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CASE SERIES

Therapeutic Effect of Abhaya Lavana with Sharapunkha Kwatha in the Management of Cholelithiasis – A Case Series

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ABSTRACT

Cholelithiasis is a worldwide medical condition, resulting from a combination of several factors such as supersaturation of bile with cholesterol, accelerated nucleation of cholesterol monohydrate in bile, and bile stasis or delayed gallbladder emptying. The treatment options for asymptomatic range from no treatment to selective cholecystectomy. Definite non-invasive management is a boon in asymptomatic and symptomatic uncomplicated gallstones. *Abhaya Lavana* is a combination of *Kshara* and *Lavana kalpana* described in classics. Its indications point toward that this combination has a definite result in cholelithiasis and associated symptoms. *Kwatha* of *Sharapunkha* as *Anupana* acts as a carrier to its site of action. To evaluate the efficacy, a pre- and post-test clinical study was conducted among the 13 participants. The clinical intervention was done with 2 g of *Abhaya Lavana* with 96 mL of *Sharapunkha Kwatha* for 45 Days. Pre- and post-assessment of the primary objective – USG and secondary objective – lipid profile were conducted after the study. The safety of the drug has been assessed by pre- and post-RFT and LFT. The study interprets a mild shift in the mean size of the largest stone, with no significant change in gallstone size in the USG abdomen. However, this study reveals notable reductions in subjective parameters such as right hypochondriac pain, indigestion, nausea, vomiting, and associated symptoms such as fever, burning chest, constipation, and right shoulder pain. This study reveals that the combined effect of *Abhaya Lavana* and *Sharapunkha Kwatha* is effective in cholelithiasis and reducing associated symptoms.

1. INTRODUCTION

Cholelithiasis also known as gallstones is a worldwide medical problem that results from a combination of several factors such as the supersaturation of bile with cholesterol, accelerated nucleation of cholesterol monohydrate in bile, and bile stasis or delayed gallbladder emptying. Gallstones are conveniently classified into cholesterol or pigment stones although the majority are of mixed composition. Gallstones contain varying quantities of calcium salts, including calcium bilirubinate, carbonate, phosphate, and palmitate, which are radio-opaque. In the most common type cholesterol gallstones, biliary sludge is gelatinous bile that contains numerous microspheroliths of calcium bilirubinate granules, cholesterol crystals, and glycoproteins; it is an important precursor to the formation of gallstones in most patients. Biliary sludge persists to form cholesterol stones.

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The prevalence of gallstones in the adult population was 6.12% (men 3.07% and women 9.6%).[1] An epidemiological study shows that in India, prevalence of cholelithiasis is about 4%.

Gallbladder stones present in one of three clinical stages: Asymptomatic, symptomatic, and with complications.[2] Cholecystectomy is recommended for cholecystolithiasis patients presenting with any symptoms. However, for patients who do not consent to surgery, it recommends oral dissolution therapy or extracorporeal shock wave lithotripsy if either is indicated.[3] Surgery is not recommended for patients with diabetes, children, or those with organ transplants. About 50% of asymptomatic cholelithiasis patients become symptomatic during follow-up annually. The treatment options for asymptomatic or silent gallstones range from no treatment to selective cholecystectomy in at-risk groups to selective cholecystectomy in all patients.[4] In light of available clinical guidelines, laparoscopic cholecystectomy remains the default option for all people with symptomatic uncomplicated gallstone disease.[5]

In the above-said circumstances, definite non-invasive management using drugs will be a boon in asymptomatic and symptomatic

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uncomplicated gallbladder stones. Various studies show that *Kshara Kalpana* has impressive results in cholelithiasis and associated symptoms due to its properties such as *Chedana, Bhedana,* and *Lekhana*. *Pleeha Yakrit Rogadhikara* chapter of *Bhaishajyaratnavali* specifies a formulation called *Abhaya Lavana* which is a strategic combination of *Kshara* and *Lavana Kalpana*.[6] Most of the indications such as *Koshtagatharoga, Anaha* (abdominal distension), *Gulma, Aşhtila* (Stoney growth in the abdomen), *Mandagni* (decreased digestive power), *Sirah Sula* (Headache), *Hrdroga, Sarkara*, and *Ashmari nashana* are associated with the symptoms of gallbladder stones.

