Clinical Evaluation of Paneeya Kshara (Oral Administration of Alkaline Medicine) in the Management of Pittashaya Ashmari (Cholelithiasis)

Govardhan Sahani Jayaraman*, Sathish Heggade Siddalingaiah1, Vivekanand Kullolli2, Hemant Toshikhane3

Abstract
Background: Cholelithiasis is one of the most expensive medical condition in terms of money spent in managing it. It is either symptomatic or asymptomatic, if not treated properly it may lead to carcinoma of gall bladder which is 5th commonest GI malignancy world-wide. In Ayurveda, Pittashaya Ashmari (Gall bladder Calculi) may be considered as Cholelithiasis. However, there is no classical reference of this condition in any of the treatises of Ayurveda. Acharya Sushruta, has explained that the corrosive nature of Kshara (alkaline materials) have a significant role in managing Ashmari.

Aim: The present study is aimed at evaluating the clinical efficacy of Paneeyakshara i.e. silk hair (Stigma maydis) of corn (Makkaya - Maize) in the management of Pittashaya Ashmari.

Materials & Methods: Single group clinical study with 30 patients fulfilling the inclusion criteria were selected from Shalya Tantra OPD, Parul Ayurved Hospital, Vadodara. Makkaya Paneeyakshara was administered in a dose of 250 mg twice a day on empty stomach with honey for 60 days.

Results: Makkaya Paneeyakshara showed statistically significant relief in the subjective and objective parameters.

Conclusion: Overall effect of therapy suggests that Makkaya Paneeyakshara provided significant improvement by dissolving the gallbladder stones which was less than 10mm within a period of 8 weeks.

Keywords: Ayurveda, Cholelithiasis, Makkaya Paneeyakshara, Pittasaya Ashmari.

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Introduction

Cholelithiasis (Gall bladder stone) is formed within the gall bladder by accumulation of bile components. [1] Cholelithiasis is one of the luxurious gastroenterological disorder which belongs to the group of complex metabolic malady that affect human, and its critical pathogenic mechanism are not well defined. The prevalence of cholesterol gallstone epidemiologically is about 4% and 10-20% in India and the western countries respectively. Every year 1-3% of people develop gall stones which breeds about 4mm in a year and gradually the incidence increases after 20 years and it reaches uttermost in 5th and 6th epochs. The prevalence of gall bladder stones varies broadly in different communities in India. The highest prevalence is seen in north Indians as compared with south Indians. [2] Gallstones are common in fat, fertile, forty and female. Women’s are affected more than men and the ratio is 4:1.

Actual mechanism of cholelithiasis gets attention from the research workers. Factors for production of gallstones are complex, multiple, interrelated and not always simple, single, or direct. In Modern medicine, to dissolve the gallstones, drugs and non-surgical methods are still at experimental level only. Even though the drug Ursodeoxy cholic acid sometimes dissolves the Cholesterol gallstones, the duration of medication is for 2 years and chances of gallstones reoccurrence may be seen once the drug is stopped. [3]

Whether the Gall stones are asymptomatic or symptomatic, it may lead to deadly complications includes emergency and compulsory cholecystectomy. About 10-15% of the population may develop a condition called Post Cholecystectomy Syndrome, which includes gastrointestinal disturbances and pain, as well as a 10 % chance of developing chronic diarrhoea, temporarily raised levels of blood cholesterol due to lack of gall bladder. Gallstones can be broken by using an Electro Shockwave Lithotripsy (ESWL) procedure and it is suitable only when there is a small number of gall stones. Hence, to prevent such complications, early management of gall stones if found accidentally by USG or X-Ray abdomen, is beneficial.

There is no direct evidence of Pittashaya Ashmari in the ancient Ayurveda treaties. It is lucidly cited in Ayurveda that putting of accurate nomenclature of a disease is not always possible and that can be assessed, diagnosed or managed by wise physician considering the Dosha (Bodily humour), Dhatu (Bodily tissues) and Mala (Waste products).

