

# Effect of Medicated Oil of *Alpinia galanga* (L) Willd. *Nasya Karma* in Patients with *Kaphaja Shira Shula* W.S.R. to Chronic Sinusitis



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# Introduction

- In Traditional Medicine *Kaphaja Shira Shula* has been known with Chronic sinusitis according to previous Ayurvedic researches
- The cardinal features of *Kaphaja Shira Shula* include headache and heaviness of head and the headache persists throughout the day and it may increase in night
- This condition is commonly associated with nasal discharge, nasal obstruction and post nasal discharge  
(Nagaraja, 2009)

# Introduction

- Chronic sinusitis is a common disease affecting over 30 million individuals globally each year with more than 200,000 people annually requiring surgical intervention  
(Deepthi *et al.*, 2012)

# Introduction

- ❑ The medicated oil of *Alpinia galanga* (L) Willd. is made up of rhizome of *A. galanga* (L) Willd. and sesamum oil in this study
- In Ayurvedic medicine 90% of the medicated oils are prepared with sesame oil base  
(Hebber, 2013)
- Pharmacological activities of *A. galanga* (L) Willd. in previous researches are anti-inflammatory, analgesic, antimicrobial activities, antibacterial activity, antifungal activity, and antioxidant activity  
(Kaushiket *al.*, 2011)

# Introduction

- It is believed that the properties of this medicated oil with *Nasya Karma* can be relieved the most signs and symptoms of *Kaphaja Shira Shula* due to aggravating of *Bahiddha Abandhana* by making to get functional property of *Akasha* as based on the concept of **Desana System of Medicine**

# Introduction

- ❖ There were 50 cases treated with *Nasya Karma* in ***Panchakarma Center*** of OPD in 100 bedded TMTH, Mandalay in 2012
- ❖ About 70% of these cases were *Kaphaja Shira Shula* W.S.R. to Chronic Sinusitis patients treated by *Nasya Karma* with medicated oils
- ❖ Therefore, it was planned to carry out clinical study for evidence based traditional medicine and to provide rational treatment for Chronic sinusitis in future

## Objectives

- 1) To assess the clinical presentation of *Kaphaja Shira Shula* patients before (day 0), during (day 8, day 16) and after treatment (day 24)
- 2) To determine the serial effect of the medicated oil of *A. galanga* (L) Willd. *Nasya Karma* in *Kaphaja Shira Shula* patients (day 0 with day 8, day 16 and day 24)

# Materials and Methods

## Study design

- ❑ Hospital based Quasi-clinical study

## Study area

- ❑ **Panchakarma Center** at Outpatient Department (O.P.D) of 100 Bedded TMTH, Mandalay



## Panchakarma Center at Outpatient Department (O.P.D) of 100 Bedded TMTH, Mandalay



## Study Population

- Thirty Three Patients with *Kaphaja Shira Shula* W.S.R. Chronic Sinusitis admitting O.P.D and attending I.P.D of 100 Bedded TMTH, Mandalay, during study period

## Study period

- The study period was started from 1<sup>st</sup> September 2013 to 31<sup>st</sup> October 2014

## Inclusion criteria

- 1) Patients above 8 years and below 80 years
- 2) Both sex
- 3) Patients with twelve weeks or longer duration of disease and two or more of the signs and symptoms of chronic sinusitis ; nasal discharge, post nasal discharge, nasal obstruction (congestion), facial pain or impaired sense of smell or heaviness of head or headache

## Exclusion criteria

1. Severe hypertension
2. Diabetes mellitus
3. Chronic alcohol drinker
4. Heavy smoker
5. Pregnant woman and lactating mother
6. Co-morbid diseases

Written informed consent was obtained from all subjects after thorough explanation about the purpose of this study

## Criteria for assessment

- 1) Headache
- 2) Heaviness of head
- 3) Nasal discharge
- 4) Post nasal discharge
- 5) Nasal obstruction
- 6) Impaired sense of smell
- 7) Facial pain

The radiological assessment - Sinus X-ray  
(Haziness/Fluid level)

### ❖ **Assessment for headache**

- 1) **Mild headache** - Headache and tenderness, patient does not clench the face when palpated
- 2) **Moderate headache** - Headache and tenderness, patient clenches the face when palpated
- 3) **Severe headache** - Headache, patient does not allow palpating the sinuses

### ❖ **Assessment for heaviness of head**

- 1) **Mild heaviness of head** - Feeling of heaviness in head during forward bending of neck once a week
- 2) **Moderate heaviness of head** - Feeling of heaviness in head during forward bending of neck more than once a week
- 3) **Severe heaviness of head** - Feeling of heaviness of head, though out the day

### **Assessment for nasal discharge**

- 1) **Mild nasal discharge** - Use <10 pieces of tissue  
(7.5 inches square) per 24 hours
- 2) **Moderate nasal discharge** - Use 10 – 20 pieces of  
tissue (7.5 inches square) per 24 hours
- 3) **Severe nasal discharge** - Use >20 pieces of tissue  
(7.5 inches square) per 24 hours

### **Assessment for nasal obstruction**

- 1) **Mild nasal obstruction** - Partial Nasal Blockage  
(Patient can breathe partially)
- 2) **Moderate nasal obstruction** - Totally Nasal Blockage  
(Patient can't breathe and nasal blockage is less than 24  
hours)
- 3) **Severe nasal obstruction** - Continuous Nasal Blockage  
(Patient can't breathe and nasal blockage is long 24 hours)

No	Assessment		Score
1	Headache	- Absent	1
		- Mild	2
		- Moderate	3
		- Severe	4
2	Heaviness of head	- Absent	1
		- Mild	2
		- Moderate	3
		- Severe	4
3	Nasal discharge	- Absent	1
		- Mild	2
		- Moderate	3
		- Severe	4
4	Post nasal discharge	- Absent	1
		- Present	2
5	Nasal obstruction	- Absent	1
		- Mild	2
		- Moderate	3
		- Severe	4
6	Impaired sense of smell	- Absent	1
		- Present	2
7	Facial pain	- Absent	1
		- Present	2
8	X-ray, (PNS view), Haziness/Fluid levels	- Absent	1
		- Present	2
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# Assessment Chart

Sl. No	Signs and Symptoms for Assessment	Score for Assessment			
		Day-0	Day-8	Day-16	Day-24
1.	Headache				
2.	Heaviness of Head				
3.	Nasal Discharge				
4.	Post Nasal Discharge				
5.	Nasal Obstruction				
6.	Impaired Sense of Smell				
7.	Facial pain				
8.	X- ray ( Haziness and Fluid Level)		—	—	

# Sample Size Calculation

- Sample size was calculated with Epi Info version - 6.04 d<sub>x</sub> as follow:

Expected prevalence of *Kaphaja Shira Shula* patients - 35 (70%)

Population Size - 50

Expected frequency - 50%

Worst Accepted % - 40%

Power - 80%

P -value - 0.05 (95% confidence interval)

Required sample size - 33

- For the sake of drop out, total 37 patients will be collected in this study

# Material

- Table with facility to lower the head portion
- ❖ Medicated oil of *A. galanga* (L) Willd. that was collected from Panchakarma Center in 100 Bedded TMTH, Mandalay
- Lukewarm medicated oil for *Abhyanga*
- 1feet square and 4 feet squares, wide cotton towels for *Svedana*
- Metallic dropper
- Spittoon, Vessel and Knee high chair
- Hot blade
- 7.5 inches square tissue papers
- X- ray
- Stethoscope and Sphygmomanometer

