



A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFECTIVENESS OF PASHANABHEDADI KWATHA IN THE MANAGEMENT OF PITTASHMARI –CASE SERIES

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ABSTRACT

Ashmari formed in pittashaya is explained as pittashmari in classics the clinical features may be correlated as agnisanga, udara shola, ajirna, chardi and aruchi. it can be correlated with cholelithiasis in contemporary science. Symptoms in general include right hypochondriac region pain radiating to back, nausea, vomiting, indigestion, abdomen discomfort. prevalence of cholelithiasis varies according to geographical distribution, sex and age. The treatment modalities of cholelithiasis in conventional science are conservative medications and surgical procedures which are expensive, involve invasive treatments, needs hospitalization and in most of the case recurrence rate is high. Ayurveda explains variety of yogas for the management of ashmari. A pashanabhedadi kwatha is indicated in pittashmari as per Rasatarangini. So this study is taken up, to explore the effect of pashanabhedadi kwatha in pittashmari keeping in view the shortcoming of different modern medical treatments.

KEYWORDS: pittashmari, pashanabhedadi kwatha.

INTRODUCTION

Cholelithiasis (Gall stones) are formed from constituents of bile, cholesterol, bile pigments, calcium salts, bilirubin, phosphate carbonate, palmitate and proteins. The prevalence of cholelithiasis 10 to 20% of the world population. The prevalence in India has been reported as 2 to 29% and seven times more common in North India. 10% of the adult patients have asymptomatic gallstones. Women are affected more than men, and the ratio is 4:1. It is said that the gallstones are common in fat, fertile, forty, female. after a long follow up, turned symptomatic with serious complications like, acute and chronic cholecystitis, empyema and mucocele of gallbladder and Carcinoma in 20%. The medical management include oral bile acids for longer duration. Recurrence is common once the medication is stopped. Gall stones can be broken up by Lithotripsy, which is suitable only when there are small number of gall stones and recurrence is seen even after the surgical removal. After cholecystectomy complications like infection, subphrenic abscess, bleeding from cystic artery and from liver bed, injury to CBD, hepatic duct, colon, duodenum, biliary stricture and fistula formation.

AIMS AND OBJECTIVES OF STUDY

a) To evaluate the efficacy of Narikela lavana in the management of cholelithiasis.

b) To evaluate the efficacy of Pashanabhedadi kwatha in the management of cholelithiasis.

c) To compare the result obtained by two formulations Narikela lavana and Pashanabhedadi kwatha in the management of cholelithiasis.

Null Hypothesis

a) There is no significant effect of Narikela lavana in the management of cholelithiasis.

b) There is no significant effect of Pashanabhedadi kwatha in the management of cholelithiasis.

c) There is no significant difference between the effect of Narikela lavana and Pashanabhedadi kwatha in the management of cholelithiasis.

Alternative Hypothesis

a) There is significant effect of Narikela lavana in the management of cholelithiasis.

b) There is significant effect of Pashanabhedadi kwatha in the management of cholelithiasis.

C) There is significant difference between the effect of Narikela lavana and Pashanabhedadi kwatha in the management of cholelithiasis.

METHODOLOGY

This study was conducted during the period of September 2022 to August 2023.

SOURCE OF DATA

Subjects with the classical features cholelithiasis attending the outpatient and inpatient department of Government Ayurveda Medical College & hospital, Sri Jayachamarajendra Institute of Indian medicine, Bengaluru are selected for the study.

SAMPLING DESIGN

A total of 40 subjects with the features of Fistula-in-ano mentioned in inclusion criteria are included for the study randomly allotted into two groups namely Group A and Group B with 20 subjects each.

- 1) Patients presenting with symptoms of cholelithiasis viz, Pain in upper and Right quadrant of abdomen, Referring pain to the inferior angle of right scapula, Vomiting, Nausea, Flatulent dyspepsia and patients who are diagnosed to have gallstones detected by ultrasonogram of abdomen or x-ray of erect abdomen.
- 2) Age 18-60years

Exclusion Criteria

- 1) Patients with features of Obstructive jaundice, Liverfailure, Acute Pancreatitis, Acute obstructive cholecystitis and Carcinoma of gallbladder.

- 2) Uncontrolled systemic disorders like Diabetesmilitus, Hypertension.
- 3) Subjects with congenital anomalies of Hepato biliary system.

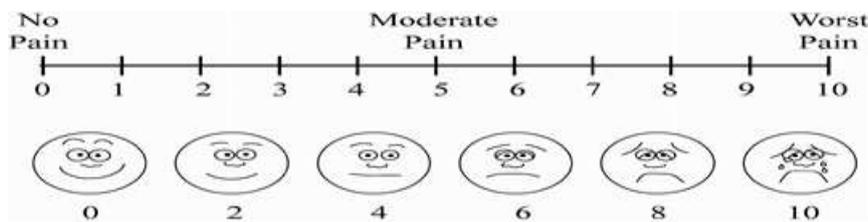
Procedure

Subjects in this group advised to take the *Pashanabhedadi kwatha* 1/2pala (24ml) with *sudha shilajatu churna* 1.5gm and *khanda sharakara churna* (1/8th part) after the break fast in morning and after the dinner in night with *sita jala* every day for 28days. Observation with respect to all the parameters were made before the treatment, on 15th day after the starting the medicine and on 30th day after the completion of treatment duration and change in the parameters were recorded in the proforma of case sheet specially prepared for the study.

Assessment will be done on the following parameters.

Subjective parameters.

