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 prevelance 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 *Utklesha* 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*.

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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 *utklesha*, *amla tiktha udgara*, *shiroruja* and *kanta hrut kukshi daha*[4].The other associated symptoms commonly seen

during *amlapitta* are *Vidbheda*, *Udara Aadmana*, *Angasadha Aantrakoojana*, *Romaharsha*, *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

H_0: Neither *sadyovamana* with *Lavanambu* nor *Ksheera* is effective in the management of *utkleshita Amlapitta*.

H_1: There is an equal effect of *sadyovamana* with *Lavanambu* and *Ksheera* in the management of *utkleshita Amlapitta*.

H_2: *sadyovamana* with *Lavanambu* is more effective than with *Ksheera* in the management of *utkleshita Amlapitta*.

H_3: *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 –

1. Collection of essential materials required for *Sadyovamana*.
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 lavana*
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*

ASSESSMENT OF *VAMANA*	
Vaigiki	No of *Vamana Vegas*
Anthiki	The end product
Maniki	The quantity of vomitus
Laingiki	Attained *shuddhi lakshanas*

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 14ᵗʰ day from where the day of treatment schedule started.

***Pathyaapathya* during treatment period and follow up period** –The patient was advised to follow below mentioned rules strictly –

1. After procedure for first *annakala yavagu* and second *annakala Krushara* was advised and for later annakala laghu, *ushna snigda anabhishyandhi aahara* was advised.
2. Avoid heavy food, sour and pungent foods, junk food and all *nidanas*.

3. Avoid skipping of food ,untimely food and sleep pattern
4. Avoid stress and negatives vibes.

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 1ˢᵗ day before starting the procedure, on the same day after procedure, on 7ᵗʰ day and on 14ᵗʰ day after follow-up. The grades for assessment of all Subjective parameters are as follows;

SUBJECTIVE PARAMETERS:

Table No.2 Shows the *Utklesha* Gradings

Grades	Symptoms
Grade 0	No *Utklesha*
Grade 1	Once in a Week
Grade 2	Once in 2-3 days
Grade 3	Every Day
Grade 4	After 2-3 hours of food intake

Table No:3 Shows the *Tikta Amla Udgara* Gradings

Grades	Symptoms
Grade 0	No *tikta amla Udgara*
Grade 1	Once in a Week
Grade 2	Once in 2-3 days
Grade 3	Every Day
Grade 4	After 2-3 hours of food intake

Table No:4 Shows the *Shiroruja* Grading

Grades	Symptoms
Grade 0	No *Shiroruja*
Grade 1	Once in a Week
Grade 2	Once in 2-3 days
Grade 3	Every Day
Grade 4	After 2-3 hours of food intake

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

Grades	Symptoms
Grade 0	No *Kanta hruth kukshi daha*
Grade 1	Once in a Week
Grade 2	Once in 2-3 days
Grade 3	Every Day
Grade 4	After 2-3 hours of food intake

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

Group	Response							
	Good Response		**Moderate Response**		**Poor Response**		**No Response**	
	No. of patients	%	No. of patients	%	No. of patients	%	No. of patients	%
Group A	11	55	08	40	01	05	00	00
Group B	09	45	10	50	01	05	00	00

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.
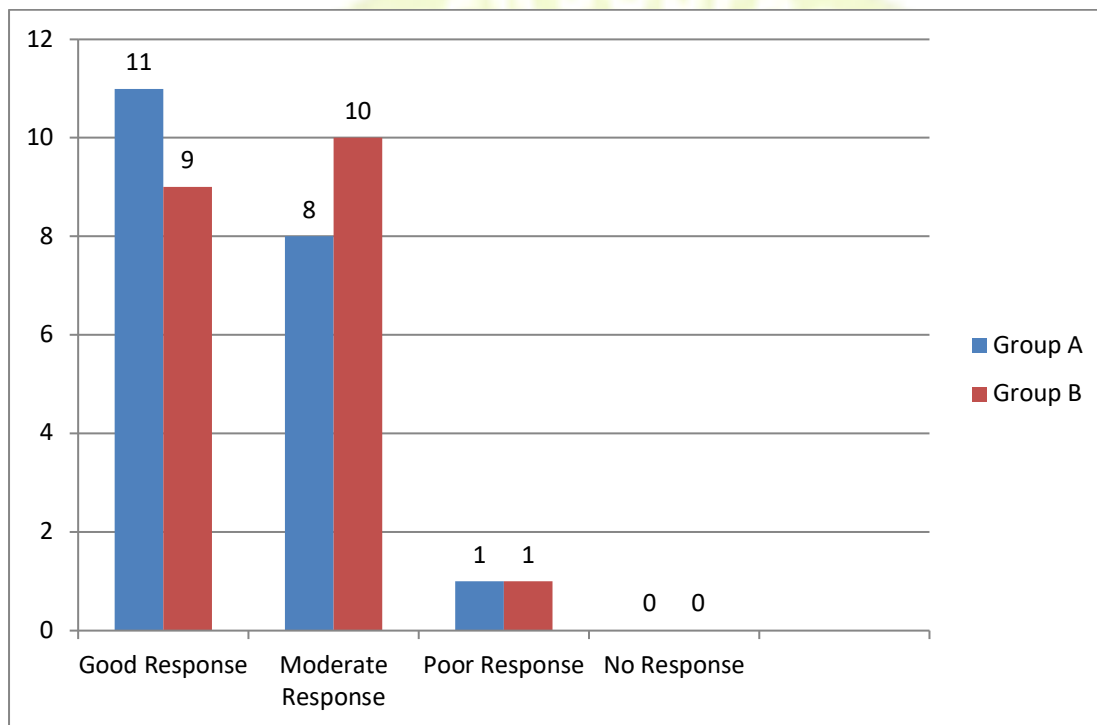
Graph No.1 Shows Overall response for the treatment

