

## “Interventional Phase II, Clinical Study to Evaluate Efficacy and Safety of *Sadyovaman* Followed by *Pachan* in *Navjwara*.”

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### ABSTRACT:

*Jwara* (fever) has been well known as a disease, which afflicts mankind since the ancient times. *Navjwara* is characterized by history of pyrexia up to seven days, heaviness, nausea, vomiting, indigestion, constipation, anorexia, cough, loss of taste and associated body ache similar to *Aamjwar*. *Jwara*, *Arochak*, *Agnimandya*, *Angamarda* are the cardinal sign and symptoms of *Navjwara*. Various *Shodhana* and *Shamana* procedures are mentioned in classics to treat *Jwara*. Indication for the *vamana* in case of *Jwara* condition is given as *Utkleshavastha* i.e. nauseatic feeling in *Ashtang Hrudaya*. So in this study 30 patients of *Navjwara* treated with *Sadyovaman* followed by *Pachan* with *Aampachak Kwatha*. Evaluation of subjects was done on 3<sup>rd</sup> and 5<sup>th</sup> day with above sign and symptoms as subjective criteria. Significant result was observed in *Navjwara*. Statistical analysis was

done by Wilcoxon Signed Rank Test for subjective criteria and Students's Paired t Test for Temperature.

**Keywords:** *Ayurveda*, *Navjwara*, *Sadyovaman*, *Saindhav Jal*, *Pachan*, *Aampachak Kwatha*.

### INTRODUCTION:

*Ayurved* is an ancient science of medicine of India. At the time of *Ayurved*, fevers were supposed as deadly and labelled as that *Jwara* is the first existed disease on the earth.

*Sushrutacharya* has mentioned that *Jwara* (the fever) is an *Aupasargik Roga* meaning a fever causes a lots of trouble and pain to the victim. Now a days fever like pyrexia of unknown origin (PUO) is not only trouble to the victim but also *Dehendriya Manastapy* for doctor also.

According to *Ayurved Jwara's* (fevers) are related to the *Annavaha Strotas* and the *Rasavaha Strotas*. Naturally, if the

digestion is disturbed, a person can suffer from any type of fever depending upon the factors involved in it. In this regards, the concept of *Agni* holds the basic position in the beginning of fevers. The vitiated *Agni* is responsible for the production of many diseases but mainly the *Jwara's* (fevers). When *Agni* is disturbed, reduced then the food ingested is not fully digested. It is only partially digested and therefore gives rise to *Ama* or the imperfectly digested food. This half or imperfectly digested food gives rise to many diseases in general but *Jwara* in particular. To control and cure the fevers many herbs and herbal combinations, many herbo-mineral and metallic combinations are recommended.

The *pratyatma linga* of *Jwara* is *Dehamanasa santapa*.

ज्वरप्रत्यात्मिकं लिंगं संतापो देहमानसः। (च.चि. ३/३१)

From the onset of *Jwara* upto 7 days it is called as *Navajwara*. Also considered as *Tarunjwara* and *Amajwara*. Body temperature refers to the temperature of the viscera and tissues of the body. The balance between heat gain and heat loss is regulated by hypothalamus, means body temperature is controlled by hypothalamus.

आसप्तरात्रं तरुणां ज्वरामाहुर्मनीषिणः।

मध्यं द्वादशरात्रं तु पुराणामत उत्तरम्॥ (च.चि. ३)

The *chikitsa sootra* for *Tarun Jwara* is *langhana*, *swedana*, *kala*, *yavagu*, *tiktarasa dravya*.

लघनं स्वेदनं कालो यवाग्वस्तिक्तको रसः।

पाचनान्यविपक्वनां दोषाणां तरुणे ज्वरे॥ (च.चि. ३/१४२,१४३)

*Vagbhata* says that, *vamana* is conducted in the following conditions such as *sadyabhuktasya sanjat Jwara*, *samajwara*. If there is *utklishta dosha*

present in *amashaya* then only *vamana* is conducted otherwise it produces *shwasa*, *anaha*, *moha*.

तत्रोक्तृष्टे समुत्थितृष्टे कफप्राये चले मले।  
सहल्लासप्रसेकात्रद्वेषकासविसूचिके॥

सद्योभुक्तस्य सञ्जाते ज्वरे सामे विशेषतः। वमनं वमनार्हस्य  
शस्तं---

श्वासातिसारसम्मोहहृद्गदोगविषम्ज्वरान्॥ (अ.ह.चि.१/४,५)

*Charakacharya* indicated *vamana* in *kapha Pradhan awastha*, *utklishta dosha* present in *amashaya*.