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



1. The assessment of Visual analogue scale the pain in the right upper quadrant of abdomen is done by following grades

Grade 0-No pain (rating zero on visualanalogue scale)

Grade1- Mild pain (rating 1to3 visualanalogue scale)

Grade2-Moderate pain(rating 4 to7 on visualanalogue scale)

Grade 3-Severepain (rating 8 to10 on visualanalogue scale)

2. Referring pain to the inferior angle of right scapula

Grade0-Absent

Grade1-Present

3. Nausea

Grade 0 -Absent

Grade1-present

4. Vomiting

Grade 0- Absent

Grade1-Present

5. Flatulent dyspepsia

Grade 0- Absent

Grade1-Present

OBJECTIVE PARAMETER

Assessment of calculus will be done by ultrasonogram abdomen and pelvis before and on 28thday after the treatment to confirm the efficacy of the treatment.

1. Assessment of size of the stones by ultrasonogram findings.

Grade0- No change in size (no response)

Grade1-Reduction of stone size upto 25%(poor response)

Grade2-Reduction of stone size more than 25%and below 50%(mild response)

Grade3-Reduction of stone size more than 50% and below 75% (moderate response)

Grade4-Reduction of stone size more than 75% and below 100% (marked response)

OVERALL ASSESSMENT

The net results obtained from various parameters of assessment by the Treatment were taken into consideration to assess the overall effect of the treatment. Poor response <25% relief from all features I.e., Poor response <25% relief from all Features I.e., pain, nausea, vomiting, flatulentdyspepsia, reduction in stone size upto 25%. Mild response >25% to <50% relief from all the features, I.e., pain, nausea, vomiting, flatulent dyspepsia, reduction in stone size more than 25%and below 50% Moderateresponse >50% to <75% relief from all the

features, i.e. pain, nausea, vomiting, flatulent dyspepsia, reduction in stone size more than 50% and below 75% Marked response >75% to <100% relief from all the features i.e. pain, nausea, vomiting, flatulent dyspepsia,

reduction in stone size more than 75% and below 100%. Student paired “t” test statistical analysis was made and results were drawn,

Assessment of Pain in Group-A

Table 01: Assessment of Pain in Group-A.

Pain	1.55	15 th	0.95	0.60	38.71	0.681	0.156	3.14	<0.05
		AT	0.20	1.35	87.10	0.587	0.135	7.55	<0.05

Effect on Pain

In this work of 20 patients studied in (cholelithiasis) with Group-A Pain revealed are given in detail in Table No.32 Statistical analysis showed that the mean score

which was 1.55 before the treatment was reduced to 0.20 after the treatment with 87.10% improvement and there is a statistically significant. (P<0.05) results are graphically represented in figure no. 01.

Table 02: Assessment of Pain in Group-B.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Pain	1.55	15 th	0.35	1.20	77.42	0.410	0.094	3.14	<0.05
		AT	0.05	1.50	96.77	0.513	0.118	7.55	<0.05

Effect on Pain

In this work of 20 patients studied in (cholelithiasis) with Group-B Pain revealed are given in detail in Table No.33. Statistical analysis showed that the mean score which was 1.55 before the treatment was reduced to 0.05 after the treatment with 96.77% improvement and there is a statistically significant. (P<0.05) results are graphically represented in figure no.02.

When the Pain was analyzed using RM-ANOVA comparing between baseline, on D15 and post intervention shows a significant difference with p< 0.05.

After comparing the results it concluded that after giving the intervention in group A the pain was decreased only after D15 which was maintained over a period. With average improvement of 77.42% on D15 and also sustained of 96.77% on post intervention.

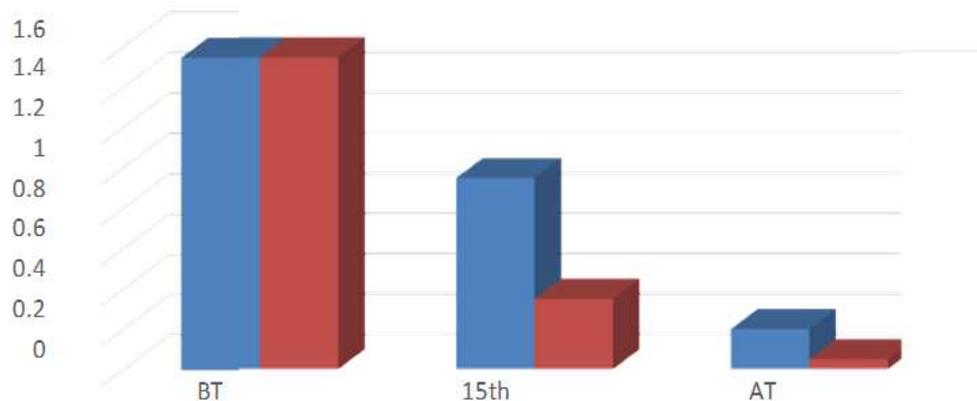


Table 3: Assessment of Referred Pain in Group-A.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Ref Pain	0.85	15 th	0.25	0.60	70.59	0.503	0.115	4.66	<0.05
		AT	0.00	0.85	100.0	0.366	0.084	10.38	<0.05

Effect on Referred Pain

An assessment of **Referred Pain** in patients of (cholelithiasis) before and after the treatment with Group-A showed reduction in the mean score from 0.85 to 0.00 after the treatment with 80% improvement. It is found to be statistically significant (P<0.05). The details

are shown with statistical data in Table No.34 and graphically represented in figure no.03.

When the Referred Pain was analyzed, using RM-ANOVA comparing between baseline on D15 and post intervention shows a significant difference with p < 0.05.

After comparing these results, it concludes that after giving the intervention in group A the Referred pain was decreased only after D15 which was maintained

over a period. With average improvement of 70.59% on D15 and also sustained of 100% on post intervention.

Table 4: Assessment of Referred Pain in Group-B.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Ref Pain	0.85	15 th	0.05	0.80	94.12	0.410	0.094	4.66	<0.05
		AT	0.00	0.85	100.0	0.366	0.084	10.38	<0.05

Effect on Referred Pain

An assessment of **Referred Pain** in patients of (cholelithiasis) before and after the treatment with Group-B showed reduction in the mean score from 0.85

to 0.00 after the treatment with 100% improvement. It is found to be statistically significant (P<0.05). The details are shown with statistical data in Table No.35 and graphically represented in figure no.04.