Fig 3; Medicated oil of *A. galanga* (L) Willd. and  
*Nasya* Cup

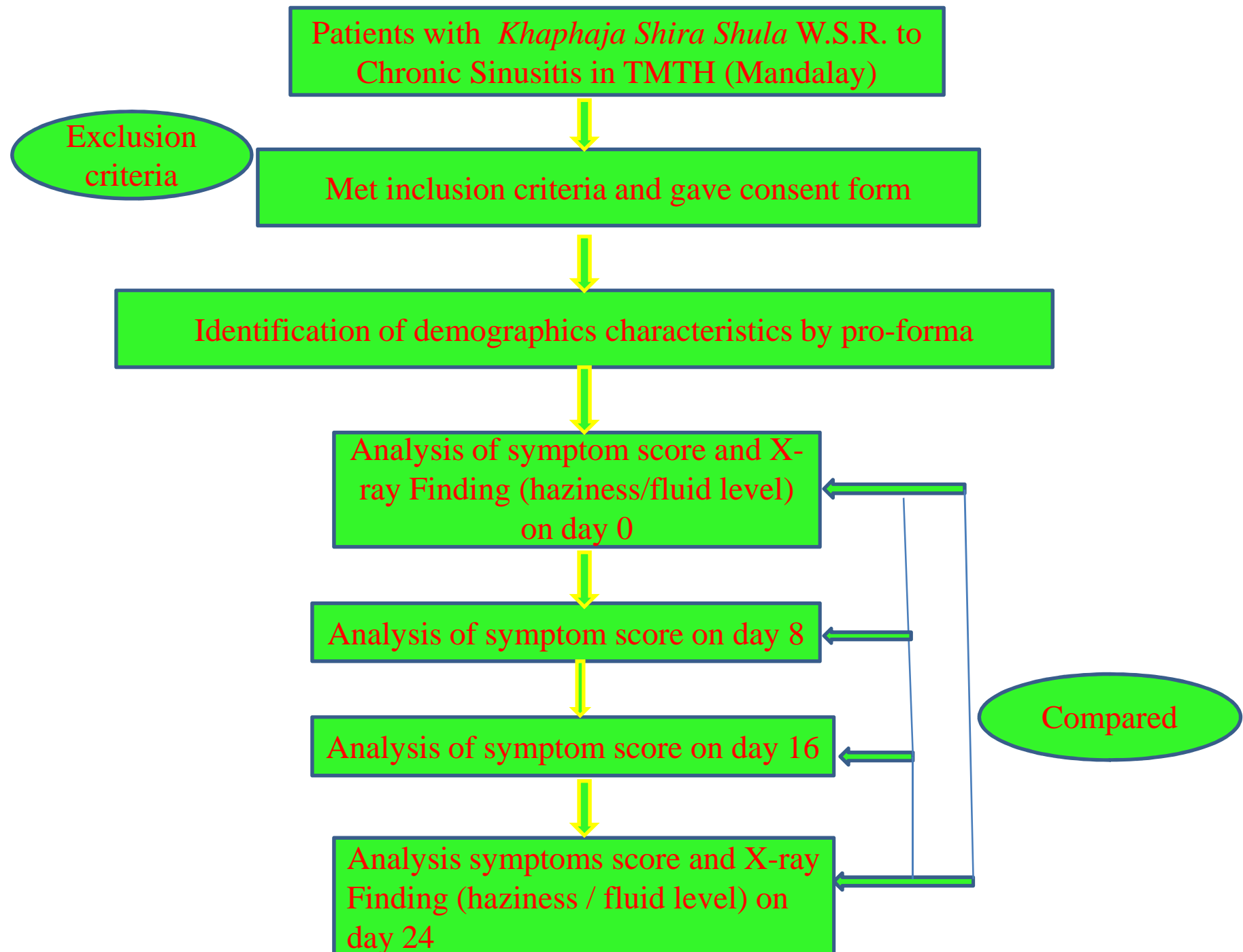


## Treatment procedure

- The subjects were selected according to including criteria
- Patients' consent was taken by using consent form
- A complete history was taken and thorough physical examinations were performed according to profoma
- All patients with *Kaphaja Shira Shula* W.S.R. to Chronic Sinusitis were personally interviewed and examined for *Prakriti* with questionnaires

- These patients were prescribed for oral administration in tablet form 2 gm of the same ratio of combination of TMF-23 and TMF-24 in three times per day (in the morning, afternoon and evening) with lukewarm water after meal during study period for the purpose of balancing *Mahabhutas* in the body
- The radiological assessment(sinus x-ray - Haziness/Fluid level) was done before and after treatment for the association of treatment outcome
- The patients were performed detailed procedure of the medicated oil *Nasya Karma*

- ❑ The treatment plan of the oil *Nasya Karma* includes
  - (1) *Purva Karma* (Preparatory therapy)
  - (2) *Pradhana Karma* (Main Therapy), and
  - (3) *Pashchat Karma* (Post therapy)
- The treatment duration of was taken 24 days and every 8<sup>th</sup> day was the rest day in this study
- The outcome data were collected and observed before treatment (on day 0) and on 8<sup>th</sup> day, 16<sup>th</sup> day and on 24<sup>th</sup> day of the treatment in this study





# Detail procedure of the oil Nasya karma

## *(1) Purva karma* (Preparatory therapy)

- Patient was placed in the supine position on the *Abhyanga* table
- The researcher stood at the head end of the table facing the foot end to carry out *Abhyanga* (External Oleation) and *Svedana* (Sudation)

## **(i) Abhyanga to the face and neck**

- Face and neck of the patient was anointed with lukewarm oil by the researcher
- Forehead, eye brows, nose, chin and maxillary areas were massaged with the linear thumb movements
- Cheek and temporal region was massaged with circular movements of the palm in both clockwise and anti-clockwise direction
- Anterior of the neck was massaged by moving the flat of palms from the base of the neck to the mandible

**Fig 4; Abhyanga to the face and neck**



## (ii) Svedana to the face and neck

- For this purpose a towel was soaked in boiling water, the water was squeezed out, the warm towel was then waved, touched and pressed on the face and anterior neck
- Thus every part of the face and anterior neck was treated with *Svedana* therapy



**Fig 5; Svedana to the face and neck**



## **(2) *Pradhana karma* (Main therapy)**

After proper completion of *Purvakarma*,  
*Pradana Karma* was done

## **(i) Position of the patient for administration of the medicated oil**

- The table used for the administration of the *Nasya* would have facility for lowering the head portion
- In the supine position of the client the head was bent backwards for about 45 degrees

## **(ii) Administration of the medicated oil**

- In case of *Navana Nasya* the medicated oil of *A. galanga* (L) Willd. was taken in a metallic dropper, and then the researcher standing at the head end of the table elevates the tip of the patients nose with the left thumb and then allows to drop the oil from the dropper in to each nostril one the other



## **(ii) Administration of the medicated oil**

- The eight drops (0.8 ml) of the medicated oil was administered in each nostril
- After dropping the oil into one nostril, the other nostril was closed with a finger and the patient was asked to take deep inhalation so that the medicine reaches deep inside the nose
- The same was repeated in the other nostril after the administration of the oil

**Fig 6; Performing *Nasya Karma* with medicated oil of *A. galanga* (L) Willd.**



### **(3) *Pashchat karma* (Post therapy)**

- Again massage and fomentation with palms was done around face, nose, head, neck and chin in supine position
- It was advised to spit out nasal secretion reaching the throat and to do gargle with warm water flowing by inhalation stream of cloves
- And the patient was advised to do that the feet was embedded into the tolerable Salt Warm Water about 15 minutes before going to bed

**Fig 7; Performing gargling with warm salt water**



**Fig 8; Performing inhalation stream**



## Data Collection and Data Analysis

- Assessments were recorded in the **pro forma** and the distribution of *Prakriti* was assessed by **questionnaires**
- The effectiveness was statistically calculated by *one sample t-test* and one way ANOVA methods by using (SPSS) version 21
- A significant level of P value was 0.05 in this study