कफप्रधानानुत्थिलान् दोषानामाशयस्थितान्॥

बुद्ध्वा ज्वरकरान् काले वम्यानां वमनैर्हरत्।

अनुपस्थितदोषाणां वमनं तरुणे ज्वरे॥ (च.चि.३/१४६,१४७)

*Sadyovaman* is the instant therapeutic emesis (purificatory procedure) conducted without *abhyantara Snehpana* (internal oleation) and *Sweda* (sudation) in aggravated *kapha* conditions. It is indicated in conditions of *Navajwara* (acute fever), *arbuda* (abscess). *Sadyovaman* is indicated in diseases of the oral cavity and throat where vitiated *kapha* (one of the fundamental humour) is the main *dosha*.

The word *Pachan* implies to the various *Pachak Kalpas* used in *Aam Jwara*. *Jwara* develops due to obstruction of *Rasawaha* and *Swedawaha strotasa* by *Aamdoshas*. *Pachan* is mainly helps in *Aam Pachan*. Obstruction in the *srotas* is reduced by *Pachan*.

In modern life style the fever is the commonly occurring disease. Rather than *Sadyovaman*, modern and other *Ayurvedic* treatment are very costly. But the *Sadyovaman* is very simple procedure. It can be perform at anytime and anywhere, so it was decided to study the topic of naming “Interventional Phase II, Clinical Study to Evaluate Efficacy and Safety of *Sadyovaman* Followed by *Pachan* in *Navajwara*”.

## AIM and OBJECTIVES:

### Aim:

“Interventional Phase II, Clinical Study to Evaluate Efficacy and Safety of *Sadyovaman* Followed By *Pachan* in *Navjwara*”.

### Objectives:

- To study the effect of *Sadyovaman* followed by *Pachan* in *Navjwara*.
- To standardize the procedure of *Sadyovaman*.
- To study the time duration of relieving sign and symptoms in *Navjwara* like *Jwara* (temperature), *Arochak*, *Agnimandya*, *Angamard*.

## Material and Methods:

### Selection of Patients:

The patients who attended the OPD and IPD Kayachikitsa Department of *Arogyashala Rugnalaya Nashik*, during the period of year 2017 and 2018. Among these, 30 patients who fulfilled the below mentioned criteria of inclusion were taken for clinical study.

#### 1) Inclusion Criteria:

- 1) Age: 20 to 60 years.
- 2) Co-operative and obedient patients and patients Eligible for *Vaman karma*.
- 3) Patients whose temperature was less than  $< 101^{\circ}\text{f}$  and  $> 99^{\circ}\text{f}$  on the first day of examination after keeping the thermometer form one full minute in the mouth cavity/ Axillary area.

4) From the onset of *Jwara* upto 7 days it is considered as *Navjwara*.

5) Patients having following symptoms - *Agnimandya*, *Arochaka*, *Jwara*, *Angamard* etc.

6) Fever with *Kaphapradhan*, *Utklishta dosha*, *Amashayashrit dosha*, *Sadyobhuktasya Sanjat Jwara*.

#### 2) Exclusive criteria:

- 1) Age:  $< 20$  and  $> 60$  years.
- 2) Un-cooperative patients.
- 3) Patients suffering from *Madhumeha* (Diabetes mellitus), *Arbud* (Cancer), *Jeerna Ucchya Rakta Chap* (Chronic Hypertension), Cardiac disease etc.
- 4) Fever with long duration other than *Navajwara* like Malaria, Tuberculosis and Typhoid etc.
- 5) Fever with Chickenpox, Measels, Smallpox, Swine Flu etc.
- 6) Any patient who is thought to be unfit to undergo this study, like alcoholics, drug addict, hysteric and violent patients.
- 7) Fever with more complications (*Updrava*).
- 8) Fever with traumatic history, surgical history.

### Research Design:

This is an Interventional Phase II, single arm, clinical study of single group.

### Material:

*Sadyovaman dravya- Lavanambu*

Preparation of *Lavanambu*- The *lavanambu* was prepared as; 15 Gm of

*Saindhav* mixed in each 1 litre of warm water and stirred till *saindhav* get dissolved in warm water. In this study we were used the *Lavanambu* in 3 - 4 litre quantity for *Sadyovaman*. The *Lavanambu* was taken as *Samprukta*.

