pippalyadi Churna in comparison with Gandhak Rasayan [8] in Gilayu w.r.t. Acute Tonsillitis, is selected for the clinical trial.

1.1 Aim

To study the efficacy of *oral pippalyadi churna* in comparison with *gandhak rasayana* in gilayu w.r.t. acute tonsillitis.

1.2 Objectives

- To assess the effect of compound formulation of oral pippalyadi churna for in gilayu w.r.t. acute tonsillitis
- To assess the effect of gandhak rasayana in gilayu w.r.t. acute tonsillitis.
- Comparison in between *oral pippalyadi churna* in comparison with *gandhak rasayana gilayu* w.r.t. acute tonsillitis.

2. Materials and methods

2.1 Research design

A Randomized Control Trial Participant

- Patients: Gilayu (Tonsillitis)
- Gender-Both Male and Female
- Age- From 12 yrs-60 yrs of age.

2.2 Sampling procedure

Comparative, Open, Random sampling

Table 1: Grouping

Groups	No. of patients	Age	Sex	Intervention	Dose/day	Duration
Group A	30	12 yrs to 60 yrs	Male and Female	Pippalyadi churna	1gm churna with <i>anupam</i> honey Before meals at morning and evening	7days
Group B	30	12 yrs to 60 yrs	Male and Female	Gandhak rasayan tb	oral 500 mg with <i>anupam</i> honey Before meals at morning and evening	7days

2.3 Selection of cases

Patients having classical signs and symptoms of gilayu were selected after clinical & objective examination. I had selected 60 patients of gilayu (tonsillitis). These patients were selected randomly Follow-up assessment was done by specially prepared case record forms of every patient to meet all baseline requirement. Follow-up signs & symptoms were recorded.

2.4 Method of selection of patients

> Inclusion criteria

- Patients having age group in between 12 to 60 years of either gender and willing to give informed consent were included
- Patient having signs and symptoms of acute tonsillitis.

> Exclusion criteria

- Diagnosed cases of Vincent Angina, Diphtheria, Necrotic tonsils, Peritonsillar abscess, Tonsillar foreign body, Tonsillar Neoplasm, Exanthomatous fever.
- Patients having age group below 12yrs and above 60 years of either gender and not willing to give informed consent were excluded.
- Acute lower respiratory Tract infection.
- Pregnant and lactating women.
- Patient with Autoimmune disorders.

Patients having sulfa drug sensitivity, etc.

> Investigations

- TLC
- DLC
- ESR
- Culture and sensitivity

➤ Drug

Contents of pippalyadi churna [9]

Pippalyadi Churna is the drug mentioned for *galrogas* in chakradatta in *mukhroga chikitsa* (*Kantharog Chikitsa*).

Table 2: Contents of pippalyadi churna

S. No	Name	Latin name	Part
1	Pippali	Piper longum	1 part
2	Pippalimula	Root of the Piper longum Linn.	1 part
3	Chavya	Piper Retrofractum vahl	1 part
4	Chitrak	Plumbago zeylanica	1 part
5	Shunthi	Zinziber officinale	1 part
6	Sarjikakshara	(Sodium Carbonate):	1 part

3. Method of preparation

1.) *Pippalyadi Churna* (PC): was prepared in the laboratory by following classical method described in 'Ayurvedic Formulary of India'. In addition, its main ingredients

include 5 traditional medicinal herbs. All the ingredients of PC were procured from the local market. For churna purpose all the above drugs should be taken in powder form in equal amount. Prior to the trial of Pippalyadi Churna, it was tested for Prevention of Food Adulteration Act (PFA), 1954 and analysis give following results.

Table 3

S. No	Particulars	Value
01	Moisture	08.40%
02	Total ash	27.15%
03	Acid insoluble ash	02.80%
04	Specific Gravity	1.280

2.) Gandhak Rasayan

Market prepared - standardized Gandhak Rasayan was used from standard Ayurvedic Pharmaceutical Company.

Diet -All Pathyakar ahar vihar mentioned in Obesity.

Diagnostics criteria - Detailed history of the patient was taken with special attention towards patient's social status, economic condition, health and hygiene. Special attention was given towards the assessment about recurrence of disease in the same patient. History of any other associated symptoms is noted. All these information recorded in *proforma*. Each individual case was examined to find out any systemic disorder and investigated in detail for parameters and any other diseases and routine investigations were carried out. Local examination of throat was done.