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**.**
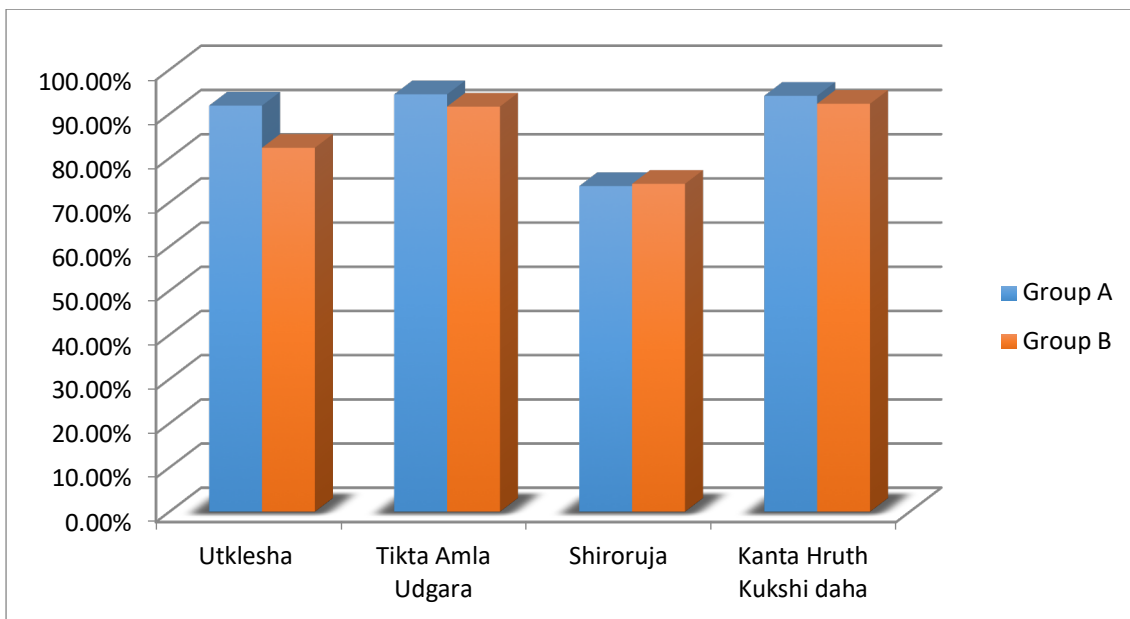
Group B –

- 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 *SADYOVAMANA*

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

Parameters	Group A	Group B
Utklesha	91.89%	82.35%
Tikta Amla Udgara	94.44%	91.66%
Shiroruja	73.68%	74.19%
Kanta Hruth Kukshi daha	94.11%	92.30%