**Sadyovaman Vidhi:** *Sadyovaman Vidhi* was performed according to Standard operative procedure based on Ayurvedic text.

**Pashchat Karma:** *Sansarjana Krama* was given with *Peyadi* for 2 days.

**Aampachak Kwatha:** (Ref. - वृद्धवैद्य)

Drug Name	Latin Name	Family
<i>Daruharidra</i>	<i>Barberris aristata</i>	Berberidaceae
<i>Devdaru</i>	<i>Cedrus deodar</i>	Pinaceae
<i>Gokshur</i>	<i>Tribulus terrestris</i>	Zygophyllaceae
<i>Guduchi</i>	<i>Tinospora cordifolia</i>	Menispermaceae
<i>Haridra</i>	<i>Curcuma longa</i>	Scitaminae(Zingiberaceae)
<i>Kirattikta</i>	<i>Swertia chirata</i>	Gentianaceae
<i>Manjishta</i>	<i>Rubia cordifolia</i>	Rubiaceae
<i>Punarnava</i>	<i>Boerhavia diffusa</i>	Nyctaginaceae
<i>Musta</i>	<i>Cyperus rotundus</i>	Cyperaceae
<i>Raktachandan</i>	<i>Ptero Carpus satalinus</i>	Leguminosae
<i>Shunthi</i>	<i>Ziziber officinale</i>	Zinziberaceae
<i>Patol</i>	<i>Tricosanthes dioica</i>	Cucurbitaceae

**Aushadha Sevan Kala – Aabhukta kala** (twice/day)

**Matra** - 40ml

**Route of Administartion:** Oral

**Duration:** 5 days

**Follow up:** D<sub>0</sub>, D<sub>03</sub>, D<sub>05</sub>

**Preparation of medicine –**

*Kwatha* was prepared as per *Sharangdhar Samhita*. Guidance of experts from the department of *Rasashastra Bhaishajya Kalpana* was taken. *Aampachak Kwatha* was standardized in research lab of our pharmacy.

#### ASSESSMENT CRITERIA:

**Criteria for assessment of result:** (Subjective Criteria)

##### 1) *Jwara* (Temperature):

Grade	Score	Feature
0	0	Normal temperature
+	1	99 <sup>0</sup> f to 100 <sup>0</sup> f
++	2	100 <sup>0</sup> f to 101 <sup>0</sup> f
+++	3	101 <sup>0</sup> f to 102 <sup>0</sup> f

##### 2) *Arochak*:

Grade	Score	Feature
0	0	Well feeling of taste of food
+	1	Mostly feeling of taste & occasional absent
++	2	Sometime feeling of taste & mostly absence of taste of meal
+++	3	Absence of taste of meal

### 3) *Agnimandya:*

Grade	Score	Feature
0	0	Eat whole food supplied with hunger after 4-5 hrs. after food
+	1	Eat whole food without hunger
++	2	Cannot take his regular meal moderate hunger after 8-10 hrs. can eat at least once a day
+++	3	Cannot take food supplied or even breakfast

### 4) *Angamarda:*

Grade	Score	Feature
0	0	No body ache
+	1	Bearable body ache
++	2	Unbearable body ache relieved by taking Analgesics and rest
+++	3	Unbearable body ache not relieved by taking Analgesics