# Result

## Table 1. Age distribution of study population

Age (group)	No. of patients	Percentage (%)
12 – 20	3	9.1
21 – 30	11	33.3
31 – 40	9	27.3
41 – 50	8	24.2
51 – 60	2	6.1
Total	33	100.0



**Table 2. Distribution of *Kaphaja Shira Shula* patients by sex**

Sex	Frequency	Percentage (%)
Male	9	27.3
Female	24	72.7
Total	33	100.0

**Table 3. Distribution of *Kaphaja Shira Shula* patients by *Prakriti***

Prikriti	No. of patients	Percentage (%)
Vata	5	15.2
Pitta	13	39.4
Kapha	15	45.5
Total	33	100.0

**Table 4. Distribution of *Kaphaja Shira Shula* patients by occupation**

Occupation	No. of Patients	Percentage (%)
Monk and Nun	5	15.2
Student	12	36.4
Teacher	1	3.0
Business People	7	21.2
Service People	6	18.2
House Maker	2	6.1
Total	33	100.0

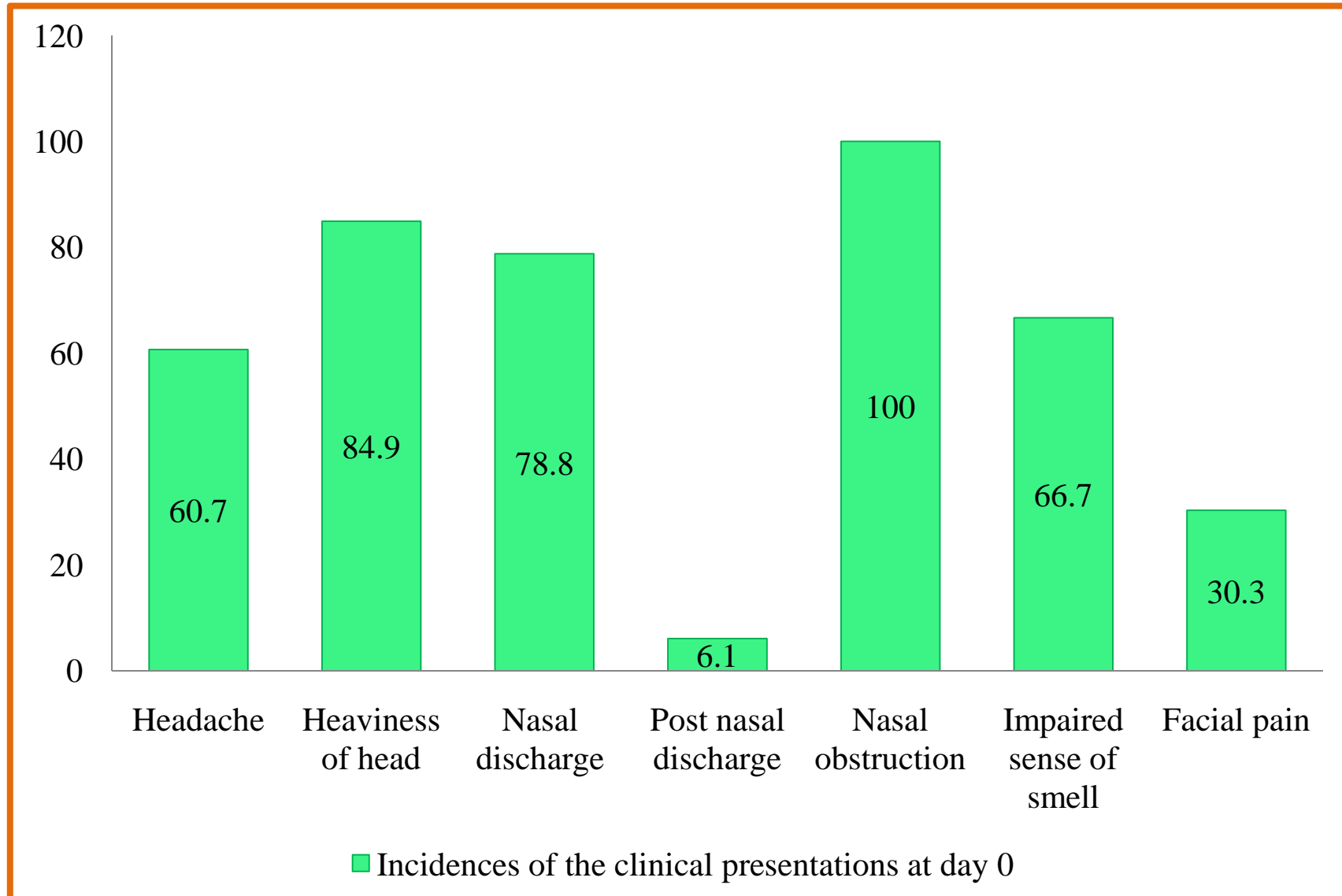
**Table 5. Incidence of *Nidana* in *Kaphaja Shira Shula* patients**

Incidence of Nidana	No. of Patients	Percentage (%)
Sheetha Sevana	26	78.8
Raja- Dhoomasevana	7	21.2
Total	33	100.0

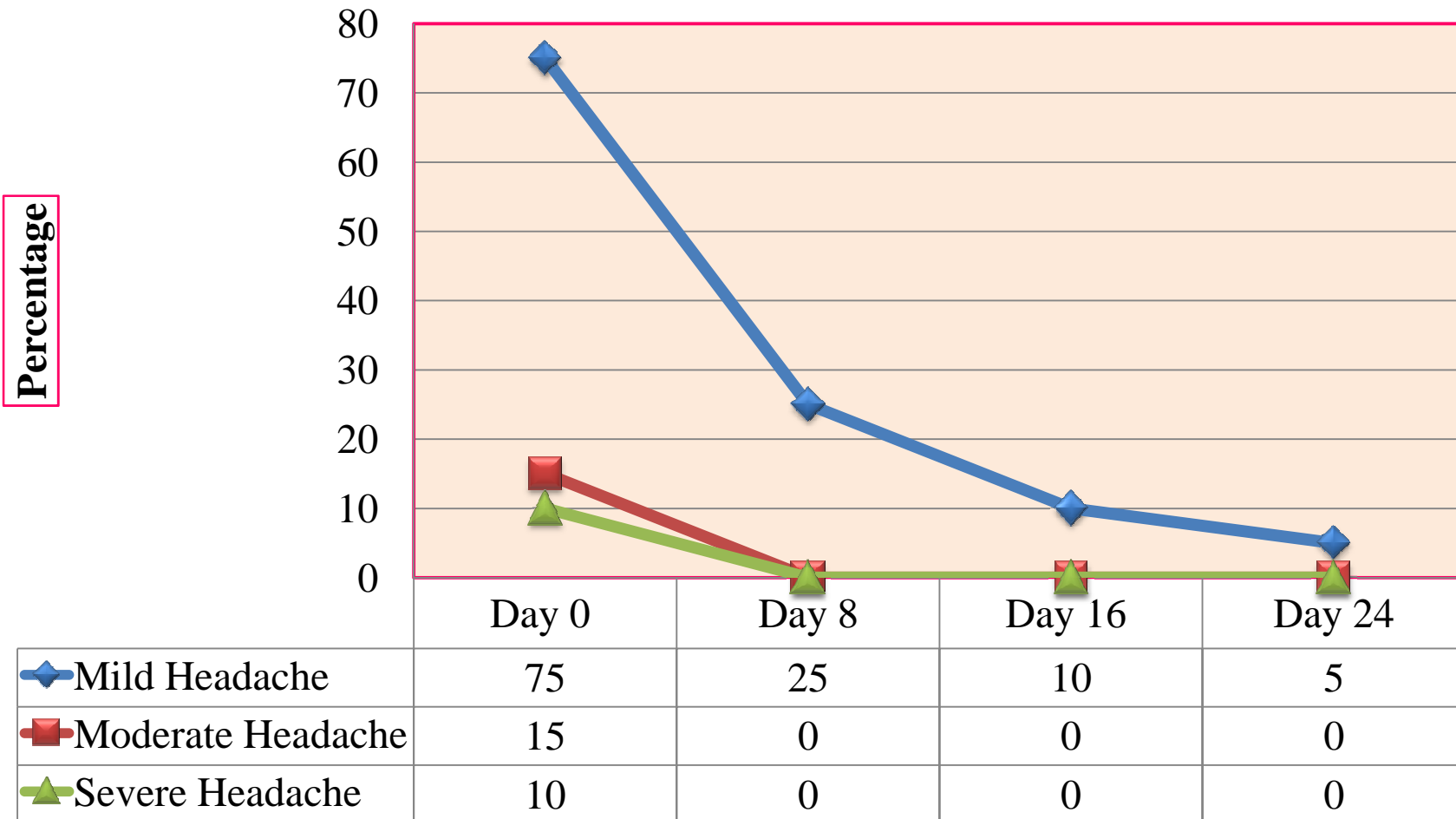
**Table 6. Showing X-ray- haziness/fluid level before treatment (day 0)**