Furthermore, gallstones form as a result of cholestasis, which is a biochemical abnormality resulting from an impairment in bile flow which can be correlated with *Apana vayu Pratiloma*. Furthermore, the major ingredient *Abhaya* was known for its *anulomana* properties. Its indications also point toward the fact that this combination has a definite result in cholelithiasis and associated symptoms by the properties of *Kshara, Lavana,* and its *anulomana* action.

Anupana, Sharapunkha (*Tephrosia purpurea* [Linn.] Pers.), and *Kwatha* help to carry the drug to its site of action and have an affinity toward the hepato-biliary system.[7] This combination is cost-effective when compared to other available conventional treatments. This study aims to evaluate the effect of *Abhaya Lavana* with *Sharapunkha Kwatha* in managing symptomatic and asymptomatic non-complicated cholelithiasis

2. MATERIALS AND METHODS

After obtaining informed consent from each participant, they were carefully chosen by meeting specific inclusion and exclusion criteria irrespective of gender, religion, and occupation, visiting the *Rasa Sastra* OPD at Vaidyaratnam Ayurveda College, Thaikkattussery, Thrissur, Kerala, and informed consent was collected from each participant. The research followed a pre-test and post-test clinical study design with a consecutive sampling method.

2.1. Inclusion Criteria

1. Participants between 18 and 60 years of age of both sexes, with the presence of asymptomatic gallbladder stones or sludge diagnosed by ultrasonography (USG).
2. Uncomplicated symptomatic gallbladder stone with occasional biliary colic.
3. Gallbladder stone with a size <15 mm

2.2. Exclusion Criteria

1. Current or previous acute cholecystitis or pancreatitis
2. Gallstones in the common bile duct or evidence of previous choledocholithiasis on the latest imaging
3. All diagnosed malignancies
4. Pregnancy or lactation
5. Evidence of empyema of the gallbladder with sepsis
6. Perforated gallbladder (refers to recent or old perforation detected on imaging)
7. Gallstone ileus
8. Renal disorders
9. Hyperlipidemia – Total cholesterol above 500 mg/dL.

2.3. Preparation of Trial Drugs

The trial drug *Abhaya Lavana* was prepared in the *Rasasastra* and *Bhaishajya Kalpana* Department of Vaidyaratnam Ayurveda College, Thrissur, Kerala, India, according to the Ayurveda Formulary of India.[8] *Sharapunkha Kashaya Churna* was made by pulverizing the roots of *T. purpurea* (Linn.) pers.[9] The raw drugs for preparation were collected from the authorized herbal medical store, and their botanical identity and quality were ascertained in the Department of *Dravyaguna Vijnana.*

2.4. Preparation of Abhaya Lavana

Reference to *Abhaya Lavana* is also seen in the Ayurvedic formulary of India and *Vaidyatarakam*, and an Ayurvedic treatise written in the Malayalam language. Medicine was prepared as per the reference in the Ayurvedic formulary of India. Equal parts of *Paribhadra, Palasa, Arka, Snuhi, Apamarga, Citraka, Varuna, Agnimantha, Vasuka, Svadamstra, Brihati, Kantakari, Putika, Asphota, Kutaja, Kosataki,* and *Punarnava* along with their roots, leaves, and stems are taken and coarsely powdered. It is then kept in a mouth-closed pot. One *Prastha* of the *Bhasma* prepared from all the ingredients is mixed with two *Drona* of water in a sturdy earthen pitcher and cooked over a low flame. It is then reduced to one-fourth of the original quantity and filtered. Into the filtrate, 1 *Prastha* of powdered *Saindhava* (rock salt), *half Prastha* of powdered *Haritaki*, and 8 Pala of *Gomutra* (cow's urine) were added. The mixture is then cooked again over low heat. Half pala each of *Ajamoda, Hingu, Triushna, Yavani, Pushkaramula,* and *Shati* is finely powdered and added to the prepared solution as *Prakshepa dravyas.*

