

A prospective comparative study of the intraoperative difficulties during laparoscopic cholecystectomy in patients taking homeopathic medications for cholelithiasis versus cholelithiasis patients with no history of homeopathic medication



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ABSTRACT

Background: Gallstone disease is one of the most prevalent gastrointestinal diseases with a substantial burden to health-care systems. Patients present with right upper quadrant pain, dyspepsia, nausea or vomiting. Owing to the side effects of allopathic drugs, many patients resort to homeopathic treatment for relief of pain. There are several homeopathic drugs that decrease the pain of cholecystitis as well as high cholesterol in these patients but cannot cure them off the disease. Finally, they come to general surgeon for cholecystectomy. We have noticed that performing laparoscopic cholecystectomy (LC) in these patients is difficult and time consuming. **Aims and Objectives:** To determine whether or not homeopathic medicine intake for treatment of cholelithiasis act as an independent factor that leads to intraoperative difficulties during LC. **Materials and Methods:** Study design: A prospective randomized comparative study. Study period: July 2022–December 2023 (18 months). Study groups: Group H = Patients with history of (H/O) intake of homeopathic medicines for treatment of cholelithiasis = 60 patients, Group N = Patients with no H/O homeopathic medicine intake = 60 patients. **Results:** Twenty-six (43.33%) patients in Group H and 11 (18.33%) patients in Group N had a difficult LC. 7 (11.67%) patients in Group H and 1 (1.67%) patient in Group N had dense adhesions around the gallbladder (GB). 13 (21.67%) patients of Group H and 3 (5%) patients of Group N had a Frozen Calot's Triangle (fibrosis and difficult Calot's triangle dissection). This was statistically significant. **Conclusion:** Our study proved that intake of homeopathic medications for the treatment of cholelithiasis leads to dense adhesions around GB as well as fibrotic adhesions leading to difficult Calot's triangle dissection leading to a difficult LC.

Key words: Laparoscopic cholecystectomy; History of Gallbladder; Gallstone disease

INTRODUCTION

Gallstone disease (GD) is one of the most prevalent gastrointestinal diseases with a substantial burden to health-care systems. GD can result in serious outcomes, such as acute biliary pancreatitis and gallbladder (GB) cancer.

The prevalence of GD has increased in recent years.¹ The classical presentation of cholecystitis includes right upper quadrant abdominal pain, demonstrated as a positive Murphy's sign on palpation if it is acute. Pain usually occurs post-meals, more after fatty meals, and may radiate to the right shoulder or back, often associated with dyspepsia,

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nausea or vomiting.² Once such symptoms occur, patients usually consult the doctors for relief of pain, but fearing the side effects of the allopathic drugs, many of them resort to alternate forms of medicine.

Homeopathy is a controversial 200-year-old whole system of complementary and alternative medicine used worldwide. It was originally developed by the German physician-chemist Samuel Hahnemann, MD, out of concerns about the toxicity of available treatments for acute and chronic illnesses of his day.³

Although skeptics reject homeopathy as chemically “implausible,”⁴ it has an excellent safety track record³ with adaptive nonlinear responses of living systems to low-dose treatments.⁵ Even Psorinum therapy is being used as an adjunct to allopathic treatment in advanced GB, periampullary and liver carcinoma.⁶

There are several homeopathic medications that are used in the treatment of cholecystitis – *Calcarea carbonica*, *Chelidonium*, *Lycopodium*, *Natrum sulphuricum*, *Nux vomica*, *Dioscorea villosa*, *Carduus marianus*, *Iris versicolor*. These medicines usually act by decreasing the pain of cholecystitis and high cholesterol in these patients⁷ but cannot cure the patient off the disease. Hence, the patient ultimately comes to the General Surgeon.

Medical treatment of gallstones is generally unsuccessful. laparoscopic cholecystectomy (LC) is considered the gold-standard treatment of symptomatic cholelithiasis and is one off the most common minimal access surgery performed by General Surgeon.⁸ However, sometimes, the procedure is difficult, challenging and time consuming due to various intraoperative difficulties that are faced by the operating surgeon which include – difficulty in port insertion, non-visualization of GB due to dense upper abdominal adhesions, difficulty in grasping fundus of GB, ductal anomalies, frozen Calot’s triangle, contracted GB, acutely inflamed or empyema GB, previous upper abdominal surgery, short cystic duct, difficulty in finding plane between GB and liver, Mirizzi syndrome, cholecystogastric or cholecystoduodenal fistula.^{9,10} In our study, we have outlined the difficulties that a General Surgeon faces while performing LC in patients who have consumed homeopathic medications for the treatment of cholecystitis.