Table 5: Assessment of Nausea in Group-A.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Nausea	0.90	15 th	0.25	0.65	72.22	0.489	0.112	5.38	<0.05
		AT	0.15	0.75	83.33	0.444	0.102	7.01	<0.05

Effect on Nausea

Magnitude of **Nausea** in patients of (cholelithiasis) before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed significant improvement (P<0.05). The mean score which was 0.90 before treatment reduced to 0.15 after the treatment with 83.33% improvement. Further the particulars are tabled below in Table No.06 and graphically represented in figure no.05.

When the Nausea was analyzed, using RM-ANOVA comparing between baseline on D15 a post intervention shows a significant difference with p < 0.05.

After comparing these results, it concludes that after giving the intervention in group A the Referred pain was decreased only after D15 which was maintained over a period. With average improvement of 94.44% on D15 and also sustained of same on post intervention.

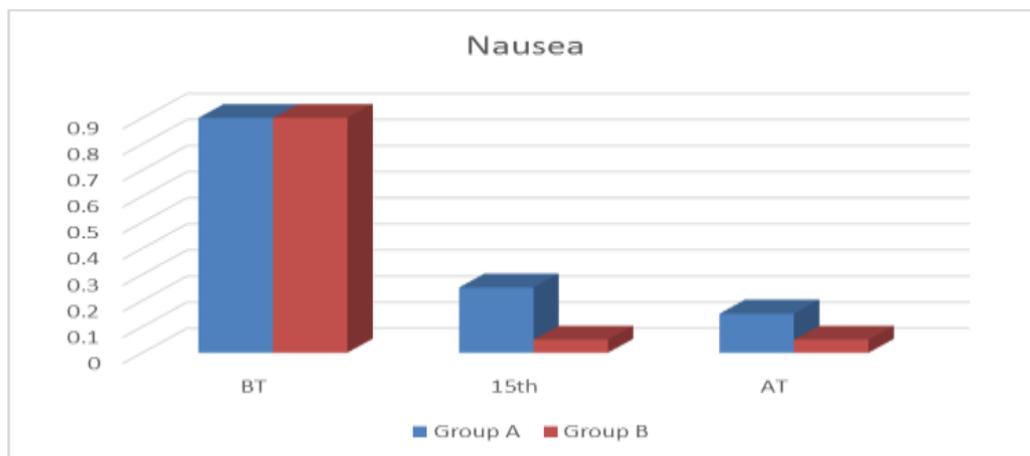


Table 6: Assessment of Flatulent Dyspepsia in Group-A.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Flatulent Dyspepsia	0.75	15 th	0.35	0.40	53.33	0.503	0.115	3.44	<0.05
		AT	0.20	0.55	73.33	0.510	0.117	3.44	<0.05

Effect on Flatulent Dyspepsia

Magnitude of **Flatulent Dyspepsia** in patients of (cholelithiasis) before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A Showed significant improvement (P<0.05). The mean score which was 0.75 before treatment

reduced to 0.20 after the treatment with 73.33% improvement. Further the particulars are tabled below in Table No.38 and graphically represented in figure no.06.

When the Flatulent dyspepsia was analyzed, using RM-ANOVA comparing between baseline on D15 and post intervention shows a significant difference with $p < 0.05$.

After comparing these results, it concludes that after giving the intervention in group A the Flatulent

dyspepsia was decreased only after D15 which was maintained over a period. With average improvement of 53.33% on D15 and also sustained of 73.33% on post intervention.

Table 7: Assessment of Flatulent Dyspepsia in Group-B.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Flatulent Dyspepsia	0.75	15 th	0.10	0.65	86.67	0.489	0.112	3.11	<0.05
		AT	0.10	0.65	86.67	0.489	0.112	4.34	<0.05

Effect on Flatulent Dyspepsia

Magnitude of **Flatulent Dyspepsia** in patients of (cholelithiasis) before and after the treatment was assessed and analyzed statistically. In patients registered in Group-B showed significant improvement ($P < 0.05$). The mean score which was 0.75 before treatment reduced to 0.10 after the treatment with 86.67% improvement. Further the particulars are tabled below in Table No.39 and graphically represented in figure no.07.

When the Flatulent dyspepsia was analyzed, using RM-ANOVA comparing between baseline on D15 and post intervention shows a significant difference with $p < 0.05$.

After comparing these results, it concludes that after giving the intervention in group A the Flatulent dyspepsia was decreased only after D15 which was maintained over a period. With average improvement of 86.67% on D15 and also sustained same on post intervention.

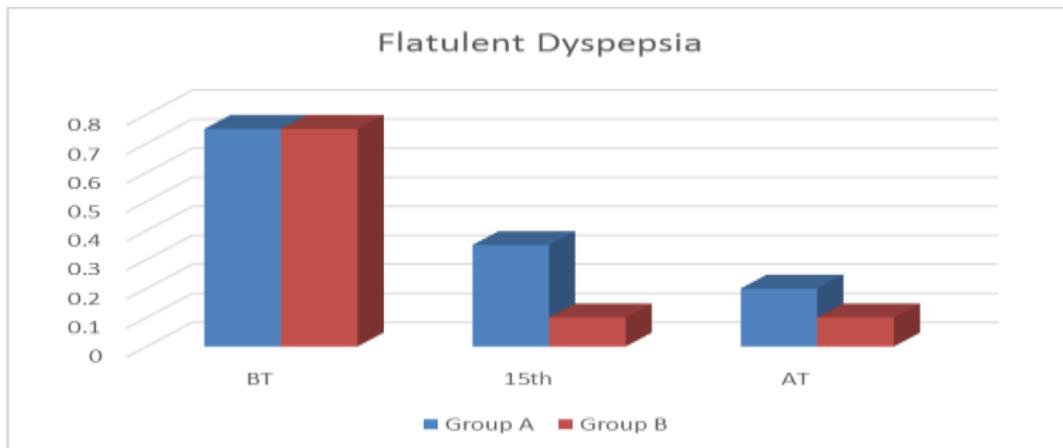


Table 8: Assessment of Vomiting in Group-A.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Vomiting	0.00	15 th	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		AT	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Effect on Vomiting