A) Tonsils

- **Presence** Look for presence or absence of tonsils
- Size Large and obstructive, small or embedded
- Symmetry Unilateral or bilateral enlargement
- Crypts White or yellow spots at the opening of crypts (follicles)
- **Membrane** *Diptheria*, Membranous tonsillitis
- **Ulcer -** Cancer, T.B., Ulcerative tonsilitis
- Mass Cystic, peduncutaled or solid mass

B) Pillars

Uniform congestion of pillars, tonsils and pharyngeal mucosa is seen.

- Patients with Body Mass Index in between 25-30kg/m2 considered as Obese.
- Patients having clinical signs & symptoms of acute tosilitis.

Follow up

- 1. Symptomatic improvement, after 3rd, 5th and 7th day.
- 2. Lab Investigations done before and after treatment.

Case Record Form: Record, of all patients included in trial is documented & follow up is mentioned in case record forms.

Clinical examination: Complete clinical examination from the point of view of obesity to diagnose & assess the condition of patient.

Criteria of Assessment: Assessment of patients was done subjectively as well as objectively.

Subjective: Symptoms of *gilayu* (tonsillitis) mentioned in the text or practically observed are assessed at each follow

up. Presence or absence of these symptoms will be registered. Different symptoms graded into four grade scales (0-3) on the basis of severity to assess the changes in clinical symptoms of *atistyhaulya*. Study of changes in gradation of each symptom was done before and after treatment

Table 4: Gradations of practically observed symptoms

S. No	Parameters	Symptoms	Scoring
		Enlarged, congested with follicle/ pus spots	3
1	Tonsillar inflammation	Enlarged, congested	2
		Congested	1
		No congestion	0
		Enlarged and tender	3
2	Jugular-Digastric	Enlarged and non-tender	2
	lymphadenitis	Just palpable	1
		palpable	0
		Pain during rest.	3
3		Pain during deglutition	2
3	Throat pain:	Mild Pain on pressing Tonsils	1
	_	No throat pain	0
		High 103°F - 105°F	3
4	F	Moderate 100°F - 103°F	2
4	Fever:	Mild 99°F - 100°F +	1
		Normal 98°F - 99°F	0

- **5.** Photography (if necessary):
- Before treatment
- After treatment

Total Effects of Therapy

Percentage of relief in symptom & signs with respect to each of patient will be as follows & will be classified as per definition described of Cured, markedly improved, Improved & Unchanged.

- 1) Cured: Complete relief in signs and symptoms along with certain lab parameter & maintenance of same condition for about one yr. without medicine will be considered as cured.
- **2) Markedly improved:** 50% & more than 50% relief in sign & symptoms of the patients along with certain definite changes in physical & biochemical parameter will be considered as markedly improved.
- **3) Improved:** 25% to 50% relief in signs & symptoms as mentioned in criteria of assessment will be considered to be improved.
- **4) Unchanged:** Patient who do not have any relief in signs, symptoms & lab investigation will be considered as unchanged. Along with this, the patient exhibiting improvement < 25% is also kept in this group.

4. Observation and results

A) Gender wise distribution of patients

Table 5: Gender wise distribution of patients

Crowns	Ma	les	Fem	Total	
Groups	Cases	%	Cases	%	Total
Experimental	14	46.67	16	53.33	30
Control	13	43.33	17	56.67	30
Total	27	45.00	33	55.00	60

Table shows the number of male and female patients in each group Here $\chi 2$ cal < $\chi 2$ table i.e., $\chi 2$ test is insignificant, it means observation in both groups are at baseline i.e., there is

no difference in gender wise selection of patients in both groups. In Experimental group Male: Female Ratio is 14:16. While in Control group 13:17. When we compare it gives $\chi 2$ value 0.06733, which is insignificant at p=0.05 level. Hence observed difference in sex wise distribution in both group is

not significant. From above table female patients were high in the study (55.00%).

B) Age wise distribution of patients

Table 6: Age wise distribution of patients

C	11-20	OYrs	21-30	OYrs	31-40	Yrs	41-50	Yrs	51-60	Yrs	Takal
Groups	Cases	%	Cases	%	Cases	%	Cases	%	Cases	%	Total
Experimental	14	46.67	9	30	4	13.33	2	6.67	1	3.33	30
Control	13	43.33	10	33.33	6	20	1	3.33	0	0	30
Total	27	45	19	31.67	10	16.67	3	5	1	1.66	60

Here $\chi^2_{\rm cal} < \chi^2_{\rm table}$ is insignificant, it means observations in both groups are at baseline i.e., there is no difference in age wise selection of patients in both groups. Total patients are subdivided into 5 ranges i.e., 11-20,21-30,31-40,41-50,51-60yrs. Higher incidence of patients was from the range of 11-20yrs. (45%). Incidence of Tonsillitis found to be lowest in 51-60yrs age group (1.66%).

