A Clinical Study On The Efficacy Of Ardhanarishvara Rasa Nasya and Nimbadi Guggulu In The Management Of Kaphaja Shiroroga W.S.R. To Sinusitis

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ABSTRACT

Kaphaja Shiroroga is one among the 11 types of Shiroroga mentioned by Aacharya Sushruta. In modern science, it can be correlated to sinusitis. Sinusitis is a major problem in the society due to its recurrent exacerbations and complications. Drugs selected for present study Ardhanarishvara rasa and Nimbadi Guggulu are having Kaphavatahara, Lekhaniya, Srotoshodhana and Shothahara properties which helps in break down of the pathogenesis of sinusitis. The chief procedure to remove Doshas from Shiras is Shodhana Nasya. Therefore Nasya with Ardhanarishvara Rasa due to its medicinal properties helps in removing the vitiated Kapha accumulated in Shiras. In present study 30 patients of Kaphaja Shiroroga (sinusitis) were selected and randomly divided into two groups of 15 patients each. Group A was treated with Ardhanarishvara Rasa Nasya and Group B was Ardhanarishvara Rasa Nasya and Nimbadi Guggulu orally. Their individual and comparative effects were revealed in the study. A significant relief was found in most of the symptoms and signs of Kaphaja Shiroroga (Sinusitis) after the trial.

Key words: Kaphaja Shiroroga, Sinusitis, Nasya, Nimbadi Guggulu

Introduction

Acharaya Sushruta has mentioned 11 types of Shiro-Roga1 in Uttar Tantra and Kaphaja Shiroroga is one of them. The clinical features of Kaphaja Shiroroga described by Aacharya Sushruta are - Guru Pratistabdham (Heaviness and fullness of head), Himam (Coldness in head), Shuna Akshikoota Vadanam (Swelling of face especially around the
eyes), Shirrohitapa (Headache), Shirogalam Kaphodipidgatham (Feeling of having a coating of phlegm inside the head and throat). Sinusitis is defined as inflammation of paranasal sinuses. 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. 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. 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. It is the fifth most common diagnosis for which antibiotics are prescribed. In India chronic sinusitis affects nearly 134 million people, making it the country with the second largest number of sufferers in the world. Sinusitis itself is rarely life threatening, but if the infection extends into surrounding deep tissues it can lead to serious complications like: orbital cellulitis, subperiosteal abscess, orbital abscess, frontal and maxillary osteomyelitis, subdural abscess, meningitis, brain abscess.

In modern science, only symptomatic relief is achieved with antibiotics, decongestants, analgesics etc., but the rate of recurrence is very high. In advanced cases, surgical procedures are advised which are expensive, and invite complications.

In Kaphaja Shiroroga, vitiated Kapha Dosha accumulates in Shiras causing obstruction in Srotas of head. Aacharya Vagbhatta has 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 drugs Ardhghanishvara Rasa and Nimbadi Guggulu selected for present study 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 Shirivirechana (Shodhana) Nasya is recommended. The term “Shirivirechana” itself denotes the process of cleansing of head. Hence Avapeeda Nasya (comes under Shirivirechana type) with Ardhghanishvara Rasa due to its medicinal properties helps in removing the vitiated Kapha there by clearing the Srotas (sinuses) situated in Shiras (skull and face).

Therefore the present study entitled “A Clinical Study on the Efficacy of Ardhghanishvara Rasa 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.

Aims and Objectives

1. Aetio-pathogenesis and clinical study of Kaphaja Shiroroga with special reference to sinusitis.

2. To evaluate the efficacy of Nasya with Ardhghanishvara Rasa in the management of Kaphaja Shiroroga (Sinusitis).

3. To evaluate the efficacy of Nasya with Ardhghanishvara Rasa and Nimbadi Guggulu orally in patients suffering from Kaphaja Shirahshoolaa (Sinusitis).

4. To compare the efficacy of trial drugs in Kaphaja Shiroroga.

Material and Methods

I. Study Design: The present study is an interventional, randomized, open label, and parallel group trial.

II. Selection of Patients

Source: Patients attending the O.P.D. and I.P.D. of Shalaka Tantra of National Institute of Ayurveda, Jaipur were screened for the present study. Freely given informed written consent was obtained from every subject prior to research participation. A research proforma was prepared to study all the conditions of patients.
Ethical clearance: Institutional Ethics Committee (IEC) approval was taken prior to initiation of research work vide letter number F10(5)/EC/2014/7224 dated 7-11-2014.

Inclusion Criteria

1. 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.
2. Patients between the age group of 8 to 80 years.

