

Effectiveness of *Nimbasava Nasya* with *Sigru Beeja* in Acute Exacerbation of Chronic Rhino Sinusitis - A Comparative Clinical Trial

Research Article

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Abstract

Chronic Rhinosinusitis is defined as a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses lasting for more than 12 weeks. Acute exacerbation of Chronic Rhinosinusitis is defined as a sudden worsening of symptoms in a patient who has chronic sinusitis. According to the science of Ayurveda, *Dushta Pratisyaya* condition, is in proximity to chronic sinusitis. *Asava* (fermented formulation) is mentioned for *Virechana Nasya* (type of Errhine therapy). *Nimbasava* is a formulation of *Asava Kalpana* prepared with *Guggulu Tikthaka Gritha Yoga* explained in *Vaatavyadhi Chikitsa*. *Sigrubeeja* (seed of *Moringa Oleifera*) and *Saindhava* (rock salt) are explained among *Shirovirechana Gana* (a group of medicines that can be used for nasal administration). The study was conducted on 30 patients of chronic sinusitis who were randomly divided into two groups and were given treatment for 7 days and follow-up after for 3 months. Out of two groups, 15 patients were given *Virechana Nasya* with *Nimbasava*, *Sigru Beeja*, and *Saindhava* for 7 days. The other 15 patients were treated as a standard control group and given the modern conventional management with Amoxicillin Clavulanate 500 mg, Fluticasone nasal spray, and Otrivin nasal drops for 7 days. The statistical analysis of data was done with the Wilcoxon Signed Rank Test and Mann-Whitney U test. During this trial, it was observed that *Nimbasava Nasya* with *Sigrubeeja* is effective in acute exacerbation of Chronic Rhinosinusitis. Pain relieving action of this *Nasya* was statistically highly significant. It was also found that the effectiveness of *Nasya* is more in reducing the recurrence of acute exacerbations of Chronic Rhinosinusitis.

Keywords: Chronic rhinosinusitis, *Asava Nasya*, *Nimbasava*, *Sigru beeja*.

Introduction

Rhinosinusitis is a frequently occurring disease, with a significant impact on quality of life and health. Chronic Rhinosinusitis is defined as a group of disorders characterised by inflammation of the mucosa of the nose and paranasal sinuses lasting for more than 12 weeks. Acute exacerbation of CRS is defined as a sudden worsening of symptoms in a patient who has chronic sinusitis with the return of symptoms to baseline after treatment. Acute infection destroys normal ciliated epithelium and impairs drainage from the sinus. Pooling and stagnation of secretions in the sinus form an ideal medium for the growth of various pathogens(1). Clinical features include purulent nasal discharge, nasal obstruction, post-nasal discharge, headache, etc. The modern conventional management is antibiotics, anti-inflammatory drugs, and nasal

decongestant sprays. According to the Sinus and Allergy Health Partnership, CRS patients will suffer for decades due to the limitation of modern management and comorbid conditions such as asthma, allergy, or aspirin sensitivity(2).

While going through the Ayurvedic literature, the etiological factors, symptomatology, and complications of the disease '*Pratishyaya*'(3)(Coryza) seem to have proximity and compatibility with Rhinosinusitis. *Pratishyaya* the word itself indicates that it is a recurrent attack and can precipitate even due to minute etiological factors(4). Improper management of *Pratishyaya* leads to a severe and complicated condition called *Dushta Pratishyaya* which is very difficult to treat and causes a lot of complications like *Badhira* (difficulty in hearing), *Andhata* (reduced vision), *Ghrananasa* (reduced perception of smell) etc(5). *Theekshna Virechana Nasya* (nasal administration of drugs with strong potency) helps to expel the accumulated *Dosha* (humors) from the *Srothas* (channels) from its root and thus prevents the recurrence.

Acharaya Vagbata explains that *Asava* (fermented liquid medium) can be used for *Nasya Karma*(6). *Nimbasava* is a formulation of *Asava Kalpana* prepared with *Guggulu Tikthaka Gritha Yoga*

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explained in *Vathavyadhi Chikitsa. Guggulu Tiktaka*(7) is an excellent preparation indicated in respiratory diseases, locomotor, and nervous system disorders, ulcers, and many other diseases. The main ingredients are *Guggulu* and *Pancha Tiktaka* drugs (*Azadirachta indica* A. Juss., *Tinospora cordifolia* (Willd.) Hook.f. and Thoms, *Adhatoda vasica* Nees, *Trichosanthes dioica* Roxb and *Solanum xanthocarpum* Schrad. & Wendl.) which have antibacterial, fungicidal and anti-inflammatory properties. Hence, it is made as a *Sandhana Kalpana*, which has *Vyavayi and Sookshma Guna*, thus penetrating the *Sukshma Srothas*. It will accelerate the mucociliary drainage and thus help the clearance of sinuses.