Aim and objectives

1. To determine whether or not homeopathic medicine intake for treatment of cholelithiasis act as an independent factor that leads to intraoperative difficulties during LC.
2. To study the following parameters in patients with history of homeopathic medicine intake for treatment

of cholelithiasis and patients with no history of (H/O) homeopathic medicine intake undergoing LC:

- a. Dense upper abdominal adhesions
- b. Difficulty in grasping GB fundus (Contracted/Fibrosed/Mucocele/Empyema/Gangrenous GB)
- c. Fibrosis and difficult Calot’s triangle dissection (Frozen Calot’s triangle)
- d. Hemorrhage from GB fossa of liver
- e. Fundus first dissection approach needed
- f. Conversion to open cholecystectomy.

MATERIALS AND METHODS

Study design

This was a prospective cohort study.

Study area

Patients coming to General Surgery Out-patient Department of College of Medicine and Sagore Dutta Hospital with symptomatic cholelithiasis.

Study period

The duration of the period was July 2022–December 2023 (18 months).

Sample size

120 patients.

Inclusion criteria

Patients admitted for elective LC in the Department of General Surgery.

Exclusion criteria

1. LC performed in combination with other laparoscopic procedure (e.g., common bile duct exploration)
2. LC performed in combination with other open procedure
3. LC performed post-ERCP
4. Patients with H/O previous abdominal surgery
5. Patients with co-existing abdominal pathology (e.g., endometriosis and hernia).

Study groups

- Group H = Patients with H/O intake of homeopathic medicines for the treatment of cholelithiasis = 60 patients
- Group N = Patients with no H/O homeopathic medicine intake = 60 patients.

Randomization

All patients with symptomatic cholelithiasis and with H/O homeopathic medicine intake for treatment of cholelithiasis were included into the study (60 such). Other group of patients who did not have H/O any homeopathic

medicine intake was chosen by “flipping a coin” technique where 60 patients with tails were chosen for the study.

Statistical analysis

Master Chart Analysis was done using SPSS software version 25.0. Pearson’s Chi-square test was used to test the significance between the variables of the two groups. $P < 0.05$ was considered statistically significant.

Methodology

After obtaining a proper informed consent, thorough history was taken in a predesigned pro forma. All cases were ultrasound diagnosed. Routine blood investigations along with other tests for procuring anesthetic fitness were done and finally patient was posted for surgery.

Technique of surgery (LC)

Standard 4 port LC was done. GB was identified. Cholecystoduodenal fold was taken down and Calot’s triangle was exposed and skeletonized until Strasberg’s critical view of safety was obtained. Cystic artery and duct were clipped with liga clips and GB taken up from GB fossa of liver by cauterization and extracted out. Hemostasis at GB fossa was achieved. Blood oozes were sucked and thorough irrigation with normal saline was given. Port sites checked and port sheath was closed with No. 1 port vicryl (polyglatin). Skin apposed with 3-0 Ethilon (monofilament polyamide). In case of difficult LC, bail-out techniques were considered.

Bail-out techniques

1. Subtotal cholecystectomy
2. Fundus first (top-down) approach
3. Conversion to open
4. Abandon.

Criteria for difficult LC

If any one or more of the below mentioned observational parameters were encountered, it was considered as difficult LC:

1. Dense upper abdominal adhesions
2. Difficulty in grasping GB fundus
3. Fibrosis and difficult Calot’s triangle dissection
4. Hemorrhage from GB fossa of liver
5. Fundus first dissection approach needed
6. Conversion to open cholecystectomy.

RESULTS

The mean age (mean±standard deviation) of Group H patients was 45.87 ± 7.07 years while that of Group N patients was 48.02 ± 9.806 years. There was no significant difference between the age of patients of the two groups ($P = 0.989$, Chi-square test). Thus, both the groups were matched in their age.

There were 37 (61.67%) females and 23 (38.33%) males in Group H whereas 41 (68.33%) females and 19 (31.67%) males in Group N. There was no significant difference among the number of females and males in both the groups ($P = 0.444$, Chi-square test). Thus, both the groups were matched in their sexes.

26 (43.33%) patients in Group H and 11 (18.33%) patients in Group N had a difficult LC. There was significant difference between the patients undergoing a difficult LC of the two groups ($P = 0.003$, Chi-square test).

7 (11.67%) patients in Group H and 1 (1.67%) patient in Group N had dense adhesions around the GB. There was significant difference between the patients having dense adhesions between the two groups ($P = 0.028$, Chi-square test).

