



ISSN 2456-3110

Vol 5 · Issue 5

Sept-Oct 2020

Journal of
**Ayurveda and Integrated
Medical Sciences**

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences



Charaka
Publications

Indexed

Clinical study to evaluate the effectiveness of *Narikela Lavana, Navasadara Yuktha Yavakshara* in comparison with *Surya* and *Navasadara Paneeya Kshara* in the management of Cholelithiasis

Dr. Nagaratna¹, Dr. Srinivas Masalekar²

¹Post Graduate Scholar, ²Associate Professor, Dept. of Shalya Tantra, Govt. Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, INDIA.

ABSTRACT

Cholelithiasis is a crystalline concretion formed within the gall bladder by accretion of bile components. Cholelithiasis can be considered as *Pittashaya Ashmari*, but there is no direct reference of this condition available in Ayurveda. In Ayurveda the effective treatment is *Paneeya Kshara*. *Surya* and *Navasadara Paneeya Kshara* is standard one and which is highly effective treatment in the management of Cholelithiasis but, persisting pain, presence of calculi has limited in its use. To overcome the lacunas present study has been carried out. This study was conducted at SJIIM Hospital Bengaluru and total of 40 patients were randomly allotted into two groups namely Group A with trial drug i.e. 2grams each of *Narikela Lavana, Navasadara, Yava Kshara* orally with *Jala* once daily in empty stomach in the morning, every day for 28 days and Group B with control drug i.e. 2grams of *Surya* and *Navasadara Paneeya Kshara* orally with *Narikela Jala* once daily in empty stomach in the morning, every day for 28 days. Assessment was made on Subjective and Objective parameters. Observations were made before the treatment and on 15th day and 30th day to know the efficacy of the treatment. The combination of *Narikela Lavana, Navasadara Yuktha Yava Kshara* showed a positive result.

Key words: Cholelithiasis, *Narikela Lavana, Navasadara, Yava Kshara, Paaneyya Kshara*.

INTRODUCTION

Cholelithiasis is a crystalline concretion formed within the gall bladder by accretion of bile components. In Greek, Chol (bile) + Lith (stone) + Iasis (process). The overall incidence of Cholelithiasis in India is 10 million cases per year and in the world is about 10-15% of

total population.^[1]

A study shows that more than 85% of people having gall stones will be asymptomatic even for years and it is believed that they do not require any treatment. But in such gall stones, after long follow up, 50% has turned symptomatic and serious complication have occurred in 20% of cases. The most dreaded complication of asymptomatic gall stone is carcinoma of gall bladder. Presence of stones in gall bladder, can lead to serious conditions as ascending cholangitis or pancreatitis, acute or chronic cholecystitis. Any of these conditions can be life threatening and are considered to be surgical emergencies and require compulsory cholecystectomy.^[2]

The drugs to dissolve gall stones or other non-surgical methods are still considered experimental in modern medicine. By overall view it is very much clear that there is no desired effect in modern medicine for the

Address for correspondence:

Dr. Nagaratna

Post Graduate Scholar, Dept. of Shalya Tantra, Govt. Ayurvedic Medical College and Hospital, Bengaluru, Karnataka, INDIA.

E-mail: nspjkarki@gmail.com

Submission Date: 13/09/2020

Accepted Date: 19/10/2020

Access this article online

Quick Response Code



Website: www.jaims.in

DOI: 10.21760/jaims.5.5.5

management of cholelithiasis and sometimes many patients are unfit for the surgery, so there is large scope in Ayurveda to manage Cholelithiasis.

Direct reference of cholelithiasis is not available in Ayurveda. In this study the reference of the formulation is from Rasa Tarangini, by considering Cholelithiasis as *Pittashoshaja Shoola* the use of *Narikela Lavana, Navasagara, Yava Kshara*^[3] being made here is expected to contribute towards the better management of Cholelithiasis. The medicine used here is cost effective, less duration, avoids surgery and has no complications.

Management by *Paneeeya Kshara* of *Surya* and *Navasagara* from the previous dissertation work is taken as standard drug for comparison.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of *Narikela Lavana, Navasagara yuktha Yava Kshara* in the management of Cholelithiasis.
2. To evaluate the efficacy of *Surya* and *Navasagara Paneeeya Kshara* in the management of Cholelithiasis.
3. To compare the result obtained by two formulations - *Narikela Lavana + Navasagara + Yava Kshara* and *Surya + Navasagara Paneeeya Kshara*.

