Research Article

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EVALUATION OF CLINICAL EFFICACY AND SAFETY OF SAINA TABLET IN THE MANAGEMENT OF SINUSITIS (*PRATISHAYA*)

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ABSTRACT

Sinusitis is one of the most distressing disease conditions affecting the quality related life of individuals, having a recurrent and chronic course with a very poor response to medicines. Though many drugs have been introduced for its management from time to time, complete recovery from the disease is still challenging for the physician. Ayurveda offers large number of single and poly herbal or herbo-mineral drugs for the management of sinusitis (*pratishaya*) and some of the best of these drugs were selected and saina tablet was formulated. The present trial was carried out to find the efficacy and safety of saina tablets on patients of sinusitis who satisfied the diagnostic and inclusion criteria. Detailed medical history to find out the causative factors like diet and lifestyle and status of disease was recorded and examination of affected areas was done. Patients willing to participate were given saina tablets in the dose of 1 tablet (380 mg each) thrice daily with lukewarm water after meal for the duration of two months with follow up every fifteen days. The primary end points were assessed on basis of improvement in sign and symptoms and quality of life (EQ 5D 5L Questionnaire). Safety assessments were hepatic function [SGPT, SGOT and Alkaline Phosphatase (ALP) and renal function (B. urea and S. Creatinine, Albumin, Globulin)] tests. The finding of the present study suggests that saina tablet is a safe and potential medicine to be used for the treatment of sinusitis.

Keywords: Efficacy and safety, Saina Tablet, Sinusitis.

INTRODUCTION

Sinusitis refers to an inflammatory condition involving the four paired structures surrounding the nasal cavities. Sinusitis affects a tremendous proportion of the population, accounts for millions of visits to primary care physicians each year and is the fifth leading disease for which antibiotics are prescribed. It is typically classified by duration of illness [acute vs. chronic]; by etiology [infection vs. non-infection]; and, when infectious, by the offending pathogen type (viral, bacterial, of fungal).[1] Conditions that can cause sinus blockage include common cold, allergic rhinitis (swelling in the inner lining of the nose), nasal polyps (small growth in the lining of the nose), or a deviated septum (a shift of septum in the nasal cavity).

Conditions that can cause sins blockage include the common cold, allergic rhinitis (swelling in the inner lining of the nose), nasal polyps (small growths in the lining of the nose) or a deviated septum (a shift in the nasal cavity). There are different types of sinusitis, includes Acute sinusitis (A sudden onset of cold-like symptoms such as runny, stuffy nose and head ache that remains for 10 to 14 days); sub-acute sinusitis (An inflammation lasting 4 to 8 weeks); chronic sinusitis (A condition characterized by sinus inflammation symptoms lasting 8 weeks or longer); Recurrent sinusitis (Several attacks within a years).[2]

Shalakya is an important branch of Ayurveda which deals with the diseases manifesting above clavicular region. Rajrshi nimi is the ancient stalwart who contributed the ophthalmology and ENT in a systemic manner as per Uttaratantra in Sushruta Samhita, where in, one separate chapter on *Pratishyaya* has been devoted after explaining *Nasagataroga*. According to Ayurveda, *Pratishyaya* can be considered as a resembling medical condition to sinusitis. It is a severe and generalized body debilitating condition, which manifest due to the migration of the *kapha, Rakta* and *Pitta* from the root of the *Nasa Pradesha* to *Shira Pradesha* (above neck), which is already vitiated by the *Vata Dosha*.[3]

Conventional medicine provides symptomatic relief, but underlined pathology goes on unchecked causing recurrence of disease. Hence people have started resorting to alternative medicine with the hope of permanent solution or to reduce the dose of conventional drugs or to avoid their side effects. In this scenario, it is challenging to find out an Ayurveda formulation which is potent, easily palatable and has minimum side effect. Drugs having *Deepana, Pachana, Srotoshodhana* and *Shothahara* actions can help to break the pathogenesis of the disease as well as prevent recurrence. Considering these facts, a clinical trial to establish clinical efficacy and safety of saina tablet was planned.

