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# THE EFFICACY OF SHIROSHOOLAGHNA NASYA AND NIMBADI GUGGULU IN THE MANAGEMENT OF KAPHAJA SHIRO ROGA WITH SPECIAL REFERANCE TO SINUSITIS

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# **ABSTRACT**

Shalakya Tantra is one among eight branches of Ayurveda which deals with the diseases of eye, ear, nose and throat along with teeth, oral cavity and diseases of head. Since it treats ailments above the neck, this branch of Ayurveda is also known as Urdhawanga chikitsa. All great classical texts of Ayurveda deal with Shalakya Tantra but in Sushruta Samhita there is detail description of the diseases pertaining to Shalakya Tantra. Almost all our ancient Acharyas have mentioned about the Shiroroga of which Shirahshoola i.e. headache is the leading symptom and also they have taken Shirah shoola as the synonym of Shiroroga. Acharaya Sushruta has mentioned 11 types of Shiroroga in Uttar Tantra and Kaphaja Shiroroga is one of them .On the basis of these clinical features, Kaphaja Shiroroga can be correlated to sinusitis in modern science. Sinusitis is a major problem in the society due to its recurrent exacerbations and complications. The treatment of sinusitis includes antibiotics, decongestants, antihistamines, analgesics and

surgical procedures. Although these treatments provide their best contributions towards the healing process, but sinusitis is not successfully combated due to its recurrence. The side – effects of the analgesics and antibiotics are well – known. Nasal decongestants have the potential for rebound congestion and development of rhinitis medicamentosa. Antihistamines dry and thicken nasal secretions; they make sinus drainage difficult and may worsen sinusitis. Added to this, the surgical procedures are expensive, and invite complications. In view of

magnitude of the problem, there is a need to elucidate a therapy within reach of the patient, free from side effects and having curative properties. Considering all the above factors, Nasya with Shiroshoolaghna and Nimbadi Guggulu orally were selected which are specifically indicated in Kaphaja Shiroroga. Randomized, open label, and parallel group trial was conducted involving 30 patients divided into two groups.

**KEYWORDS:** Nasal decongestants have the potential for rebound congestion and development of rhinitis medicamentosa.

# INTRODUCTION

Sinusitis is defined as inflammation of paranasal sinuses. Paranasal sinuses are air filled chambers in the skull (behind the forehead, nasal bones, cheeks, and eyes) that are lined with mucus membrane which is continuous with that of nasal cavity. There are four paired paranasal sinuses: maxillary, ethmoid, sphenoid, and frontal. Normally each is filled with air and communicates with the nasal lumen through an ostium. Secretions produced in the sinuses flow by ciliary action through the ostia and drain into the nasal cavity. Because the nasal mucosa is simultaneously involved and because sinusitis rarely occurs without concurrent rhinitis, rhinosinusitis is now the preferred term for this condition.

Sinusitis is a major problem in the society due to its recurrent exacerbations and complications. Due to increased environment pollution and busy life style in present era, incidence of rhinitis is increasing which leads to sinusitis if not properly treated. Signs and symptoms of sinusitis are headache, pain and swelling of affected sinus, heaviness in head, nasal discharge, nasal obstruction, post nasal drip, low grade fever, halitosis, anorexia, periorbital swelling, lassitude etc.

Rhinosinusitis is one of the most commonly diagnosed chronic illnesses occurring annually. On the basis of clinical features, Kaphaja Shiroroga can be correlated to sinusitis in modern science In Kaphaja Shiroroga, vitiated Kapha Dosha accumulates in Shiras causing obstruction in Srotas of head. Aacharyas have mentioned that the drugs used for the treatment of Kaphaja Shiroroga should have Katu, Ruksha, Ushna and Teekshna properties for removal of Kapha and Shodhana of Srotas. The contents of Shiroshoolaghna nasya and Nimbadi Guggulu have these properties along with analgesic, antibiotic and anti-inflammatory effect and thus help in breakdown of the pathogenesis of sinusitis.

In Ayurveda, Nasya is the chief procedure to remove Doshas (infectious material) from Shiras as it is quoted that "Nasa hi Shiraso Dwaram". In Kaphaja Shiroroga treatment Shirovirechana (Shodhana) Nasya is recommended. The term "Shirovirechana" itself denotes the process of cleansing of head. Hence Avapeeda Nasya (comes under Shirovirechana type) with Shiroshoolaghna due to its medicinal properties helps in removing the vitiated Kapha thereby clearing the Srotas (sinuses) situated in Shiras (skull and face).

