A Comparative Clinical Study To Assess The Effect Of Sadyovamana With Lavanambu & Ksheera W.S.R. To Utkleshita Dosha In Amlapitta.

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ABSTRACT: Amlapitta is a lifestyle disorder, kaphapittaja amashayaottavyadhi caused by the impairment of Agni (pitta). Utkleshita Amlapitta is the avastha of a disease which produces symptoms like utklesha, amla tiktha udgara, shiroruja and kanta hrut kukshi daha which are taken as subjective parameter in current study. The other associated symptoms commonly seen during amlapitta are Vidbheda, Udara Aadmana, Angasadha Aantrakoojana, Romaharsha, Aruchi and Gurukoshta. Amlapitta can be corelated to Gastritis with prevalence rate around 10 millions in India. Prolong dependency on contemporary medicine showed side effects with 40% not responding to the treatment. In such situation, for quick relief one can adopt sadyovamana as Avastika Chikitsa for Samprapti Vighatana. To prove the same through clinical trial Sadyovamana using Lavanambu and Ksheera with group A and group B respectively are selected for comparative study. Results showed highly Statistical significance with P value <0.001 in both the groups in almost all the parameters. When compared using unpaired ‘t’ test both group showed equally significance. Thus treatment is patient friendly, very effective, intervenes with minimal preparatory procedures, hospitalization, expenses and very easy procedure which can be adopted even at OPD level. So the study also strongly emphasizes that all the Ayurveda fraternity to adopt Sadyovamana in any diseases if Utkleshha present in amashaya with due care, so that the pros & cons are highlighted through n number of trials in many diseases.

Keywords: Utkleshita Amlapitta, Sadyovamana, Lavanambu, Ksheera.
INTRODUCTION:

In the era of the IT and Nanotechnology the fast food and ‘Cola’ culture has rooted deeply in current generation. Modern lifestyle, following unscientific pattern of food intake, suppression of urges, hampered biological clock, increased mental stress\(^1\), and indiscriminate use of NSAIDs for instant pain relief imbalances body elements *Vata, Pitta & Kapha* leading to various metabolic disorders including *Amlapitta*. *Amlapitta* is a *kaphapittaja amashayaottavyadhi*\(^2\) caused by the impairment of *Agni (pitta)*\(^3\) and also it denotes the stage of *Agni dushti* more than a single disease. *Utkleshita avastha* is the condition of disease producing *lakshanas* like *uktlesha, amla tiktha udgara, shiroruja* and *kanta hrut kukshi daha*\(^4\). The other associated symptoms commonly seen during *amlapitta* are *Vidbheda, Udara Aadmana, Angasadha Aantrakoojana, Romahrsha, Aruchi* and *Gurukoshta*. The line of treatment in contemporary medicine is *life style modification, use of h2 receptor blocking agents and proton pump inhibitors*. Prolong use of antacids produce complications like nausea, diarrhoea, headache, constipation and skin rashes\(^5\) however over 40%\(^6\) not responds to the treatment though on medications. In such situation for quick relief from symptoms one can adopt *sadyovamana*\(^7\) as *Avastika Chikitsa*\(^8\) for *Samprapti Vighatana* and this may prove to be efficacious. The current study deals with *Sadyovamana* on *Utkleshita Lakshanas* of *Amlapitta*. *Sadyovamana* does *Agnivrudi* by removing...
utklesha in amashaya which starts to correct the disease from base level.

Thus it cut down the chain of pathology at specific stages; shortens the duration of disease as well as treatment and enhances the efficacy of Shamana Ausadhi. Practically easy to adopt at OPD level, patient friendly, very effective and intervenes with minimal preparatory procedures, hospitalization & expenses. By considering all these reviews this study is taken up to establish a hypothesis through clinical trial.

**AIMS AND OBJECTIVES OF THE STUDY**

1. To analyse the effect of sadyovamana with Lavanambu in Utkleshita Amlapitta.
2. To analyse the effect of sadyovamana with Ksheera in Utkleshita Amlapitta.
3. To compare the effect of sadyovamana with Lavanambu and Ksheera in the management of Utkleshita Amlapitta.

**HYPOTHESIS**

H₀: Neither sadyovamana with Lavanambu nor Ksheera is effective in the management of utkleshita Amlapitta.

H₁: There is an equal effect of sadyovamana with Lavanambu and Ksheera in the management of utkleshita Amlapitta.

H₂: sadyovamana with Lavanambu is more effective than with Ksheera in the management of utkleshita Amlapitta.

H₃: sadyovamana with Ksheera is more effective than with Lavanambu in the management of utkleshita Amlapitta.