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

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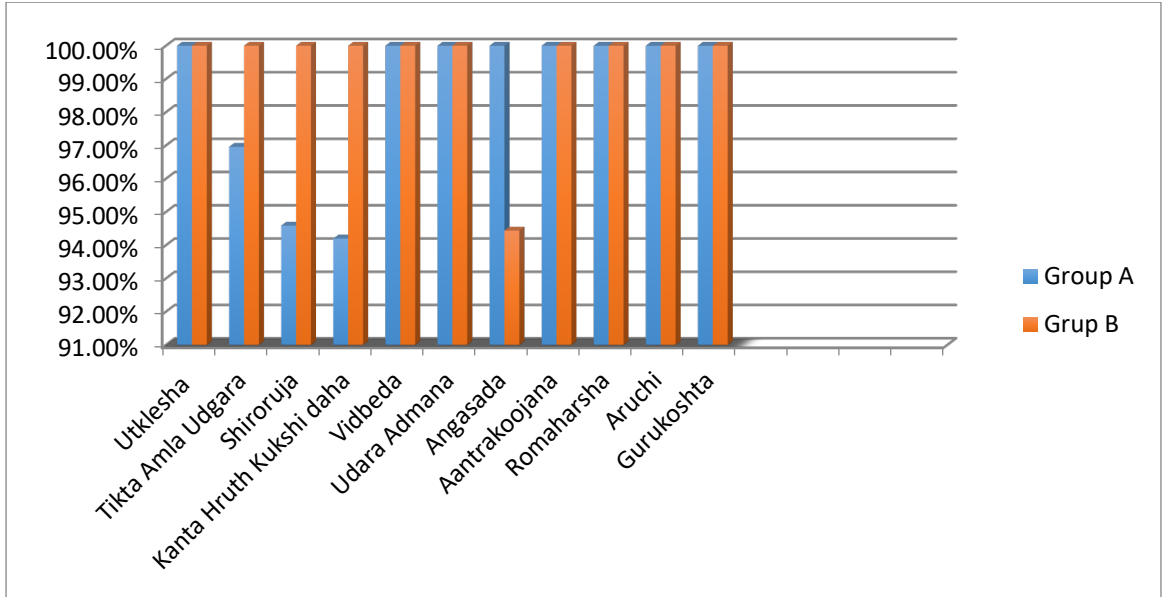
Graph No.3 shows Comparison of results in both groups – after treatment on 7th day

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

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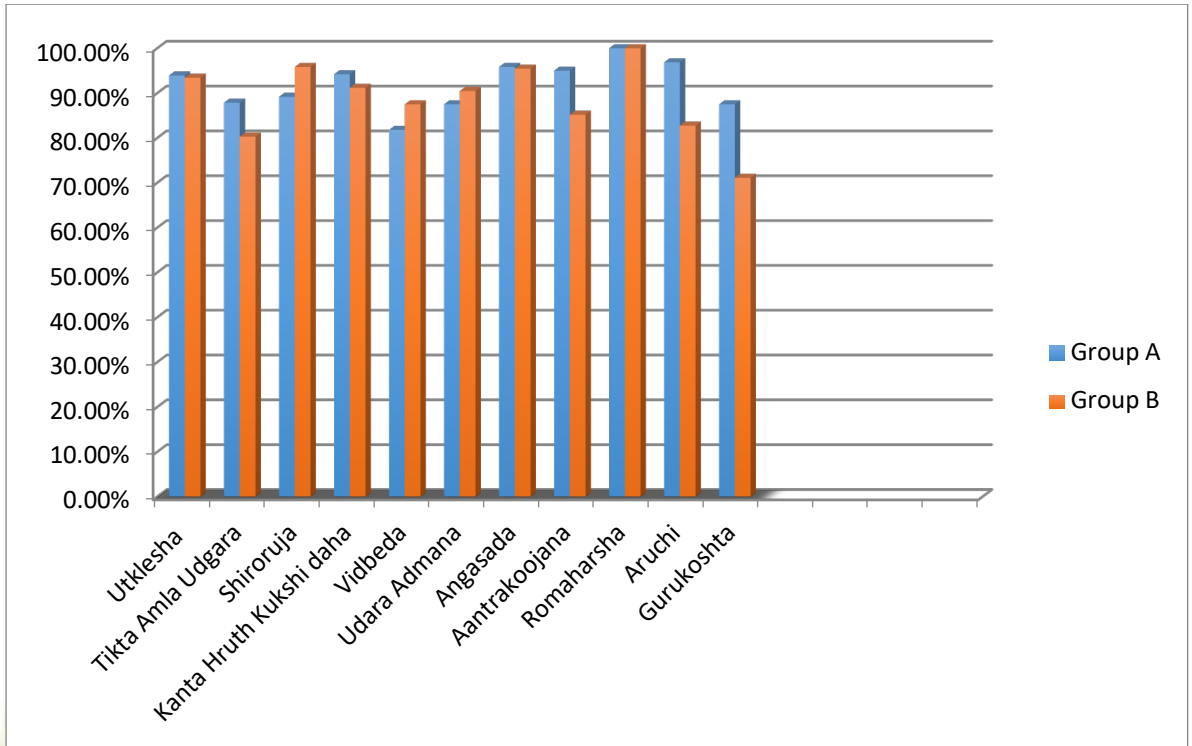
Graph No.4 shows Comparison of results in both groups – after treatment of 14ᵗʰ day

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

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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 *Jihvalaulyata*. 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, Shirashoola, 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 lot of water. It also advices to take more leafy vegetables, low fat-proteins, food containing flavonoids like brightly coloured fruits , vegetables and foods rich in fibres[345].

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.

Ushnodaka

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: intra-ganglionic 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[346].

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*

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 <0.001and 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 <0.05and 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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