Pittashaya Ashmari is the coined term which can be considered as Cholelithiasis. Acharya Sushruta specifically mentions Paneeya Kshara (Oral administration of Alkaline medicine) and Kshara (Alkaline) in the management of Ashmari (Stone) due to its Ksharana (Corrosive) property, by which the Ashmari gets easily dissolved. [4-5]

Corn silk is the yellowish thread like strands known as stigma which is derived from the female flower of maize. These stigmas are usually the waste material from corn cultivation and are available in abundance. India stands at 5th position by cultivating 23.7 million tons annually. [6] It is widely available in Tamil Nadu, Maharashtra, Gujarat, Rajasthan, Uttar Pradesh and Punjab. The drug which possess diuretic, anti-hyperlipidemic as well as anti-inflammatory properties was kept in the thought process of the disease and a drug “Makkaya” (Silk hair of corn) prepared in the form of Paneeya Ashmari was prepared and evaluated in the management of Cholelithiasis.

Materials & Methods

Study Design: Open clinical study.

Settings: Patients with classical features of Cholelithiasis irrespective of age, sex, religion, socioeconomic status and those who are incidentally found to be have cholelithiasis through USG reports, were selected from O.P.D and I.P.D, Parul Ayurveda Hospital, Vadodara, Gujarat.

The study has been reported as per the Consolidated Standards of Reporting Trials (CONSORT) statement 2013. [7]

Informed Consent:
An informed written consent was obtained from all included participants. The consent form was prepared in accordance with the guidelines of WHO Research Ethical standards and procedures for research with human beings. [8]

Inclusion Criteria
1. Patients presenting with clinical features of Cholelithiasis.
2. Asymptomatic patients who are diagnosed to have Cholelithiasis accidentally by USG.
3. Subjects of either sex with multiple stones which are 1cm -5cm.

Exclusion Criteria
1. Patients who are Ayogya (contraindicated) for Paneeya Kshara by Acharya Sushruta.
2. Patients with Cholelithiasis associated with complications such as acute obstructive Cholecystitis, acute pancreatitis, liver failure, carcinoma of gallbladder.

3. Uncontrolled other systemic disorders.

Laboratory Investigation
Hb %, TC, DC, ESR, Random Blood sugar, Liver Function Test, Lipid Profile, Serum lipase /amylase, and Ultrasonography of Abdomen were carried out before and after treatment, i.e., on the 30th, and 60th day.

Ethical clearance
Ethical clearance was obtained from IEC (PIA/IECHR/2016-17/SHALYA/009) and this study was registered in Clinical Trial Registry of India (CTRI/2017/04/008389). [9]

Posology
The Makkaya Paneeyakshara was given in capsule form, 250mg twice a day, before food, in morning and evening with honey for 60 days.

Note 1: For dose fixation the prepared medicine was filled in 250mg capsules and patients were asked open the capsule and to take out the medicine and add along with Madhu (Honey).

Follow-up
The outcomes were measured after screening at Baseline (BT), at the end of 8 weeks (AT) and at the end of 12th week (Follow up).

Criteria for assessment
The improvement in the patients was assessed mainly on the basis of relief in sign and symptoms of Pittasaya Ashmari (Cholelithiasis).

Outcome measures
• Changes in VAS Scale (By Grading) [10]
• Changes in pain, nausea, vomiting, flatulent and dyspepsia.
• Changes in stone size in USG.

Parameters of the study
A. Subjective
1. Pain and discomfort in right upper quadrant of abdomen
   Grade 0 – Absence of pain (No pain)
   Grade 1 – Pain present, but does not disturb routine and sleep (Mild pain)
   Grade 2 – Pain present which disturbs routine and sleep (Moderate)
   Grade 3 – Sever pain which does not allow to have recumbent position (severe)
2. Nausea
   Grade 0 – Absent
   Grade 1 – Present
3. Vomiting
   Grade 0 – Absent
   Grade 1 – Present
4. Flatulent dyspepsia
   Grade 0 – Absent
   Grade 1 – Present

B. Objective
Size of the stones, assessed by USG 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 up to 50% and below 75% (Mild response)
Grade 3 – Reduction of stone size up to 75% and below 100% (Marked response)

Statistical Design:
The data generated in the clinical study was analysed by applying student ‘t’ test using Statistical software Sigma stat 3.5.

Observation
A total of thirty-seven patients were registered for this study. Among them seven patients were excluded, as they did not fulfil the inclusion criteria. Thirty patients fulfilling the inclusion criteria were given intervention.