Saina tablet is combination of few classical formulations which are well indicated in Ayurvedic text for such pathological condition. It is composed of *Tribhuvana kirti rasa*[4], *Mahasudarshan Churna*[5] in extract from and extract of *Amrita* processed in decoctions of *Tulasi*, *Vasa*, *Kulinjan, Yasti* and *Kantakari*. All the formulations and herbs of saina tablets are well reported individually to be useful in cough and cold in various classical as well as modern literatures. However, combination of them has not been evaluated for their safety and efficacy so far. Hence, present clinical trial is planned to assess role of saina tablet for the management of sinusitis.

Aims and Objectives

Primary Objective

To assess the clinical efficacy and safety of Saina tablets in the management of sinusitis (*Pratishyaya*)

Secondary Objective

To assess quality of life of the patients during the management of sinusitis

Hypothesis

Null Hypothesis (H0)

Saina Tablet is not effective and safe in the management of sinusitis (*Pratishyaya*)

Alternate Hypothesis (H1)

Saina tablet is effective and safe in the management of Sinusitis (*Pratishyaya*)

METHOD

Plan of clinical study

The present study was a Prospective, Open label, Single arm trial conducted on the outpatients of shalakya tantra department, IPGT and RA, Gujarat Ayurved University, Jamnagar. The study is carried out for a period of 1 year from November 2015 to November 2016 after obtaining approval from the Institutional Ethics Committee (Letter: no. PGT/7/-A/ETHI/2014 – 2015/1470). The trial was registered under Clinical Trial Registry of India (CTRI/ /2015/11/006386). Single batch saina tablets were procured in strips of 20 Tablets from Ayurchem Products for dispensing to Trial patients. CTRI NO.:- CTRI/2016/01/006547.

Selection of patients for clinical study

For the purpose of present clinical study, patients suffering from sinusitis fulfilling the inclusion criteria of diagnosis and willing to give their consent to participate in the clinical trial, were selected irrespective of their sex, caste, religion, habitat from OPD of I. P.G.T and R.A. Hospital, Gujarat Ayurved University, Jamnagar.

Criteria for diagnosis

Diagnosis of the disease is done as per the presenting symptoms such as *Shirahshoola* (Headache), *Shirogaurava* (Heaviness of head), *Nasasrava* (Rhinorrhea), *Nasavarodha* (Nasal obstruction), *Gandha Agrahyata* (Loss of smell), *Mukhadaurgandhya* (Halitosis),

Kasa (Cough), *Swarabheda* (Change of voice), *Aruchi* (Anorexia), *Jwara* (Fever), *Kshavathu* (sneezing) and postnasal drip and radiologist changes specific for sinusitis.[9]

Pre-treatment observation

All the selected patients were taken for the registration process after explaining them objectives of clinical trial and taking their consents. After preliminary registration, diagnostic medical history was taken according to both Ayurveda and modern clinical methods. Detailed Performa was filled to assess the status of the patient.

Inclusion criteria

- Patients fulfilling the diagnostic criteria of allergic and acute sinusitis.
- Willing and able to participate in the study.
- Patient of either sex with age between 18 to 60 years.

Exclusion criteria

- Patient having chronic and recurrent sinusitis.
- Patients with poorly controlled Hypertension or with uncontrolled Diabetes Mellitus and having a past history of a trial fibrillation, Acute coronary syndrome, Myocardial infarction, Stroke or serve arrhythmia in the last 6 months.
- Patients on prolonged medication with corticosteroids, antidepressants, anti-cholinergic, etc. or any other drugs that may have an influence on the outcome of the study.
- H/o hypersensitivity to any of the trial drugs or their ingredients.
- Pregnant /lactating women.
- Those with middle ear infections, tinnitus, vertigo etc.
- Patients with history of malignancy.
- Patient age less than 18 years and more than 60 years.

Investigations

Following investigations were carried out before initiating the administrations of trial drug after completion of course of the treatments to confirm the diagnosis the out other pathogenesis and to the treatment to confirm the diagnosis and rule out other pathogenesis to assess safety aspects.

- Hematology: Hemoglobin, RBC, WBC, DLC, ESR. (Westergren method)
- Bio-chemistry: FBS, KFT, LFT
- Urine Analysis: Routine and Microscopic test.
- Radiology: Radiological examination of paranasal sinuses.