Even though the reference is available in the literature, no initiation has been made in practicing 'Asava Nasya' and no studies on this topic have been conducted yet. *Nimbasava* along with *Sigrubeeja* and *Saindava* is found to be very cost effective. In this study, an effort has been made to evaluate the effectiveness of *Virechana Nasya* in acute exacerbation of Chronic Rhinosinusitis in comparison with modern conventional management.

Materials and Methods

Selection of Cases

The study was conducted on 30 diagnosed patients with acute exacerbation of Chronic Rhinosinusitis. The patients were selected from O.P.D. and I.P.D. of Govt Ayurveda College, Tripunithura, and Private hospital, Ernakulam with a computer-generated random table.

Intervention

- Group A- In this group 15 patients were registered and given *Virechana Nasya* with *Nimbasava*, *Sigr Beeja*, and *Saindava*.
- Group B- The Control group of 15 patients was on allopathic medication

Duration of trial: 7 days in each group

Dose of nasya: 8 *Bindu* in each nostril

Follow-up: was carried out for 3 months after the completion of treatment to see the recurrence rate and longstanding effect of therapy.

Diagnostic criteria :(Taskforce on Rhinosinusitis [TFR] 1996)

Table 1: Diagnostic criteria of Chronic sinusitis

Major Factors	Minor Factors
<ul style="list-style-type: none"> • Facial pain/ pressure • Nasal obstruction • Nasal discharge / discolored • post nasal drip • Hyposmia/ Anosmia • Purulence in examination • Fever (acute only) 	<ul style="list-style-type: none"> • Headache Fever (all nonacute) • Halitosis Dental pain • Fatigue • Cough • Ear pain/pressure/fullness

* Two major or One major with two minor criteria required.

Inclusion criteria

- Patients with the recurrence of the symptoms of CRS at least 4 times a year.
- Age: 18 - 60 years irrespective of gender, caste, and socio-economic status.
- Patients with written informed consent

Exclusion criteria

- Patients exhibiting gross anatomical distortion of the septum or Osteomeatal complex
- Patients with nasal polyp
- Persons contraindicated for *Nasyakarma*.
- Pregnant and lactating women.
- Patients with other systemic diseases like carcinoma, hypertension, DM, and cardiac diseases.

Intervention

In group A (trial group)

Nasya with *Nimbasava*(2ml), *Sigr Beeja* powder (3 pinch), *Saindava* (1 pinch) mixed well and strained . From this, 8 *Bindu* in each nostril at morning 8 am.

Purva Karma

Mukha Abhyanga with *Ksheerabala Taila*. *Swedana* over face and neck with closed and packed eyes.

Pradhana Karma

In *Pradhana Karma*, the drug in liquid form is administered into the nostrils in *gokarna* in the head-low position of the patient and massage over the face.

Paschat Karma

Dhoomapana

3 puffs of *dhooma* inhale through nose and exhale through mouth. *Kabala* with luke warm water.

In group B (Control group)

Oral administration of Amoxicillin Clavulanate 500 mg bd for 5 days, Fluticasone nasal spray, and otrivin nasal drops for 14 days.

Assessment criteria

Table 2: Assessment scale of symptoms

Criteria	Symptoms	Score
Headache and facial pain	Based on the VAS scale	0-10
	Nil	0
	Mild (easily tolerable)	1
	Moderate (bothersome hard to tolerate, interferes with daily routine)	2
Post nasal drip	Severe (so bad, which interferes with daily routine)	3
	Nil	0
	Occasionally present	1
	Frequently present	2
Nasal discharge	Continuous throughout	3

Nasal obstruction	Not a problem	0
	Very mild problem	1
	Moderate problem	2
	Fairly bad problem	3
	Severe problem which interferes daily routine.	4
Diminished sense of smell	No loss of smell	0
	Can't smell the mild odor	1
	Can't smell the moderate odor	2
	Can't smell a strong odor	3
Halitosis	No odor	0
	Barely noticeable	1
	Slight but noticeable	2
	Moderately noticeable	3
	Strongly noticeable	4
	Extremely strong which causes social stigma	5
Recurrence of exacerbations	No recurrence	0
	Once in three months	1
	Once in a month	2
	Twice in a month	3
	Once in a week	4
X-ray PNS	No opacification	0
	Partial opacification	1
	Total opacification	2