Therefore the present study entitled "A Clinical Study on the Efficacy of Shiroshoolaghna Nasya and Nimbadi Guggulu in the Management of Kaphaja Shiroroga w.s.r. to Sinusitis" had been designed to analyze and evaluate the complete concept and etiopathogenesis of sinusitis vis-à-vis Kaphaja Shiroroga based on clinical study, as a whole in light of Ayurvedic and modern concepts.

#### MATERIALS AND METHODS

#### AIMS AND OBJECTIVES

A clinical study on the efficacy of Shiroshoolaghna Nasya and Nimbadi Guggulu in the management of Kaphaja Shiro Roga with special reference to Sinusitis.

# STUDY DESIGN

The present study is an interventional, randomized, open label, and parallel group trial.

# SOURCE OF DATA

Patients attending the O.P.D. and I.P.D., Department of Shalakya Tantra, Sri Sai Ayurvedic P. G. Medical College & Hospital, Sarsol, Aligarh were screened for the present study.

For diagnosis, detailed medical history was taken and physical examination was done according to both Ayurvedic and modern clinical methods. A research proforma was prepared to study all the conditions of patients.

# **INCLUSION CRITERIA**

- Patients fulfilling the diagnostic criteria which were based on the signs and symptoms of Kaphaja Shiroroga explained in Ayurvedic classics and sinusitis as per modern science.
- Patients between the age group of 16 to 50 years.

### **EXCLUSION CRITERIA**

> Patients not willing for the trial were excluded.

- > Pregnant women.
- Patients aged below 8 years and above 80 years.
- ➤ Patients with chronic debilitating infectious diseases.
- ➤ Patients suffering from pain and facial swelling due to alveolar abscess, cellulitis of cheek, furuncle, angioneurotic oedema, trigeminal neuralgia, temporal arteritis.
- > Patients with malignancies of sinuses.

# **GROUPING OF PATIENTS**

In the present study 32 clinically diagnosed patients of Kaphaja Shiroroga (Sinusitis) were selected and randomly divided into two groups.. Out of these 32 patients 30 patients completed the trial.

Group – A: 15 patients of Kaphaja Shiroroga (Sinusitis) were given Shiroshoolaghna Nasya.

**Group – B:** 15 patients of Kaphaja Shiroroga (Sinusitis) were given Shiroshoolaghna Nasya and Nimbadi Guggulu orally.

#### FORMULATION OF THE DRUG

Shiroshoolaghna Nasya and Nimbadi Guggulu were prepared in the GMP certified pharmacy of Sri Sai Ayurvedic P. G. Medical College & Hospital, Sarsol, Aligarh, U.P. - 202001.

# NIMBADI GUGGULU

This formulation is described in Brihat Nighantu Ratnakar 6<sup>th</sup> part, Shiro roga adhikara for Kaphaja shiroroga. In the present study, it was prescribed as two tablets of 500 mg each in morning and evening for 30 days. Contents are.

- ✓ Nimba.
- ✓ Vibhitaka.
- ✓ Aamalki.
- ✓ Haritaki.
- ✓ Vasa.
- ✓ Katu Patola.
- ✓ Guggulu.

# SHIROSHOOLAGHNA NASYA

This yoga is described in **Bhaisajya Ratanavali Shiro roga adhikara** (65/71). In its preparation Spatika powder and Karpura powder were taken in the given amount and mixed. The powder was rubbed with water and given through nose in the form of Avapeeda nasya in

the dose of 2 drops in each nostril for 5 days with 7 days gap in between two sittings. Contents are.

- ✓ Spatika.
- ✓ Karpura.

# ADMINISTRATION OF DRUGS

# i) Shiroshoolaghna Nasya

- **Dose:** 2 drops per nostril.
- **Duration:** Two sittings of 5 days with interval of 7 days.
- Route and form of Administration: Nasal route by means of Nasya in the form of drops.

# ii) Nimbadi Guggulu

- **Dose:** 2 tablets of 500 mg twice daily with luke warm water.
- **Duration:** 1 month.
- Route and form of administration: Orally in the form of tablets.