Magnitude of Vomiting in patients of (cholelithiasis) before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-A group showed no significant improvement ($P > 0.05$). The mean score which was 0.00 before treatment reduced to 0.00 after the treatment with 0% improvement. Further the

particulars are tabled below in Table No.40 and graphically represented in figure no.08.

When the Vomiting was analyzed, using RM-ANOVA comparing between baseline on D15 and post intervention shows a significant difference with $p 0.00$.

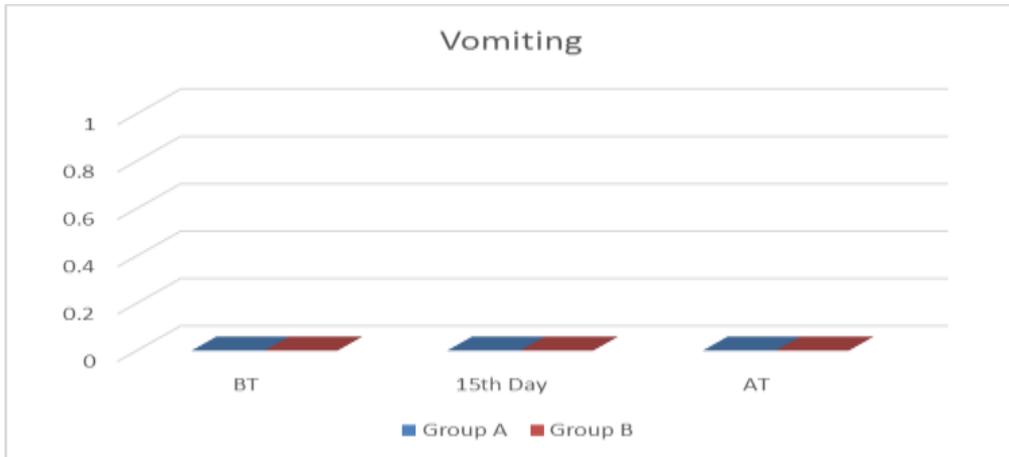
Table 9: Assessment of Vomiting in Group-B.

SYMPTOM	Mean score				%	S.D (±)	S.E (±)	t value	p value
	BT			BT-AT					
Vomiting	0.00	15 th	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		AT	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Effect on Vomiting

Magnitude of Vomiting in patients of (cholelithiasis) before and after the treatment was assessed and analyzed statistically. In patients registered in GROUP-B group showed no significant improvement ($P>0.05$). The mean

score which was 0.00 before treatment reduced to 0.00 after the treatment with 0.00% improvement. Further the particulars are tabled below in Table No.41 and graphically represented in figure no.09.

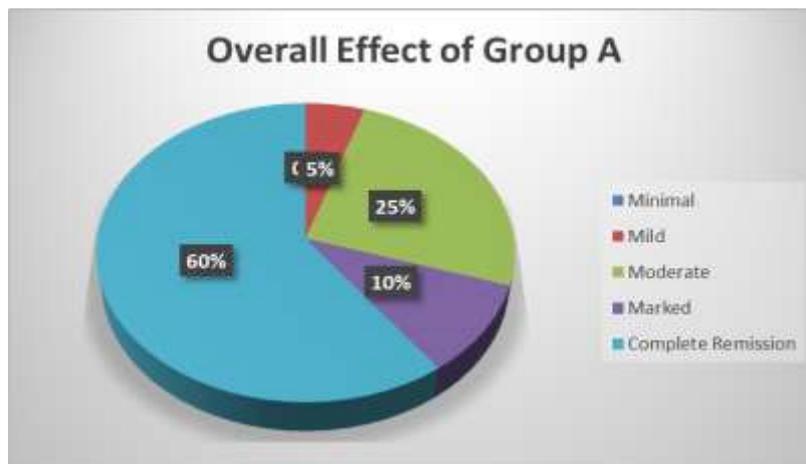


ASSESSMENT OF TOTAL EFFECT OF THERAPY

Table No. 10: Overall effect of *Pashanabhedadi kwatha* in Group-A.

Result on group A.

EFFECT OF TREATMENT IN GROUP - A		
Class	Grading	No of patients
0-25%	Minimal	0
26%-50%	Mild	1
51% - 75%	Moderate	5
76% - 99%	Marked	2
100%	Complete Remission	12



Effects of *Narikela lavana* in Group-B

ASSESSMENT OF TOTAL EFFECT OF THERAPY

Table No. 11: Overall effect in Group-B.