• Maximum patients belonged to 31-40 years of age group (36.7%), Hindu religion (56.7%); Males (56.7%); Upper middle class (33.3%); employees (70%) and literate (26.7%). Maximum patients were having mixed diet (86.7%); moderate appetite (96.6%); sound sleep (96.6%); Virrudha Ahara (Incompatible foods) (96.6%); irregular bowel habits (80%); addiction of tobacco (56.7%); maximum patients belonged to Pitta Kapha Prakruti (50%); Jarana Shakti (Digestive capacity) (73.3%).

• All patients (100%) were having nausea and dyspepsia.

• Maximum patients were having Multiple Gallstones (63.3%).
Results

Effect of therapy on subjective parameters:

• **Pain**: Among the 30 subjects, 7 patients were having pain. Although gall stones are mostly asymptomatic but spasmodic type of pain which lasts for less than a minute was present. There were 100% (<0.002) of pain relief which shows the *Makkaya Kshara* is highly significant. This may be attributed to the *Vata Anulomana* (regular movement of *Vata*) and *Vata Samana* (pacification) properties of *Makkaya Paneeyakshara* leading to relief of the spasm of gallbladder, cystic duct and also reducing the irritation to the inflamed stomach wall by means of bringing in the value added natural qualities of bile. Thus the *Vidagdhata* (Corrosive nature) of *Pitta* and pain (Anti-inflammatory activity) is reduced. [11]

• **Nausea**: 29 subjects, among 30 were having the complaint. There was 100% (<0.001) relief which shows that *Makkaya Kshara* alters the mechanism by *Anulomana* of *Vata* by which the symptoms get reduced.

• **Vomiting**: Among 30 subjects, 4 patients were having complaint and it was reduced after the treatment in 100% (<0.003) of patients.

• **Dyspepsia**: All subjects were having the complaint of dyspepsia which was reduced in 100% of them (<0.001). (Graph no.1)

Effect of therapy on Objective Parameters:

• **Tenderness**: Among the 30 subjects, 7 were having Grade-2 type (tenderness with palpation and without grimace). After treatment 100% (<0.002) relief was seen. *Makkaya Kshara* possess Anti-inflammatory properties by which it might have reduced the tenderness. [11]

• **Effect of therapy on stones**: Among the 30 subjects, 19 patients were with single stones and 11 patients with multiple stones. Smallest stone size was 3 mm and the largest size were measuring 20 mm.

The most effective reduction in stones was seen when the stones size was less than 10 mm. Approximately there was 2-3 mm reduction in size in 4 weeks and that too when the stones were made up of cholesterol compounds. Over all, approximately 6-7 mm of stone size was reduced.

When the stone size was more than 10 mm, the effectiveness and the reduction of stone was less. Approximately there was 0-1 mm reduction in size in 4 weeks and that too when the stones were made up of cholesterol compounds. Over all, approximately reduction of 3-4 mm in stone size was seen.

Graph No. 1 Showing the Results on Subjective Parameters

Graph No. 2 Showing the Results on Objective parameter (Average Size of Stone evaluated by USG)
Stones as a sludge:
• Among 30 subjects, 3 patient’s gallstones become as a sludge. That means the cholesterol stones liquefied in a time period of 15-30 days which was observed during this study.

Effect of therapy on lipid profile:
All the parameters of lipid profile S. Cholesterol, Triglycerides, LDL, HDL showed statistically significant changes at p<0.001 (Graph no. 3) which can be attributed to the potential lithotriptic and Anti-Hyperlipidemia property of drug.[11]

Discussion
There is no specific Nidana (Aetiology) mentioned in any Ayurveda texts regarding the Pittashaya Ashmari. Nidana such as Guru Anna-Pana (Heavy diets), Ahita Ahara-Vihara (Unwholesome foods and activities) and Atiprayoga (Over use) of Kapha Vridhikara Ahara-Vihara (Kapha increasing foods and activities) are mentioned in the context of Ashmari. Due to the Nidana Sevana, Kapha gets accumulated which produces symptoms like Aalsya (Laziness), Gaurav (Heaviness), Manda Ushmata (Decreased digestive fire) which leads to accumulation of Kapha in Pittashaya (Gallbladder). Now the mixture of Kapha and Pitta in the Pittashaya leads to the formation of biliary sludge causing the obstruction in the passage of Vayu. Hence the Vata gets vitiated by its Rukshadi Gunas (Dry etc. properties) and forms Varta Svarupa (Solid form) sludge which is termed as Pittashaya Ashmari.