Table 1: Ingredients of Saina tablets

Ingredient Name	Part used	Quantity
Mahasudarshana Ghana	Formulation	200 mg
Guduchi Ghana	Formulation	100 mg
Tribhuvana Kirti Rasa	Formulation	80 mg
Processed with (*Bhavna Dravya*)		
Tulasi (Ocimum sanctum)	Aerial	QS
Vasa (Adhatoda vasica)	Leaves	QS
Kulinjan (Alpinia galangal)	Rhizome	QS
Yashtimadhu (Glycyrrhiza glabra)	Root	QS
Kantkari (Solanum xanthocarpum)	Whole plant	QS

Dose and Duration

Patients enrolled for the study received saina tablets in the dose of 1 tablet thrice daily (each of 380 mg), after meal with warm orally for 2 months. Records of the patients and dispensed medicine were maintained in drug inventory form. All subjects were advised specific diet and lifestyle modifications during the clinical trial per follows:

Do's

Consumption of Lukewarm water with light diet dominant in *Tikta* and *Katu Rasa*, *Ruksh*a, *Laghu*, and *Tikshan Guna* was advised.

Don'ts

Heavy dietary items such as flour of *Masha* (black gram), diet dominant in *Madhura Rasa, Viruddha Aahara*, cold water, curd,

cold beverages, ice creams, daytime sleeping, suppression of natural urges, exposure to cold, wind, staying in A.C.; excess of stress and excessive exertion will be advised to be avoided.[6,7]

ADR (Adverse drug reaction): No adverse drug reaction was found during the entire study period.

Follow up

Follow up of the study was carried out of for the one month after completion of the treatment at fortnight interval.

ADR (Adverse drug reaction)

No Adverse drug reaction was found during the entire study period.

Criteria for assessment

- Parameters for assessment of and clinical features: *Nasarava* (Rhinorrhea) *Nsavarodha* (Nasal obstruction), *Gandha Agrahyata* (Loss of smell), *Shirahshoola* (headache), *Shirahgaurava* (Heaviness of head), *Mukhadaurgandhya* (Halitosis), *Kasa* (Cough), *Swarabheda* (Change of voice), *Aruchi* (Anorexia), *Jwara* (Fever), *Kashvathu* (Sneezing) and post nasal drip. These were assessed on every fortnight.
- Severity of sinus symptoms to be assessed by single- item sinus-symptom Severity Assessment (SIA)
- Quality of life assessed by the EQ-5D questionnaire.[8]
- Parameters for assessment of safety: Liver function test (SGPT, SGOT, Alkaline Phosphate, and Total Bilirubin) and renal function test (Blood urea, Serum Creatinine, Albumin and Globulin).

Overall assessment of therapy

Overall effect of the drug was assessed on the basis of the criteria:

- Complete Remission-100%
- Significant improvement-More than 50%
- Mild Improvement-25 to 50%
- Unchanged-Less than 25%

Statistical analysis

For the analysis the efficacy and safety of the trial drug and to check its statistical significance, paired" 't' test was applied, and the results were interpreted as significant if p value < 0.05 to < 0.001