**MATERIALS AND METHODS**

**SOURCE OF DATA**

The patients attending the Panchakarma OPD and IPD of Dhanvantari Ayurveda College and Hospital, Siddapur, with complaints of Utkleshita dosha in Amlapitta were screened. Out of these, 40 patients who fulfilled the below mentioned Inclusion criteria were selected for the study. Demographic Data and Data related to disease were collected as per the case proforma.

**INCLUSION CRITERIA:**

1. Patients having utkleshita Amlapitta lakshanas.
2. Age group of 16-60 years.
3. *Vamana arhas.*

**EXCLUSION CRITERIA:**

1. Patients with diabetic mellitus, hypertension, thyroidism, cardiac pathology, peptic ulcers, carcinomas, haemetmesis, maleana, anaemia and immunodeficiency disorders like AIDS.
2. *Vamana anarhas*

**STUDY DESIGN** - It is a “single blind randomized comparative clinical trial” and a total of 40 patients were randomly distributed to two groups equally i.e. Group A and Group B (20 patients each).

**SAMPLE SIZE AND GROUPING**

A minimum of 40 patients, fulfilling the inclusion criteria of *Utkleshita dosha* in *Amlapitta* were selected for the study irrespective of sex, religion, occupation and socioeconomic status and randomly distributed into 2 groups of 20 patients each.

**Group A** - 20 patients were subjected to *Sadyovamana* with *Koshna Lavanambu.*

**Group B** - 20 patients were subjected to *Sadyovamana* with *Koshna Ksheera.*

**RANDOMIZATION AND BLINDING** – This is a single blind study where the patients were randomly assigned to both the groups in order to avoid bias. The patients selected for the trial were listed in sequential order from numbers 1 to 40. The patients who were allocated the serial numbers 1,3,5,7…. etc were assigned to Group A and the patients who were allocated the serial numbers 2,4,6,8 …. etc were assigned to Group B.

**DURATION OF THE STUDY** –

Duration of Treatment – Patients from both the groups were treated for 14 days counting day of *Vamana* as 1

Follow-up - After 7 days and 14 days

Total Duration of the Study – 14 days

**METHOD OF THERAPEUTIC INTERVENTION** –

*Sadyovamana* was conducted to the patients of both the groups. There is difference only in the drugs used for the procedure. The whole procedure is same in both the groups.
Treatment Schedule –

Group A – Sadyovamana with Koshna Lavanambu

Group B – Sadyovamana with Koshna Ksheera

POORVA KARMA –

2. Preparation of the medicine
3. Preparation of the patient

Materials required –

1. Koshna Lavanambu for Group A / Koshna Ksheera for Group B
2. Saindava lava
3. Jala
4. Ksheera
5. 2 big vessels
6. Measuring cup
7. Glass
8. Chair –1
9. Gas stove
10. A spoon for stirring
11. A small towel
12. Vamana pita
13. Haridra choorna
14. Gruta
15. Triphala choorna
16. Honey

Preparation of the medicine –

Preparation of lavanambu:-

For 1 litre of luke warm water 10 gms of salts added and stirred well till it becomes a homogeneous mixture. The total quantity depends on person to person as total dose of lavanambu is based on Akanta pana.

Preparation of Koshna Ksheera:-

The fresh cow’s milk is collected and boiled properly. Before starting procedure it’s made to luke warm and administered to patient till Akanta.

Preparation of Haridra dhoomapana:-

1 tsp of Haridra choorna is mixed with sufficient quantity of ghruta,filled in the dhooma yantra.

Preparation of Kavala:-

2 tsp of Triphala choorna is mixed with sufficient quantity of honey, bolus is done.

Preparation of the patient –

Ask the patient to void bowel and bladder. The patient is made to sit comfortably over handed chair in front of vamana peeta. Vitals recorded before initiating the procedure.
PRADHANA KARMA – In early morning patient has to sit facing towards east. Advice to drink *sukoshna lavanambu / sukoshna Ksheera* till *Akantapana*. If needed tickling of throat is advised. Forehead of the patient has to be supported by *vaidya*.

Massage the back of patient during *Vegas*. *Vegas* have to be continued till *laghu kosta* attained. Assessment of *vamana* is done using the table mentioned below.

Table No: 1 Shows assessment criteria for *Vamana*

<table>
<thead>
<tr>
<th>ASSESSMENT OF VAMANA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaigiki</strong></td>
</tr>
<tr>
<td><strong>Anthiki</strong></td>
</tr>
<tr>
<td><strong>Maniki</strong></td>
</tr>
<tr>
<td><strong>Laingiki</strong></td>
</tr>
</tbody>
</table>

PASCHAT KARMA –

*Haridra Dhoomapana* followed by *Triphala Kavala* is done on patient. Vitals are recorded after procedure. Patient is advised to take rest and *laghu aahara* for a day. This is decided based on patient *Agni bala*. In current study to maintain rationality advised to take gruel during first *aahara kala* and *Krushara* during second *aahara kala*. *Pathya* is advised during study duration.