Observations

The observations made on 30 patients of Chronic Sinusitis showed that the maximum number of patients were of the age group of 21-30 years (40.6 %), females (63 %), Hindu (50 %), higher secondary passed (48%), married (67%), housewives (30 %), lower middle class (50 %), urban habitat (57 %). The majority of the patients had good sleep patterns (52%), *Vata- Pitha Prakriti* (27%), *Tamasa Prakriti* (53%), *Madhyama Sara* (48%), *Madhyama Samhanan* (60%), *Madhyama Satmya* (67%), *Madhyama Satva* (64%), *Madhyama Agni* (47%). The maximum *Nidana* (etiological factors) observed in patients shows that 63.33% of patients were using *Madhurarasa Pradhana Ahara* followed by *Guruahara* i.e. 60%. 30% of them were taking *Virudhanna* and 20% were taking oily food. 16.66% of patients were taking *Abhishyandi Ahara*. Among *Viharaja* factors 73.33% were habituated to *Ayayama*, 33.33% to *Divaswapna*, and 16.66% to *Ratrijagarana*. 23.33% were sleeping immediately after food intake. Among environmental factors 33.33% were exposed to cold atmosphere, 30% were affected with seasonal changes and 26.66% were exposed to polluted air. The chief complaints reported from the patients were headache and post-nasal drip (100%), nasal obstruction (93%), facial pain and nasal discharge (86.6%), halitosis (73%), and diminished sense of smell (40%).

Results

The clinical data presented here is based on the 30 patients of trial work.

Effect of therapy on chief complaints

In Group A (Wilcoxon signed rank test) (n=15) (Table 3)

The present study showed 75% relief in the headache which is highly significant statistically ($p < 0.001$), while 76% and 79% relief in facial pain and post nasal drip respectively observed which were also highly significant statistically. The study also shows 66.7 % relief in nasal discharge which was significant statistically (< 0.01) 64% relief in nasal obstruction which was also significant statistically (< 0.01), 73% relief noted in a diminished sense of smell which was statistically significant (< 0.01), 65% relief noted in halitosis which was significant statistically (< 0.01), 87% change noted in non-recurrence of symptoms which was statistically highly significant (< 0.001) and 42% change noted in X-ray PNS which was also statistically significant (< 0.05).

Table 3: Effect of Virechana nasya in 15 patients of chronic sinusitis in group A

Symptoms	Mean value			% relief	SD	P value
	BT	AT	D			
Headache	8.4	2.1	6.3	75%	1.5	<0.001
Facial pain	4.5	1.1	3.4	76%	2.3	<0.01
Post nasal drip	2.5	0.53	1.97	79%	0.51	<0.01
Nasal discharge	1.8	0.6	1.2	66.7%	0.73	< 0.01
Nasal obstruction	2.5	0.9	1.6	64%	1.06	<0.01
Diminished sense of smell	1.47	0.4	1.07	73%	1.2	<0.01
Halitosis	1.53	0.53	1	65%	1.2	<0.01
Recurrence of exacerbations	3.1	0.4	2.7	87%	0.79	<0.001
X-ray PNS	1.26	0.73	0.53	42%	0.45	<0.05

In Group B (Wilcoxon signed rank test) (n=15) (Table 4)

The present study showed 85% relief in the headache which is highly significant statistically ($p < 0.001$), while 92 % and 100 % relief in facial pain and post nasal drip respectively observed which were also highly significant statistically ($p < 0.001$). The study also shows that 91 % relief in nasal discharge which was significant statistically (< 0.01) 88% relief in nasal obstruction which was also significant statistically (< 0.01), 63% relief noted in a diminished sense of smell which was statistically significant (< 0.01), 74 % relief noted in halitosis which was significant statistically (< 0.01), 28 % change noted in non-recurrence of symptoms which was statistically significant (< 0.05) and 48% change noted in X-ray PNS which was also statistically significant (< 0.05).