MATERIALS AND METHODS

Source of data

The subjects with or without symptoms of *Pittashaya Ashmari* which can be co-related with Cholelithiasis were selected from SJIIM Hospital, Bengaluru.

Method of collection of data

A total of 40 subjects presented with classical features of *Pittashaya Ashmari* and presence of calculi confirmed by Ultra sonogram of abdomen and pelvis and Asymptomatic subjects who were diagnosed to have gall stones, detected accidentally by x-ray or Ultra sonogram of abdomen were selected for the study and same were randomly allotted into 2 groups namely Group-A and Group-B with 20 subjects each.

Inclusion Criteria

Subjects presenting with symptoms of Cholelithiasis viz. pain in upper right quadrant of the abdomen, referring pain to the inferior angle of right scapula, vomiting, nausea, flatulent dyspepsia and also asymptomatic subjects who are diagnosed to have gall stones, detected accidentally by x-ray or Ultra sonogram of abdomen.

Exclusion Criteria

- Subjects who are contraindicated (*Ayogya*) for *Paneeeya Kshara*.
- Subjects suffering from other systemic disorders and condition which interfere with the treatment and requiring surgical intervention will be excluded.
- Subjects with gall stones associated with complications, such as acute cholecystitis, acute pancreatitis, liver failure, carcinoma of gall bladder and any other pathological condition presenting the sign jaundice.
- Immune compromised patients

Note: The pathological conditions mentioned in exclusion criteria were ruled out after considering the clinical features and conducting required investigations.

Materials Used

- 2grams each of *Narikela Lavana, Navasagara yuktha Yava Kshara*.
- 2grams of *Surya Navasagara Paneeeya Kshara*.
- *Jala* in sufficient quantity.
- *Narikela Jala* sufficient quantity.

Diagnostic criteria: Diagnosis was established, on the basis of history, signs and symptoms and investigations.

Investigation

Ultra Sonogram: Abdomen and pelvis – done before and after treatment.

Treatment

Procedure of treatment in Group A

Subjects in this group were advised to take the combination of 2grams each of *Narikela Lavana*, *Navasagara* and *Yava Kshara* orally with *Jala* (Water) once daily in empty stomach in the morning, every day for 28 days.

Procedure of treatment on Group B

Subjects in this group were advised to take the combination of 2grams of *Surya* and *Navasagara Paneeya Kshara* orally with *Narikela Jala* once daily in empty stomach in the morning, every day for 28 days.

Assessment Criteria

Assessment will be done on the following parameters.

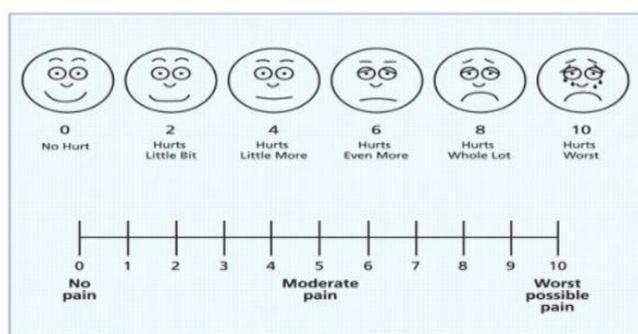
Subjective Parameter

1. Pain in right upper quadrant of abdomen
2. Referred pain to inferior angle of right scapula.
3. Nausea
4. Vomiting
5. Flatulent dyspepsia

Grading of the Parameters

1. The assessment of the pain in the right upper quadrant of abdomen is done by Visual Analogue Scale

Figure 1: Visual analogue scale



- Grade 0 – No pain (Rating Zero on Visual Analogue Scale)
- Grade 1 – Mild pain (Rating 1 to 3 Visual Analogue Scale)

- Grade 2 – Moderate pain (Rating 4 to 7 on Visual Analogue Scale)
 - Grade 3 – Severe pain (Rating 8 to 10 on Visual Analogue Scale)
2. Referring pain to the inferior angle of right scapula
 - Grade 0 – Absent
 - Grade 1 – Present
 3. Nausea
 - Grade 0 – Absent
 - Grade 1 – Present
 4. Vomiting
 - Grade 0 – Absent
 - Grade 1 – Present
 5. Flatulent dyspepsia
 - Grade 0 – Absent
 - Grade 1 – Present

Objective Parameter

Assessment of calculus will be done by Ultra sonogram abdomen and pelvis before the treatment and on 30th day after the treatment to confirm the efficacy of the treatment.