C) Occupation wise distribution of patients

Table 7: Occupation wise distribution of patients

Groups	Stud	lent	House	wife	Laboui	r work	Servic	e T	otal
Groups	Cases	%	Cases	%	Cases	%	Cases	%	
Experimental	18	60	06	20	4	13.33	2	6.67	30
Control	20	66.67	05	16.67	3	10	2	6.67	30
Total	38	63.33	11	18.33	7	11.67	4	6.67	60

 χ^2_{cal} =0.2871 χ^2_{table} =3.84 P > 0.05 Here χ^2_{cal} < χ^2_{table} is insignificant, it means observations in both groups are at baseline i.e., there i s no difference in occupation wise selection of patients in both groups. Patients were classified into 4 groups i.e., Student, House wife, Labour work, Service. The table shows the number of patients in each group and graph represents the same. The higher incidence of patients was seen in student group i.e., 63.33%.

D) Residence wise distribution of patients

Table 8: Residence wise distribution of patients

Cwarma	Url	oan	Ru	Total	
Groups	Cases	%	Cases	%	Total
Experimental	23	76.67	7	23.33	30
Control	25	83.33	5	16.67	30
Total	48	80.00	12	20.00	60

 χ^2_{cal} =0.4167 χ^2_{table} =3.84 P > 0.05, The above table shows the distribution of patients of both groups into urban and rural group. Here χ^2_{cal} < χ^2_{table} i.e., χ^2_{table} is insignificant, it means observation in both groups are at baseline i.e., there is no difference in residence wise selection of patients in both groups. Table represents the same. Higher incidence of patients was from urban area (80.00%).

E) Comparison of the changes in Tonsillar inflammation Experimental Group: Comparison by Unpaired 't' test

Below both groups were compared for tonsillar inflammation, it was found that, there was total difference of 0.3 with t value 2.4936, which is significant at p=0.05 significance level. Hence, drug of experimental is more effective than the drug of control.

Table 9: Comparison of the changes in Tonsillar inflammation Experimental Group: Comparison by Unpaired 't' test

T. Inflammation	I-II	II-III	III-IV	I-IV
MEAN 0F DIF	0.2333	0.1	-0.0333	0.3
COMB.VAR	0.1505	0.1705	0.2802	0.2172
COMB.SD	0.3880	0.4130	0.5293	0.4661
SE	0.1001	0.1066	0.1366	0.1203
T	2.32962	0.9380	-0.2439	2.4936
t table	2.00	2.00	2.00	2.00
P	P<0.05	P>0.05	P>0.05	P<0.05

F) Effect of treatment on Throat Pain

Table 10: Effect of treatment on Throat Pain

Throat pain	I-II	II-III	III-IV	I-IV
MEAN 0F DIF	0.3	0.0666	0.1333	0.5
COMB.VAR	0.2695	0.1770	0.2436	0.5247
COMB.SD	0.5191	0.4207	0.4936	0.7243
SE	0.1339	0.1085	0.1274	0.1869
T	2.2388	0.6139	1.0465	2.6743
t table	2.00	2.00	2.00	2.00
P	P<0.05	P>0.05	P>0.05	P<0.05

When both groups were compared for throat pain, it was found that, there was total difference of 0.5 with t value 2.6743, which is significant at p=0.05 significance level. Hence, drug of experimental is more effective than the drug of control.

G) Effect of treatment on fever: By comparison by Unpaired 't' test

Table 11: Effect of treatment on fever: By comparison by Unpaired 't' test

FEVER	I-II	II-III	III-IV	I-IV
MEAN 0F DIF	0.5666	-0.0666	-0.1666	0.3333
COMB.VAR	0.2649	0.2011	0.1867	0.2632
COMB.SD	0.5147	0.4484	0.4321	0.5130
SE	0.1328	0.1157	0.1115	0.1324
T	4.2654	-0.5759	-1.4941	2.5172
t table	2.00	2.00	2.00	2.00
P	P<0.05	P>0.05	P>0.05	P<0.05

When both groups were compared for fever, it was found that, there was total difference of 0.3333 with t value 2.5172, which is significant at p=0.05 significance level. Hence, drug of experimental is more effective than the drug of control.

