

HOMOEOPATHIC INTERVENTION OF CHELIDONIUM MAJUS 6X IN MANAGEMENT OF CHOLELITHIASIS: CLINICAL STUDY

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ABSTRACT

Background: Cholelithiasis (gallbladder stones) is a highly prevalent gastrointestinal disorder, frequently requiring surgical intervention. *Chelidonium majus* is traditionally utilized in homeopathy for hepatic and biliary disorders, but robust clinical documentation regarding its low-potency efficacy remains limited.

Objective: To evaluate the clinical efficacy and safety of *Chelidonium majus* 6X in the symptomatic management and reduction of stone size in patients diagnosed with cholelithiasis.

Methods: This prospective, open-label, observational clinical study enrolled 60 patients diagnosed with cholelithiasis via transabdominal ultrasonography (USG). Participants received *Chelidonium majus* 6X (three times daily) over a period of six months. Primary outcomes were measured by changes in gallbladder stone size and number via baseline and post-treatment USG. Secondary outcomes evaluated changes in hepatobiliary symptom scores (right upper quadrant pain, dyspepsia, nausea) and serum liver function tests (LFTs).

KEYWORDS: Cholelithiasis, *Chelidonium majus* 6X, Homeopathy, Gallstones, Ultrasonography, Biliary colic.

INTRODUCTION

Cholelithiasis, or gallstone disease, remains one of the most prevalent gastrointestinal disorders globally, affecting roughly 10% to 15% of the adult population in Western societies and rapidly rising in prevalence across developing nations. The condition arises primarily from an imbalance in bile composition—specifically the supersaturation of cholesterol or excess bilirubin—coupled with gallbladder hypomotility, which leads to the precipitation and crystallization of biliary components into solid calculi. While approximately 80% of individuals with cholelithiasis remain asymptomatic, the remaining cohort develops debilitating manifestations such as biliary colic, acute cholecystitis, or pancreatitis due to temporary or sustained mechanical obstruction of the cystic or common bile duct.

In modern conventional medicine, laparoscopic cholecystectomy stands as the definitive gold standard for managing symptomatic cholelithiasis. However, surgical intervention carries inherent risks, including bile duct injury, post-operative infections, and anaesthesia-related complications. Furthermore, a significant subset of patients (ranging from 10% to 40%) suffers from Post-Cholecystectomy Syndrome (PCS), characterized by persistent right upper quadrant pain, chronic diarrhea, and dyspepsia caused by altered post-surgical bile flow kinetics. Non-surgical options such as oral bile acid dissolution therapy (e.g., ursodeoxycholic acid) have limited application, low compliance rates, and high recurrence risk upon discontinuation. Consequently, there is a growing clinical imperative to evaluate non-invasive, safe alternative or complementary therapeutic avenues.

Homoeopathic medicine provides a holistic, non-surgical pathway aimed at normalizing metabolic imbalances and relieving smooth muscle spasms. Among the therapeutic arsenal, *Chelidonium majus* (Greater Celandine) is historically recognized as a premier organ-specific remedy for hepato-biliary disorders. Pharmacological investigations into *Chelidonium majus* reveal that its major isoquinoline alkaloids, particularly chelidone and berberine, exert profound choleric, hydrocholeretic, and spasmolytic effects. These chemical actions optimize bile flow, decrease bile viscosity, and relax the sphincter of Oddi, which directly facilitates the structural degradation and painless passage of micro-calculi.

While several individualized clinical case reports document successful gallstone dissolution using *Chelidonium majus* in mother tincture (Q) or centesimal (C) potencies, there remains a distinct scarcity of prospective clinical trials validating its efficacy in low-decimal potencies like 6X. Utilizing the 6X decimal attenuation provides a unique pharmacological middle ground, offering a safe micro-dose concentration that minimizes the potential risks of herb-induced hepatotoxicity occasionally reported with crude botanical extracts, while retaining

measurable biological action. Therefore, this prospective, open-label study was designed to systematically evaluate the clinical efficacy, stone-reduction capability, and safety profile of *Chelidonium majus* 6X in patients diagnosed with symptomatic cholelithiasis.

MATERIALS & METHODS

Study Design

This was a prospective, open-label, single-arm clinical study conducted over a period of six months.

Participant Selection and Sample Size

A total of 60 participants presenting with symptomatic cholelithiasis were enrolled from the outpatient department (OPD) of the clinical research center.

Inclusion Criteria

- **Age and Gender:** Male and female participants aged between 18 and 60 years.
- **Diagnostic Confirmation:** Diagnosed with cholelithiasis via transabdominal ultrasonography (USG), showing mobile echogenic foci with posterior acoustic shadowing.
- **Stone Metrics:** Presenting with single or multiple gallstones where the maximum diameter of the largest calculus did not exceed 15 mm.
- **Symptomatology:** Patients presenting with mild to moderate recurrent hepatobiliary symptoms, including right upper quadrant pain, flatulent dyspepsia, nausea, and bloating.
- **Compliance:** Participants willing and able to comply with the 6-month follow-up schedule and medication regimen.