PRECAUTIONS

Necessary investigations are to be done when in need. Throughout the study careful observation is needed including vomitus as its one among assessment criteria.

**Follow up** – The patient was advised to report on the 7th day for follow up counting from where the day of treatment schedule started.
Second follow up was on 14\textsuperscript{th} day from where the day of treatment schedule started.

\textit{Pathyaapathy} during treatment period and follow up period – The patient was advised to follow below mentioned rules strictly –

1. After procedure for first \textit{annakala yavagu} and second \textit{annakala Krushara} was advised and for later \textit{annakala laghu, ushna snigda anabhishyandhi aahara} was advised.
2. Avoid heavy food, sour and pungent foods, junk food and all \textit{nidanas}.
3. Avoid skipping of food, untimely food and sleep pattern
4. Avoid stress and negatives vibes.

\textbf{ASSESSMENT CRITERIA} –

- The assessment of the study is concluded by clinical and statistical analysis.
- Subjective Parameters were used to assess the response to the treatment. Assessment was done on 1\textsuperscript{st} day before starting the procedure, on the same day after procedure, on 7\textsuperscript{th} day and on 14\textsuperscript{th} day after follow-up. The grades for assessment of all Subjective parameters are as follows;

\textbf{SUBJECTIVE PARAMETERS:}

Table No.2 Shows the \textit{Utklesha} Gradings

<table>
<thead>
<tr>
<th>Grades</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No \textit{Utklesha}</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Once in a Week</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Once in 2-3 days</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Every Day</td>
</tr>
<tr>
<td>Grade 4</td>
<td>After 2-3 hours of food intake</td>
</tr>
</tbody>
</table>
Table No: 3 Shows the *Tikta Amla Udgara* Grading:

<table>
<thead>
<tr>
<th>Grades</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No <em>tikta amla Udgara</em></td>
</tr>
<tr>
<td>Grade 1</td>
<td>Once in a Week</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Once in 2-3 days</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Every Day</td>
</tr>
<tr>
<td>Grade 4</td>
<td>After 2-3 hours of food intake</td>
</tr>
</tbody>
</table>

Table No: 4 Shows the *Shiroruja* Grading:

<table>
<thead>
<tr>
<th>Grades</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No <em>Shiroruja</em></td>
</tr>
<tr>
<td>Grade 1</td>
<td>Once in a Week</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Once in 2-3 days</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Every Day</td>
</tr>
<tr>
<td>Grade 4</td>
<td>After 2-3 hours of food intake</td>
</tr>
</tbody>
</table>

Table No: 5 Shows the *Kanta kukshi daha* Grading:

<table>
<thead>
<tr>
<th>Grades</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No <em>Kanta hruth kukshi daha</em></td>
</tr>
<tr>
<td>Grade 1</td>
<td>Once in a Week</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Once in 2-3 days</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Every Day</td>
</tr>
<tr>
<td>Grade 4</td>
<td>After 2-3 hours of food intake</td>
</tr>
</tbody>
</table>
CLINICAL ANALYSIS

The sum points of all the parameters of assessment before and after treatment were taken into consideration and the total effect of the treatment was assessed as follows –
- Good Response
- Moderate Response
- Poor Response
- No Response

STATISTICAL ANALYSIS

Based on the data obtained and the observations recorded, analysis of the effect of the treatment was done statistically by calculating the mean, standard deviation, standard error, t-value, p-value by using paired ‘t’ test and unpaired ‘t’ test.

RESULTS

CLINICAL ANALYSIS

Distribution of Overall response for the treatment

The sum points of all the parameters of assessment before and after treatment were taken into consideration and the total effect of the treatment was assessed as follows –
1. Good Response >61
2. Moderate Response 41-60
3. Poor Response 40-21
4. No Response <20

Table No.6 Shows Overall response for the treatment

<table>
<thead>
<tr>
<th></th>
<th>Response</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Good Response</td>
<td>Moderate</td>
<td>Poor</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. of patients</td>
<td>Response</td>
<td>Response</td>
<td>Response</td>
<td></td>
</tr>
<tr>
<td>Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>11</td>
<td>55</td>
<td>08</td>
<td>40</td>
<td>01</td>
</tr>
<tr>
<td>B</td>
<td>09</td>
<td>45</td>
<td>10</td>
<td>50</td>
<td>01</td>
</tr>
</tbody>
</table>
**Group A**: Among 20 patients, 11 patients i.e. 55% showed Good Response, 08 patients i.e. 40% showed Moderate response, 01 patients i.e. 05% showed Poor Response, 00 patients i.e. 00% showed No Response for the treatment.

**Group B**: Among 20 patients, 09 patients i.e. 45% showed Good Response, 10 patients i.e. 50% showed Moderate response, 01 patients i.e. 05% showed Poor Response, 00 patients i.e. 00% showed No Response for the treatment.