2.5. Methodology

Participants taking anti-hyperlipidemic drugs were monitored and followed up separately. No specific diet and medication change is advised during the study. Participants were administered *Abhaya Lavana* 2 g with 96 mL *Sharapunkha Kwatha* once daily given for 45 days in the middle of breakfast. Pre- and post-assessment of the participants were done by subjective parameters such as right hypochondriac pain, indigestion, nausea, and vomiting and objective parameters such as fever, burning chest, constipation, and the right shoulder pain. USG abdomen was done to find the change in the size of the stones and the reduction in sludge formation before and after the study. A lipid profile (serum cholesterol, triglycerides, and LDL) was done to assess if any relation persists between incidents of cholelithiasis and increased lipid values. The pain was assessed by the Visual Analog Scale with Zero to Ten numbers. Liver function test (SGOT, SGPT, alkaline phosphatase, total bilirubin, direct and indirect bilirubin, serum proteins, serum albumin, serum globulin, and A/G ratio) and renal function test (urea, uric acid, and creatinine) were conducted before and after the study to evaluate the safety of the drug.

The data, compiled using Microsoft Excel 2016, underwent statistical analysis utilizing SPSS software. Kolmogorov–Smirnov test has been used to check the normality of continuous data. For the data found to be normal, to compare the mean before and after treatment, paired t-tests have been used. For the data that are not normal, non-parametric test, Friedman test, and Wilcoxon signed rank test have been used.

3. RESULTS

In the present study, out of 13 participants, eight are females and the maximum number of participants is 41–60 years. 38% complained of disturbed sleep due to pain and 85% preferred the non-vegetarian diet. While assessing before treatment, 69% had normal body mass index (BMI).

Wilcoxon signed-rank test is used to check the frequency distribution according to the grading of the largest size of gallstones in USG, and mean size does not differ significantly (Z: −0.356, $P = 0.722$). The mean size of the largest size of gallstone is 8.69, but it reduced slightly to 8.55 after 45 days (Table 1).

Friedman test is used to check the signs and symptoms such as pain in the right hypochondrium, fever, colicky pain, abdominal distention, indigestion, burning chest, constipation, pain on the right shoulder, nausea, and vomiting (Table 2).

The right hypochondriac pain – The mean pain differs significantly (Chi-square: 28.054, $P = 0$). Mean pain at the beginning was 4.38, but it reduced to 0.31 after 15 days. Thereafter reduced to zero.

Fever – Mean symptomatic change in fever differs significantly (Chi-square: 15, $P = 0.002$). The mean symptomatic change in fever at the beginning is 0.69, but it has reduced to 0.

Colicky pain – mean symptomatic change in colicky pain differs significantly (Chi-square: 9, $P = 0.029$). The mean symptomatic change in colicky pain at the beginning is 0.69, but it has reduced to 0.

Abdominal distention – mean symptomatic change in abdominal distention differs significantly (Chi-square: 28.714, $P = 0$). The mean symptomatic change in abdominal distention at the beginning is 1.46, but it has reduced to 0.08 on the 15th day, thereafter reduced to zero.

Indigestion – mean symptomatic change in indigestion differs significantly (Chi-square: 20.556, $P = 0$). The mean symptomatic change in indigestion at the beginning is 1.23, but it has reduced to 0.23 on the 15th day, and to 0.08 on the 30th day, thereafter reduced to zero on the 45th day.

Burning chest – mean symptomatic change in burning chest differs significantly (Chi-square: 24.429, $P = 0$). The mean symptomatic change in burning chest at the beginning is 1.38, but it has reduced to 0.15 on the 15th day, thereafter reduced to zero.

Constipation – mean symptomatic change in constipation differs significantly (Chi-square: 11.182, $P = 0.011$). The mean symptomatic change in constipation at the beginning is 0.62, but it has reduced to 0.23 on the 15th day, thereafter reduced to zero.

Pain on right shoulder – mean symptomatic change in pain on the right shoulder differs significantly (Chi-square: 12, $P = 0.007$). The mean symptomatic change in pain on the right shoulder at the beginning is 0.62, but it has reduced to zero.

Nausea – mean symptomatic change in nausea differs significantly (Chi-square: 12, $P = 0.007$). The mean symptomatic change in nausea at the beginning is 0.62, but it has reduced to zero.

