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Therapeutic efficacy of Siddha Herbo mineral formulation *Kollu Kudineer* in the management of *Saththi pitham* (Cholelithiasis) – A Pilot study

Dr. V. Kalaivani*[1], Dr. S. M. Chitra[2], Dr. M. Muthukumaran[3]

[1]PG Scholar, Department of PG Noi Naadal, Government Siddha Medical College, Chennai.
[2]Lecturer, PhD, Department of PG Noi Naadal, Government Siddha Medical College, Chennai.
[3]Professor and HOD, Department of PG Noi Naadal, Government Siddha Medical College, Chennai.
*Corresponding author: Dr.V. Kalaivani, PG Scholar, Department of PG Noi Naadal, Government Siddha Medical College, Chennai.
E-mail: *kalaivel104@gmail com*

Abstract

Background: Cholelithiasis is a common gastrointestinal disorder with increasing prevalence in the Indian population. Prevalence of gallstone in India was found to be 6.12% in the adult population. While surgical management like laparoscopic cholecystectomy remains the standard approach, there is growing interest in traditional systems of medicine such as Siddha for non-invasive and holistic alternatives. *Kollu Kudineer*, a classical Siddha formulation has been traditionally used to manage gallbladder-related disorders.

Objective: To determine the effect of *Kollu kudineer*, a Siddha herbomineral formulation in *Saththi pitham* (Cholelithiasis) patients.

Method: The pilot study was conducted at the Government Siddha Medical College Hospital, Chennai. Twenty patients were recruited in the study those meeting with inclusion and exclusion criteria. They were treated with 40 ml of *Kollu kudineer* once a day (before food) for 90 days. All the patients were taken Ultrasonogram abdomen before and after treatment.

Result: After 3 months of treatment, a significant number of patients showed clinical improvement with reduction in symptoms such as abdominal pain, bloating, pain or burning sensation present in the epigastrium and dyspepsia. Follow-up ultrasonography revealed a reduction in gallstone size in several cases, with complete dissolution in a one case. No adverse effects were reported during the course of therapy.

Conclusion: *Kollu kudineer* has shown effectiveness in the treatment of *Saththi pitham* (Cholelithiasis) patients.

Keywords: Cholelithiasis, Saththi pitham, Siddha Medicine, Kollu Kudineer, USG abdomen.

1. Introduction

Cholelithiasis defined as the formation of calculi within the gallbladder, is one of the most common hepatobiliary disorders encountered globally. There are primarily composed of cholesterol or bilirubin derivatives and result from a complex interplay of factors including bile supersaturation, gallbladder hypomotility and crystal nucleation.[1] Cholesterol stones account for approximately 80% of cases, while pigment stones are more common in regions with high incidences of haemolytic disease or biliary infections.[1,3] Globally, the pooled prevalence of gallstones is estimated at 6.1% (95% CI: 5.6–6.5), with an incidence rate of 0.47 per 100 person-years.[3] In India, the overall adult prevalence is reported between 4–7%, with notable geographic differences.[2,3] Modern management includes dietary regulation, pharmacological interventions like bile acid therapy, and primarily laparoscopic cholecystectomy for symptomatic cases.[1] However, concerns regarding recurrence, surgical risk and cost have led to increasing interest in traditional medical systems, particularly in India.[2]

In Siddha system, cholelithiasis may be interpreted under the concept of *Piththappai Kalladaippu* (gallbladder obstruction by calculi), where vitiated Pitham and derangement of vatham contribute to stone formation. Traditional formulations emphasize dissolution and expulsion of these concretions using decoctions with choleretic, litholytic and digestive actions. Hence the present study was showed therapeutic efficacy of Siddha herbomineral formulation *Kollu kudineer* in the management of *Saththi pitham* (Cholelithiasis).