As this study was targeted on evaluating the efficacy of Makkaya Kshara on Pittashaya Ashmari, Bhedana (Breaking property) and Ksharana of Stone were required. Ayurveda classics have not mentioned about the Corn (Zea mays) as well as Corn silk (Stigma maydis). But in later period, there is an evidence of word Makkaya[11] (Indian corn) but no detailed description can be found as Corn was brought to India at later 19th century. Makkaya has been used for various medical purpose for its effective therapeutic use like diuresis, anti-inflammatory, anti-hyperlipidemia effects etc. [12] In south India, especially in Tamil Nadu this corn silk has been used by folklore practitioners with drastic effects in gall stones as well as bladder stone. Dried Makkaya hairs were collected, made into Paneeyakshara and [13] administered in patients of Pittashaya Ashmari.

Probable mode of action
The prepared Makkaya Kshara even though does not have the detail explanation regarding its properties, the probable effects of Kshara can be considered along with predictable properties. The Kshara having the properties of “Ksharanat” (corrosive effect) might have probably acted mechanically on the calculi to disintegrate its molecules thereby resulting into lithotriptic action.

Whereas by its Virya (Potency), it has got potentiality to increase the Agni of Pachaka (Digestive fire), Bhutagni (Elemental fire) as well as Dhatwagni (Tissue metabolism) which helped to make the metabolic corrections in the pathogenesis of Gallbladder stones.

Graph No.3 Showing the effect of trial drug on lipid profile
The Makkaya Kshara possess the properties as of Makkaya hairs but with more potency because of preparatory methods. Pittashaya Ashmari requires Vyadhi Pratyanika Chikitsa (Antagonistic to the disease) for disintegration of a stone which can be achieved by Ksharana property and Dosh Pratyanika Chikitsa (Antagonistic to the humour) thus exerting Pitta and pacifying Kapha due to its Tikta Rasa (Bitter taste) Laghu Ruksha Guna (Light-Dry property), Ushna Virya (Hot potency) and Katu Vipaka (Pungent post digestive effect). [15]

Further, the Ushna Virya of Kshara, Agni Deepana (Appetite stimulant) and Kapha Vilayana (Scraping) might have occurred by which concentration of bile is checked by reducing mucous hyper secretion and hyper-lipidemia. Motility of the gallbladder is improved due to the Vata Anulomana (Directing Vata in right direction) property of Kshara due to its Prabhava (Special therapeutic action), thus dissolving the stone and correcting the metabolic causes to prevent the further formation of Pitta Ashmari (Cholelithiasis).

Pitta Samana by Tikta Rasa reduces the chemical irritation to the inflamed gall bladder to reduce the Shoola (Pain). Dysphagia may be considered as Admana along with Annadevsha (it may be presented clinically with nausea or Chardi (Vomiting) due to Agni Mandya). Makkaya Paneeya Kshara acts by causing Vata Anulomana and correction in Dravyatuh Vridhi and improvement in the Guna and Karma (Action) of Pachaka Pitta.

Mode of action based on modern protocol:
Corn silk possess various metabolic effects in many diseases. The drug possesses anti-Hyperlipidemia effect, diuresis effect as well as Anti-inflammatory effects. [14] Corn silk possess flavonoids [10] which shows significantly lowering effects on the levels of TC, TG, LDL and increasing the level of HDL, thereby it helps in liquefaction of gall stones formed due to cholesterol. With the diuretic (Lithotriptic) effect the liquefied bile will be filtered and excreted through the urine. Beta Sitosterol which was said to be useful by means of producing more amount of urine out flow will make the bile to flow out through urine. [16]

The normal pH level of gallbladder bile is about 6.80 to 7.65. Bile in the gallbladder becomes more acidic the longer a person keeps fasting. In order to neutralize the acidity alkali is used, like in hypertrophy of tissue for Lekhana (desloughing) action and in calculi for breaking them. [17]

Conclusion
Paneeya Kshara transpires to be a useful treatment modality for Pittashaya Ashmari. Makkaya Paneeya Kshara is effective in correcting the mechanism of Gallbladder with significant improvement in both subjective and objective parameters. In toto, from this study it can be concluded that Makkaya Paneeya Kshara is an effective treatment for cholelithiasis and is deprived of any complications.

Image no.1: Silk Corn
References
5. Ibidem Sushruta Samhita (4) Sutra sthana, 11th chapter, 8th shiloka, p. 46

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