7 (11.67%) patients of Group H and 2 (3.33%) patients of Group N had difficulty in grasping fundus of GB. There was no significant difference between the patients with difficulty in grasping GB fundus during LC of the two groups ($P = 0.083$, Chi-square test).

13 (21.67%) patients of Group H and 3 (5%) patients of Group N had a Frozen Calot’s Triangle (fibrosis and difficult Calot’s triangle dissection). There was significant difference among the patients with Frozen Calot’s triangle of the two groups ($P = 0.007$, Chi-square test).

2 (3.33%) patients of Group H and 2 (3.33%) patients of Group N had hemorrhage from GB during LC that was controlled with intervention. There was no significant difference between the patients with hemorrhage from GB fossa of the two groups ($P = 1$, Chi-square test).

6 (10%) patients of Group H and 1 (1.67%) patient of Group N had undergone fundus first approach for LC. There was no significant difference between the patients undergoing fundus first approach of the two groups ($P = 0.051$, Chi-square test).

Subtotal Cholecystectomy was done in 3 (5%) patients of Group H and 1 (1.67%) patient of Group N. There was no significant difference between the patients undergoing subtotal cholecystectomy of the two groups ($P = 0.309$, Chi-square test).

3 (5%) patients of Group H had undergone conversion to open cholecystectomy while no patients in Group N underwent conversion. There was no significant difference between the patients undergoing conversion to open cholecystectomy of the two groups ($P = 0.079$, Chi-square test) (Table 1).

Table 1: Intraoperative parameters of all patients summarized

Parameters	Count (%)		P
	Group H	Group N	
No difficulty	34 (56.67)	49 (81.67)	
Difficult LC	26 (43.33)	11 (18.33)	0.003 significant
Dense adhesions around GB	7 (11.67)	1 (1.67)	0.028 significant
Difficulty in grasping fundus	7 (11.67)	2 (3.33)	NS
Frozen Calot's triangle	13 (21.67)	3 (5)	0.007 significant
Hemorrhage from GB fossa	2 (3.33)	2 (3.33)	NS
Fundus first approach	6 (10)	1 (1.67)	NS
Subtotal cholecystectomy	3 (5)	1 (1.67)	NS
Conversion to open cholecystectomy	3 (5)	0	NS

NS: Not significant, GB: Gallbladder, LC: Laparoscopic cholecystectomy

DISCUSSION

In our study, we found that, in our sample, the incidence of difficult LC in the homeopathic group was greater than the non-homeopathic group. On statistical analysis of significance, the difference was significant, thus can be applied to the general population as a whole.

Furthermore, after calculating the relative risk, we found that incidence rate of difficult LC is 2.3 times higher in patients taking homeopathic medications for cholelithiasis than the patients with no homeopathic treatment history.

Again, on calculating the attributable risk, we found that 57.7% of the difficult LC among the homeopathic patients' group was due to intake of homeopathic drugs. Thus, difficult LC might be eliminated if homeopathic treatment for cholelithiasis is prevented.

Thus, we come to the conclusion that homeopathic medicine intake for treatment of cholelithiasis act as an independent factor that leads to intraoperative difficulties during LC.

In our study, on assessing the parameters suggesting difficulty, dense upper abdominal adhesions around GB and a fibrosed frozen Calot's triangle difficult to dissect out and skeletonize showed significant difference in their occurrence when compared to patients of both the homeopathic and non-homeopathic groups. The most common parameter to occur was fibrosis and difficult Calot's triangle dissection which was significantly different between the two groups. We also found that the homeopathic groups of patients had increased rate of conversion to open surgery but that was not statistically significant. Vivek et al.,¹¹ has tried to develop a predictive scoring method for difficult LC. Rahman and Agarwal⁹ studied diabetes as an independent factor that can predict a difficult LC. But none have studied the influence of homeopathic medicine treatment for cholelithiasis as a predictive factor for difficult LC.

Limitations of the study

1. Sample size was small. Only 60 patients in each group was taken.
2. Study was conducted in a single centre.
3. Study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

CONCLUSION

Our study proved that patients taking homeopathic medications for the treatment of cholelithiasis have significant upper abdominal adhesions and a frozen fibrosed Calot's triangle that is difficult to dissect and skeletonize, leading to a difficult LC. Thus, it can be concluded that homeopathic medicine intake for the treatment of cholelithiasis act as an independent factor that leads to intraoperative difficulties during LC.

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