**Clinical Interpretation**

By comparing the overall response for the treatment, it can be concluded that Sadyovamana using Lavanambu and Ksheera are having equal effectiveness.

**EFFECT OF SADYOVAMANA IN AMLAPITTA USING STATISTICAL ANALYSIS**

Analysis of the effect of the treatment was done statistically by calculating the mean, standard deviation, standard error, t-value, p-value by using paired t test and unpaired t test.
**Paired t test**

**Statistical Interpretation** –
Based on paired t test, the following observations were recorded –

**Subjective Parameters after Sadyovamana** –
Changes in subjective parameters after Sadyovamana are as follows –

**Group A** –
- Changes recorded in all the subjective parameters were highly significant.

**Group B** –
- Changes recorded in all the subjective parameters were highly significant.

Based on Statistical Analysis by paired t test, overall improvements observed in subjective parameters is equally significant even in follow up after 7th and 14th day.

**Unpaired t test**

**COMPARISION OF RESULTS IN BOTH GROUPS – AFTER SADYOVARANA**

Table No: 7 shows comparison of Results in both groups – after Sadyovamana

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utklesha</td>
<td>91.89%</td>
<td>82.35%</td>
</tr>
<tr>
<td>Tikta Amla Udgara</td>
<td>94.44%</td>
<td>91.66%</td>
</tr>
<tr>
<td>Shiroruja</td>
<td>73.68%</td>
<td>74.19%</td>
</tr>
<tr>
<td>Kanta Hruth Kukshi daha</td>
<td>94.11%</td>
<td>92.30%</td>
</tr>
</tbody>
</table>
Graph No: 2 shows comparison of Results in both groups – after Sadyovamana

Comparisons of results in both groups – after treatment of 7th day

Table No. 8 showing Comparison of Results in both groups – after treatment of 7th day

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utklesha</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Tikta Amla Udgara</td>
<td>96.96%</td>
<td>100%</td>
</tr>
<tr>
<td>Shiroruja</td>
<td>94.59%</td>
<td>100%</td>
</tr>
<tr>
<td>Kanta Hruth Kukshi daha</td>
<td>94.20%</td>
<td>100%</td>
</tr>
<tr>
<td>Vidbheda</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Udara Aadmana</td>
<td>100%</td>
<td>94.44%</td>
</tr>
<tr>
<td>Angasadha</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Aantrakoojana</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Romaharsha</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Aruchi</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Gurukoshta</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Graph No.3 shows Comparison of results in both groups – after treatment on 7th day

Comparisons of results in both groups – after treatment of 14th day

Table No. 9 shows Comparison of Results in both groups – after treatment of 14th day

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utklesha</td>
<td>93.93%</td>
<td>93.44%</td>
</tr>
<tr>
<td>Tikta Amla Udgara</td>
<td>87.87%</td>
<td>80.30%</td>
</tr>
<tr>
<td>Shiroruja</td>
<td>89.18%</td>
<td>95.83%</td>
</tr>
<tr>
<td>Kanta Hruth Kukshi daha</td>
<td>94.20%</td>
<td>91.17%</td>
</tr>
<tr>
<td>Vidbheda</td>
<td>81.81%</td>
<td>87.5%</td>
</tr>
<tr>
<td>Udara Aadmana</td>
<td>87.5%</td>
<td>90.47%</td>
</tr>
<tr>
<td>Angasadha</td>
<td>95.83%</td>
<td>95.45%</td>
</tr>
<tr>
<td>Aantrakoojana</td>
<td>95%</td>
<td>85.18%</td>
</tr>
<tr>
<td>Romaharshar</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Aruchi</td>
<td>96.87%</td>
<td>82.75%</td>
</tr>
<tr>
<td>Gurukoshta</td>
<td>87.50%</td>
<td>71.11%</td>
</tr>
</tbody>
</table>
Graph No.4 shows Comparison of results in both groups – after treatment of 14th day

Based on unpaired ‘t’ test, the following observations were recorded –

Soon after Sadyovamana- On comparing the results between Group A and Group B, the difference between the two groups is statistically non significant w.r.t the rest of the parameters.

After 7th day - On comparing the results between Group A and Group B, the difference between the two groups is statistically non significant w.r.t the rest of the parameters.

After 14th day - On comparing the results between Group A and Group B, the difference between the two groups is statistically non significant w.r.t the rest of the parameters.
DISCUSSION

DISCUSSION ON THE DISEASE

The disease is understood in better way by Nidana Panchaka i.e. Nidana (aetiology), Purvarupa (premonitory symptoms), Roopa (symptoms), Upashaya (therapeutic diagnosis) and Samprapti (pathogenesis).