OBSERVATIONS

For the present clinical trial, 60 patients were registered. All the patients completed the two months treatment of Saina tablet as per the presided protocol Maximum of these patients were form the group of 21-30 (33.33%) followed by 31-40 years age group (28.33) and were females (66.66%) especially housewives (50.00%) Belonging to Hindu religion (73.33%), married (85.00%), graduates (25.00%), followed by uneducated (23.33%), middle class of the society (26.66%) and vegetarians (68.33%) almost half of these patients come from dusty and polluted area (50%), mostly without any family history of sinusitis (85.00%) and were under allopathic medication (43.33%), their dietetic habit consisted mostly *Samashana* (48.33%) i.e., Taking *Pathya* and *Apathya* food at the same time predominant in *Madhura Rasa* (46.66%) guru (56.66%), *Snigdha* (51.66%) and *Ushna* (76.66%) *Guna* and had tea as their supplementary diet (56.66%). Most of them had *Vishamagni* (41.66%) but with regular bowel habits (70.00%). The main etiological factors for the disease included dietic factors like *Ajirna*/ indigestion (51.66%), *Atyambupana* /excessive water intake (18.33%), *Astiseetambu sevana*/ drinking excessive cold water (23.33%), *Anyadeshambupana* /drinking water from different regions (03.33%) and habitual factors like *Vegadharana* / suppression of natural urges (16.66%), *Rajasevana* / exposure to dust and allergen (63.33%) *Rituvaishamya* / change in climatic conditions (95.00%), *Nishajagarana* / awakening in night (38.33), *Atidiwaswapna* / excessive day time sleep (13.33%), *Atyashr*u / excessive weeping (21.66%), *Atidhumasevana* / exposure to smoke (16.66%) and *Jalakreeda* / excessive bathing habits (05.00%). All of the patients had impaired *Rasavaha Srotas* (100%), followed by involvement of *Annavaha* (60.00%), *Udakavaha* (28.33%) and *Pranavaha Srotas* (28.33%).

On taking medical history, all patients had *Shirahshoola* with heaviness of head (100.00%), Followed by *Nasarava* (68.33%), *Nasavarodha* (66.66%), *Kasa* (55.00%), *Jwara* (45.00%), *Mukhadaurgandhya* (15.00%) and *Gandha Agrahyata* (11.66%) Associated complaints included postnasal discharge (83.33%), *Kshavathu* / excessive bouts of sneezing (70.00%), Anorexia (46.66%) and Voice disturbance (33.33%).

Chief sinuses involved in these patients were right frontal (98.33%), Left frontal (96.66%), Ethmoidal (65.00%) and maxillary sinuses (43.33). Nasal examination revealed turbinate hypertrophy (80.00%), Pale blue Mucosa (63.33%), Discharge (71.66%), Deviated septum (41.66%), Nasal spur (05.00%) and Polyposis (05.00%), Radiological examination revealed haziness in left frontal (88.33%), right frontal (86.66%), Left maxillary (58.33%) and right maxillary (55.00%). Disease duration of most of the patients was in the range of 1-2 weeks (33.33%).

Effect of treatment

Data of the 60 patients who completed full two months of treatment with saina tablet were utilized for the analysis of the effect provided. There was statistically significant improvement in all the major symptoms of sinusitis like *Shirahshoola, Nasarava, Nasavarodha, Jwara, Kasa, Mukhadaurgandhya* and *Gandha Agrahyata* radiological findings of the sinus after the study showed significant improvement Overall effect of the therapy showed that significant improvement was reported in 88.30% of the patients, mild improvement in 05.00% while complete remission was reported in 06.70% of the patients. No patients remained unchanged after the treatment. The quality of the life of sinusitis patients improved due to decrease of disability from 05.76 to 03.14. Their health score improved from 76.22 to 85.67. These changes reported in quality of life were statistically highly significant.

Safety profile

There were no significant changes in blood levels of Total and Differential WBC count, Platelet count, Fasting Blood Sugar and serum levels of SGPT, SGOT, Albumin, Globulin and Creatinine at post treatment as compared to the baseline and remained within limits before and the after treatment. Although there was significant increase in serum alkaline Phosphatase, Urea and Bilirubin, these were within normal limits. In addition, during the full course of treatment with saina tablets and even in follow up period, none of the patients reported any untoward complaints. All these point to the fact that Saina tablet is safe.

Effect of treatment on objective criteria

Table 2: Effect of Saina tablet on radiological finding (n = 60)

Sinus (Haziness)	Mean value (IU/ml)		Difference	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	p	
Right frontal	1.03	0.82	0.21	18.75 ↓	0.46	0.06	3.52	< 0.001	S
Left frontal	1.03	0.84	0.20	16.96 ↓	0.44	0.06	3.31	< 0.002	S
Right maxillary	1.19	0.64	0.54	44.59 ↓	0.62	0.11	4.89	< 0.001	S
Left maxillary	1.12	0.61	0.51	43.90 ↓	0.59	0.09	5.44	< 0.001	S

BT = before treatment. AT = after treatment. % = Percentage. SD = Standard deviation, SE = Standard error. IS = Insignificant. ↓ Indicates decrease ↑ Indicates increase.