1. Assessment of size of the stones by Ultra sonogram findings.
 - Grade 0 – No change in size (no response)
 - Grade 1 – Reduction of stone size up to 25% (poor response)
 - Grade 2 - Reduction of stone size more than 25% and below 50% (mild response)
 - Grade 3 - Reduction of stone size more than 50% and below 75% (moderate response)
 - Grade 4 - Reduction of stone size more than 75% and below 100% (marked response)

Follow-Up Period

In cases where calculi was totally expelled or disintegrated, the duration of 2 months was fixed to

observe the possible recurrence. However, patients were advised to consult immediately if they notice any related symptoms.

OBSERVATION AND RESULT

Observation

Statistical results of administration of *Narikela Lavana*, *Navasagara* and *Yava Kshara* in Group A and *Surya* and *Navasagara Paneeya Kshara* in Group B of patients suffering from Cholelithiasis before and after treatment are analyzed as below.

- Age:** Out of total 40 subjects in Group A and Group B, Maximum patients i.e. 25% were in the age group 41-50 years. In Group A: 30% of patients belonged to 41-50 years & In group B 25% of patients belonged to age group 18-30 years and 51 -60 years.
- Gender:** Out of total 40 subjects in Group A and Group B, 57.5% were males and 42.5% were females. In Group A: 60% were males and 40% were females, in Group B: 55% were Males and 45% were females.
- Socio economic status:** Out of total 40 subjects in Group A and Group B, Maximum patients i.e. 62.5% belongs to Higher middle class. In Group A 65% were Higher middle class. In Group B % were Higher Middle class.
- Occupation:** Out of total 40 subjects in Group A & Group B Maximum subjects i.e.32.5% were Employees. In Group A 30% belongs to Employees and Retired persons. In Group B 35% belongs to Employees.
- Religion:** Out of total 40 subjects in group A and Group B, maximum subjects i.e. 92.5% were Hindus. In Group A 85% were Hindus, While in group B 100% were Hindus.
- Diet:** Out of total 40 subjects in Group A and Group B, maximum subjects i.e. 97.5% were taking mixed diet and 2.5% vegetarian. In Group A: 95% were taking mixed diet and 5% vegetarian, In Group B 100% were taking mixed diet.

- Agni:** Out of total 40 subjects in Group A & Group B, maximum subjects i.e. 60% were in *Mandagni*. In Group A 35% belongs to *Mandagni*. In Group B 85% belongs to *Mandagni*.
- Koshta:** Out of total 40 subjects in Group A & Group B, maximum subjects i.e. 70% were in *Madhyama Koshta*. In Group A 55% belongs to *Madhyama Koshta*. In Group B 85% belongs to *Madhyama Koshta*.
- Prakruti:** Out of total 40 subjects in Group A and Group B, maximum patients i.e. 70% belongs to *Pitta Kapha Prakruti*. In Group A 55% belongs to *Pitta Kapha Prakruti*. In Group B 85% belongs to *Pitta Kapha Prakruti*.

RESULTS

Table 1: Effect of Kshara on Pain

Pain	Mean Score			% of reduction	SD (±)	SE (±)	T value	P Value
	BT	AT	BT-AT					
Group A	1.85	0.35	1.5	81.08%	0.262	0.059	6.532	<0.001
Group B	1.30	0.45	0.85	65.38%	0.196	0.044	3.928	<0.001

Comparative effect on pain is showed in Table no. 1, which says mean score 1.85 before treatment in Group A was reduced to 0.35 after the treatment with 81.08% reduction & it is statistically significant ($p < 0.0001$). In Group B the mean score 1.30 before treatment was reduced to 0.45 after the treatment with 65.38% reduction which is statistically significant ($p < 0.0001$).

