International Surgery Journal
Mohan A et al. Int Surg J. 2024 Sep;11(9):1506-1509
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: https://dx.doi.org/10.18203/2349-2902.isj20242450

Original Research Article

Role of laparoscopic cholecystectomy in atypical/asymptomatic gall stone disease patients: a randomized controlled trial from a tertiary care centre in North India

Ajay Mohan, Anurag Kushwaha, Muppana Veerabhadra Venkata Sai Srikanth, Mehul Gupta, Yashwant Singh Rathore*, Sunil Chumber

Department of Surgical Disciplines, AIIMS, New Delhi, India

Received: 11 July 2024
Revised: 09 August2024
Accepted: 13 August 2024

***Correspondence:**
Dr. Yashwant Singh Rathore,
E-mail: dryashvant.r@gmail.com

ABSTRACT

Background: Gallstone disease (GSD) exhibits considerable heterogeneity, ranging from biliary colic to severe complications such as acute cholecystitis and gallstone pancreatitis. The majority of cases have no prior history of biliary symptoms and are diagnosed incidentally, often labelled as "asymptomatic GSD." Detailed questioning often reveals the presence of vague abdominal discomfort such as pain, dyspepsia, and flatulence.
Methods: In this study, we randomized patients with asymptomatic or atypical gallstone disease into two groups: Group A (Control group) and Group B (Interventional group), where standard laparoscopic cholecystectomy was performed. All patients were followed up at 1 week, 6 months, and 12 months to monitor the development of biliary symptoms, postoperative complaints, and the impact on atypical gastrointestinal symptoms.
Results: The results showed no significant change in atypical symptoms from the initial presentation at the 1-year follow-up in the control group. There were no serious biliary complications or hospitalizations for this subgroup of patients. Among the 13 patients in the observation arm, three (23.1%) underwent laparoscopic cholecystectomy due to the development of biliary colic during the follow-up.
Conclusions: In conclusion, laparoscopic cholecystectomy does not appear to improve atypical abdominal symptoms or decrease the risk of gallbladder carcinoma in patients with asymptomatic GSD from North India. However, surgical intervention may be offered to patients with large stone sizes, as they are at increased risk of becoming symptomatic within 1 year, as observed in our study.

Keywords: Atypical gallstones, Asymptomatic gallstones, Laparoscopic cholecystectomy

INTRODUCTION

Gallstone disease (GSD) presents a heterogeneous clinical picture, ranging from biliary colic to severe complications such as acute cholecystitis, gallstone pancreatitis, and gallbladder carcinoma (CaGB). Over 70% of diagnosed cases involve patients without prior biliary symptoms, typically discovered incidentally during radiological evaluations for unrelated abdominal conditions.[1] Although these cases are labeled as "asymptomatic GSD," detailed questioning often reveals vague abdominal discomfort such as pain, dyspepsia, and flatulence.[2,3]

The management of asymptomatic GSD remains controversial, as these vague symptoms are common in individuals without GSD, and the risk of long-term complications in asymptomatic GSD is lower than in symptomatic GSD.[4] On the other hand, evidence of improved quality of life post-cholecystectomy in

asymptomatic GSD and the rise of minimally invasive surgery have prompted some to consider surgical intervention even in the absence of biliary colic. Another significant concern is the potential for severe complications such as gallbladder cancer (CaGB), which, although rare globally (prevalence<0.3%), is more common in North India, contributing to about 10% of the global burden.

Notably, CaGB often occurs in patients with a history of symptomatic GSD, but it can also develop in those with asymptomatic GSD.[5] Given its poor prognosis once diagnosed, evaluating the natural history of asymptomatic GSD in high-risk populations like North India is crucial to determine if prophylactic cholecystectomy could be beneficial.[6,7]

This study aimed to evaluate the impact of laparoscopic cholecystectomy on atypical symptoms in patients with asymptomatic GSD and to assess the potential benefits of prophylactic cholecystectomy in preventing CaGB in North India.

METHODS

This randomized controlled trial (RCT) was conducted at All India Institute of Medical Sciences, (AIIMS) New Delhi, a tertiary care hospital from January 2020 to August 2021. Ethical clearance was obtained from the Institute ethics committee (Ref No: IECPG-726/12/2019).