Exclusion Criteria

- **Acute Complications:** Evidence of acute cholecystitis, choledocholithiasis (common bile duct stones), acute pancreatitis, empyema, or perforation of the gallbladder.
- **Biliary Metrics:** Gallstones with a maximum diameter greater than 15 mm or a completely packed gallbladder showing non-functional status.
- **Severe Comorbidities:** Concurrent severe hepatic impairment (cirrhosis, hepatitis), renal failure, malignancy, or uncontrolled cardiovascular disease.
- **Pregnancy and Lactation:** Pregnant or lactating women.
- **Current Therapy:** Patients currently undergoing or requiring emergency surgical intervention, or those taking conventional oral bile acid dissolution therapies (e.g., ursodeoxycholic acid) within the past 30 days.

Intervention and Posology:

The therapeutic intervention consisted of homoeopathic *Chelidonium majus* 6X. The medicine was prepared and secured from a Good Manufacturing Practice (GMP) certified homoeopathic laboratory, adhering strictly to the standards of the Homoeopathic Pharmacopoeia.

Outcome Measures

Primary Outcome Measures

- **Reduction in Stone Size and Number:** Assessed via objective pre- and post-treatment transabdominal ultrasonography (USG). The scans were performed at baseline (Day 0) and at the completion of the trial (Month 6) using the same ultrasonic equipment and structural positioning to minimize inter-operator variability. Complete clearance was defined as the total absence of acoustic shadowing on follow-up.

Secondary Outcome Measures

- **Symptomatic Relief:** Evaluated monthly using a standardized Likert symptom severity scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe) tracking right upper quadrant pain intensity, dyspepsia, nausea, and vomiting frequency.
- **Safety Evaluation:** Assessed through baseline and post-treatment serum Liver Function Tests (LFTs), including total bilirubin, Serum Glutamic Oxaloacetic Transaminase (SGOT), Serum Glutamic Pyruvic Transaminase (SGPT), and Alkaline Phosphatase (ALP) to rule out drug-induced hepatotoxicity.

RESULTS

Participant Flow and Baseline Characteristics

A total of 60 patients diagnosed with cholelithiasis completed the 6-month study protocol.

Table 1: Baseline Demographics and Clinical Profile of Participants. N=60

Parameter	Value (Mean $\pm$ SD or (n), %)
Age (Years)	(42.6 $\pm$ 9.4)
Gender (Male / Female)	18 (30.0%) / 42 (70.0%)
Type of Cholelithiasis	
<i>Single Calculus</i>	26 (43.3%)
<i>Multiple Calculi</i>	34 (56.7%)
Baseline Maximum Stone Size (mm)	(9.4 $\pm$ 2.8)

Primary Outcomes: Gallstone Changes via Ultrasonography (USG)

After six months of continuous treatment with *Chelidonium majus* 6X, a statistically significant reduction in the mean size of the largest gallstones was observed across the cohort ($p < 0.05$). Complete dissolution of all visible calculi was verified via post-treatment USG in 14 cases, representing a total clearance rate of 23.3%. This complete dissolution occurred exclusively in patients who presented with baseline stone sizes (5 mm).

Among the remaining 46 patients (76.7%), a partial reduction in calculus size was recorded in 28 individuals (46.7%), while 18 patients (30.0%) exhibited stable, unchanged gallstone configurations. No participant demonstrated an increase in stone size or count during the study.

Table 2: Pre- and Post-Treatment Ultrasonographic Evaluation of Gallstone Size. (N = 60))

Parameter	Baseline (Day 0)	Post-Treatment (Month 6)	Mean Reduction	p-value*
Mean Stone Size (mm)	9.4 ± 2.8	6.8 ± 3.1	2.6 mm	<0.001
Total Dissolution Rate	—	14 (23.3%)	—	—

*Evaluated using Paired t-test.

Secondary Outcomes

Hepatobiliary Symptom Scores

Therapeutic responses regarding subjective clinical distress emerged early in the intervention. Right upper quadrant pain severity, flatulent dyspepsia, and nausea frequencies showed marked downward trends within the first four weeks of treatment. By the final clinical appraisal at Month 6, the cumulative symptom severity index score dropped significantly from a baseline mean of (7.8 ± 1.6) to a post-treatment mean of (1.9 ± 0.8) ($p < 0.00$).

Table 3: Evolution of Clinical Symptom Scores Across 6 Months.