	Before treatment (day 0)		
	No. of Patients	Percentage (%)	
<b>Present</b>	9	27.3	
<b>Absent</b>	24	72.7	
<b>Total</b>	33	100.0	

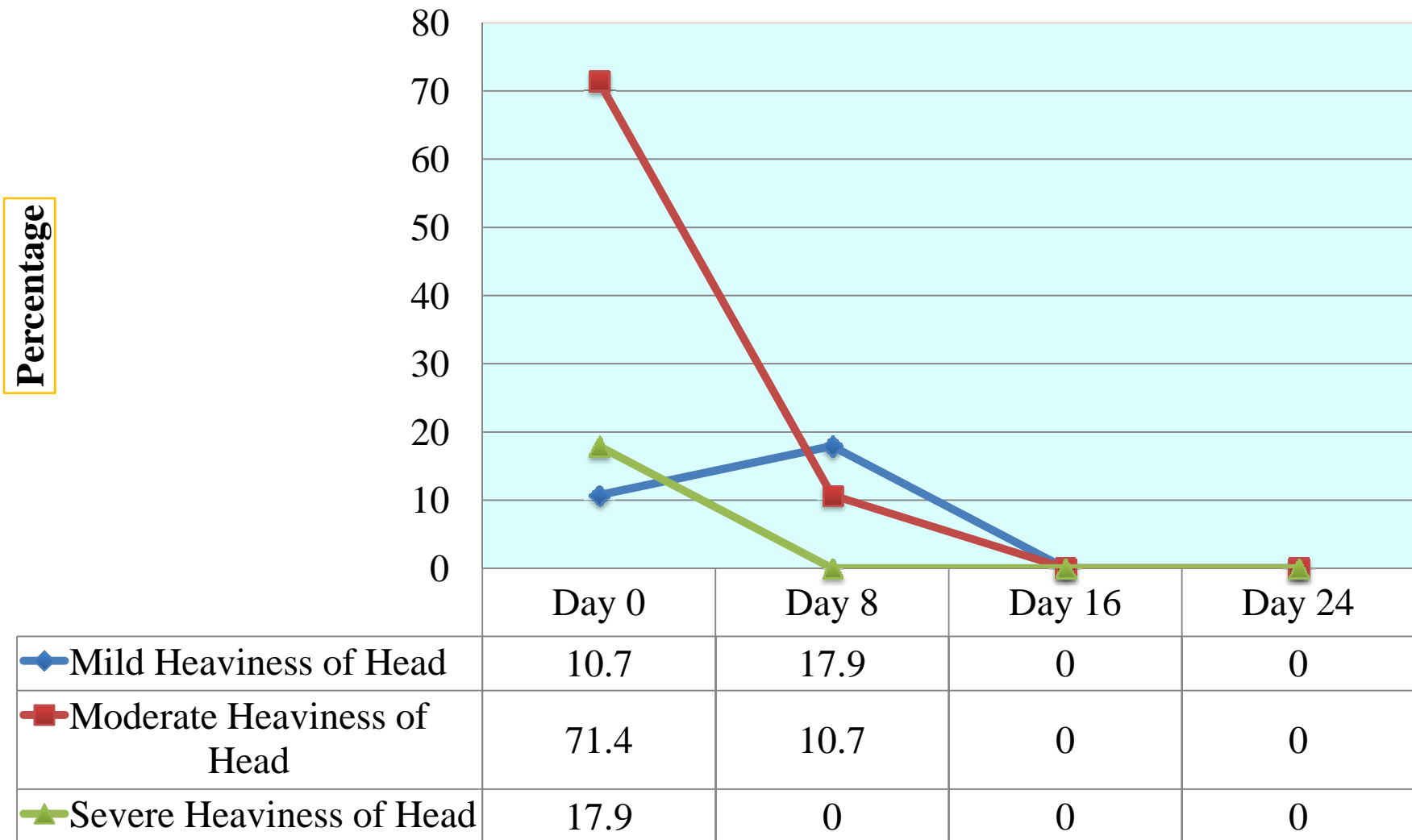
## Incidences of the clinical presentation of *Khaphaja Shira Shula* patients W.S.R. to Chronic Sinusitis before treatment