## INVESTIGATION:

1) CBC

2) Urine – a) Routine

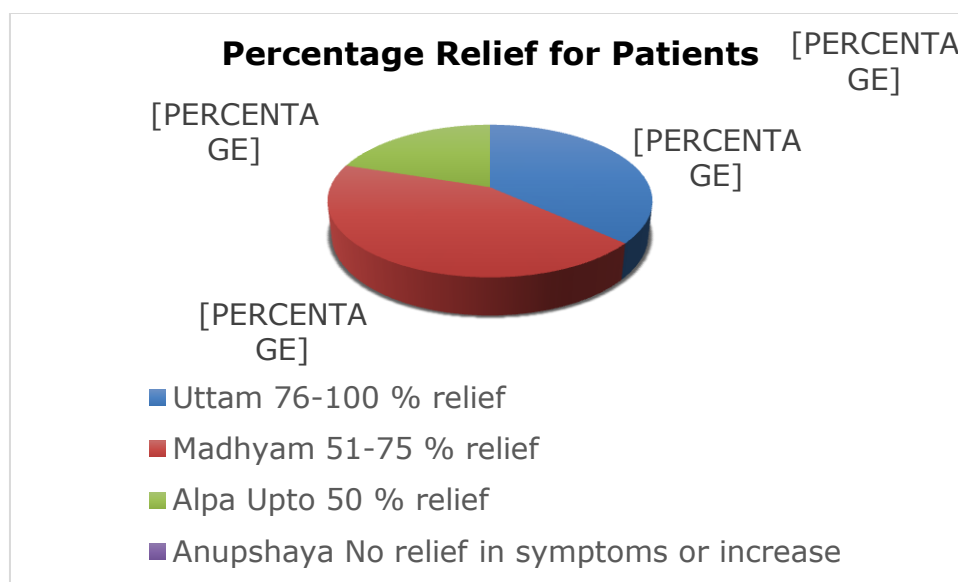
b) Microscopic

**OBJECTIVE CRITERIA:** Body Temperature

**OBSERVATION and RESULTS:**

Distribution of patients according to overall effect of therapy:

<i>Upashaya</i>	Percent Relief	No. Of Patients	Percent
<i>Uttam</i>	76-100 % relief	11	37
<i>Madhyam</i>	51-75 % relief	13	43
<i>Alpa</i>	Upto 50 % relief	6	20
<i>Anupshaya</i>	No relief in symptoms or increase	0	0

**Statistical Analysis****Subjective Parameters (By Wilcoxon Signed Rank Test)****A) Jwara:**

BT/AT	N	Mean	Median	W	P
BT	30	1.197	2	210	<0.0001
AT	30	0.900	1		

**B) Arochak:**

BT/AT	N	Mean	Median	W	P
BT	30	1.933	2	406	<0.0001
AT	30	0.400	0		

**C) Agnimandya:**

BT/AT	N	Mean	Median	W	P
BT	30	1.633	2	351	<0.0001
AT	30	0.366	0		

**D) Angamarda:**

BT/AT	N	Mean	Median	W	P
BT	30	1.933	2	406	<0.0001
AT	30	0.433	0		

**Objective Parameters (By Paired t Test)****Temperature (<sup>0</sup>F)**

BT/AT	N	Mean	SD	t	P
BT	30	100.30	0.510	8.054	<0.0001
AT	30	99.037	0.827		

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in above sign and symptoms. Hence it is concluded that *Sadyovaman* followed by *Pachan* is highly effective to reduce above all sign symptoms in *Navjwara*.

**Effect of therapy according to relief in Patient's score**

Pt. No.	Group A				Pt. No.	Group A			
	B.T.	A.T.	Relieved	Relief %		B.T.	A.T.	Relieved	Relief %
1	8	1	7	87.5	16	7	2	5	71.43
2	7	0	7	100	17	8	2	6	75
3	8	1	7	87.5	18	8	2	6	75
4	8	2	6	75	19	7	2	5	71.43
5	6	0	6	100	20	8	1	7	87.5
6	8	1	7	87.5	21	8	2	6	75
7	6	5	1	16.67	22	6	1	5	83.33
8	7	4	3	42.86	23	8	2	6	75
9	11	3	8	72.73	24	9	3	6	66.67
10	8	2	6	75	25	4	3	1	25
11	10	3	7	70	26	8	5	3	37.5
12	9	2	7	77.78	27	7	4	3	42.86
13	6	0	6	100	28	7	2	5	71.43
14	5	1	4	80	29	7	4	3	42.86
15	7	3	4	57.14	30	8	0	8	100



### Effect of therapy according to relief in Symptom's score:

Sr . N o.	Symptoms (Group A)	B. T.	A. T.	Relieved	% Relief
1	<i>Jwara</i>	59	27	32	54.24
2	<i>Arochak</i>	58	12	46	79.31
3	<i>Agnimandya</i>	49	11	38	77.55
4	<i>Angamarda</i>	58	13	45	77.59

### Discussion

The study was aimed to evaluate the efficacy and safety of *Sadyovaman* followed by *Pachan* in *Navjwara*, for assessing the results of following symptoms for subjective criteria *Jwara* (temperature), *Arochak*, *Agnimandya* and *Angamarda* were selected.