EFFECT OF TREATMENT IN GROUP - B		
Class	Grading	No of patients
0-25%	Minimal	0
26%-20%	Mild	0
51% - 75%	Moderate	2
76% - 99%	Marked	1
100%	Complete Remission	17

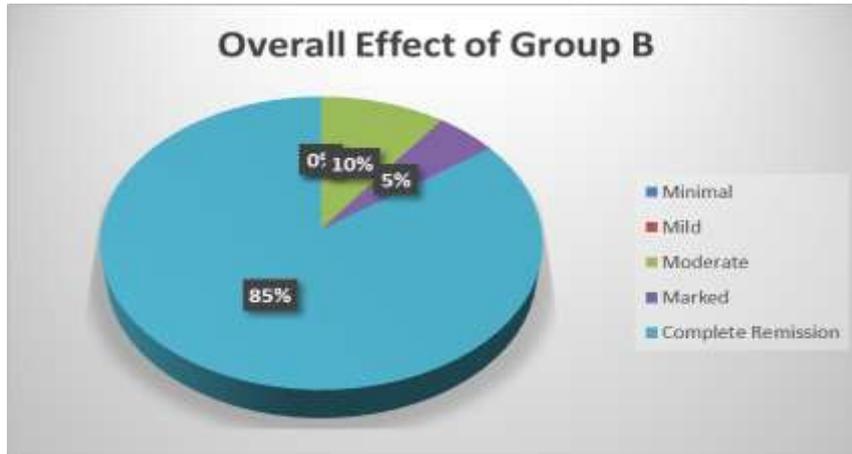


Table No. 12: Comparative results of Group-A and Group-B.

Signs and Symptoms	Group A (Mean Score)	Group B (Mean Score)	SD	SE	T Value	P Value
Pain	0.90	0.65	0.284	0.065	1.76	<0.05
Ref Pain	0.37	0.30	0.137	0.031	1.14	>0.05
Nausea	0.43	0.33	0.190	0.044	1.37	>0.05
Flatulent Dyspepsia	0.43	0.32	0.224	0.051	0.00	>0.05
Vomiting	0.00	0.00	0.00	0.00	0.00	0.00

Table no. 13: Comparative results of Group A and Group B.

Group A	Group B	Mean Difference	SE (±)	T value	P value
87.92	95.67	7.75	2.92	1.82	<0.05

Comparative analysis of the overall effect of the treatments in both the groups was done by statistically with unpaired t test. The test shows that the treatment is

significant in Group B when compared to Group A. Group A overall result is 87.92% and Group B overall result is 95.67%.

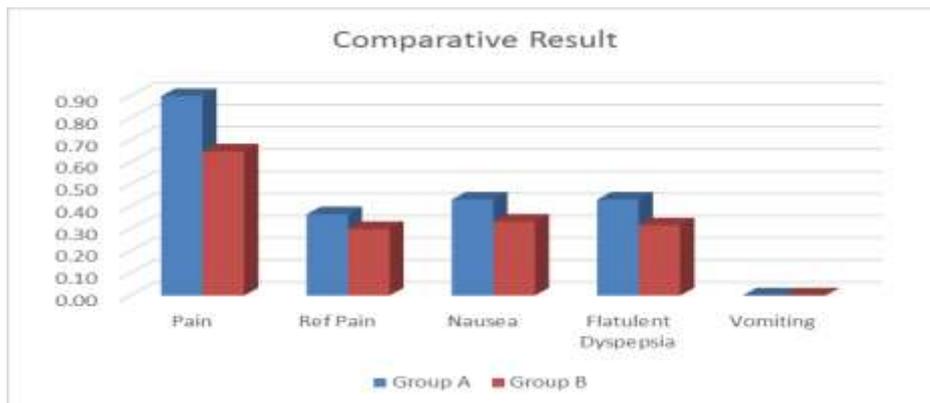


Chart no. 13: Comparative results of Group-A and Group-B.

After 28days of treatment, over all response of the drug on signs and symptoms were collectively presented here in nutshell.

Pashanabhedadi kwatha showed 60% complete remission and 25% of moderate response.

Narikela lavana showed complete remission in 85% and moderate response 10%.

Group A	Group B	Mean Difference	SE (±)	T value	P value
87.92	95.67	7.75	2.92	1.82	<0.05
Group A	Group B	Mean Difference	SE (±)	T value	P value
87.92	95.67	7.75	2.92	1.82	<0.05
Group A	Group B	Mean Difference	SE (±)	T value	P value
87.92	95.67	7.75	2.92	1.82	<0.05

Overall response based on the signs and symptoms is statistically insignificant in both groups. On comparison of results of both the groups after treatment insignificant difference was found in all symptoms; however percentage improvement is slightly better in standard

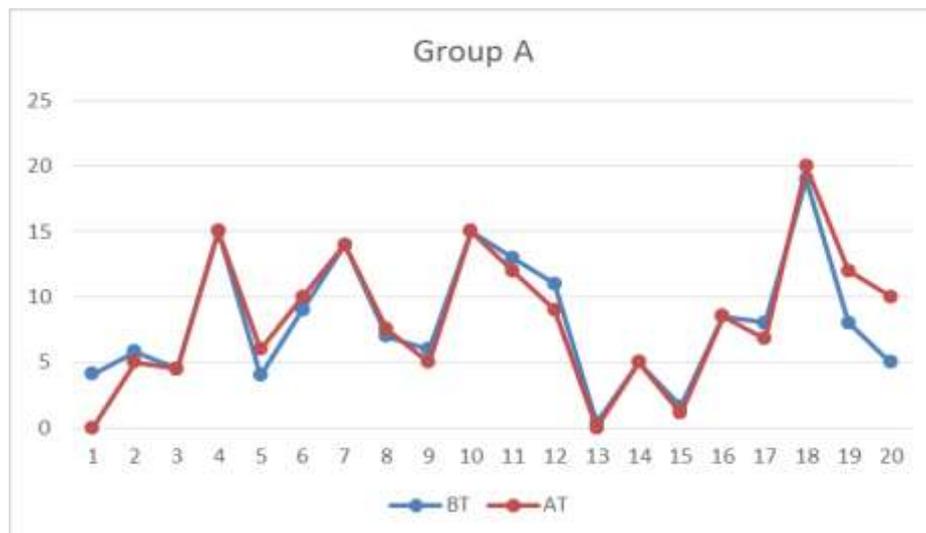
group, showing the standard group is slightly better than trial group in curing symptoms of cholelithiasis. The standard group *Narikela lavana* is more efficacious than trial group (*Pashanabhedadi kwatha*).