# **INVESTIGATIONS**

- X-Ray PNS
- Hb%, TLC, DLC, ESR
- Absolute eosinophil count

# **FOLLOW UP**

A follow – up was done for one and half month after completion of the treatment at fortnight intervals to check status of the patients.

# DISCONTINUATION CRITERIA

Patient who discontinued the treatment for some reason or did not returned for the final follow up were discontinued from study.

# **ASSESSMENT CRITERIA**

For assessment of the efficacy of the trial therapy, both subjective and objective parameters were adopted.

# **Subjective Criteria**

Sr.	Symptoms	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
1.	Shiroabhitapa (Headache)	No headache	Occasionally with low intensity	Frequently with moderate intensity but not disturbing daily work	Always with moderate intensity and sometimes disturbing routine work	Always with severe intensity and disturbing the routine work
2.	Shiroguruta (Heaviness in head)	No heaviness	Mild (heaviness on forward bending)	Moderate (frequent heaviness not disturbing routine work)	Severe (continuous heaviness disturbing routine work)	
3.	Galam Kaphaupadi gdam (Post nasal drip)	No post nasal discharge	– Frequent	Continuous		
4.	Shunakshikoota vadanam (Periorbital and facial oedema)	No periorbital and facial swelling	Mild and intermittent swelling on upper orbital area	Moderate, persistent swelling involving upper and lower orbital area	Severe swelling involving complete face	
5.	Nasal obstruction	No obstruction	Partially, occasionally and unilateral	Partially, occasionally and bilateral	Complete, frequently and unilateral	Always, complete and bilateral
6.	Nasal discharge	No discharge	Occasional	Frequent	Continuous and heavy	
7.	Tenderness over sinuses	No tenderness	Mild tenderness (pain on high pressure)	Moderate tenderness (pain on moderate pressure)	Severe tenderness (pain on mild pressure)	

Sr. no.	Sinus	Right	Left	Total
1	Maxillary (0,1,2,3)			
2	Frontal (0,1,2,3)			
3	Ethmoid (0,1,2,3)			
Overall t	otal score			

# **Objective Criteria**

# 1) Haziness in sinuses in X-ray

- 0 no abnormality
- 1 Partial opacification
- 2 Total opacification

(Modified from Lund-Mackay Score)

Sr. no.	Sinus	Right	Left	Total
1	Maxillary (0,1,2)			
2	Frontal (0,1,2)			
3	Ethmoid (0,1,2)			

# **OVERALL TOTAL RESULTS**

The pattern of clinical improvement in various subjective and objective parameters were recorded and measured statistically in two groups, by using Graph pad instat 3 and the obtained results are as follows.

# SHOWING EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS IN GROUP – A.

S.	Symptoms	Mo	ean	Dif.	% of	SD	SE	W	P	Results
No.	Symptoms	BT	AT	DII.	Change	שט	SE	VV	r	Results
1	Shiroabhitapa (Headache)	1.86	0.66	1.20	64.27	0.86	0.22	78	0.0005 p<0.001	ES
2	Shiroguruta (Heaviness in head)	1.33	0.33	1.00	75.01	0.65	0.16	78	0.0005 p<0.001	ES
3	Kaphaupadigdam Galam (Post nasal drip)	0.93	0.46	0.46	50.02	0.63	0.16	21	0.0313 p<0.05	S
4	Shunakshikootavadanam (Periorbital and Facial edema)	0.26	0.06	0.20	74.99	0.41	0.10	6	0.2500 p>0.05	NS
5	Nasal obstruction	1.86	0.86	1.00	53.56	0.65	0.16	91	0.0002 p<0.001	ES
6	Nasal discharge	1.20	0.46	0.73	61.10	0.70	0.18	45	0.0039 p<0.01	VS
7	Tenderness over sinuses	2.40	0.66	1.73	72.20	1.98	0.51	36	0.0078 p<0.01	VS

# SHOWING EFFECT OF THERAPY IN OBJECTIVE PARAMETERS IN GROUP - A

S.	S. S.		Mean		% of	SD	SE	$\mathbf{w}$	D	Results
No.	Symptoms	BT	AT	Dif.	Change	SD	SE	VV	r	Results
1.	Haziness in sinuses in X-ray PNS	5.40	4.26	1.13	20.98	0.74	0.19	78	0.0005 p<0.001	ES

# ANALYSIS OF PARAMETERS OF GROUP - A

- Statistically Extremely Significant (p<0.001) results were found in Shiroabhitapa/Headache (64.27%), Shiroguruta/Heaviness in head (75.01%), Nasal obstruction (53.56%) and Haziness in sinuses in X-ray PNS (20.98%).
- Statistically Very Significant (p<0.01) results were found in Nasal discharge (61.10%) and Tenderness over sinuses (72.20%).