Nidana

Nidana includes mainly Aharaja, Viharaja and Manasika nidana

Aharaja Nidana-

Various types of Viruddhaahara, excess of Pitta aggravating factors like Katu, Amla, lavana, Vidahi, etc, untimely consumption of food and following against the dietetic code are directly responsible for the vitiation of Pitta. The morbidity of Vata as well as Kapha also has significant role in Amlapitta which cannot be denied. Acharya Kashyapa has described that, Amlapitta occurs mostly to the persons who are having the Jihvalauylata. By looking in to the above said Nidanas, it can be concluded that in present era most of persons who ignores rules and regimen of dietics with the repetitive and excessive intake of spicy and junk food by today’s young generation falls pray for most of the metabolic disorders including Amlapitta.

Viharaja Nidana

This group includes addiction to Smoking, Alcohol, Drug abuse, Suppression of urges, Sedentary life style, Untimely sleep pattern, Excessive use of gadgets, Night parties, Night outs etc., causes the disturbance of the equilibrium of Pitta which further affects the normal digestion process resulting into Amlapitta.

Manasika Nidana

Due to excessive stressful and target oriented life and anger, anxiety, greed etc causes pitta prakopa, would affect the normal physiology of digestion. Either there will be a lesser secretion or untimely secretion or excessive secretion of the digestive juice leads to Amlapitta.

Anupa Desha and Sharath rutu are also important factors responsible for genesis of Amlapitta.

Poorva rupa

No specific Purvarupas are mentioned in Ayurvedic classics. By applying yukti and practical knowledge, it can be inferred that Agnimandya and Ajeerna especially Vidagdaajeerna is the successive stages towards the manifestation of Amlapitta. These even observed in the patients, thus considered as probable Purvarupas.
Annavaha and Purishavaha Srotodusti lakshanas can also be considered as Purvarupa of Amlapitta.

**Roopa**

Ancient Acharyas has given detailed description about the symptoms of Amlapitta along with specific symptoms according to different types of Amlapitta. For medical intervention it can be grouped as utkleshita lakshanas, Samanya Lakshanas, Dhatugata Lakshanas, Koshtagata and shakagata Lakshanas. Current study mainly deals with utkleshita lakshanas which deals with dosha in more expulsive stage with minimal intervention. Here Vidagda Pitta results in Shuktapaka which is a peculiar stage of Samprapti, hence the Pratyatma lakshanas produced by Shuktapaka includes Aruchi, Avipaka, Tikta Amla Udgara, Kanta-hruth kukshi daha, Shirasghula, Utklesha and Vanti. Rest other symptoms are mostly specific to agnimandya, pitta prakopa lakshanas with respect to dhatus and ashaya involved. Nausea, Abdominal bloating, Abdominal Pain, Sour Belching, Loss of appetite, Vomiting and Chest burn are the features of Gastritis which is correlated to Amlapitta.

**Samprapti**

The various Nidanas causes the vitiation of Pitta-Kapha Dosha along with involvement of samana vata. Agnimandya, Ajeerna (Vidagda) and Amlapitta are the successive stages of agni dushti. Here Mandagni, Vidhagdhata and Shuktapaka of ingested food in Amashaya are peculiar stages of Amlapitta. Here understanding of samprapti starts from agnimandya and similarly intension of treatment is correcting the agni rather than only focusing on Pitta Shamana.

**Upashaya Anupashaya**

The patya followed mainly according to dosha predominance, which are elaborated below;

*Vataja Amlapitta*–Snigda Upashaya

Pittaja Amlapitta Swadu and Sheeta Upashaya

Kaphaja Amlapitta - Ruksha and Ushna Upashaya

The Pathya Dravyas mentioned can be taken as Upashaya of Amlapitta. On the other hand the Anupashaya of Amlapitta is not mentioned separately in classics. So here the causative factors as well as the Apathya Dravyas are taken as Anupashaya.

The Contemporary Science give importance to life style modifications like...
eating six small meals instead of three large meals and drinking lots of water. It also advises to take more leafy vegetables, low fat-proteins, food containing flavonoids like brightly coloured fruits, vegetables and foods rich in fibres.

**Treatment**

Though Kashyapa mentioned the entire disease in detail, by seeing the prevalence of disease one can understand the fact that, there is lacuna in adopting the treatment principles. So it’s very essential to analyze the disease from its very base level i.e. amla and pitta guna, agni, aama pradoshaja vikara, vidagdaajeerna which are hidden in the term and samprapti of Amlapitta which reflects on treatment. The treatment principle of Amlapitta is Vamana, Virechana, Basti, and Raktamokshana followed by Shamana therapy. As the integrity of human body is solely influenced by status of Agni physician’s main work is to maintain Agni. When the disease Amlapitta is reviewed from multidimensional aspect its concluded that basically it starts due to vitiation of agni. Thus all these Shodana therapy influence on agni by igniting it. As current study focuses on utkleshita doshas in Amlapitta, Sadyovamana is selected as a tool to breakdown the pathogenesis of same.