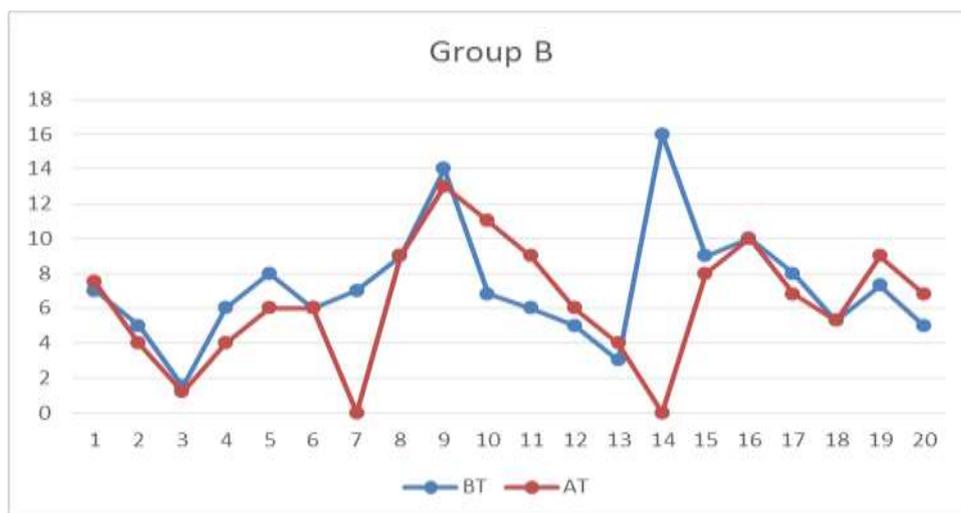
REDUCTION IN STONE SIZE

1) INCIDENCE OF STONE SIZE IN GROUP A AND GROUP B

Table No. 14: Incidence of stone size in Group A and Group B.

GROUP A				GROUP B			
Sl no	BT	AT	% of reduction	Sl no	BT	AT	% of reduction
1	4.1	0	100.00	1	7	7.5	-7.14
2	5.8	5	13.79	2	5	4	20.00
3	4.5	4.5	0.00	3	1.5	1.2	20.00
4	15	15	0.00	4	6	4	33.33
5	4	6	-50.00	5	8	6	25.00
6	9	10	-11.11	6	6	6	0.00
7	14	14	0.00	7	7	0	100.00
8	7	7.5	-7.14	8	9	9	0.00
9	6	5	16.67	9	14	13	7.14
10	15	15	0.00	10	6.8	11	-61.76
11	13	12	7.69	11	6	9	-50.00
12	11	9	18.18	12	5	6	-20.00
13	0.4	0	100.00	13	3	4	-33.33
14	5	5	0.00	14	16	0	100.00
15	1.6	1.1	31.25	15	9	8	11.11
16	8.5	8.5	0.00	16	10	10	0.00
17	8	6.8	15.00	17	8	6.8	15.00
18	19	20	-5.26	18	5.3	5.3	0.00
19	8	12	-50.00	19	7.3	9	-23.29
20	5	10	-100.00	20	5	6.8	-36.00





Comparative effect on stone size reduction is showed in table no. 33 which says mean score 8.1 before treatment in Group A was 8.32 after the treatment with +1.52% reduction and it is statistically significant ($p < 0.0001$). In Group B the mean score 7.24 before treatment in Group A was 6.33 after the treatment with +12.62% reduction statistically significant ($p < 0.0001$).

DISCUSSION

Discussion is the important part of any research work. It provides a platform for re-examining the whole work, which is a key part of any scientific and methodological research work, even in classics, this has been highlighted and accepted in the name of vimarsha i.e. discussion before coming to any conclusion. Discussion is divided in the following sections.

- Discussion on selection of the topic.
- Discussion on Disease.
- Discussion on Drugs.
- Discussion on Chikitsa.
- Discussion on Observation – Demographic data, Subjective parameter, Objective parameter.
- Discussion on overall Assessment.
- Discussion on Mode of action.

DISCUSSION ON SELECTION OF THE TOPIC

1. Cholelithiasis is one of the most expensive medical conditions in terms of money spent in managing it. It is either symptomatic or asymptomatic, the complications of gall stones are Hydrops of gall bladder, Acute obstructive cholecystitis, Mucocele, Empyema, Gangrene, Perforation, Obstructive jaundice, Acute pancreatitis and Gall stone ileus. If not treated properly it may lead to carcinoma of gall bladder which is 5th commonest GI malignancy world-wide. The overall incidence of Cholelithiasis in India is 10 million cases per year in the world is about 10-15% of total population.

2. The drugs to dissolve gall stones or non-surgical methods are still considered experimental in modern medicine. Cholesterol gall stones can sometimes be dissolved by oral Ursodeoxycholic acid, but it may be required that the patient takes this medication for 2 years.

Gall stones may recur however once the drug is stopped. At the same time it may produce side effects like mild diarrhea and temporarily raised levels of blood cholesterol and liver enzyme transaminase.

3. Gall stones can be broken up using a procedure called the Lithotripsy, but the Biliary tract does not provide such a simple passage for fragment stones. The cystic duct is not an easy channel to pass for fragmented calculi.

4. The surgical management of Cholelithiasis is Cholecystectomy. However about 10-15% of population may develop a condition called Post cholecystectomy syndrome and sometimes many patients are unfit for the surgery. By overall view it is very much clear that there is no desired conservative effect in modern medicine for the management of cholelithiasis. Hence present study is conducted to know the efficacy of Ayurvedic medicines in the management of Cholelithiasis.

DISCUSSION ON DISEASE

1. The disease Pittashaya Ashmari is no where mentioned in Prevedic or Vedic period. There are references available in Samhitha Kaala about this condition which can be correlated to the features of Cholelithiasis.