H) Effect of treatment on Lymphadenopathy: By Comparison by Unpaired 't' test

Table 12: Effect of treatment on Lymphadenopathy: By Comparison by Unpaired 't' test

Lymphadenopathy	I-II	II-III	III-IV	I-IV
MEAN 0F DIF	0.2	0	-0.1666	0.0333
COMB.VAR	0.3126	0.2540	0.1247	0.6488
COMB.SD	0.5591	0.5040	0.3531	0.8055
SE	0.1443	0.1300	0.0911	0.2079
T	1.3858	0	-1.8285	0.1603
t table	2.00	2.00	2.00	2.00
P	P>0.05	P>0.05	P>0.05	P>0.05

When both groups were compared for Lymphadenopathy, it was found that, there was total difference of 0.0333 with t value 0.1603, which is insignificant at p=0.05 significance level. Hence, treatment given in both groups are equally effective.

I) Total effect of therapy

Table 13: Total effect of therapy

Groups	Cured		Relieved		Not cured		
	Cases	%	Cases	%	Cases	%	Total
Experimental	19	63.33	06	20.00	05	16.67	30
Control	10	33.33	13	43.33	07	23.33	30
Total	29	48.33	19	31.67	12	20.00	60

Calculated χ^2 cal is lesser than the χ^2 table value. Hence, χ^2 test is insignificant. It shows there is difference in treatment between experimental and control group i.e., the drug used for experimental group is more effective than the drug used for control group

6. Discussion

A Study entitled Comparative Clinical Study of oral pippalyadi churna in comparison with gandhak rasayana in Gilayu w.r.t. acute tonsillitis-A Comparative Study was under taken. At the end of the study, following points can be concluded on the basis of Observations made in the form of Tables & Graphs and minutely discussed in the previous chapters, following conclusion are drawn.

In age wise distribution of the patients, out of 60 patients 27 cases (i.e., 45%) were found in age group 11-20 years. This may be due to the patients of this age group are more prone to catch infection or incidental selection. Also, this age group is having *kapha prabalya* than another group.

In residence wise distribution of patients, maximum number of patients i.e., 48 out of 60 were found from urban area as compare to rural area. This may be due to over consciousness of parents towards health or may be due to more polluted environment in urban area.

In occupation wise distribution of patients out of 60 patient's students are more i.e., 38 out of 60 patients. It may be due to patient are more prone to the infection in school, college, park and overcrowded areas. In this group there is special attention towards fast foods cold foods, cold drinks, bakery products or may be due to more consciousness of the parents regarding to their child health. Patients' data of both groups were taken and analyzed with the help of student paired 't' test. The 't' test is applied to assess the significance of the effect of the drug and unpaired 't' test

was applied to compare the effect of both the treatment, because all the parameters are converted into numerical.

By statistical analysis, it was found that, in all parameters tonsillar inflammation, throat pain, i.e., lymphadenopathy student paired 't' test is significant in both the group, but when we do comparison of both the groups by applying unpaired 't' test, the test is significant in all the parameters. i.e., the parameters tonsillar inflammation, throat pain, fever shows significant improvement than the control group but the parameter lymphadenopathy shows equal improvement in experimental and control group. It shows the drug of experimental group is more effective that the drug of control groups. In experimental group 19 patients cured, 6 relieved and 5 not cured, while in control group 10 cured, 13 relieved and 7 not cured. By applying c ² test to this data, we find out total effect of therapy where c² test is insignificant.

Objective of the study was to find Ayurvedic remedy for Gilayu and reduce severity of throat infection. After complete assessment it was found that in experimental group 19 patients cured, 6 patients relieved and 5 patients not cured. In control group 10 patients cured, 13 relieved and 7 patients not cured. Experimental group shows good results in tonsilar inflammation, throat pain, fever than control while experimental and control group shows equal results in lymphadenopathy. Experimental group is more significant than control group.

7. Conclusion

Pippalyadi churna has provided better result in almost all the parameters than Gandhaka rasayan in Gilayu. It is safe, cost effective and easy procedure to perform. It decreases severity of throat infection. Hence the role of drug in this disease is proved. Further research with new ideas can be done by increasing sample size, by continuing therapy for longer period and by making an ointment of drug powder used in trial, which can be applied easily to relieved acute tonsillitis completely.

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