Kollu Kudineer, an herbomineral decoction is a time-honoured formulation cited in classical Siddha literature (*Gunapadam Mooligai vaguppu* – Materia Medica part-I) for managing gallbladder and urinary calculi.[4]

2. Materials and Methods

Therapeutic intervention – *Kollu Kudineer*

Table :1 Ingredients of *Kollu Kudineer*

S.NO	Ingredient's name	Part	Quantity
1.	Kollu (*Macrotyloma uniflorum*)	Seed	35gm
2.	Indhuppu (Sodium chloride impura)	Salt	1.3 gm
3.	Water	-	350 ml

Preparation of *Kollu Kudineer*

Purified Kollu was powdered into coarse powder using stone mortar pestle. 35 gm of Kollu powder was mixed with 350 ml of water and allowed to boil until it attains 1/8 of its original quantity. Then filtered kudineer was added with 1.3 gm of Indhuppu. The dosage was 40 ml (once in a day/ before food) and the duration was 3 months.

Ethical approval

This study was conducted in outpatient department of Government Siddha Medical College Hospital attached to Arignar Anna Government Hospital of Indian Medicine, Arumbakkam, Chennai-106 with standard protocol which is approved by Institutional Ethics Committee (IEC No: GSMC-CH-1243/ME-11/064/2024). The trial has been registered in clinical trial registry of India (CTRI/2024/06/068814). Before enrolment into the study the informed consent was obtained from the patients.

3. Conduct of the study

A total of 20 patients between 20 to 60 years of age with clinical features of abdominal bloating, pain present in right upper quadrant, right shoulder/back, Nausea, vomiting, pain or burning sensation present in epigastric region and gallbladder stone noted in USG findings are chosen for enrolment based on inclusion criteria. Patients who are all selected under the criteria are treated with *KOLLU KUDINEER* 40 ml once a day before food for 90 days. At each visit once in 10 days symptoms were clearly noted for clinical assessment. The patients were asked to follow the dietary regimen and lifestyle modification during the treatment and follow up period.

USG abdomen and necessary investigations were performed for all the patients two times that is before starting the treatment and after completion of the treatment.

4. Study outcome

Study outcome was defined as Reduction in clinical symptoms and decrease in size of the gallbladder stone in USG abdomen.

5. Results

In the present study, twenty patients were selected based on the inclusion criteria. Among them, all 20 patients (100%) presented with abdominal bloating, heartburn and excessive gas were reported in 14 patients (70%), while 10 patients (50%) experienced pain in the right upper quadrant. Pain in the right shoulder or back was noted in 5 patients (25%) and 4 patients (20%) reported epigastric pain accompanied by nausea and vomiting.

In the present study, the sex distribution showed that 70% of the participants were female and 30% were male. The age distribution revealed that 45% of participants were between 30–40 years, 30% were between 40–50 years and 25% were between 50–60 years. Regarding dietary patterns, 90% consumed a mixed diet while 10% followed a vegetarian diet. In terms of habits, 85% reported consumption of tea, coffee or milk, 10% consumed alcohol and 5% were smokers.

After treatment a significant number of patients showed clinical improvement with reduction in symptoms such as abdominal pain, bloating, pain or burning sensation present in the epigastrium, nausea, vomiting and dyspepsia. Follow-up ultrasonography revealed a reduction in gallstone size in several cases, with complete dissolution in a one case. There were no adverse events reported during the study and no recurrence of gallstone for the patient who exhibit no evidence of gallbladder stone after treatment in USG abdomen during the follow-up period of 6 months.