**DISCUSSION ON THE DRUG USED**

Though the very simple drugs are taken for study, its efficacy is understood by analyzing the pharmacodynamic and kinetic action, both in terms of Ayurveda and contemporary science with clinical trials. Though the contact of drug used with the stomach wall is for very few minutes, but its cent percent action is reflected through relief from symptoms.

The drugs used in the study are
1. Lavanambu
2. Ksheera.

**Koshna Lavanambu**

It’s a combination of lavana and Ushnodaka which is prepared easily just by mixing into a homogeneous mixture. The properties of lavana and Ushnodaka are discussed below;

**Lavana**

Lavana is having snigda, Ushna and Teekshna guna. Its action on gut wall as proved in earlier studies states that, administering mild irritants like 2–5% sodium chloride increased the secretion of prostaglandins and other factors like nitric oxide, leptin, ghrelin, cholecystokinin and gastrin releasing peptide and facilitate ‘Adaptive Cytoprotection’ to protect gastric mucosa.
Treatment with 5% sodium chloride enhanced mucosal blood flow, mucous secretion, mucosal proliferation and decreased acid secretion. Also, the DNA content in the gastric juice reduced, indicating decreased mucosal damage and cell shredding. Interestingly, following exposure to sodium chloride, histological visible mucosal necrosis and plasma protein leakage into the gastric lumen thus becomes a potent ulcer protecting agent.

Ushnoda
It produces very mild irritating effect on gut wall thus enhances the reflex mechanism.

Ksheera
It’s both Vamanopaga and Virechanopaga. Its effect depends on kavaigunya present and site involved. Earlier study proved that, milk provides a temporary buffering to gastric acid and neutralizing gastric acid for 20 minutes.

DISCUSSION ON THE PROCEDURE

Discussion on Sadyovamana–
Quick elimination of vitiated dosha through oral route is called sadyovamana. It’s done in Kapha Pitta utklesha in Amashayotha Vyadhi with no restriction with respect to time and Pre-Post operative procedures. These are dealt wisely using yukti according to Dosha Dushya bala and avasta. Sadyovamana forms the frontline treatment in the disorders involving the utkleshita Kapha at its own site, combination of Kapha- Pitta Utklesha or Kapha utklesha associated with pitta-vata. The drugs which are used here are mostly vamanopaga which are having qualities similar to that of Vamaka dravyas.

Probable Mode of action of Sadyovamana using Lavanambu

Vagus as the key moderator of vomiting, manifested in strict co-ordination of nucleus tractus solitarius with area postrema, brainstem vestibular centres, sensory and emotional areas and several other areas of the brain.

Two distinct vagal afferent mechanoreceptors from the stomach: intraganglionic laminar ending (IGLE) and intramuscular array (IMA) respond to distension and smooth muscle contractions and also function as tension receptors. These vagal afferents carry the mechanical information to the nucleus tractus solitarius (NTS) from stomach through jugular and nodose ganglion. After distension of the stomach, NTS signals dorsal motor nucleus of Vagus to initiate vomiting. The neuronal firing of vagal afferents decrease, resulting
in relaxation of gastric wall tone and reduction of acid production.

Earlier studies showed that, administering mild irritants like 2–5% sodium chloride increased the secretion of prostaglandins and other factors like nitric oxide, leptin, ghrelin, Cholecystokinin and gastrin releasing peptide and facilitate ‘Adaptive Cytoprotection’ to protect gastric mucosa by enhancing mucosal blood flow, mucous secretion, mucosal proliferation and decreased acid secretion. Also, the DNA content in the gastric juice reduced indicating decreased mucosal damage and cell shredding. These distinct findings also point towards Sadyovamana as a potent ulcer protecting agent.

Thus it can be concluded that Sadyovamana using Lavanambu is produced due to stretch effect and drug effect with added beneficiaries.

**Probable Mode of action of Sadyovamana using Koshna Ksheera**

Here mode of action is same as above; the only difference is drug influence during & post procedure. Earlier studies on milk states that, both protein and calcium in it stimulate acid secretion by producing gastrin release or possibly by direct stimulation of the parietal cell but it’s also proved by Bingle and Lennard-Jones that, milk provides a temporary buffering effect to gastric acid and neutralizing gastric acid for only 20 minutes.\(^{46}\)

*Sadyovamana* using *Koshna Ksheera* is taken as cross reference in the current study. The *Ksheera Akantapana* stimulates mechanoreceptors in stomach and induces vomiting. Additionally milk remains only for few minutes and gets evacuated before its digestion, produces temporary buffering effect, neutralises acids, cleanses the stomach and produces smoothening effect over the wall of stomach by its own qualities.