Table 3: Effect of treatment on chief complaints

Symptoms	Mean value		Difference	%	Paired 't' test				Significance
	BT	AT			S.D.	S.E.	't'	P	
Sirahshoola N = 60	2.33	0.17	2.17	93.47 ↓	0.56	0.07	30.11	< 0.001	S
Nasasrava N = 41	2.19	0.29	1.90	86.58 ↓	0.89	0.14	13.70	< 0.001	S
Nasa-varodha N = 47	1.85	0.17	1.68	91.49 ↓	0.56	0.08	20.73	< 0.001	S
Jwara N = 27	01	00	01	100 ↓	00	00	+ inf	< 0.001	S
Kasa N = 32	1.16	0.06	1.09	95.31 ↓	0.39	0.07	15.86	< 0.001	S
Gandha agrahyata N = 8	1.62	0.25	1.37	89.58 ↓	0.52	0.18	07.51	< 0.001	S
Mukha daurgandhya N = 9	1.55	0.11	1.44	96.30 ↓	0.53	0.17	08.22	< 0.001	S

BT = before treatment. AT = after treatment. % = Percentage. SD = Standard deviation, SE = Standard error. IS = Insignificant. ↓ Indicates decrease ↑ Indicates increase

Table 4: Effect of treatment on sinus tenderness

Symptoms	Mean value		Difference	%	Paired 't' test				Significance
	BT	AT			S.D.	S.E.	't'	P	
Rt. Frontal N = 59	1.71	0.12	1.59	95.20 ↓	0.53	0.07	23.13	< 0.001	S
Lt. Frontal N = 59	1.69	0.13	1.56	94.63 ↓	0.50	0.06	23.82	< 0.001	S
Rt. Maxillary N = 28	1.43	0.11	1.32	95.24 ↓	0.55	0.10	12.76	< 0.001	S
Lt. Maxillary N = 28	1.46	0.07	1.39	97.02 ↓	0.57	0.11	13.00	< 0.001	S
Rt. Ethmoid N = 39	1.60	0.10	1.50	95.17 ↓	0.51	0.08	18.25	< 0.001	S
Lt. Ethmoid N = 59	1.56	0.10	1.46	95.30 ↓	0.50	0.08	18.07	< 0.001	S

BT = before treatment. AT = after treatment. % = Percentage. SD = Standard deviation, SE = Standard error. IS = Insignificant. ↓ Indicates decrease ↑ Indicates increase

Table 5: Effect of Saina tablet on Quality of life and Health

Aspect	Mean value		Difference	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
Quality of life	5.76	3.14	2.62	42.49 ↑	2.29	0.30	8.65	< 0.001	S
VAS score on health	76.22	85.67	9.45	12.40 ↑	4.35	0.56	-16.84	< 0.001	S

Table 6: Effect of saina tablet on hematological parameters (n = 60)

Parameter	Mean value		Difference	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
Hb (gm%)	12.78	12.82	-0.04	0.67 ↑	0.91	0.12	-0.34	0.73	IS
Total W.B.C. (/Cumm)	7038.33	6948.3	90	0.49 ↓	1239.42	160.01	0.56	0.57	IS
Neutrophils (%)	56.78	57.3	-0.51	1.37 ↑	6.69	0.86	0.59	0.52	IS
Lymphocytes (%)	35.65	34.93	0.71	1.37 ↓	5.54	0.71	1.00	0.32	IS
Eosinophil's (%)	4.93	4.90	0.03	14.78 ↓	3.91	0.50	0.06	0.95	IS
Monocytes (%)	2.61	2.51	0.10	1.80 ↓	0.97	0.12	0.79	0.42	IS
ESR	21.34	19.86	1.475	20.48 ↓	15.61	2.01	0.73	0.46	IS
PCV (%)	37.89	37.97	-0.08	0.58 ↑	2.75	0.35	-0.22	0.82	IS
RBC (mil/cumm)	4.63	4.68	0.05	1.72 ↑	0.37	0.05	1.10	0.27	IS
Platelet count (10^3/ul)	322	330	-8.48	17.68 ↑	63	8.13	-1.04	0.30	IS