## Assessment of Headache of *Kaphaja Shira Shula* Patients

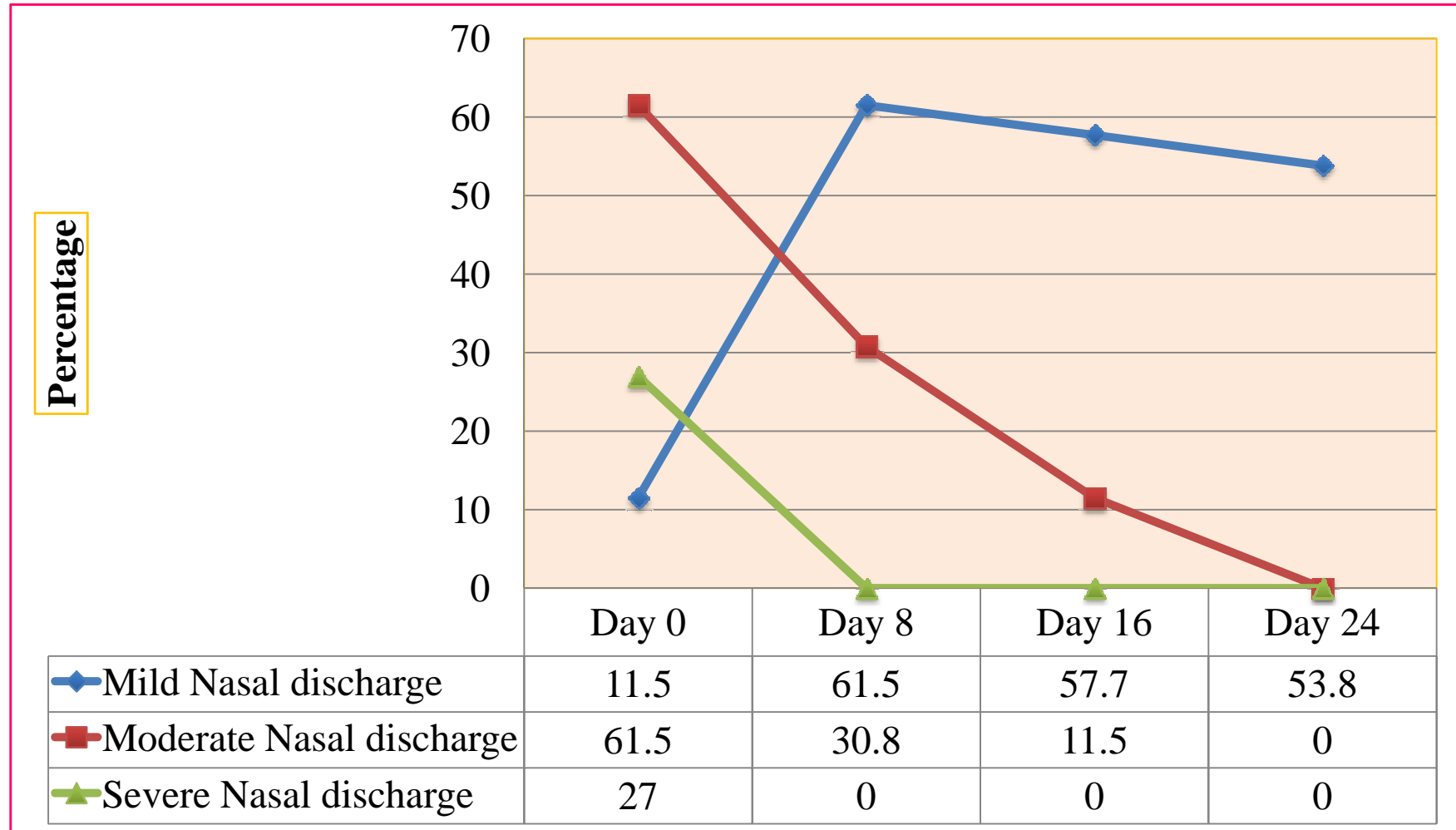


## Assessment of Heaviness of head of *Kaphaja Shira Shula* Patients

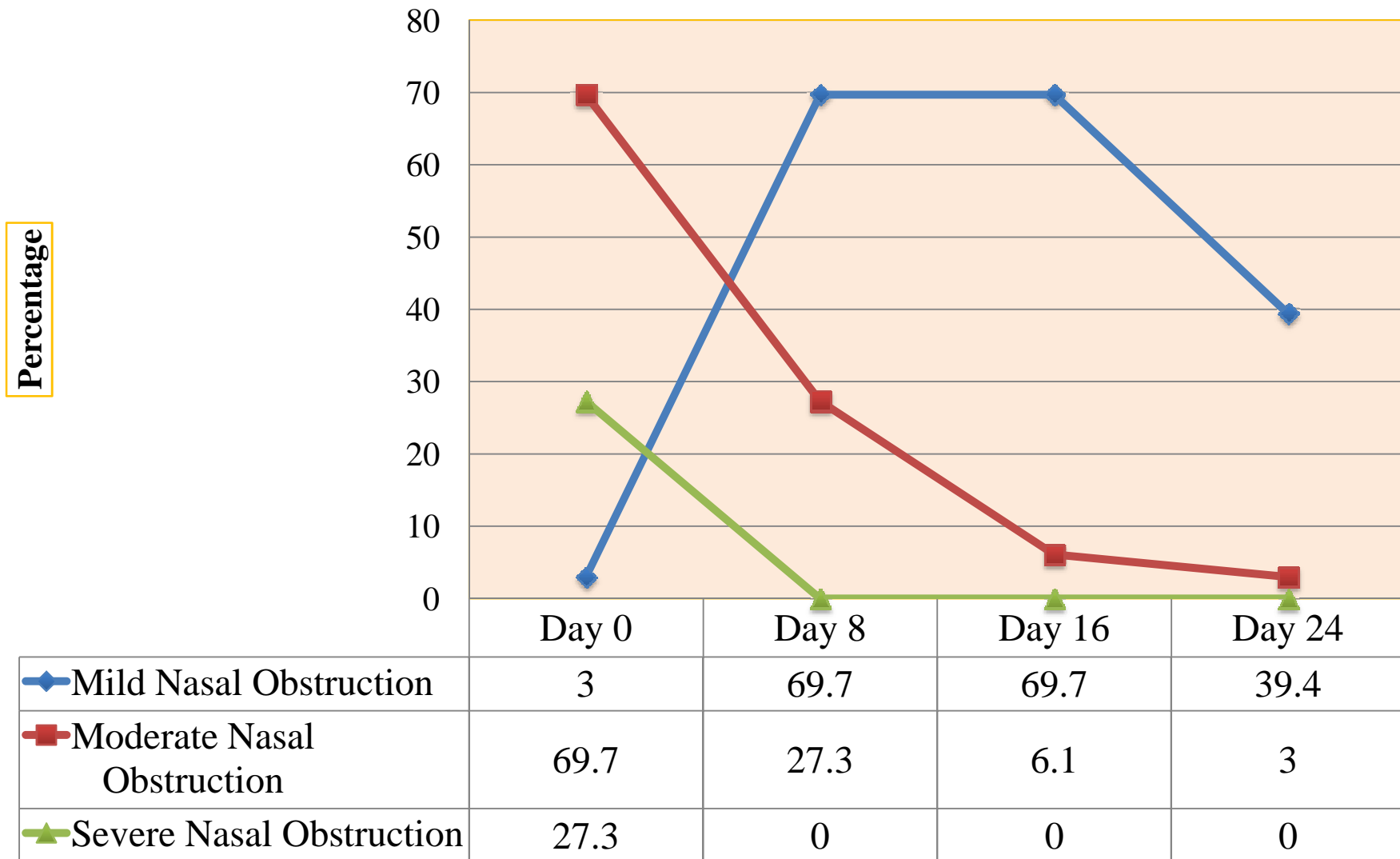




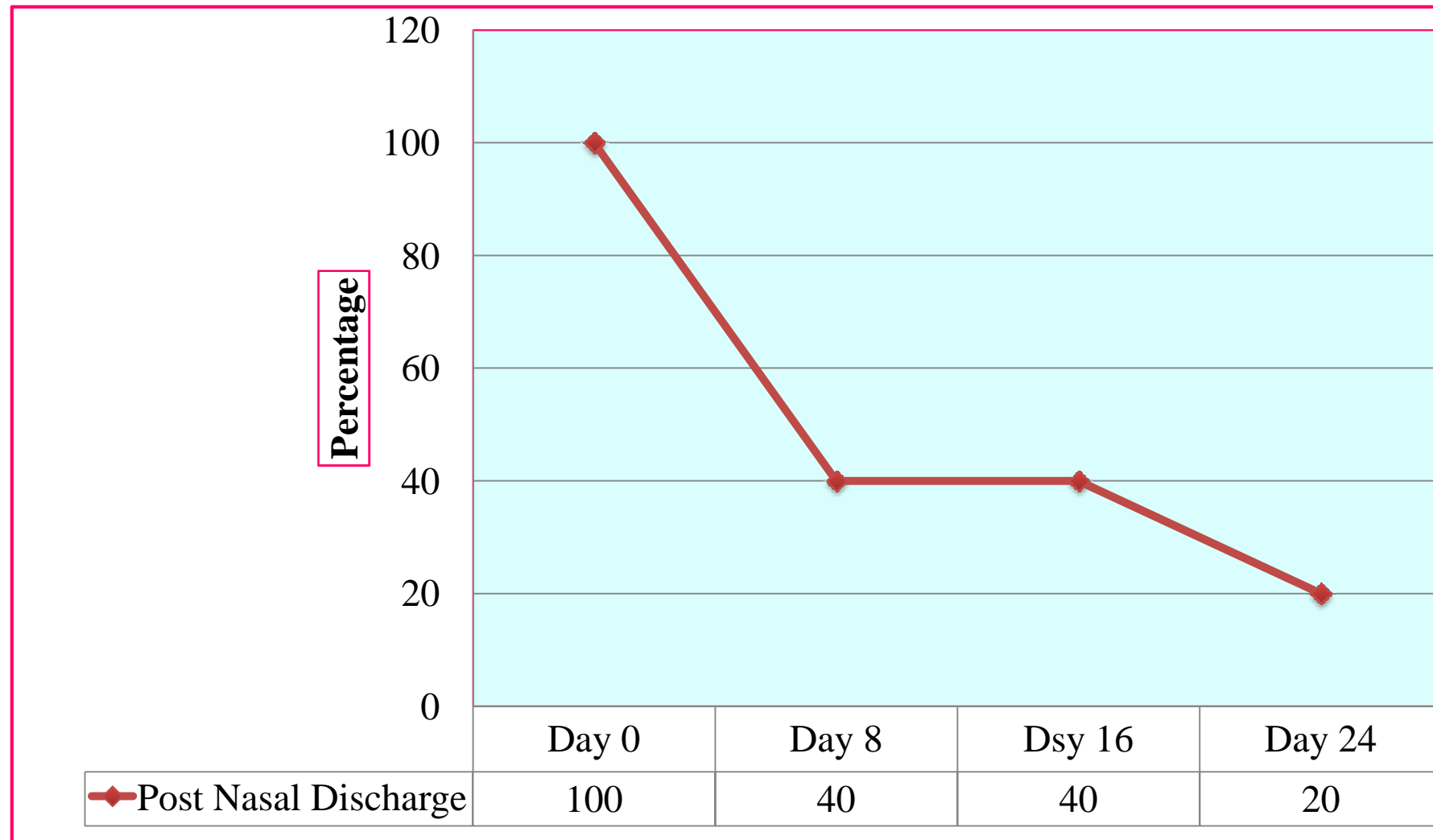
## The Assessment of Nasal Discharge in *Kaphaja Shira Shula* Patients