- Statistically Significant (p<0.05) result was found in Kaphaupadigdam Galam/ Post nasal drip (50.02%)
- Statistically Not Significant (p>0.05) result was found in Shunakshikootavadana/ Periorbital and Facial edema (74.99%).

# SHOWING EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS IN GROUP – B.

S.	Comptoms	Me	ean	Dif.	% of	SD	SE	W	P	Results
No.	Symptoms	BT	AT	DII.	Change	SD	SE	VV	r	Results
1	Shiroabhitapa (Headache)	1.86	0.60	1.26	67.86	1.10	0.28	66	P=0.001	ES
2	Shiroguruta (Heaviness in head)	1.93	0.66	1.26	65.54	0.70	0.18	91	0.0002 p<0.001	ES
3	Kaphaupadigdam Galam (Post nasal drip)	1.13	0.46	0.66	58.84	0.61	0.15	45	0.0039 p<0.01	VS
4	Shunakshikootavadanam (Periorbital and Facial edema)	0.20	0.06	0.13	66.65	0.35	0.09	3	0.5000 p>0.05	NS
5	Nasal obstruction	1.40	0.53	0.86	61.90	0.63	0.16	66	P=0.001	ES
6	Nasal discharge	1.13	0.26	0.86	76.49	0.83	0.21	45	0.0039 p<0.01	VS
7	Tenderness over sinuses	3.40	0.86	2.53	74.50	3.33	0.86	36	0.0078 p<0.01	VS

# SHOWING EFFECT OF THERAPY IN OBJECTIVE PARAMETERS IN GROUP - B

S	Symptoms	Me	Mean Dif.		% of	SD	SE	W	р	Results
No	Symptoms	BT	AT	DII.	Change	SD	SE	**	1	Results
1.	Haziness in sinuses in X-ray PNS	6.20	4.06	2.13	34.40	2.23	0.57	66	P=0.001	ES

# ANALYSIS OF PARAMETERS OF GROUP - B

- Statistically Extremely Significant (p≤0.001) results were found in Shiroabhitapa/Headache (67.86%), Shiroguruta/Heaviness in head (65.54%), Nasal obstruction (61.90%), and Haziness in sinuses in X-ray PNS (34.40%).
- Statistically Very Significant (p<0.01) results were found in Kaphaupadigdam Galam/ Post nasal drip (58.84%), Nasal discharge (76.49%), and Tenderness over sinuses (74.50%).
- Statistically Not Significant (p>0.05) result was found in Shunakshikootavadana/Periorbital and Facial edema (66.65).

# INTERGROUP COMPARISION

To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric in subjective and objective parameters so we used Mann-Whitney Test. The results are as follows.

# INTERGROUP COMPARISON OF SUBJECTIVE PARAMETERS OF KAPHAJA SHIROROGA

S.	Symptoma	Me	ean	SD		SE		U	P	Results
No.	Symptoms	$G_{A}$	$G_{B}$	$G_{A}$	$G_B$	$G_{A}$	$G_{B}$	U	r	Results
1	Shiroabhitapa (Headache)	1.20	1.26	0.86	1.10	0.22	0.28	113.50	>0.05	NS
2	Shiroguruta (Heaviness in head)	1.00	1.26	0.65	0.70	0.16	0.18	136.50	>0.05	NS
3	Kaphaupadigdam Galam (Post nasal drip)	0.46	0.66	0.63	0.61	0.16	0.15	133.50	>0.05	NS
4	Shunakshikootavadanam (Periorbital and Facial edema)	0.20	0.13	0.41	0.35	0.10	0.09	120	>0.05	NS
5	Nasal obstruction	1.00	0.86	0.65	0.63	0.16	0.16	121	>0.05	NS
6	Nasal discharge	0.73	0.86	0.70	0.83	0.18	0.21	121.50	>0.05	NS
7	Tenderness over sinuses	1.73	2.53	1.98	3.33	0.51	0.86	122	>0.05	NS