BT = before treatment. AT = after treatment. % = Percentage. SD = Standard deviation, SE = Standard error. IS = Insignificant. ↓ Indicates decrease ↑ Indicates increase

Table 7: **Effect of saina tablet on biochemical investigations (n = 60)**

Biochemical Parameter	Mean value		Df	%	Paired 't' test				Significance
	BT	AT			S.D. (±)	S.E. (±)	't'	P	
FBS (mg/dL)	90.60	91.47	-0.87	-4.38 ↓	24.97	3.22	-0.27	0.79	IS
Blood urea (mg/dL)	21.42	23.18	-1.77 ↑	12.57 ↑	6.81	0.88	-2.00	0.04	S
S. Creatinine (mg/dL)	0.82	0.85	-0.03	-6.52 ↑	0.19	0.02	-1.20	0.2	IS
SGPT (IU/L)	17.27	17.10	0.17	11	6.90	0.89	0.18	0.85	IS
SGOT (IU/L)	24.22	23.23	0.98	0.73	6.60	0.85	1.15	0.25	IS
Bilirubin (Total)	0.60	0.69	-0.08	24.52	0.29	0.83	-2.35	0.02	S
Alkaline Phosphatase (IU/L)	50.85	57.08	-6.23	-18.11	18.23	2.35	-2.64	0.01	S
Albumin	3.95	3.90	0.04	0.20	0.53	0.07	0.60	0.54	IS
Globulin	2.97	3.06	-0.09	-8.32	0.99	0.12	-0.73	0.46	IS

BT = before treatment. AT = after treatment. % = Percentage. SD = Standard deviation, SE = Standard error. IS = Insignificant ↓ Indicates decrease. ↑ Indicates increase Df = Difference

Table 8: Overall effect of therapy

Overall Effect	No. of patients	% of patients
Complete remission	04.00	06.67
Significant improvement	53.00	88.33
Mild improvement	03.00	05.00
Unchanged	00	00

RESULTS

Significant change in post-treatment scores of cardinal features of sinusitis, and quality of life were observed as compared to baseline scores. Treatment with saina tablet for two months in sinusitis patients showed normal kidney and liver function tests.

DISCUSSION

Demographic Factors

Age

60 patients of the age group of 18-60 years were registered into the present study. Among them, maximum patients were belonging to the group of 21-30 (33.30%) followed by 31-40

years age group (28.33) which shows its predominance in young population. It is an age in which a person starts has career. In this stage of life, *Dhatukshaya* and *balahani* will occur, *Vyadhikshamatwa* gradually decrease and accumulation of *Dosha* occurs. Middle aged people are more exposed to physical, mental, social and financial stress and strain. They are most exposed to pollution and due to busy lifestyle won't be able to look after their health. All these lead to *Agnimandya, Ama* and *Vata Kapha Prakopa* and decreases *Vyadhikshamatw*a which makes this group more prone for this disease.

Sex

In this study sample, it was observed that most of the patients were females (66.66%) especially housewives (50.00%) belonging to Hindu religion (73.33%) and married (89.33%). Generally, females have *Sukumara Prakriti*. They are more exposed to heat, dust and pollution. Being the care givers of family, females neglect their own personal health and following faulty diet and lifestyle which directly leads to *Agnimandya* formation and *Ama* and *Prakopa* of *Kapha* and *Vata*. Since Jamnagar is predominantly occupied by Hindus, a direct association of religion and the disease cannot be drawn.

Socio-economic status and habitat

In this study sample, maximum patients belonged to middle class (83.33%). Occurrence of high percentage morbidity in middle class may be due to unwholesome and faulty dietetic habits and sedentary lifestyle. Another possibility may be that middle-class people are most prone to stress and strain. Moreover, patients usually approaching government hospitals for treatment belong to lower or middle strata of the society. 50.00% of patients were from polluted and dusty surrounding. These are the unavoidable etiological factors due to which patient's immune factors decrease and probably didn't get complete relief after taking the allopathic medicine.