Fig:1 Sex distribution of the study participants

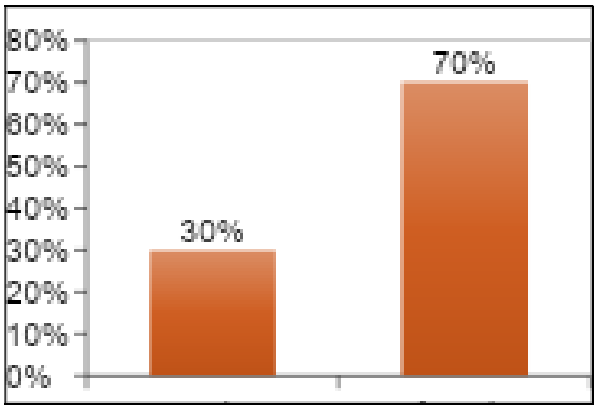

Fig:2 Age distribution of the study participants

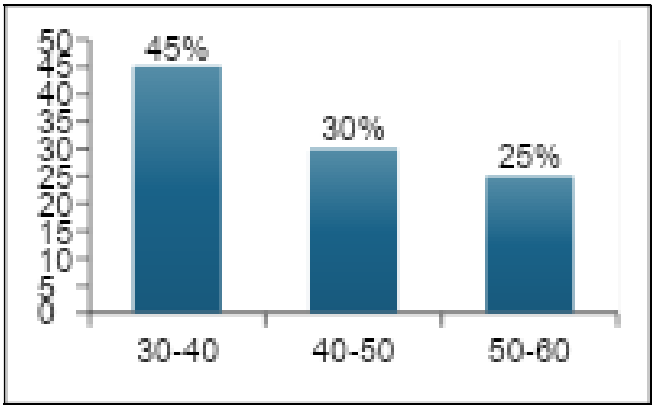

Fig:3 Diet

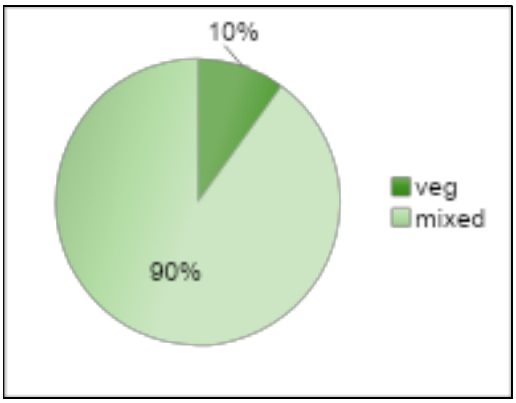

Fig:4 Habits

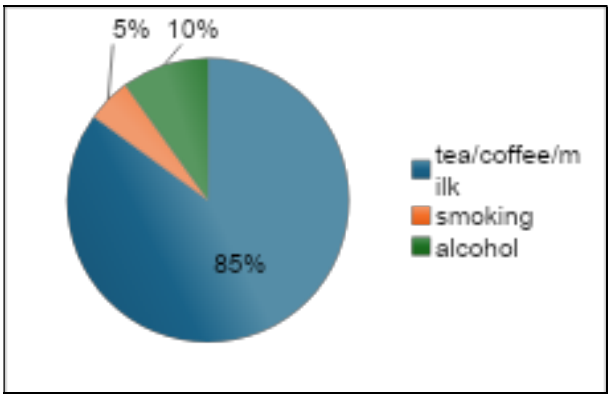

Fig: 5 Clinical Features

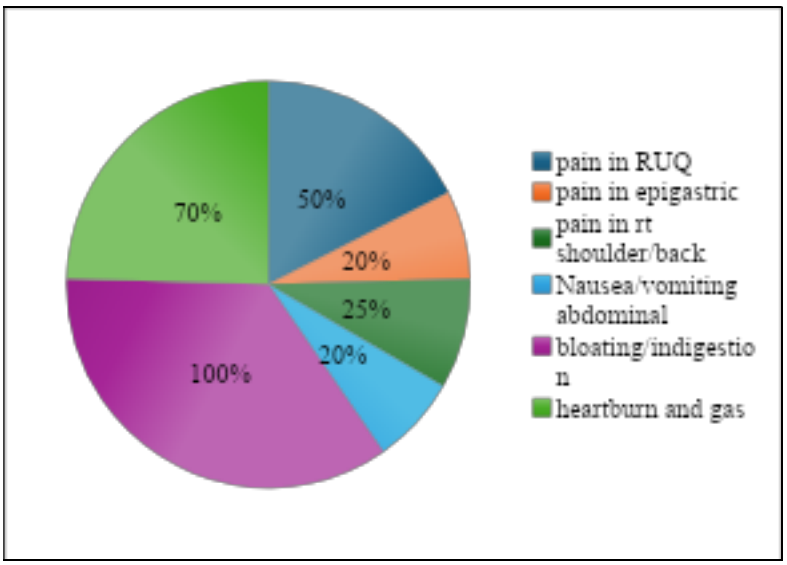

Table: 2 Changes in the size and no of stones in USG

Case no	Age	Sex	USG (before)	USG (After)
1	42	Female	14 mm	10 – 11 mm
2	46	Female	15 mm	3 mm
3	41	Female	9.9 mm	Nil
4	39	Female	(3-5) 13 mm	2 calculi 12mm
5	42	Female	7.9 mm	7.7 mm
6	35	Female	(10-12) 6mm	(7-8) 11mm
7	60	Male	2 calculi 8mm	Single 8 mm
8	38	Female	8 mm	8.5 mm
9	32	Female	6 mm	4 mm
10	34	Male	22 mm	16 mm
11	42	Female	20 mm	10 mm

12	54	Male	8-12 mm	9 mm
13	53	Male	8 mm	7 mm
14	33	Female	6 mm	5 mm
15	52	Female	5.5 mm	5.4 mm
16	38	Male	(3-4) 5 mm	2 calculi 5 mm
17	40	Female	15 mm	10 mm
18	30	Female	(5-6) 3-4 mm	Few calculi 4mm
19	57	Male	6.7 mm	6.9 mm
20	34	Female	7mm	7.2mm

Table: 3 Paired Samples Statistics

Statistical Analysis					
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	USG Before	9.9050	20	5.07507	1.13482
	USG After	7.5350	20	3.63915	.81374

Table: 4 Paired Sample T test

	Paired Differences					t	Df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 USG Before USG After	2.37000	4.12975	.92344	.43722	4.30278	2.566	19	.019*

* Since the p-value (0.019) was less than 0.05, This indicates a statistically significant difference between the before treatment (9.90) and after treatment (7.53). It shows that the given drug act effectively on treatment of Saththi pitham (Cholelithiasis) patients.

6. Discussion

According to Siddha literature, gallstones are considered a manifestation of Azhal vitiation accompanied by Iyam accumulation (Stagnation) and vatham involvement (pain). An imbalance in the Thirithosham leads to impaired bile secretion, cholesterol accumulation and stone formation in the gallbladder.