# INTERGROUP COMPARISON OF OBJECTIVE PARAMETER OF KAPHAJA SHIROROGA

S.	Symptoms	Me	ean	S	D	S	E	TT	D	Results
No	Symptoms	$G_{A}$	$G_{B}$	$G_{A}$	$G_{B}$	$G_{A}$	$G_{B}$	U	r	Results
1	Haziness in sinuses in X-ray PNS	1.13	2.13	0.74	2.23	0.19	0.57	138	>0.05	NS

Intergroup comparison of efficacy of two therapies on subjective and objective parameters of Kaphaja Shiroroga/Sinusitis as per table no. 36 and 37 shows that all the parameters have p value >0.05 which is statistically Not Significant. This shows that there is no statistical difference in efficacy of both treatments.

# SHOWS THE % WISE IMPROVEMENT IN SIGNS AND SYMPTOMS OF BOTH GROUPS

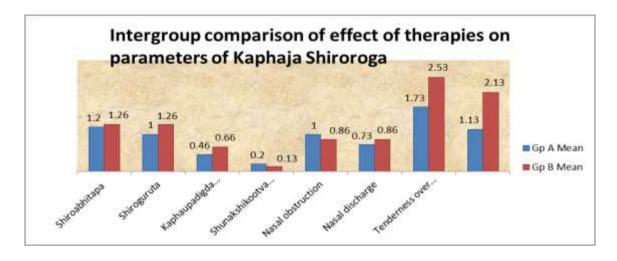
C No	Condinal symptoms	Result in	percentage
S. 140.	Cardinal symptoms	Group A	Group B
1	Shiroabhitapa (Headache)	64.27	67.86
2	Shiroguruta (Heaviness in head)	75.01	65.54
3	Kaphaupadigdam Galam (Post nasal drip)	50.02	58.84
4	Shunakshikootavadanam (Periorbital and Facial edema)	74.99	66.65
5	Nasal obstruction	53.56	61.90
6	Nasal discharge	61.10	76.49

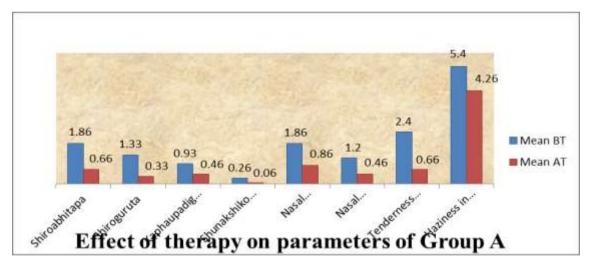
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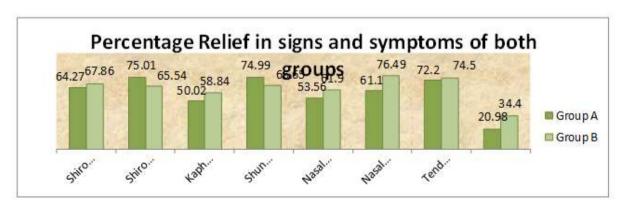
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7	Tenderness over sinuses	72.20	74.50
8	Haziness in sinuses in X-ray PNS	20.98	34.40
Average Percentage of relief		59.07	63.27

Comparing the symptomatic improvement in both groups it was found that average percentage of relief was higher in Group B i.e. 63.27%, followed by Group A i.e. 59.07%. It shows that effect of therapy was a little more in Group B in comparison to Group A.