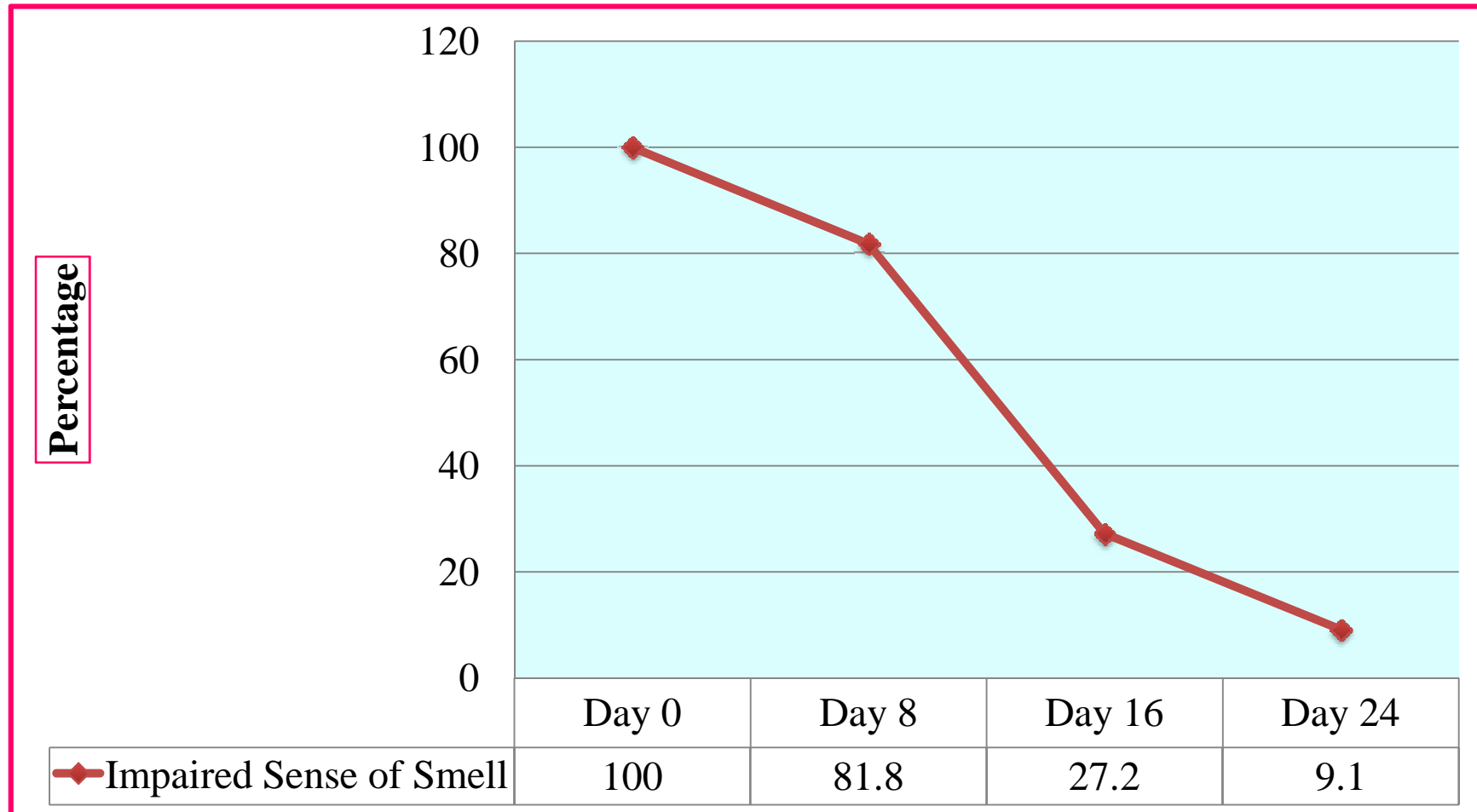
## Assessment of Nasal obstruction of *Kaphaja Shira Shula* Patients



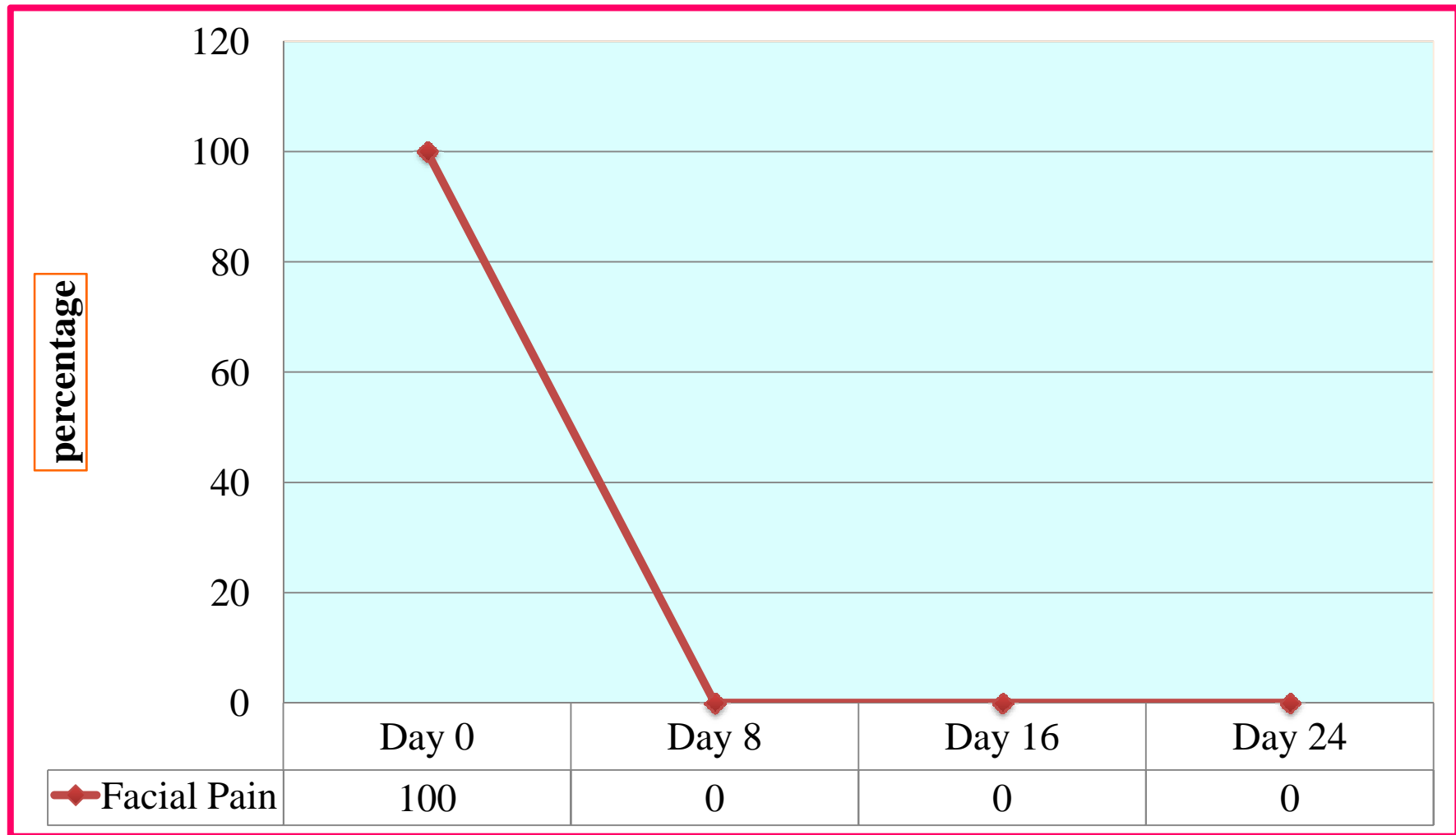
## Assessment of Post Nasal Discharge of *Kaphaja Shira Shula* Patients