Vomiting – mean symptomatic change in vomiting differs significantly (Chi-square: 12, $P = 0.007$). The mean symptomatic change in vomiting at the beginning is 0.62, but it has reduced to zero.

S. cholesterol before and after treatment is normally distributed (Kolmogorov–Smirnov test). A paired *t*-test is used to check the S. cholesterol frequency. Mean S. cholesterol does not differ significantly (t: 0.254). The mean S. cholesterol at the beginning is 1.927, but it reduces to 1.904 after 45 days, but not significantly ($P = 0.804 > 0.05$).

Serum triglycerides before and after treatment are normally distributed (Kolmogorov–Smirnov test). Paired t-test is used to check the serum triglycerides frequency. Mean serum triglycerides do not differ significantly (t: 1.358). The mean serum triglycerides at the beginning are 1.22, but it reduces to 1.09 after 45 days, but not significantly ($P = 0.199 > 0.05$).

HDL cholesterol before and after treatment are normally distributed (Kolmogorov–Smirnov test). A paired *t*-test is used to check the HDL cholesterol frequency. The mean HDL cholesterol does not differ significantly (t: 0.325). The mean HDL cholesterol at the beginning is 48.38, but it reduces to 47.38 after 45 days, but not significantly ($P = 0.751 > 0.05$).

LDL cholesterol before and after treatment are normally distributed (Kolmogorov–Smirnov test). A paired *t*-test is used to check the LDL cholesterol frequency. The mean LDL cholesterol does not differ significantly (t: 1.025). The mean LDL cholesterol at the beginning is 1.2, but it reduces to 1.09 after 45 days, but not significantly ($P = 0.325 > 0.05$).

Liver function test and renal function test were conducted before and after the study to evaluate the safety of the drug. No significant changes in the values were noticed after the study and all values were within the limit, thereby the safety of the drug was assured.

4. DISCUSSION

Study findings indicate a slight shift in the mean size of the largest stone, with no significant change in gallstone size in the USG abdomen, possibly due to the study's brief duration. Wilcoxon signed-rank test is used to check the frequency distribution according to the grading of the largest size of gallstones in USG, and mean size does not differ significantly (Z: −0.356, $P = 0.722$). The mean size of the largest size of gallstone is 8.69, but it reduces slightly to 8.55 after 45 days. In many participants, the stone size remained the same, some showed slight changes in the size. Significant changes were seen in the size of stones in post-USG of two participants and significant changes in the amount of sludge mass were noted in one participant. They were not included in the study as the age of the participants was above 60/the size of the stone was above 15 mm. All were in the exclusion criteria of the study.

However, this study reveals notable reductions in subjective parameters such as right hypochondriac pain, indigestion, nausea, vomiting, and associated symptoms such as fever, burning chest, constipation, and right shoulder pain.

Previous studies show that there are some positive relations between serum LDL, triglycerides, cholesterol, and cholelithiasis. Furthermore, a high-fat diet is a risk factor for gallbladder disease. Pre- and post-lipid profile tests were conducted. It was found that values of total cholesterol, triglycerides, and LDL were reduced after the intervention. However, it was not statistically significant. All the values after the study were within the normal limit. The liver plays the main role in lipid metabolism and *Abhaya Lavana* and *Sharapunkha Kwatha* have effect on liver cells and significant results may occur in these parameters using an increased dose for a longer period.

4.1. Biochemical Parameters (Liver Function Test and Renal Function Test)

The liver function test (SGOT, SGPT, alkaline phosphatase, total bilirubin, direct and indirect bilirubin, serum proteins, serum albumin, serum globulin, and A/G ratio) and renal function test (urea, uric acid, and creatinine) were conducted before and after the study to evaluate the safety of the drug. No significant changes in the values

were noticed after the study and all values were within the limit, and thereby, the safety of the drug was assured.