Table 4: Effect of modern treatment in 15 patients of chronic sinusitis in group B

Symptoms	Mean value			% relief	SD	P value
	BT	AT	D			
Headache	7.4	1.13	6.27	85%	1.5	<0.001
Facial pain	5	0.4	4.6	92%	1.9	<0.001
Post nasal drip	2.3	0	2.3	100%	0.51	<0.001
Nasal discharge	1.46	0.13	1.33	91%	0.35	<0.001
Nasal obstruction	2.46	0.3	1.16	88%	1.18	<0.001
Diminished sense of smell	0.8	0.3	0.5	63%	1.2	<0.01
Halitosis	1.8	0.47	1.33	74%	1.4	<0.01
Recurrence of exacerbations	2.5	1.8	0.7	28%	0.9	<0.05
X-ray PNS	1.27	0.67	0.6	48%	0.45	<0.05

Comparison of Group A & Group B

When the two groups were compared by the Wilcoxon Mann Whitney U test, the U value obtained after follow-up in the case of recurrence of symptoms was 3 which is statistically highly significant. Even though the treatment given was statistically significant in each group, the reduction in recurrence of symptoms obtained in Group A in comparison with Group B was statistically significant (p<0.01).ie treatment provided in both groups was not equally effective. The control group got better results in all symptoms except in the diminished sense of smell and the rate of recurrence of exacerbations. The trial group showed statistically highly significant results in reducing the recurrence of exacerbations in comparison with the control group.

Table 5: Comparison of Group A & Group B

Symptoms	Group A- AT (Asava Nasya)	Group B- AT (Allopathic management)	U value -AT (Wilcoxon Mann Whitney U)	P value
Headache	75%	85%	105	>0.05
Facial pain	76%	92%	74	>0.05
Post nasal drip	79%	100%	97	>0.05
Nasal discharge	67%	91%	104	>0.05
Nasal obstruction	64%	88%	43	<0.05
Diminished sense of smell	73%	63%	54	>0.05
Halitosis	65%	74%	101	>0.05
Recurrence of exacerbation	87%	28%	3(AF)	<0.01
X-ray	42%	48%	23(AF)	>0.05

Discussion

Nasya is the chief *Sodhana* procedure selected because this is the one and only procedure which can

perform *Uttamangashudhi*. There are mainly three types of nasya ie *Shamana*, *Virechana* and *Brimhana*. Among these *Virechana nasya* is indicated for *Shirasoola* and *kaphapradhana roga*. Here *Virechana nasya* is selected as here the aim is to expel out the accumulated Dosha from the sinuses. The medicines indicated for *virechana nasya* are *Sneha* processed with *Theekshna dravya*, *Kalka*, *Madhu*, *Saindhava* and *Asava*. Here *taila nasya* will not be beneficial because of the physical weight it exerts over the ciliary mucosa which may hamper the mucociliary clearance. This may be the reason for contra indication of *Tailanasya* in *Navapeenasa*. The lower the molecular weight, higher will be the absorption of drug through the nasal mucosa.

Thus *asava kalpana* was selected which assumed to spread fastly over the mucosa , which absorbs rapidly through the mucosal lining through its *theekshna*, *sookshma*, *vyavayi* nature. Since it is an alcoholic medium, the ph will be acidic , the absorption of drugs through the mucosa will be more in acidic medium. The pH of nasal mucosa is approximately 5.5 to 6.5⁸. during the phase of infections it changes to alkaline pH eg.. sinusitis – 6.8 to 7.6, rhinitis – 7.2 to 8.3. Here pH of this nasya yoga is found to be 3.8.

Selection of drugs

Nimbasava is an *asava kalpana* of *Guggulutikthaka yoga* mentioned in *vatha vyadhi chikitsa*. It is formulation indicated in *sarva urdhwa jathrugatarogas*, *peenasa*, *swasa* and *kasa* also has its action on deeper *dhathus*, *vathakapha hara* property. The main ingredients are *guggulu* and *pancha tikthaka drugs*; which has anti bacterial, fungicidal and anti inflammatory properties. *Sigrubeeja* (seeds of *Moringa oleifera* Lam.) is one among *Shirovirechanagana* explained in *Brihathrayee* which has *theekshna*, *ushna*, and *kaphavathahara* properties. *Acharya Bhavaprakasa* specifically indicated *sigrubeejanasya* for *shirasoola*. On adding *saindhava* to this nasya yoga, the piercing property of the medicine increases as it has *sookshma*, and *lekhana* property. The combination of these drugs can be used for *virechana nasya* for expelling vitiated *doshas* from *shiras*. This combination of nasya yoga is having dominance of *thikta rasa* (71%) followed by *katu rasa*(65%), *virya* of the formulation can be considered *ushna* (78%). *Nasya* yoga is found to have *kapha vata hara* property.

Probable Mode of Action

The individual properties of each drug add up to make *kaphavatahara* action with *sookshma*, *teekshnaguna* altogether. These properties helped in easy penetration and removal of obstruction in the nasal *ostia* facilitating easy expulsion of *dushtakapha* lead to *vaatanulomana*. These drugs helped in *draveekarana* (liquefaction) and *chedana* (expulsion) of vitiated Dosha.