2. Acharya Sushruta quotes Pittashaya is one among the Asta Ashaya.

3. Paneeya kshara is indicated in Ashmari.

4. Acharya Vagbhata quotes, Ashmari formed in the Basti is similar to the Ashmari formed in the Pittashaya of the Cow. So the Ashmari formed in the Pittashaya of the humans, is similar to the Gorochana can be considered as Pittashaya Ashmari

5. The reference of Pittashaya Ashamari samprapti is dealt in Rasa Tarangini. Under the context of Narikela Lavana Guna Karma, Rasa Tarangini Kaara quotes, Vata prakopa in the Pittashaya causes the shoshana of Pitta Dasha in the Pittashaya which later leads to the manifestation of shoola. By considering Cholelithiasis as Pittashoshaja shola, the present study is carried out to know the efficacy of Pashanabhedadi kwatha in the management Cholelithiasis.

DISCUSSION ON DRUGS

The trial drug selected for the present study is Pashanabhedadi kwatha.

1. Narikela lavana is said to be pachaka, amla pitta hara, pittashamaka, pittashoshaja shoola hara. Here, Narikela lavana contains albumin, globulin, amino acids and acetic acids.
2. Pashanabhedai kwatha is indicated in Pittaj ashmari.
3. Pashanabheda drug is best in Tridosaghna, Ashmariaghna, Shoolahara, Dahahara, Pliha rogahara, Vranahara. Shilajatu is having properties of Ashmariaghna, Shoothara, cures Agnimandya, Udarashoolahara and useful in all Udara vikaras. And khanda sharakara acts as Dahahara, Pittahara.

DISCUSSION ON CHIKITSA

The types of treatment can be classified as

1. Nidana parivarjana,
2. Prakrutivighatana and
3. Apakarshana

1) Nidana parivarjana: for any disease to get rid of, the etiological factors must be kept at mind, in spite of giving the best available treatment, chance of recurrence of the disease is more. As Pittashmari is one among such disease, if Nidana parivarjana is not done, the disease may become further aggravated and presents with complications. In the early stage of Pittashmari, by following Nidana parivarjana and adopting Pathya apathya, one can treat successfully and even the recurrence rate of Pittashmari can be minimized.

2) Prakruthi vighatana: this is achieved by performing shodhana and shamana line of therapies which break the pathophysiology process which is responsible for the causes of disease and its progression.

3) Apakarshana: the word meaning of Apakarshana is removal of treatment, then as described in the classics, the Nirharana of Ashmari by the surgical intervention is ultimate. Hence surgery can be considered as Apakarshana treatment in Ashmari. Pathya plays an important role as much as of medicine. Patient treated by Shodhana, Shaman or Shashtra karma, should follow the regimens to avoid progress and recurrence. The subjects of both the groups were advised to follow specific Pathyapathya.

DISCUSSION ON DEMOGRAPHIC DATA

A total 40 subjects were taken for the study for a period of 3 months. The data gained were used for demographic and disease related observations.

1. Gender Most of the patients recruited for the study were female 23(57.50%) followed by males 17(42.50%). This shows that female are more prone to get gallstones rather than males in this study pregnancy is also a major risk factor for gallstone formation, the risk is related to the number of pregnancies.
2. Sex hormone are most likely to be responsible for the increased risk. Estrogen increases biliary cholesterol secretion causing cholesterol super

saturation of bile. Thus, hormone replacement therapy in postmenopausal women and oral contraceptives also been described to be associated with an increase risk for gallstone.

3. Age I of the disease. In this disease, if the calculi are not responding for any shodhana or shamana line The age for inclusion criteria was set from 18years to 80years. Maximum number of subjects (25%) belongs to 28-37years and 48-57 years of age group (table no.21) followed by 38-47 years (17.50%). Which matches with the textual statistics. Though Pittashaya ashmari can occur at any age but middle age group are more prone for occurrence of Pittashaya ashmari. So the present data is supportive of this fact. Because stressful life style and increased workload of this age leads to irregular dietary habit and ignorance to health as well.
4. Occupation Out of total 40 subjects in Group A and Group B maximum subjects i.e 50% employees. Because they will be leading to stressful life, improper diet which leads to the formation of gall stones.
4. Religion Out of total 40 subjects in Group A and in Group B, maximum subjects i.e 82.50% Hindus, 15% muslims. Due to the culture of having more of rituals like fasting, more intake of milk sources, fatty foods can be rated high for incidence in this study.
5. Marital status Out of total 40 subjects in Group A and Group B, 85% married, 15% unmarried.
6. socio economic status:
7. Out of total 40 subjects in Group A and Group B, maximum patients i.e 85% middle class peoples are mostly having irregular dietary habits, fasting which leads to vitiation of Agni and Dosha resulting in diseased condition.
8. Agni Out of total 40 subjects in Group A and Group B maximum subjects i.e 55% Vishama agni. Due to Vishama agni, the Pachaka pitta will get hamper which leads to the development and progression of Pittashaya ashmari.
9. Prakruthi Out of total 40 subjects in Group A and Group B, maximum subjects i.e 50% belongs to Pittakapha prakruthi, 42.50% belongs to Vata-pitta prakruthi, 7.50% in vata-kapha prakruthi. Solidification of kapha dosha is responsible for the formation of gall stones.
10. Diet Out of total 40 subjects in Group A and Group B, maximum subjects i.e 75% were taking mixed diet and 25% vegetarian. The maximum subjects were consuming mixed diet, regular intake of Non veg, curd, fatty and spicy food which contains more amounts of fat and cholesterol. Due to the high intake there will be increased level of cholesterol in the blood which are one among the cause of disease.
11. Koshta Out of total 40 subjects in Group A and Group B maximum subjects i.e. 65% were in madhyama koshta.
12. Vyasana: Out of total 40 subjects in Group A and Group B, maximum subjects i.e. 92.50% were not having any habits.