4.2. Probable Mode of Action of Drug

The intervention of the study was the administration of two drugs. The main drug was *Abhaya Lavana* and decoction of *Sharapunkha* was given as *Anupana*. *Abhaya Lavana* is a judicial combination of *Kshara Kalpana, Lavana, Hareethaki*, and other *Deepana Pachana* and *Soola hara* drugs. It is explained in the context of *Yakrit Pleeha roga in Bhaishajya ratnavali*. *Yoga* is indicated in conditions such as diseases of *Koshta* including *Yakridodara, Plihodara, Anaha, Gulma, Aşhtila, Grandhi, Chidrodara, Hrdroga, Sarkara,* and *Asmari.* Even though *Pithasaya Asmari* is not said in the indications, it can be assumed that the drug is having action in gallbladder stone by the context of the explanation of *yoga* and its indications. The term *Sarkara* and *Asmari* denotes any concretions in *Sareera avayava*. Detailed descriptions of *Asmari* of *Vrikka* and *Mutrasaya* can be seen in all scriptures of *Ayurveda*. It is not possible to conclude that the formation of *Sarkara a*nd *Asmari* is possible only in the above-said areas. The *sanchaya* of *Kapha dosha* and the role of *Vatha* in *Shoshanna* are undoubtful in the structural manifestation of *Ashmari* and *Sarkara*. Major causes of the formation of gallbladder stones include disturbed cholesterol metabolism, precipitation of cholesterol, changes in the concentration of bile due to various reasons, and obstruction of bile flow from the gallbladder. This situation is to be understood with the *Kapha dosha sanchaya* in the gallbladder, *Agni vaishamya*, *Pratiloma of Vata dosha,* and *Srothovaigunya.*

Abhaya Lavana has predominantly *Lavana Kashaya* and *Katu rasa* from the *Avayava Prabhava,* and it can be concluded that this combination is *Theekshna Ushna, anulomana, Chedana, Lekhana*, *Bhedana, Srothosodhana*, and *Kaphavatahara*. All *Kshara* preparations have *Ashmari Bhedana* properties. *Gomutra* which plays a major role in *yoga* also has *Kshara guna* which is helpful in the *Chedana* and *Bhedana* of stones. The formation of sludge is the precursor stage of gallstone formation; *Pratiloma* of *Vata dosha* and "*Srothovaigunya"* can be the main causes of sludge formation. *Haritaki* and *Saindhava* possess potent *"Vatanulomana"* properties. *Saindhava* is *Snigdha* in guna and "*Bandhavidmapana hrit,"* i.e., to remove a mass or deposits. *Rachana guna* of *Saindhava* helps in the flow of bile from the gallbladder and through the extra biliary apparatus. *Snigdha* and *Anulomana guna* also help to eradicate the chance of future stone formation.

Different types of pain manifestations are due to *Srothovaigunyam* and *Prathilomagathi* of *Vata, Hareethaki,* and *Saindhava* help in this direction. *Gomutra* is *Soolahara* and *Gulma hara*. Drugs such as *Trikatu, Yavani, Ajamoda, Hingu,* and *Pushkara moola* have strong *Soolahara* and *Gulma hara* properties. Pain on the right shoulder is referred to as pain and it disappears as the pain in the primary site is relieved.

Indigestion is a major symptom of cholelithiasis. Indigestion is due to a lack of *Vatanulomyam* and *Agnimandhya. Katu Lavana rasa* and *Theekshna Ushna guna* of the combination helps to improve *Agni.* Most of the drugs possess *Deepan*a and *Pachana guna*. This helps to ward off indigestion. Nausea and vomiting are due to the *Pratiloma gati* of *Udana Vata*. The Vatanulomana action of *Abhaya Lavana* also reflects on the *Udana Vata.*

Constipated bowel or *Malabandha* is due to *Srothovibandha,* Rooksha guna *Vardhan* of *vata dosha,* and hence, *Apanavaigunya. Saindhava* and *Shunti* are *Snigdha* and *Vibandhajith*. *Hareethaki* is *Anulomana* and *Vibandhahara* and *Gomutra* are *Varcho grahapaham*. These above-mentioned properties help to remove constipation. Abdominal distension is due to improper digestion, drugs help to improve digestion and also help to relieve abdominal distention. Indications of *Abhaya Lavana* also contain *Anahaharatwa*. Ingredients such as *Hareethaki, Gomutra, Shunti, Hingu,* and *Yavani* possess *Anahaharatwa* property. Burning the chest is due to improper digestion. Usually, *katu teekshan ushna guna* of this combination causes *Pitha vriddhi*. However, the burning chest in this case is not due to vitiated *Pitha* but due to improper digestion due to *Vata vaigunya*. All the participants felt better after taking medicine, and this strongly supports this principle even though *Abhaya Lavana* is having *katu teekshan ushna guna.*