# **DISCUSSION ON RESULT**

# Effect of therapy on subjective and objective parameters in both groups

- Relief in the symptom of **Shiroabhitapa** (**Headache**) was 64.27% in Group A (p<0.001) and 67.86% in Group B (p=0.001) and all these values were statistically extremely significant.
- Results of therapy in symptom of **Shiroguruta** (Heaviness in head) in patients of both the groups were statistically extremely significant (p<0.001). The percentage of relief was 75.01% and 65.54% in Group A and Group B respectively.
- Relief in the symptom of **Kaphaupadigdham Galam (Post nasal drip)** was 50.02% in Group A (p<0.05) which is statistically significant and 58.84% in Group B with p<0.01 which is very significant statistically.
- Results of therapy in symptom of Shunakshikootavadanam (Periorbital and Facial edema) in patients of both the groups were statistically not significant (p>0.05). The percentage of relief was 74.99% and 66.65% in Group A and Group B respectively.
- In Nasal obstruction, 53.56% relief was observed in Group A which is statistically extremely significant (p<0.001) and 61.90% relief was found in Group B which is statistically extremely significant (p=0.001).
- Effect of therapy on Nasal discharge was 61.10 % in Group A, while 76.49 % in Group B. Both these values are statistically very significant (p<0.01). But Group B showed better result.
- Results of therapy in symptom of **Tenderness over sinuses** in patients of both the groups were statistically very significant (p<0.01). The percentage of relief was 72.20% and 74.50% in Group A and Group B respectively.
- 20.98% of improvement in **Haziness in sinuses** in X-ray PNS was observed in Group A (p<0.001) and 34.40% were in Group B (p=0.001), both of them were statistically extremely significant.

# Comparison of effect of therapy in both the groups

Intergroup comparison of efficacy of two therapies on subjective and objective parameters of Kaphaja Shiroroga/sinusitis shows that all the parameters have p value >0.05 which is statistically not significant. This shows that there is no statistical difference in efficacy of both treatments.

But on comparing the symptomatic improvement in both groups it was found that average percentage of relief was higher in 'Group B' i.e. 63.27%, followed by Group A i.e. 59.07%. It shows that effect of therapy was a little more in Group B in comparison to Group A.

It is clear from the above description that in both the group statistically extremely significant relief was observed in symptoms like headache, heaviness in head and nasal obstruction and very significant results in nasal discharge and tenderness over sinuses. It could be attributed to Avapeeda nasya which is a Shodhana nasya. Here Purvakarma i.e. Abhyanga helped in Dosha Mardavkaran, steam inhalation helped in Kapha Vilayana and Nasya being Vyadhi pratyanika helped in relieving the symptoms. Nasya dravyas are quickly absorbed and produce rapid local and systemic effects. Nasya dravyas in Shiroshoolaghna Nasya have proven anti-inflammatory, Kaphavataghna and Teekshna property which helped in mucociliary clearance. These drugs helped in relieving mucosal edema, clearing nasal obstruction. Mechanical obstruction in sinus ostia was removed, thereby causing free drainage of mucous from the sinuses.

Average percentage of relief was more in Group B treated with Shiroshoolaghna nasya and internal medication of Nimbadi Guggulu. Nimbadi Guggulu, mentioned in the classic for Duhsaha (unbearable) Shiroruja of Vata-Kapha origin, a combination of Nimba, Triphala, Patola Vasa and Guggulu, have proven Shothahara (anti-inflammatory), Vednahara (analgesic), antimicrobial and immune modulatory effects. Thus it helped in reduction of inflammation and infection and thereby sinuses get proper drainage and ventilation. Thus shirashoola was reduced.

# **CONCLUSION**

- In management of Kaphaja Shiroroga, main concentration is given to the Dosha Apkarshana from Urdhvajatru Pradesha and the main treatment which can drain the retained discharge (vitiated Kapha) from the sinuses is Shodhana Nasya.
- Nose being the doorway to head and Nasya drug extracts the morbid Doshas from the head. Therefore Shiroshoolaghna Nasya which is a teekshna Avapeeda nasya was selected and administered in group A and in group B it was combined with Nimbadi Guggulu orally to evaluate its role with or without internal medications
- ✓ In present study it was found that maximum patients were having chronic type of sinusitis
  and the sinuses affected were maxillary (maximum) followed by ethmoid and frontal.

- Statistically extremely significant results were found in Headache, Heaviness in head, Nasal obstruction and Haziness in sinuses and very significant results were found in nasal discharge and tenderness over sinuses in both group.
- The symptomatic improvement was considerable in all the subjective parameters. But the overall percentage change was less in haziness in sinuses in X ray PNS.
- On inter group comparison of all assessment criteria, no statistically significant difference was observed between two therapies. However average percentage of relief (symptomatic improvement) was higher in Group B which received combined treatment followed by Group A which received only Nasya therapy.
- Hence it can be concluded that combined use of Nimbadi Guggulu and Shiroshoolaghna Nasya is more effective for controlling the disease Kaphaja Shiroroga (Sinusitis).

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