## Assessment of Impaired Sense of Smell of *Kaphaja Shira Shula* Patients



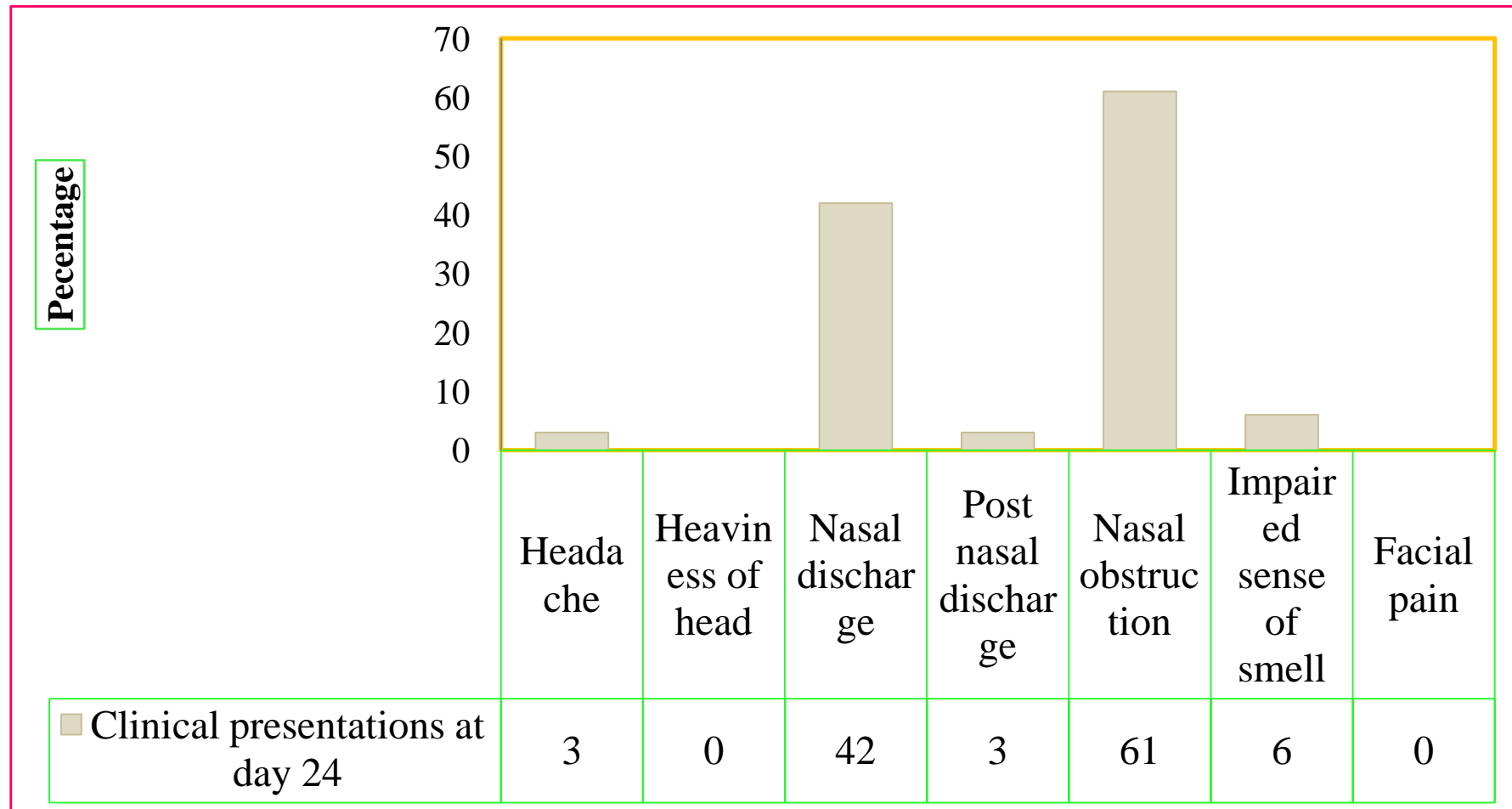
## Assessment of Facial Pain of *Kaphaja Shira Shula* Patients



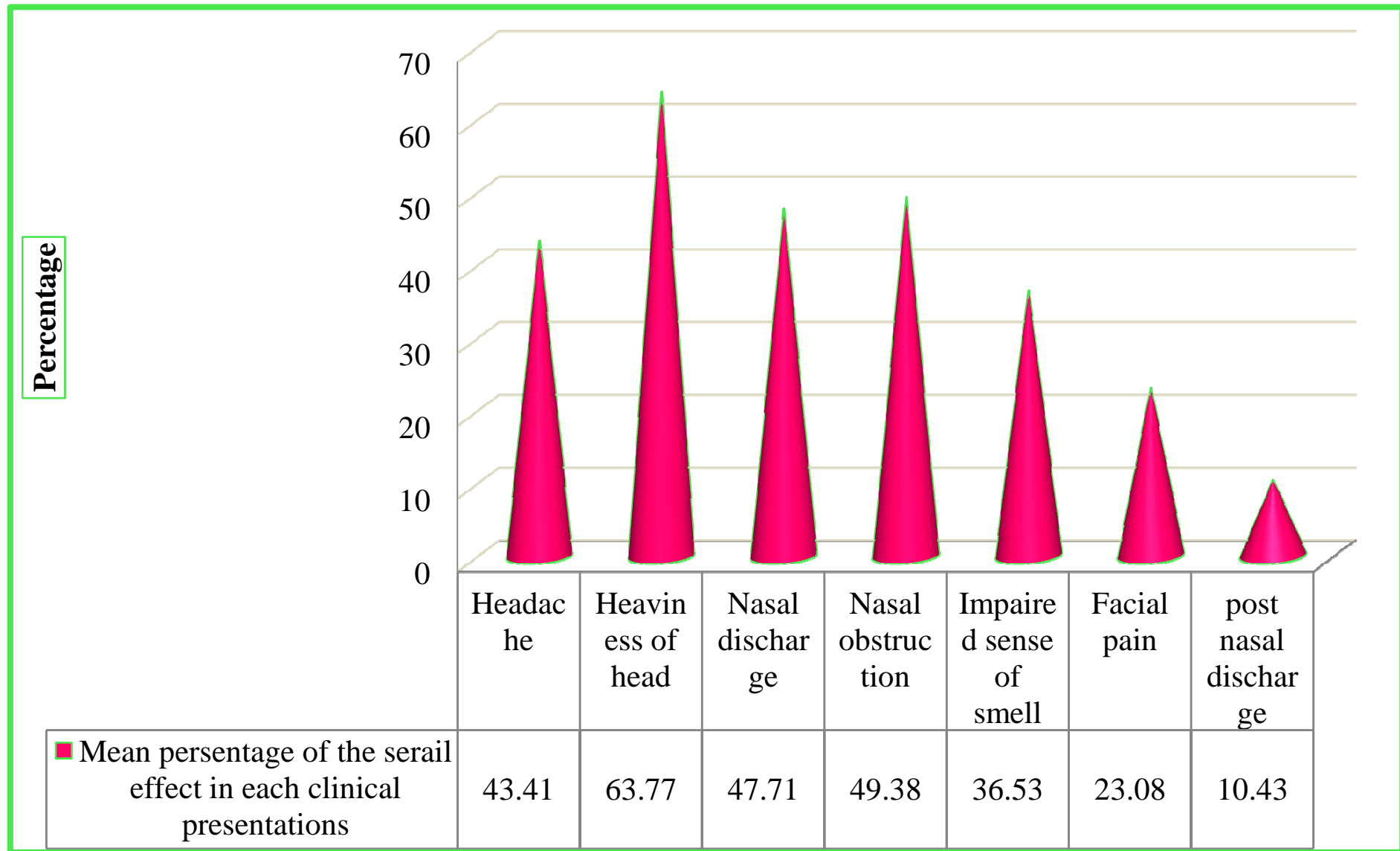
**Table 2. Percent improvement of each clinical presentation after treatment**