Table 2: Effect of Kshara on Referred pain

Referred pain	Mean Score			%	SD (±)	SE (±)	T value	P value
	BT	AT	BT-AT					
Group A	0.35	0.00	0.35	100%	0.489	0.109	1.368	<0.0001
Group B	0.05	0.05	0	0	0	0	0	<1.000

Comparative effect on Referred pain is showed in Table no. 2, which says mean score 0.35 before treatment in Group A was reduced to 0.0 after the treatment with 100% reduction & it is statistically significant ($p < 0.0001$). In Group B the mean score 0.05 before treatment was same i.e. 0.05 after the treatment with 0% reduction which is statistically not significant ($p > 1.000$).

Table 3: Effect of Kshara in Nausea

Nausea	Mean Score			%	SD (±)	SE (±)	T value	P value
	BT	AT	BT-AT					
Group A	0.65	0.0	0.65	100	0.489	0.109	5.940	<0.0001
Group B	0.40	0.05	0.35	87.5	0.279	0.062	2.559	<0.0001

Comparative effect on Nausea is showed in Table no. 3, which says mean score 0.65 before treatment in Group A was reduced to 0.0 after the treatment with 100% reduction & it is statistically significant ($p < 0.0001$). In Group B the mean score 0.40 before treatment was reduced to 0.05 after the treatment with 87.5% reduction which is statistically significant ($p < 0.0001$).

Table 4: Effect of Kshara on Vomiting

Vomiting	Mean Score			%	SD (±)	SE (±)	T value	P Value
	BT	AT	BT-AT					
Group A	0.45	0.0	0.45	100	0.51	0.114	3.943	<0.0001
Group B	0.0	0.0	0	0	0.0	0.00	Error	Error

Comparative effect on Vomiting is showed in Table no. 4, which says mean score 0.45 before treatment in Group A was reduced to 0.0 after the treatment with 100% reduction & it is statistically significant ($p < 0.0001$). In Group B, the mean score 0.00 before

treatment i.e. zero patient had a history of vomiting, so the test cannot be performed.

Table 5: Effect of Kshara on flatulent dyspepsia

Flatulent dyspepsia	Mean Score			%	SD (±)	SE (±)	T value	P value
	BT	AT	BT-AT					
Group A	1.00	0.0	1	100	0	0	1.831	<0.0001
Group B	0.90	0.05	0.85	94.4	0.084	0.019	12.	<0.0001

Comparative effect on Flatulent dyspepsia is showed in Table no. 5, which says mean score 1.00 before treatment in Group A was reduced to 0.0 after the treatment with 100% reduction & it is statistically significant ($p < 0.0001$). In Group B the mean score 0.90 before treatment was reduced to 0.05 after the treatment with 94.4% reduction which is statistically significant ($p < 0.0001$).

Table 6: Effect of treatment on stone size reduction

Stone size reduction	Mean Score			% of reduction	SD (±)	SE (±)	T value	P value
	BT	AT	BT-AT					
Group A	4.0	2.05	1.95	48.75%	0.826	0.185	10.563	<0.0001
Group B	4.0	3.10	0.90	22.5%	0.718	0.161	5.604	<0.0001

Comparative effect on stone size reduction is showed in Table no. 6, which says mean score 4.00 before treatment in Group A was reduced to 2.05 after the treatment with 48.75% reduction & it is statistically significant ($p < 0.0001$). In Group B the mean score 4.00 before treatment was reduced to 3.10 after the treatment with 22.5% reduction which is statistically significant ($p < 0.0001$).

Total effect of therapy**Table 7: Total effect of therapy in Group A**

Class	Grading	No. of patients	% of patients
0%	No response	0	0
1-25%	Poor response	0	0
26-50%	Moderate response	0	0
51-75%	Good response	2	10%
76-100%	Excellent response	18	90%

Table 8: Total effect of therapy in Group B

Class	Grading	No. of patients	% of patients
0%	No response	0	0
1-25%	Poor response	2	10%
26-50%	Moderate response	6	30%
51-75%	Good response	9	45%
76-100%	Excellent response	3	15%

DISCUSSION

Pittashmari is said to be *Tridoshaja Vyadhi*, still *Kapha* plays a major role in the formation of the stone. *Kledaka Kapha* and *Guru, Snigdha Guna* form the basis of *Ashmari* formation. *Ruksha Guna* of *Apaana Vata* and *Ushna Guna* of *Pitta* hardens the *Kapha* which acts as nidus, upon which aggregation of *Dosha* takes place and finally results in *Pittashmari*.