The *samyak nasya lakshana* mentioned by *Acharyas* clearly indicates that nasya has specific role in pacifying the symptoms of Chronic sinusitis. Moreover *sadya sleshma virecana* action of *nasya* is also clearly mentioned in *Astangasamgraha*.

The *Swedana* before *Nasya karma* liquifies the *utklishta kapha* and augments its expulsion out of various *srotas*. It has mucolytic effect. *Swedana* also causes vasodilatation which in turn increases the permeability of blood vessels. This also leads to faster absorption of drug.

The instillation of medicine in a head low position appears to be the most effective way of decongesting the ostia of the sinuses. The momentary hyperaemia helps in easy drug absorption via the rich vascular plexus of the nose and thus directly enter circulation. Thus *nasya* becomes the least expensive *sodhana* with multifaceted utility and quicker action. *Dhoomapaana* is also done to expel residual mucous lodged in *naasa* and *kantha*. *Kabala* removed the *upalepatva* & adhered *kapha* in *vaktra*. No side effect was noticed in the patients except that slight irritation and burning sensation in nose and throat which was reported by 95 % cases, which was relieved in no time.

Group B patients, were treated with oral administration of Amoxicillin Clavulanate, Fluticasone nasal spray, and otrivin nasal drops (control group). Statistically highly significant changes were found in most of the symptoms i.e., headache, facial pain, post nasal drip, nasal discharge, and nasal obstruction. Significant changes were noted in the rest of the symptoms. These drugs are directly indicated in the treatment of acute sinusitis.

Conclusion

It is concluded that *Virechana Nasya* with *Nimbasaava*, *Sigrubeeja*, and *Saindhava* is highly effective in alleviating the symptoms of acute exacerbation of chronic sinusitis. Allopathic drugs were slightly more effective and sudden relief was noted on the symptoms except in diminished sense of smell. However, the result was not sustained during and after follow-up in the control group. The research showed a long-term sustained effect of *Virechana Nasya* during and after the follow-up period. No severe adverse effect of the trial drug was observed during the study.

References

1. Dhingra P. L. Diseases of Ear Nose and Throat. Reed Elsevier India private limited. New Delhi 4th edition reprint 2007. chapter 37, pg.no185
2. Philpott CM, Erskine S, Hopkins C, Kumar N, Anari S, Kara N, Sunkaraneni S, Ray J, Clark A, Wilson A; CRES group; Erskine S, Philpott C, Clark A, Hopkins C, Robertson A, Ahmed S, Kara N, Carrie S, Sunkaraneni V, Ray J, Anari S, Jervis P, Panesaar J, Farboud A, Kumar N, Cathcart R, Almeyda R, Khalil H, Prinsley P, Mansell N, Salam M, Hobson J, Woods J, Coombes E. Prevalence of asthma, aspirin sensitivity and allergy in chronic rhinosinusitis: data from the UK National Chronic Rhinosinusitis Epidemiology Study. Respir Res. 2018 Jun 27;19(1):129. doi: 10.1186/s12931-018-0823-y. PMID: 29945606; PMCID: PMC6020303.
3. Yadavji Trikamji Acharya. Nibandhasangraha Commentary of Sri Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana of Susrutasamhita. Chaukhamba Surbharathi Prakshan; Sutrasthana 1/7.
4. Amarsingha .Amarakosha with commentary of Bhanuji Dikshita; IInd edition (1982), Chaukhambha Sanskrit Sansthan, Varanasi.
5. Shusruta, Nibandhasangraha Commentary of Sri Dalhanacharya and Nyayachandrika Panjika of Sri Gayadasacharya on Nidanasthana of Susrutasamhita Sutrasthana 24/15-17
6. Vaidya Yadavji Trikamji Acharya. Sarvangasundara of Arunadatta and Ayurvedarasayana of Hemadri on Astangahridayam, Chaukhamba SurbharatiPrakashan Varanasi, Edition reprint 2005. Sutra sthana 20/1
7. Vagbhata, Ashtanga Hridaya Sarvangasundara of Arunadatta and Ayurveda Rasayana of Hemadri, Chowkhamba surbharati Prakashan, Varanasi, 2007, Chikitsa sthana chapter 21 shloka 57 , page 726
8. England RJ, Homer JJ, Knight LC, Ell SR. Nasal pH measurement: a reliable and repeatable parameter. Clin Otolaryngol Allied Sci. 1999 Feb ; 24 (1) : 67 - 8 . doi : 10.1046/j.1365-2273.1999.00223.x. PMID: 10196653.