<b>Clinical presentations</b>	<b>Before</b>	<b>After</b>	
	<b>No. of patient</b>	<b>Totally improvement</b>	<b>Percent(%) Improvement</b>
<b>Effect of heaviness of head</b>	<b>28</b>	<b>28</b>	<b>100</b>
<b>Effect of facial pain</b>	<b>10</b>	<b>10</b>	<b>100</b>
<b>Effect of headache</b>	<b>20</b>	<b>19</b>	<b>95</b>
<b>Effect of impaired sense of smell</b>	<b>22</b>	<b>20</b>	<b>90.91</b>
<b>Effect of post nasal discharge</b>	<b>5</b>	<b>4</b>	<b>80</b>
<b>Effect of nasal discharge</b>	<b>26</b>	<b>12</b>	<b>46.15</b>
<b>Effect of nasal obstruction</b>	<b>33</b>	<b>13</b>	<b>39.39</b>

## Clinical presentations of *Kaphaja shira shula* Patients W.S.R. to Chronic sinusitis after treatment



## Mean percentage of the serial effect in each clinical presentations





❖ The results of mean percentage in the clinical presentations are; Headache, heaviness of head, nasal discharge, nasal obstruction, impaired sense of smell were found by  $p < 0.000$  and facial pain and post nasal discharge were found by  $p < 0.001$  and  $p < 0.04$  respectively.

<b>Overall basis level percent improvement</b>		<b>No. of Patients</b>	<b>Mean Percentage (%)</b>
<b>Improvement</b>	<b>&lt;= 20.00</b>	<b>1</b>	<b>3.0</b>
<b>Mild Improvement</b>	<b>20.01 - 40.00</b>	<b>12</b>	<b>36.4</b>
<b>Moderate Improvement</b>	<b>40.01 - 60.00</b>	<b>18</b>	<b>54.5</b>
<b>Marked Improvement</b>	<b>60.01 - 80.00</b>	<b>2</b>	<b>6.1</b>
<b>Total</b>		<b>33</b>	<b>100.0</b>

According to *one-sample t-test*, the **overall serial effect** of the medicated oil of *A. galanga* (L) Willd.*Nasya Karma* in patients with *Kaphaja Shira Shula* W.S.R. to Chronic Sinusitis are shown in the following table;

Percent improvement	N	Mean	Std Deviation	Mean Difference	95% Confidence interval of the Difference		T	p-Value
					Lower	Upper		
day 0 -day 8	33	28.38	11.69	28.38	24.23	32.52	13.94	.000
day 0 -day 16	33	38.98	10.31	38.98	35.32	42.63	21.70	.000
day 0 -day 24	33	42.79	10.33	42.79	39.13	46.45	23.79	.000

## Discussion

- ❑ It was observed that the majority of cases(33.3%) were between 21-30 year and the second most common age group was 31-40 year (27.3%)
- ❑ It had been described that the highest incidence age group was between 20-39 year(Swe-Swe-Mar, 1996), 21-30 year(Khin-Khin-Mu, 2004) and 20-40 year age group(Chaw-Chaw-Su, 2005)
- ❑ This indicates that the highest incidence age of *Kaphaja Shira Shula* W.S.R. to chronic sinusitis is similar to these studies

- ❖ In the Traditional Medicine concept, this may be due to *Kapha Prakriti* people are more predominant in *Kapha dosha* than *Pitta* and *Vata Prakriti* people and *Kapha dosha* is the main vitiated *dosha* in patients with *Kaphaja Shira Shula* disease
- ❖ Most of *nidana* Like (*Sheetha Sevana* and *Raja-Dhooma sevana*)described in the classics were observed in the patients with *Kaphaja Shira Shula* in this study

- ✓ There were no statistically significant differences between the clinical presentations and current age, sex, *Prakriti*, occupation, *Nidana* and X-ray finding (Haziness/Fluid level) according to findings from this study
- ✓ It can be considered due to small number of cases and requires to be studied in larger group of population

- ✓ The five most prevalent clinical presentations of *Kaphaja Shira Shula* W.S.R to chronic sinusitis in 33 patients were in order to nasal obstruction, heaviness of head, nasal discharge, impaired sense of smell and headache

- ✓ In the serial effect of the therapy according to the clinical presentations of patients with *Kaphaja Shira Shula* in mean percentage, this study could be proved that headache, heaviness of head, nasal discharge, nasal obstruction, impaired sense of smell were statistically highly significant relief( $p<0.000$ ) and facial pain ( $p<0.001$ ) and post nasal discharge ( $p<0.04$ ) were statistically significant relief after treatment with this medicated oil *Nasya Karma*



- ✓ The overall serial effect of the medicated oil of *A. galanga* (L) Willd. *Nasya Karma* in patients with *Kaphaja Shira Shula* W.S.R. to chronic sinusitis was moderate level improvement in highly significant ( $p < 0.000$ ) after treatment

➤ It is proved that the properties of this medicated oil with *Nasya Karma* can be relieved the most signs and symptoms of *Kaphaja Shira Shula* due to aggravating of *Bahiddha Abandhana* by making to get functional property of *Akasha* as based on the concept of Desana System of Medicine

## Conclusion and Suggestion

- ❖ The findings obtained from this study could be proved that the medicated oil of *A.galanga* (L) Willd. *Nasya Karma* is safe and effective in the management of the patients with *Kaphaja Shira Shula* W.S.R. to chronic sinusitis
- ❖ High claims cannot be made well as regard the total outcome and the factor association with the disease because of small sample size
- ❖ It is recommended that further study should be done with large sample size, long course and the high dose of the medicated oil and classified to the disease with or without nasal polyp in criteria for optimal treatment

## Conclusion and Suggestion

- ❖ It is also suggested that this therapy with the special oral medication should be given in the management of *Kaphaja Shira Shula* W.S.R. to chronic sinusitis
- ❖ The therapy was simple, easy, safe and effective in heaviness of head, headache, facial pain, impaired sense of smell, nasal discharge, post nasal discharge and nasal obstruction of *Kaphaja Shira Shula* W.S.R. to chronic sinusitis and required no hospitalization and could be any Traditional Clinic

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*Thank You For Your Attention*