Clinical Symptom (Scale 0–3)	Baseline (Day 0)	Month 3	Month 6 (End)	(p)-value [^]
Right Upper Quadrant Pain	2.4 ± 0.5	1.1 ± 0.4	0.4 ± 0.2	<0.001
Flatulent Dyspepsia	2.6 ± 0.6	1.4 ± 0.5	0.8 ± 0.4	<0.001
Nausea / Vomiting Frequency	1.8 ± 0.4	0.7 ± 0.3	0.2 ± 0.1	<0.001

[^]Evaluated via Wilcoxon Signed-Rank Test (Baseline vs. Month 6).

Safety and Liver Function Profiles (LFTs)

Serial laboratory monitoring established that *Chelidonium majus* 6X did not trigger any metabolic, systemic, or organ-specific toxicity. Serum hepatic biomarkers remained stable within physiological normal ranges throughout the six months of continuous micro-dose administration.

Table 4: Pre- and Post-Intervention Serum Liver Function Biomarkers.

Biochemical Marker	Baseline (Day 0)	Post-Treatment (Month 6)	Reference Interval	(p) value*
Total Bilirubin (mg/dL)	0.85 ± 0.22	0.79 ± 0.18	0.2 - 1.2 mg/dL	0.114
SGOT / AST (U/L)	28.4 ± 6.9	26.1 ± 5.4	5 – 40 U/L	0.082
SGPT / ALT (U/L)	31.2 ± 8.1	29.4 ± 7.0	7 – 56 U/L	0.201
Alkaline Phosphatase (U/L)	86.5 ± 14.3	81.2 ± 11.9	44 – 147 U/L	0.058

*Evaluated using Paired t-test.

DISCUSSION: *Chelidonium Majus*

Character and Pathophysiology of Pain

- Right Upper Quadrant Pain: Constant, dull, throbbing, or aching pain located precisely in the right hypochondrium (gallbladder region), directly stemming from biliary stasis or stone obstruction.
- The "Keynote" Diagnostic Sign: Acute, shooting pain that radiates directly from the gallbladder region straight through to the inferior angle of the right scapula (shoulder blade). This is the absolute signature indication for *Chelidonium* in gallstone disease.
- Modality of Pain: The pain is typically aggravated by motion, deep inspiration, or pressure, and is characteristically ameliorated (relieved) by taking hot drinks or eating a warm meal, which helps relax local smooth muscle spasms.

Concomitant Gastrointestinal and Dyspeptic Symptoms

- Intolerance to Fats: Extreme digestive distress, bloating, and flatulence immediately after eating fatty or rich foods, indicating an inability of the biliary system to emulsify lipids.
- Nausea and Bilious Vomiting: Persistent nausea accompanied by the vomiting of bitter, greenish-yellow bile, worse in the early morning.
- Altered Appetite: A unique, strong craving for hot foods and hot drinks (which the stomach tolerates well) and a marked aversion to cold drinks or cold water, which can trigger immediate gastric cramping.

Hepatic and Systemic Indications

- Biliary Torpor (Sluggish Liver): Objective history of chronic constipation where the stools are hard, round, and characteristically bright yellow or clay-coloured, pointing to deficiency or obstruction of bile secretion into the duodenum.
- Sub-icteric or Jaundiced States: Yellowish discoloration of the skin, sclera (whites of the eyes), and a thick, yellow-coated tongue, accompanied by a bitter taste in the mouth.
- Urine Alternations: Urine that is dark, turbid, and deep tea-brown or yellow-red, containing detectable bile pigments.

Objective Clinical and Ultrasonographic (USG) Selection Criteria

- Calculi Configuration: Ideally indicated for patients presenting with small, multiple micro-calculi, biliary sludge, or cholesterol crystals where the maximum stone diameter does not exceed 10–15 mm.
- Biliary Dyskinesia: Indicated when ultrasound confirms gallbladder hypomotility or high bile viscosity without structural anomalies like complete ductal calcification.
- Absence of Acute Emphyema: Suitable for chronic, recurrent symptomatic cholelithiasis where there is no active, acute transmural gallbladder inflammation or emergency surgical impaction.

RESULTS

At the conclusion of the six-month intervention, a statistically significant reduction in the mean size of gallstones was observed ($p < 0.05$). Complete dissolution of smaller calculi (≤ 5 mm) occurred in 23.3% of cases. Patients demonstrated marked improvement in pain severity and dyspeptic symptoms within the first four weeks. Liver enzyme profiles remained stable within normal limits, and no adverse events were reported.

CONCLUSION

Homoeopathic preparation of *Chelidonium majus* 6X exhibits therapeutic potential as a safe and effective non-invasive intervention for the management of cholelithiasis, particularly for symptomatic relief and the reduction of smaller gallstones. Further randomized controlled trials are warranted to validate these findings.

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