DISCUSSION BASED ON SUBJECTIVE PARAMETERS

1. Pain Both the groups showed significant result in pain. Group A showed significant reduction in the pain by 87.10% and group B showed significant reduction in pain by 96.77%. So Group B has comparatively good out come in pain management. This may be attributed due to Vatanulomana and Vata shamaka properties of Narikela Lavana leading to relieving the spasm of Gall bladder, cystic duct and also reducing the irritation to the Vidhgdhata of Pitta and relieving the pain.
2. Referred pain Group A showed significant reduction in the referred pain by 80% and in group B 100% reduction, it shows the combination of Narikela Lavana is beneficial in treating referred pain.
3. Nausea Both the groups showed significant result in nausea. Group A showed significant reduction in the nausea by 83.33% and group B showed significant reduction in nausea by 94.44%. So group B has comparatively good out come in nausea management. This shows Narikela Lavana is beneficial in treating Nausea.
4. Vomiting Group A and Group B 0%, zero patient had a history of vomiting.
5. Flatulent dyspepsia Both the groups showed significant result in flatulent dyspepsia Group A showed significant reduction in the flatulent dyspepsia by 73.33% and group B showed significant reduction in flatulent dyspepsia by 86.67%. So group B has comparatively good out come in flatulent dyspepsia management.
6. Both groups showed significant result in case of single stone symptoms relieving and stone size reduction is good out come as compared with multiple gall stones.
7. Average size reduction in Group A is +1.52% and in Group B is +12.62%.

DISCUSSION ON OBJECTIVE PARAMETERS

1. Effect of therapy on stone Both the groups showed significant result in pain. Group A showed significant reduction in the stone size by +1.52% and group B showed significant reduction in stone size by +12.62 %. So group B has comparatively good out come in stone size reduction.

DISCUSSION ON OVERALL ASSESSMENT

After 28 days of treatment, over all response of the drug on signs and symptoms were collectively presented here in a nutshell Pashanabhedadi kwatha showed minimal response 60%, moderate response in 25% and Narikela lavana showed complete remission in 85%, Marked response in 5%, moderate response in 10%, Poor response in 09%. Over all response based on the signs and symptoms is statistically insignificant in both groups, On comparison of results of both the groups after treatment insignificant difference was found in all symptoms; however percentage improvement is slightly better in standard group, showing the standard group is slightly better than trial group in curing symptoms of Cholelithiasis. The standard group (Narikela Lavana) is

more efficacious than trial group (Pashanabhedadi kwatha) due to synergetic action of its ingredients. Out of 40patients, total 4 patients gall stone fully dissolved 2patients from each group. Group A having big stone size of 16mm and Group B is having stone size of 4.1mm is dissolved completely.

FOLLOW UP STUDY

The patients were advised to review once in a month after completion of treatment for next 3 months. No recurrence in subjective parameters was reported by the patients within this period. They were instructed to maintain fat free diet throughout the study period.

DISCUSSION ON MODE OF ACTION

Pittashmari is said to be Tridoshaja vyadhi, still kapha plays a major role in the formation of the stone. Kledaka kapha is Guru, Snigdha guna form the basis of Ashmari formation. Ruksha guna of Apaana vata and ushna guna of Pitta hardens the kapha, upon which aggregation of dosha takes place and finally results in Pittashmari. Therefore the management should be vilayana or lysis of the Ashmari, vata and pitta are to be brought back normalcy. Samprapti vighatana at the level of formation of calculi become the goal of treatment. The combination of Narikela lavana possesses properties like shoolahara, pachana, and deepana which try to reverse the samprapti of Pittashmari.

1. In the context of Narikela Lavana guna karma, Vaidya Kashinath shashtri quotes, that Narikela Lavana is having effect as Pittashoshaja shoola hara.
2. Narikela Lavana is one of the classical formulations of Ayurveda, which comes under Kshara kalpana because it possess the properties of Kshara due to this, Narikela Lavana is also named as Narikela Kshara by some scholars of Ayurveda Narikela Lavana is Pachaka, Pittanashaka, Pittashoshaja skoolahara.
3. 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 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.

CONCLUSION

Following conclusions were drawn from the present study clinical study with treatment and observation.

- 1) Out of the 40 patients of Cholelithiasis included in the study, 20 patients were treated with *Pashanbhedadi kwatha* under Group A and 20 patients were treated with *Narikela lavana* in Group B.
- 2) In the present study it was observed that Cholelithiasis was common in age group of 28-37years, Out of total 40 patients in group A and group B, maximum patients were in age Group 28-37years. They were 25%. Group wise division: They were 40% and10% respectively in A and B Group

3) Gender wise females were more affected than males. Out of 40 patients in group A and Group B, maximum patients were female 23. They were 57.50%. Group wise division: They were 60% and 55% respectively in A and B Group.

4) Occupation wise it was more common in Employees. Out of total 40 patients in Group A and Group B, maximum patients **Occupation** were Employees (50%).

Group wise division: In, Group A, they were 45% and in Group B they were 55%.

5) Religion wise it was more common in Hindu, Out of total 40 patients in Group A and Group B, maximum patients **Religion** were Hindu (82.50%). Group wise division: In, Group A, they were 80% and in Group B they were 85%.



Fig. No. 27: Ingredients Of Narikela Lavana.



Fig. No. 28: Raw Narikela Lavana.



Fig. No. 29: A) Puta, B) Narikela Lavana.



Fig. No. 30: A) Shudha Shilajatu Pareeksha.



Fig. No. 30: B) Shudha Shilajathu Pareeksha.



Fig. No. 31: Shilajathu.



Fig. No. 32: Shilajathu Churna.



Fig. No. 33: Khanda Sharkara Churna.



Fig. No. 34: Pashanabheda.

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