Chronicity

Since chronic cases of sinusitis were excluded from the study, all the patients had their disease duration within 2-month period of them, majority were of acute cases of sinusitis (51.66%) and the rest were having sub-acute sinusitis (48.33%).

Agni and Dietetic habit

Most of the patients had the habit of *Samashana* (48.33%) i.e., taking *Pathya* and *Apathy*a food at the same time predominant in *Madhura rasa* (46.66%), *Guru* (56.66%), *Sinigdha* (51.66%), and *Ushna* (76.66%) *Gun*a. Most of them had *Vishamagni* (41.66%) 50.00% of the patients have reported *Mandagni* in this study. Their food habit makes them more prone to *Agnidushti* and deceased *Vyadhikshamatw*a. Agni is one of the predisposing factors of the disease. Faulty and reduced food intake is responsible for lowered immunity and will promote recurrent episodes of the disease. All of the patients had impaired *Rasavaha srotas* (100%), followed by involvement of *Annavah*a (60.00%), *Udakavaha* (28.33%) and *PranavahaSrota*s (28.33%). *Agnidushti* directly causes *Annavaha* and *Rasavaha Sroto Dushti* leading to decreased *Vyadhikshamatw*a and improper formation of *Dhatu*s. As a result, the disease will enter a chronic stage and causes repeated recurrences.

Etiological factors

The main etiological factors for the disease included dietic factors like *Ajirna* (51.66%), *Atyambupana* (18.33%), *Atiseetambu sevana* (23.33%), *Anyadesambupana* (03.33%) and habitual factors like *Vegadharana* (16.66%), *Rajasevana* (63.33%), *Rituvaishamy*a (95.00%), *Nishajagarana* (38.33), *Atidiwaswapna* (13.33%), *Atyashru* (21.66%), *Atidhumasev*a (16.66%) and *Jalakreeda* (05.00%) and Jalakreeda (05.00%). All of the patients had impaired *Rasavaha Srotas* (100%), Followed by involvement of *Annavaha* (60.00%), *Udakavaha* (28.33%) and *Pranavaha Srotas* (28.33%)

Nasal examination

Nasal examination revealed turbinate hypertrophy in majority of patients (80.00%). This hypertrophied turbinate's play a major role in blockage of sinus ostia which hampers the natural drainage system. Pale blue mucosa was found in most of the patients (63.33%) which is a clear indication of nasal allergy. The rest had congested mucosa which is due to inflammatory process. Deviated septum was observed in 46.66% of patients. DNS not only results the blockages of the side to which the septum deviates but also causes compensatory hypertrophy of the turbinate on the opposite side and may results in bilateral nasal obstruction. This bilateral nasal obstruction may block the frontal sinus ostium and the draining the ethmoids and maxillary sinuses whish lead the sinusitis to chronic phase.

Chief and associated complaints

Sirahshoola with heaviness of the head was observed in 100.00% of person followed by *Nasasrava* (68.33%), *Nasavarodha* (66.66%), *Kasa* (55.00%), *Jwara* (45.00%), *Mukhadaurgandhya* (15.00%) and *Gandhajnana* (11.66%). Associated complaints included postnasal discharge (83.33%), *Kshavathu* (70.00%), Anorexia (46.66%) and voice disturbances (33.33%) *Shirahshoo*la associated with heaviness is the characteristics feature of the disease. Deviated nasal septum and hypertrophied turbinates may cause and worsen the conditions like *Nasarava* and *Nasavarodha*. Postnasal drip is a result of excessive secretions in the sinuses. It also results in a lot of descending infections and dry irritant cough. Recurrent bouts of sneezing occur as a result of persistent allergy and as a result to eliminate the infections pathogens from the upper respiratory tract. *Swarabheda* (change of voice) is due to absence of nasal resonance. The obstructed nostril and presence of discharge is inside the sinus after the normal resonance mechanism. The paralysis of cilia and occlusion of ostia will cause the retention of pus in sinuses. So, the long-standing retention will make the pus fault smelling and this is responsible for the *Mukhadaurgandhya.*