Exclusion criteria

1. Patients not willing for the trial were excluded.
2. Pregnant women.
3. Patients with chronic debilitating infectious diseases.
4. Patients suffering from pain and facial swelling due to alveolar abscess, cellulitis of cheek, furuncle, angioneurotic oedema, trigeminal neuralgia, temporal arteritis.
5. Patients with malignancies of sinuses.

III. Grouping of patients:

In the present study 34 clinically diagnosed patients of Kaphaja Shiroroga (Sinusitis) were selected and randomly divided into two groups. Randomization was done on the basis of random number table. Out of these 34 patients 30 patients completed the trial.

Group A: 15 patients of Kaphaja Shiroroga (Sinusitis) were given Nasya with Ardhanarishvara Rasa.

Group B: 15 patients of Kaphaja Shiroroga (Sinusitis) were given Ardhanarishvara Rasa for Nasya and Nimbadi Guggulu orally.

IV. Administration of Drugs:

i) Ardhanarishvara Rasa

- **Dose**: 4 drops per nostril
- **Duration**: Two sittings of 7 days with interval of 7 days

ii) Nimbadi Guggulu

- **Dose**: 2 tablets of 500 mg twice daily orally with luke warm water
- **Duration**: 1 month

V. Investigations: X-Ray PNS, Hb%, TLC, DLC, ESR, Absolute eosinophil count

VI. 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.

Assessment Criteria

For assessment of the efficacy of the trial therapy, following subjective and objective parameters were adopted:

**Subjective criteria:**

1) Shiroabhitapa (Headache)
2) Shiroguruta (Heaviness in head)
3) Galam Kaphaupadigdham (Post nasal drip)
4) Shunakshikootavadanam (Periorbital and facial oedema)
5) Nasal obstruction
6) Nasal discharge
7) Tenderness over sinuses

**Objective criteria:**

1) Haziness in sinuses in X-ray

Statistical Analysis

Various observations made and results obtained were computed statistically using Graph Pad Instat 3 software. Individual A and B group: Wilcoxon matched pairs signed ranks test for nonparametric data. Intergroup comparison between A and B group: Mann Whitney test for nonparametric data. The obtained results were interpreted as:

- Not significant \( p > 0.05 \)
- Significant \( p \leq 0.05 \)
- Very significant \( p \leq 0.01 \)
- Extremely significant \( p \leq 0.001 \)
Observation and Results

In the present trial total 34 patients were registered at the beginning but 4 patients discontinued the trial before its completion and therefore had to be excluded out of the trial. So observation and results of 30 patients are given below:

Observations:

In present study, maximum numbers of patients were in the age group of 21-30 years (33.33%), male and female were equal. Majority of patients had chronic type of sinusitis (80%) and 73.33% had seasonal attacks of the disease. Maximum patients had mild headache (70%), thick (muco-purulent) nasal discharge (40%), 46.66% patients had right and left frontal sinus tenderness on palpation and maximum patients 93.33% had left maxillary sinus opacity followed by 83.33% with right maxillary sinus opacity in X-Ray PNS.

Among 30 patients, headache was found in 93.33% patients, Shiroguruta in 90% patients, 50% patients had Kaphaupadigdham Galam (post nasal discharge), 23.33% patients were with complaint of Periorbital or Facial edema (Shuna Akshikootavadanam), 86.66% patients had nasal obstruction and nasal discharge was found in 66.66% patients.

Results:

Table I. Effect of therapy on subjective parameters in Group A
(Wilcoxon matched paired single ranked test)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Symptoms</th>
<th>Mean</th>
<th>Dif.</th>
<th>% of Change</th>
<th>SD</th>
<th>SE</th>
<th>W</th>
<th>P</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Shiroabhitapa (Headache)</td>
<td>1.86</td>
<td>0.66</td>
<td>1.20</td>
<td>64.27</td>
<td>0.86</td>
<td>0.22</td>
<td>78</td>
<td>0.0005</td>
</tr>
<tr>
<td>2</td>
<td>Shiroguruta (Heaviness in head)</td>
<td>1.33</td>
<td>0.33</td>
<td>1.00</td>
<td>75.01</td>
<td>0.65</td>
<td>0.16</td>
<td>78</td>
<td>0.0005</td>
</tr>
<tr>
<td>3</td>
<td>Kaphaupadigdham Galam (Post nasal drip)</td>
<td>0.93</td>
<td>0.46</td>
<td>0.46</td>
<td>50.02</td>
<td>0.63</td>
<td>0.16</td>
<td>21</td>
<td>0.0313</td>
</tr>
<tr>
<td>4</td>
<td>Shunakshikoot-avadanam (Periorbital and Facial edema)</td>
<td>0.26</td>
<td>0.06</td>
<td>0.20</td>
<td>74.99</td>
<td>0.41</td>
<td>0.10</td>
<td>6</td>
<td>0.2500</td>
</tr>
<tr>
<td>5</td>
<td>Nasal obstruction</td>
<td>1.86</td>
<td>0.86</td>
<td>1.00</td>
<td>53.56</td>
<td>0.65</td>
<td>0.16</td>
<td>91</td>
<td>0.0002</td>
</tr>
<tr>
<td>6</td>
<td>Nasal discharge</td>
<td>1.20</td>
<td>0.46</td>
<td>0.73</td>
<td>61.10</td>
<td>0.70</td>
<td>0.18</td>
<td>45</td>
<td>0.0039</td>
</tr>
<tr>
<td>7</td>
<td>Tenderness over sinuses</td>
<td>2.40</td>
<td>0.66</td>
<td>1.73</td>
<td>72.20</td>
<td>1.98</td>
<td>0.51</td>
<td>36</td>
<td>0.0078</td>
</tr>
</tbody>
</table>
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Table II. Effect of therapy on subjective parameters in Group B
(Wilcoxon matched paired single ranked test)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Symptoms</th>
<th>Mean BT</th>
<th>Dif. AT</th>
<th>% of Change</th>
<th>SD</th>
<th>SE</th>
<th>W</th>
<th>P</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Shiroabhitapa (Headache)</td>
<td>1.86</td>
<td>0.60</td>
<td>1.26</td>
<td>67.86</td>
<td>1.10</td>
<td>0.28</td>
<td>66</td>
<td>P=0.001</td>
</tr>
<tr>
<td>2</td>
<td>Shiroguruta (Heaviness in head)</td>
<td>1.93</td>
<td>0.66</td>
<td>1.26</td>
<td>65.94</td>
<td>0.70</td>
<td>0.18</td>
<td>91</td>
<td>0.0002</td>
</tr>
<tr>
<td>3</td>
<td>Kaphaupadigdham Galam (Post nasal drip)</td>
<td>1.13</td>
<td>0.46</td>
<td>0.66</td>
<td>58.84</td>
<td>0.61</td>
<td>0.15</td>
<td>45</td>
<td>0.0039</td>
</tr>
<tr>
<td>4</td>
<td>Shunakshikootavadanam (Periorbital and Facial edema)</td>
<td>0.20</td>
<td>0.06</td>
<td>0.13</td>
<td>66.65</td>
<td>0.35</td>
<td>0.09</td>
<td>3</td>
<td>0.5000</td>
</tr>
<tr>
<td>5</td>
<td>Nasal obstruction</td>
<td>1.40</td>
<td>0.53</td>
<td>0.86</td>
<td>61.90</td>
<td>0.63</td>
<td>0.16</td>
<td>66</td>
<td>P=0.001</td>
</tr>
<tr>
<td>6</td>
<td>Nasal discharge</td>
<td>1.13</td>
<td>0.26</td>
<td>0.86</td>
<td>76.49</td>
<td>0.83</td>
<td>0.21</td>
<td>45</td>
<td>0.0039</td>
</tr>
<tr>
<td>7</td>
<td>Tenderness over sinuses</td>
<td>3.40</td>
<td>0.86</td>
<td>2.53</td>
<td>74.50</td>
<td>3.33</td>
<td>0.86</td>
<td>36</td>
<td>0.0078</td>
</tr>
</tbody>
</table>