Siddha medicine provides extensive references for the management of such conditions. One such formulation is Kollu Kudineer, mentioned in Materia Medica. Kollu (Macrotyloma uniflorum) possesses an astringent and bitter taste, along with veppa veeriyam and kaarpu pirivu. It has documented lithotriptic[5] and anticholelithic

properties[6]. Indhuppu (Sodium chloride impura) is also included in the preparation and is known for its analgesic, anti-inflammatory[7], and diuretic activities.[8]

In the present study, 20 patients diagnosed with gallstones were treated with Kollu Kudineer for three months. Most clinical symptoms improved within 2–3 weeks. Ultrasonography was performed before and after treatment to evaluate stone size reduction. Before treatment, the maximum stone size was 22 mm and the minimum was 4 mm, with a mean size of 9.9 mm. After treatment, the maximum size reduced to 16 mm, and in some cases, complete stone clearance was achieved (minimum size 0 mm). The mean size reduced to 7.5 mm, with an average reduction of 2.3 mm.

Statistical analysis using the paired sample t-test yielded a p-value of <0.05, indicating that the reduction in stone size and symptom relief were statistically significant. These results highlight the positive prognosis of cholelithiasis with Kollu Kudineer treatment.

7. Conclusion

Kollu kudineer is found to be safe and effective therapy for the management of Saththi pitham (cholelithiasis) by balancing vitiated thirithosham, particularly Azhal and Iyam. It enhanced digestion, improved bile flow and supported the dissolution or size reduction of gallstones. Moreover, there is no adverse reaction throughout the study. Hence the Kollu kudineer may offer a promising non - surgical approach to the management of Saththi pitham (cholelithiasis).

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