**DISCUSSION ON THE METHODOLOGY**

**Poorva Karma**-

*Sadyovamana* requires either no or minimal pre-operative requirements according to *dosha* involved which signifies the simplicity of the procedure.

**Dose of Saindava Lavana for Preparation of Lavanambu**

The water for the gut cleansing must be physiological salt water, the same salt concentration as the body’s own, 0.9%. This allows the water to leave the stomach more quickly, while maintaining the same
osmotic pressure upon both sides of the gut wall. This means that, the body neither absorbs nor yields salt or water in significant quantities and thus evacuates out. This is taken as a cross reference to decide dose of salt while preparing Lavanambu. Per litre only 9 gm of salt is enough but in current study round figure is taken as 10gm/litre.

**Pradhana Karma-**
Here intension is removal of only utkleshita dosha and care should be taken not to enforce on Vegas, if done so, finally ends up in vata prakopa along with other Upadravas. As it’s a Sadyoshodana less importance is given on assessment criterias like Vaigiki, Maniki, Anthiki and Laingiki, because Sadyo Shodana is mainly assessed by changes in the gradings of parameters selected for study rather than assessment criteria. Palatability was observed more in lavanambu than with Ksheera for Akantapana. Both had same potency in initiation of Vegas and removing the utkleshita dosha with no Upadravas is observed in the study.

**Paschat Karma-**
Sthanika chikitsa like Dhoomapana and Kavala are done to remove shesha dosha. Samsarjana krama is planned according to agnibala. In this study first aahara kala is planned with yavagu and second with kichidi, once again to maintain rationality and to prevent bias during study. These both are laghu for digestion and kindles the agni.

**Discussion on Inclusion Criteria –**
Patients between the age group of 16-60 years are having more incidence of Amlapitta. Among them who are indicated for vamana and having utkleshita lakshanas are only selected for study as Sadyovamana is done only in such conditions. Patients were randomly selected irrespective of sex, occupation, religion etc. during study.

**Discussion on Exclusion Criteria –**
Patients who are contraindicated for vamana with history of diabetic mellitus, hypertension, thyroidism, cardiac pathology, peptic ulcers, carcinomas, haemetmesis, malena, anaemia and immunodeficiency disorders like AIDS are excluded for study because there is chances of getting complications as well as drug interactions with the ongoing drugs.

**Discussion on Subjective Parameters –**
The classification of Utklesha lakshanas and non Utklesha lakshanas are based on analyses. By the same, application of need
of *sadyovamana* is possible. Subjective parameters are *Utklesha, Tikta Amla udgara, Shiroruja* and *Kanta hruth kukshi daha*. These four are considered as *utklesha lakshanas*. The symptoms commonly found along with *utklesha lakshanas* are *Vidbheda, Udara aadmana, Angasadha, Antrakoojana, Romaharsha, Aruchi* and *gurukoshta*. These are *agni dushti lakshanas* which are part and parcel in the pathogenesis of *amlapitta* as well as the benefits of *Sadyovamana* are seen on these parameters, so these are also considered as subjective parameters during study.

**DISCUSSION ON THE RESULTS OF CLINICAL TRIAL**

**DISCUSSION ON CLINICAL ANALYSIS**

**OVERALL ASSESSMENT OF THE TREATMENT**

The sum points of all the parameters of assessment before and after treatment were taken into consideration and the total effect of the treatment was assessed as Good Response, Moderate response, Poor Response and No Response.

- Null number for No response from both group.

- One Patient from each group showed Poor Response to treatment.

- 8 Patients from Group A and 10 Patients from Group B showed Moderate Response to treatment.

- 11 Patients from Group A and 09 Patients from Group B showed Good Response to treatment. By comparing the overall response for the treatment, it can be concluded that *Sadyovamana* using *Lavanambu* and *Ksheera* are having equal effectiveness. Thus $H_1$ hypothesis is proved.

**DISCUSSION ON STATISTICAL ANALYSIS**

Soon after *Sadyovamana* in both groups 100% reduction was present in all *Utkleshita Lakshanas* (4).

**After Treatment on 7th day and on 14th day**

*Utklesha*

**Group A**

100% reduction after 7th day and 93.93% reduction after 14th day were observed.

**Group B**

100 % reduction after 7th day and 93.44% reduction after 14th day were observed.
Both are highly significant at the level of <0.001.

**Tikta amla udgara**

**Group A**
96.96% reduction after 7th day and 87.87% reduction after 14th day were observed.

**Group B**
100 % reduction after 7th day and 80.30% reduction after 14th day were observed.
Both are highly significant at the level of <0.001

**Shiroruja**

**Group A**
94.59% reduction after 7th day and 89.18% reduction after 14th day were observed.

**Group B**
100 % reduction after 7th day and 95.83% reduction after 14th day were observed.
Both are highly significant at the level of <0.001

**Kanta Hruth Kukshi daha**

**Group A**
94.20% reduction after 7th day and 94.20% reduction after 14th day were observed.

**Group B**
100 % reduction after 7th day and 91.17% reduction after 14th day were observed.
Both are highly significant at the level of <0.001.