Table 9: Probable mode of drug action

No.	Ingredient Name	*Guna*	*Karma*
1.	*Mahasudarshana Ghana*		*Tridoshahara, Sarva Jwarahara, Swasahara, Kasahara.*
2.	*Amrita (Tinospora cordifolia)* (Wild) Miers	*Tikta, Kashaya Rasa, Ushna Virya, Madhura Vipaka* and *Laghu.*	*Balya, Dipana, Rasayana, Samgrahi, Tridosasamaka, Raktashodhaka, Jvaraghna.*
3.	*Tribhuvana Kirti Rasa*		*Vatakapha Jwarahara, Taruna Jwarahara, Sannipata Jwarahara*
4.	*Tulasi (Ocimum sanctum)*	*Katu, Tikta, Kashaya Rasa, Ushna Virya, Katu Vipaka* and *Laghu, Ruksha, Tikshna.*	*Dipana, Kaphavatahara, Pittavardhini, Hridya, Ruchya, Durgandhihara.*
5.	*Vasa (Adhatoda vasica)*	*Tikta, Kashaya Rasa, Sita Virya, Katupaka* and *Laghu.*	*Kaphavatahara, Kasaghna.*
6.	*Kulinjan (Alpinia galangal)*	*Tikta Rasa, Ushna Virya, Katu Vipaka* and *Guru.*	*Amapachana, Kaphavatahara*
7.	*Yashtimadhu (Glycyrrhiza glabra)*	*Madhura Rasa* and *Vipika, Sita Virya* and *Guru, Snigdha.*	*Balya, Vatapittajit, Raktaprasadana.*
8.	*Kantkari (Solanum xanthocarpum)*	*Katu, Tikta Rasa, Ushna Virya, Katu Vipaka* and *Laghu, Ruksha.*	*Shothahara, Dipana, Pachana, Amadashanashaka, Kanthya.*

In pathogenesis of *Pratishyaya*, there occurs *Agnimandya*, leading to *Kleda Avastha*, *Amasanchay*a and *Srotorodha* in *Nasa Pradesha* causing vitiation of *Tridosha, Rasa- Rakta Dhatus* and *Pranavaha Sroto Dusti*. So, the treatment goal is to achieve *Agnidipan*a, *Amapschana* and *Srotoshodhana* of *Nasagata Srotos*. On analyzing the content of saina tablet, majority of the ingredients possess *Dipana, Pachana, Srotoshodhana, Tridosha Shamana* and *Balya* properties. The combination is having predominantly *Tikta, Kashya, Katu Rasa, Laghu, Rusha Guna, Ushna Virya* and *Katu Vipaka*. This helps in achieving *Kleda Shoshana* and *Srotoshodhana* thereby reducing nasal secretions and congestion. Due to *Ushna Virya* and *Katu Vipaka* of the ingredients, there occurs *Srotomarga Vivarana* improving sinus drainage. The main ingredients – *Mahasudarshana* extract is having Antipyretic, analgesic, Rasa Rakta *Dushtihara* and *Swasa Kasahara* properties. This helps in relieving the pain, nasal obstruction and cough associated with the disease. *Tribhuvana kirti rasa* is also having antipyretic and analgesic activity. *Guduchi* is considered as the best *Rasayana* drug having antipyretic, Anti-inflammatory, Anti- allergic, Analgesic and immunomodulatory activities. Due to these properties the medicine reduces inflammatory process and restores the resistance of nasal mucosa against infections. The *Bhavana dravyas* like *Tulsi*, *Vasa* and *Kantakari* have antibiotic, analgesic, antipyretic, anti-inflammatory, anti-tussive and immunomodulatory activities. These have site specific action on nasopharyngeal area thereby restoring its normalcy. Moreover, the process of Bhavana increases the potency of the medicine thereby rendering it effective in minimum dosage. The drug absorption rate and the bioavailability of the main ingredients are also enhanced by this process. Because of the site-specific action of the drugs in the *Nasa Pradesha*, acting at the level of Agni, *Ama*, *Srotas* and *Dhatus* Saina tablet is effective in the management of sinusitis (*Pratishyaya*)

CONCLUSION

Finding of present clinical trial indicates that administration of saina tablet in the patients of sinusitis is effective and safe. Hence saina tablet has definite role in management of sinusitis.

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