At that time of *Ayurved*, Fevers were considered as deadly & described as that *Jwara* is the first existed disease on the earth. *Jwara* is considered as most important among all diseases as it afflicts *shareera*, *indriya* and *manas*. It is certain at the time of birth and death. From the onset of *Jwara* upto 7 days it is considered as *Navjwara*.

*Navjwara* is very common, the most important *Samprapti* (pathology) according to *Ayurved* is *Agnimandya* (reduced digestive power) followed by *Ama Sanchiti* (accumulation of half-digested food) and its *Prasar* (circulation) all over the body giving rise to symptoms like *Jwara* (temperature), *Arochak*, *Agnimandya*, *Angamarda* etc.

these are very common and the patient feels uneasy.

*Navjwara* correlated with fever, Fever is when human's body temperature goes above the 36-37<sup>0</sup> Centigrade (98-100<sup>0</sup> Fahrenheit). It is a common medical sign. Other terms for a fever include pyrexia and controlled hyperthermia. As the body temperature goes up the person may feel cold until it levels off and stops rising. People's normal body temperatures may vary and are affected by factors such as eating, exercise, sleeping and what time of the day it is. Our body temperature is usually at its highest at around 6 p.m. and as its lowest at about 3 a.m.

The distribution of patients according to age, sex, education, *Prakruti*, *Koshtha* and *Agni*, mainly the important distribution given below.

In regards to *Prakruti vata-pittaj* was 43.00%, *pitta-kaphaj* was 33.00% and *vata-kaphaj* 20.00% of *Prakruti*. Here we taken the *Navjwara* as *Kaphapradhan* and the treatment for it as *Sadyovaman* so *Prakruti* plays an important role in causing *Navjwara*.

While regarding *Koshtha* majority were *Madhyam Koshtha* 77.00%, 20.00% patients were *Mrudu* and 3.00% patients were *Krura Koshtha*. The *Koshtha* also had effect in causing *Navjwara*.

*Sama Agni* was 47.00%, 17.00% were *Visham*, 33.00% *Manda* and 3.00% patients were *Tikshna Agni* respectively. *Agnimandya* also a cause for *Navjwara*. It is an effective factor for causing *Navjwara*.



Statistically the parameters like *Jwara*, *Arochak*, *Agnimandya* and *Angamarda* presented with highly significant results. Also the effect of therapy is statistically significant for temperature.

After studying all the data thoroughly it was detected that out of 30 patients, 11 (37.00%) patients received *Uttam*, 13 (43.00%) were *Madhyam*, 6 (20.00%) patients were received *Alpa Upashaya* and 0 (0%) patients received *Anupashaya*. That means *Sadyovaman* followed by *Pachan* is effective in *Navjwara*.

#### **Samprapti Ghataka:**

<i>Udbhava Sthana</i>	<i>Amashaya</i>
<i>Dosha</i>	<i>Pitta Pradhan</i> <i>Tridoshaj</i>
<i>Dushya</i>	<i>Rasa, Rakta</i>
<i>Srotas</i>	<i>Sweadavaha,</i> <i>Rasavaha</i>
<i>Sroto-Dushti</i> <i>Prakar</i>	<i>Samya</i>
<i>Vyakta Sthan</i>	<i>Sarvanga (All over</i> <i>the body)</i>
<i>Ama</i>	<i>Jatharagi Janya</i> <i>Ama</i>
<i>Roga-Marga</i>	<i>Bahyaroga Marga</i>

#### **Mode of Action:**

*Saindhav* used in the form of *Lavanambu* for *Sadyovaman* in this study. By its *Snigdha*, *Tikshna*, *Sukshma* guna and had the properties like *Tridoshar* and *Sukshmasrotogamitva* act to reduce the *Jwara*. Above all the contents of *Aampachak Kwatha* act as *Jwaraghna*, *Kaphaghna* by *Guna* and *Karma* etc. and

also it removes (*Niraharnar*) the *Shesha Dosha* after *Sadyovaman*.

#### **Conclusion**

In this study entitled; “**Interventional Phase II, Clinical Study to Evaluate Efficacy and Safety of Sadyovaman Followed by Pachan in Navjwara**” following conclusion is drawn:

Based on statistical test of significance, the *Sadyovaman* followed by *Pachan* is very effective in reducing *Jwara* (temperature), *Arochak*, *Agnimandya* and *Angamarda* observed in *Navjwara*.

Thus it can be concluded that *Sadyovaman* followed by *Pachan* is significantly effective and safe in the management of *Navjwara*.

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