Therefore the management should be *Vilayana* or lysis of the nidus, *Vata* and *Pitta* are to be brought back normalcy.

Samprapti Vighatana at the level of formation of calculi become the main goal of treatment. The combination of *Narikela Lavana*, *Navasadara Yuktha Yava Kshara* possesses properties like *Bhedana*,

Shoola Hara, *Ksharana*, *Lekhana*, *Pachana* and *Deepana* which try to reverse the *Samprapti* of *Pittashmari*.

Narikela Lavana is a Nano crystalline material which consists of activated carbon and other elements like Na, Cl, Mg etc. the porous surface of activated charcoal has a negative electric charge which will attract the positive charged unwanted toxins and gas and help to remove them. It also helps in moving unwanted bacteria through the digestive tract faster so that before they multiply and spread, they are eliminated from the body.

Navasadara is said to be *Tridoshgna*, *Sukshma*, *Jataragni Deepaka*, *Pitta Saaraka*. It acts as expectorant, Hence it is beneficial in treating *Pittashmari*.

Yava Kshara is said to be *Ruksha*, *Kapha Pittashamaka*, *Shoolahara*, *Medohara*, *Agnivardhaka* and *Gulmahara*. It is useful in dyspepsia, abdominal pain, vomiting and obesity. It has diuretic property.

Kshra is a remedy formed by process of *Bhasmikiranana*, filtration, evaporation termed as *Sanskaras*. During the process of drying it undergo *Kala*, *Vata* and *Atapa Sanskara*. Which makes the drug dry and same *Gunasa* of *Vata*. During *Bhasmikiranana* process it undergo *Agnisanskara* which make the drug *Kaphagna* and *Vatagna*. Afterwards its get settled with water for whole night here *Jala* and *Prithvimahabhuta* will act, Build capacity to break. Further, the more it again undergoes *Agnisanskara*. During the whole process *Rasa*, *Veerya*, *Vipaka* of *Dravya* all changes and a new formulation i.e. *Kshara* is obtained. Which is of *Lavana Rasa*, *Ushna Veerya*, it dissolves and by *Prabhava* it expel out the *Pittashaya Ashmari*.

Kshara having the properties of *Ksharanath* might have probably acted mechanically on the calculi to disintegrate its molecules thereby resulting in lithotriptic action. Whereas by *Veerya* it has got potentiality to increase the *Pachakagni*, *Bhutagni*, as well as *Dhatwagni* which helped to make the metabolic corrections in the pathogenesis of Gallbladder stones. Further, the *Ushna Veerya* of

Kshara, Agni Deepana and *Kapha Vilayana* might have occurred by which concentration of bile is checked by reducing mucous hyper secretion and hyperlipidemia. Motility of Gall bladder is improved due to the *Vata Anulomana*. Property of *Kshara* due to *Prabhava*, thus dissolving the stone and correcting the metabolic causes to prevent the further formation of *Pittashmari*.

CONCLUSION

In the present study it was observed that Cholelithiasis was common in age group of 41-50 years, Males were more affected than Females, Occupation wise it was more common in Employees, more in Higher middle class people, more in *Mandagni* people, *Madhyama Koshta* people, *Pitta Kapha Prakrithi* people and was more in people with mixed dietary habits. The combination of *Narikela Lavana, Navasagara Yuktha Yava Kshara* shown significant result in all subjective and objective criteria, when compared to *Surya* and *Navasagara Paneeya Kshara*. The preparation of *Narikela Lavana, Navasagara Yuktha Yava Kshara* is simple, palatable, easy for administration, free from side effects and therapeutic efficacy is good. So, it can be adopted as a remedy for treatment of Cholelithiasis.

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How to cite this article: Dr. Nagaratna, Dr. Srinivas Masalekar. Clinical study to evaluate the effectiveness of Narikela Lavana, Navasagara Yuktha Yavakshara in comparison with Surya and Navasagara Paneeya Kshara in the management of Cholelithiasis. J Ayurveda Integr Med Sci 2020;5:39-45. <http://dx.doi.org/10.21760/jaims.5.5.5>

Source of Support: Nil, **Conflict of Interest:** None declared.

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