**Vidbheda**

**Group A**
100% reduction after 7th day and 81.81% reduction after 14th day were observed.

**Group B**
100 % reduction after 7th day and 87.50% reduction after 14th day were observed.
Both are highly significant at the level of <0.001.

**Udara Aadmana**

**Group A**
100% reduction after 7th day and 87.50% reduction after 14th day were observed.

**Group B**
94.44 % reduction after 7th day and 90.47 % reduction after 14th day were observed.
Group A shows highly significant at the level of <0.001 and group B shows statistically significant at the level of <0.05.

**Angasadha**

**Group A**
100% reduction after 7th day and 95.83% reduction after 14th day were observed.

**Group B**
100 % reduction after 7th day and 95.45% reduction after 14th day were observed.
Both are statistically significant at the level of <0.05.
Aantrakoojana

Group A
100% reduction after 7th day and 95% reduction after 14th day were observed.

Group B
100% reduction after 7th day and 85.18% reduction after 14th day were observed.
Both are statistically significant at the level of <0.05.

Romaharsha

Group A
100% reduction after 7th day and 100% reduction after 14th day were observed.

Group B
100% reduction after 7th day and 93.44% reduction after 14th day were observed.
Group A shows statistically significance at the level of <0.05 and group B shows non significant at the level of >0.05.

Aruchi

Group A
100% reduction after 7th day and 96.87% reduction after 14th day were observed.

Group B
100% reduction after 7th day and 82.75% reduction after 14th day were observed.
Both are highly significant at the level of <0.001.

Gurukoshta

Group A
100% reduction after 7th day and 87.50% reduction after 14th day were observed.

Group B
100% reduction after 7th day and 71.11% reduction after 14th day were observed.
Both are highly significant at the level of <0.001.

CONCLUSION

Distinct etiological factors in terms of Aahara, Vihara, Manasika and Deshadi factors vitiates Agni and Doshas in turn leading to Shuktapaka, giving rise to the disease entity Amlapitta, which holds good till date. Even though it is a Pitta predominant disease, the other two doshas also play a significant role and accordingly symptoms are exhibited. Diagnosing Utklesha condition is a key to adopt Sadyovamana which cut down the chain of pathology at specific stages; shortens the duration of disease as well as treatment and enhances the efficacy of Shamana Ausadhi. Present comparative study i.e. Sadyovamana using Lavanambu and Ksheera showed a highly Statistical
significance with P value <0.001 in both the groups in almost all the parameters. When compared using unpaired ‘t’ test both are equally significant thus proving the $h_1$ hypothesis.

Its patient friendly, very effective, intervenes with minimal preparatory procedures, hospitalization, expenses and very easy procedure which can be adopted even at OPD level. So the study also strongly emphasizes that all the ayurveda fraternity to adopt Sadyovamana in any diseases if Utklesha present in amashaya with due care, so that the pros & cons are highlighted through n number of trials in many diseases.

LIMITATIONS OF STUDY

- Cannot conduct Sadyovamana in children, old aged, pregnant woman, patients with debility and known cases of peptic ulcers etc because it may cause haemorrhage or other complications with respect to vamana.
- Could not able to incorporate endoscopic study because of its expensiveness and lack of availability of screening around study area.

SCOPE FOR FURTHER STUDY

1. When we analyze logically, references for sadyovamana are mentioned in classics using below mentioned dravyas, thus widens opportunity to conduct research on Sadyovamana in below mentioned diseases with those dravyas mentioned in the classics.

- Jwara-Sura, Tittira Mamsa rasa
- Ama Jwara-Lavanambu
- Pittaja Jwara-Lavanambu
- Ajeerna-Vacha, Lavanambu
- Alasaka-Ushna Lavanambu
- Visoochika-Ushna Lavanambu
- Visha-Madanaphala, Shunti
- Amlapitta-Lavanambu, Ksheera, Ikshurasa
- Madatyaya-Ikshurasa, Madya
2. As sample size was only 40 for study and due to time constraint cannot conclude the effectiveness of treatment for large population. So current study and result promotes for further trials with large sample size. Hence it becomes viable option to explore through further clinical trials & reliable approach towards Ayurvedic management.

3. By doing research in large scale emphasis for developing Standard Operative Protocols in combating *Utklesha* Conditions through *Ayurveda*.

4. The same study can be incorporated with endoscopic intervention for assessing the parameters to confirm the results, this can be done through further clinical trials to upgrade and establish the research in a microscopic language.

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