Decoction of *Sharapunkha* was given as *Anupana* for *Abhaya Lavana*. It is indicated in *Yakrit Pliha roga* in Ayurveda scriptures. Furthermore, animal research has demonstrated *T. purpurea* to be hepatoprotective. *T. purpurea* ethanol extracts can effectively reduce inflammation in both the acute and chronic phases and it can significantly inhibit the responses to thermal stimulus.[10] The effect of *Sharapunkha* decoction on bowel habits as well as the urinary bladder is the first proof which brings into light the action of the drug on smooth muscles of the gut and the urinary bladder.[11] From the study, it is assumed that participants who suffered from subacute and chronic infections might have benefited from the decoction of *Sharapunkha*. Sludge formation in the gallbladder is the precursor stage of gallbladder stones. Action on smooth muscles of the gut is helping in the movement of bile and removal of sludge.

5. CONCLUSIONS

Cholelithiasis is a worldwide medical problem, by the presence of one or more calculi (gallstones) in the gallbladder, results from a combination of several factors such as supersaturation of bile with cholesterol, accelerated nucleation of cholesterol monohydrate in bile, and bile stasis or delayed gallbladder emptying. This study was to find the effect of *Abhaya Lavana* with *Sharapunkha Kwatha* in asymptomatic and symptomatic uncomplicated gallstones. Assessment of subjective parameters such as pain and associated symptoms was done on the 15th, 30th, and 45th day. There was a slight change in the mean of the largest size of the stone, and there was no significant change in the size of gallstones in the USG abdomen. A significant decrease in the subjective parameters such as the right hypochondriac pain, indigestion, nausea, and vomiting and in associated symptoms such as fever, burning chest, constipation, and the right shoulder pain was evident in the study. Total cholesterol, triglycerides, and LDL were reduced after the intervention. However, it was not statistically significant. The values were within the normal limits. No significant changes in the values of RFT and LFT were noticed after the study and all values were within the limit and thereby the safety of the drug was assured. *Abhaya Lavana* with *Sharapunkha kwatha* proved more effective in the symptomatic management of cholelithiasis.

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7. AUTHORS' CONTRIBUTIONS

All the authors contributed equally to the design and execution of the article.

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9. ETHICAL APPROVALS

The study was approved by the Institutional Ethical Committee Ref. No.IEC-29/11/02/2023/ECC dated, March 02, 2023

10. CONFLICTS OF INTEREST

Nil.

11. DATA AVAILABILITY

This is an original manuscript, and all data are available for only review purposes from the principal investigators.

12. PUBLISHERS NOTE

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Table 1: Size of the stone

Assessment parameters	0th day	45th day
Size of stone (USG abdomen)	8.69±3.301	8.55±3.595

Table 2: Associated signs and symptoms

Assessment parameters	0th day	15th day	30th day	45th day
Pain on right hypochondrium	4.38±2.364	0.31±0.751	0.00±0.00	0.23±0.832
fever	0.69±0.947	0.00±0.00	0.00±0.00	0.00±0.00
Colicky pain	0.46±0.877	0.00±0.00	0.00±0.00	0.00±0.00
Abdominal distention	1.46±0.877	0.08±0.277	0.00±0.00	0.00±0.00
indigestion	1.23±1.013	0.23±0.599	0.08±0.277	0.00±0.00
Burning chest	1.38±0.961	0.15±0.555	0.00±0.00	0.00±0.00
Constipation	0.62±0.961	0.23±0.439	0.00±0.00	0.00±0.00
Pain in the right shoulder	0.62±0.961	0.00±0.00	0.00±0.00	0.00±0.00
Nausea	0.62±0.961	0.00±0.00	0.00±0.00	0.00±0.00
Vomiting	0.62±0.961	0.00±0.00	0.00±0.00	0.00±0.00