Table III. Intergroup comparison of subjective parameters of *Kaphaja Shiroroga* (Mann Whitney test)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Symptoms</th>
<th>Mean G&lt;sub&gt;A&lt;/sub&gt;</th>
<th>SD G&lt;sub&gt;A&lt;/sub&gt;</th>
<th>SE G&lt;sub&gt;A&lt;/sub&gt;</th>
<th>Mean G&lt;sub&gt;B&lt;/sub&gt;</th>
<th>SD G&lt;sub&gt;B&lt;/sub&gt;</th>
<th>SE G&lt;sub&gt;B&lt;/sub&gt;</th>
<th>U</th>
<th>P</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Shiroabhitapa (Headache)</td>
<td>1.20</td>
<td>0.86</td>
<td>1.10</td>
<td>1.26</td>
<td>0.86</td>
<td>1.10</td>
<td>113.50</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>2</td>
<td>Shiroguruta</td>
<td>1.00</td>
<td>0.65</td>
<td>0.70</td>
<td>1.26</td>
<td>0.70</td>
<td>0.70</td>
<td>136.50</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>3</td>
<td>Kaphaupadigdham Galam (Post nasal drip)</td>
<td>0.46</td>
<td>0.63</td>
<td>0.61</td>
<td>0.66</td>
<td>0.61</td>
<td>0.61</td>
<td>133.50</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>4</td>
<td>Shunakshikootavadanam (Periorbital and Facial edema)</td>
<td>0.20</td>
<td>0.41</td>
<td>0.35</td>
<td>0.13</td>
<td>0.35</td>
<td>0.35</td>
<td>120</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>5</td>
<td>Nasal obstruction</td>
<td>1.00</td>
<td>0.65</td>
<td>0.63</td>
<td>0.86</td>
<td>0.63</td>
<td>0.63</td>
<td>121</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>6</td>
<td>Nasal discharge</td>
<td>0.73</td>
<td>0.70</td>
<td>0.83</td>
<td>0.86</td>
<td>0.83</td>
<td>0.83</td>
<td>121.50</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
<tr>
<td>7</td>
<td>Tenderness over sinuses</td>
<td>1.73</td>
<td>1.98</td>
<td>3.33</td>
<td>2.53</td>
<td>3.33</td>
<td>3.33</td>
<td>122</td>
<td>&gt;0.05</td>
<td>NS</td>
</tr>
</tbody>
</table>
Discussion

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.

Intergroup comparison of efficacy of two therapies on subjective and objective parameters of KaphajaShiroroga/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 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. NasyaDravyas are quickly absorbed and produce rapid local and systemic effects. Nasya Dravyas in Ardhanarishvara 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 Ardhanarishvara Rasa Nasya and internal medication of Nimbadi Guggulu. Nimbadi Guggulu, mentioned in the classic for Dubsha (unbearable) Shiroruja of Vata-Kapha origin, a combination of Nimba, Triphala, Patola Vasa and Guggulu, have proven Shothahara (anti-inflammatory), Vodahara (analgesic), antimicrobial and immune modulatory effects. Thus it helped in reduction of inflammation and infection and thereby sinuses get proper drainage and ventilation and hence relief in the symptoms of Kaphaja Shiroroga.

Conclusion

Shiras (head) is one of the most vital organs of body and forms the root of body where the entire special sense organs - eyes, ears, nose, and tongue are situated. Therefore paranasal sinuses which are air filled spaces in the bones of skull are one among the structures of Shiras. In management of Kaphaja Shiroroga, main concentration is given to the Doshapakarshana from Urdbhvajatra Pradesha and the main treatment which can drain the retained discharge (vitiated Kapha) from the sinuses is Shodhana Nasya. In the present study, Nasya with Ardhanarishvararasa which is a Teekshna Avapeeda Nasya showed considerable relief in both groups. Combined use of Nimbadi Guggulu and Ardhanarishwara Rasa Nasyais more effective for controlling the disease Kaphaja Shiroroga (Sinusitis). Study should be carried out on large sample to ascertain the effect of drug.

References

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**Sarangsh**

कफज शिरोमेंग आचार्य सुधुत्र द्वारा उद्धिखेत ११ प्रकार के शिरोमेंगों में से एक है। आधुनिक चिकित्सा विज्ञान में इसका सामन्यत: से साहसम्बन्ध किया जा सकता है। पुनर्वर्तन प्राकृति और उपदेशों के कारण सामन्यता समाज में एक बड़ी समस्या है। वर्तमान अध्ययन के लिए चर्चित औषधियों अर्धमार्गश्चर रस एवं निम्बादि गुंगुलु कफवात्तर, लेखन, खोताश्चर और शोधार्गुण्युक्त हैं जो कि सामान्यता की समस्या को समाधान बनाने में सहायक हैं। शिर: प्रदेश के दो प्रमुख का मानक को निरोजन के लिए शोधन नस्य मुख्य प्रक्रिया है। इसलिए, अर्धमार्गश्चर रस नस्य शिर में संचित विकृत कफ को निरोजन में सहायक नहीं है। वर्तमान अध्ययन में कफज शिरोमेंग के 30 रोगियों का चयन नस्य शिर के 15-15 रोगियों के 2 समूहों में विभाजित किया गया। ग्रुप ए को अर्धमार्गश्चर रस नस्य एवं ग्रुप बी को अर्धमार्गश्चर रस नस्य और निम्बादि गुंगुलु मुख द्वारा रूप से दिया गया। दोनों समूहों के व्यक्तिगत और तुलनात्मक प्रभाव का अध्ययन किया गया। परीक्षण के बाद कफज शिरोमेंग के अधिकांश लक्षणों में महत्वपूर्ण परिवर्तन प्राप्त हुए।