All individuals diagnosed with GSD but not presenting with biliary colic at the initial clinical visit were enrolled. The target sample size was 100, but was reduced due to the COVID-19 pandemic. Patients were randomized into Group A (Control group) and Group B (Interventional group) using block randomization with variable block sizes.

Patients in Group B underwent standard 4-port laparoscopic cholecystectomy performed by a single surgical team. Follow-ups were conducted at 1 week, 6 months, and 12 months to monitor the development of biliary symptoms, postoperative complaints, and atypical gastrointestinal symptoms.

Inclusion criteria

It includes gall stone diseases with no biliary symptoms. Vague abdominal symptoms like dyspepsia, bloating, gastritis (pain anywhere in abdomen other than right upper quadrant and epigastrium are not included under biliary symptoms). Age>18 years old and <65 years old. Proper consent available and willing to follow up till 1 year. Patients with gall bladder polyps <1 cm.

Exclusion criteria

Exclusion criteria include the patient refusal. Age<18 years and >65 years old. Gall stone disease with any biliary symptoms in the past. Not willing to follow up. Pregnant patients with gall stone disease. Patients awaiting organ transplantation. Patients with porcelain gall bladder and gall bladder polyps >1 cm.

Statistical analysis

Continuous variables were analyzed using mean, median, mode, standard deviation, variance, and range. Nominal variables were analyzed using frequencies and proportions. Parametric data sets were compared using the student's t-test or one-way ANOVA, while non-parametric data sets were compared using the chi-square test, Mann-Whitney U test, or Kruskal-Walli's test. A p value of <0.05 was considered significant.

RESULTS

The study enrolled 26 patients, with 13 in each group (Group A-Control group and Group B-Interventional group). The cohort was 61.5% female (n=16), with all participants from the Indo-Gangetic plain. The mean age was 42.2±13.1 years, and the mean BMI was 27.6±4.12 kg/m² (Table 1).

Table 1: Demographic data.

Parameter	Observational group (n=13)	Interventional group (n=13)	P value
Age	43.3±13.7	40.9±13.6	0.32
Gender			0.31
Male	4 (30%)	6 (46%)	
Female	9 (69%)	7 (53%)	

The most common symptoms at enrolment were mild abdominal pain not localized to the right upper quadrant (RUQ) and dyspepsia, each reported by 61% of the cohort. Other symptoms included bloating, abdominal fullness, altered bowel habits, and anorexia. No significant difference was found in baseline demographics or presentation between the two groups, nor in baseline biochemical evaluations (Table 2).

Table 2: Comparison of biochemical parameters at the time of registration during the study.

Parameter	Observational group (n=13)	Interventional group (n=13)	P value
Haemoglobin	12.5±1.05	12.9±1.21	0.82
TLC	7865±2483	7260±1899.8	0.24
Total bilirubin	0.83±0.27	0.71±0.24	0.125
SGOT	24.53±8.66	33.64±15.4	0.96
SGPT	25±13.4	34.17±21.85	0.89

In the observation arm, three patients (23.1%) underwent laparoscopic cholecystectomy due to the development of

biliary colic during follow-up. The mean pain score at enrollment, assessed via the Visual Analogue Score (VAS), was 2.1 out of 10, with a peak score of 8 during biliary colic episodes.

For the 10 patients who continued with watchful waiting, the mean VAS score at 1 year was 1.8. No serious biliary complications, hospitalizations, or major postoperative complications were observed. Histopathological evaluation of the gallbladders from the three operated cases revealed mild inflammatory changes.

All 13 patients in the interventional arm underwent laparoscopic cholecystectomy. The mean pain score was 2.7 at enrollment and 2.3 at the 1-year follow-up. No significant pain episodes (VAS score>3) were reported postoperatively. The mean hospital stay was 3.23±0.43 days, with no major postoperative complications. Histopathological examination showed chronic cholecystitis in 53% of cases, with no evidence of dysplasia or CaGB (Table 3).

Table 3: Symptomatic outcome in interventional group after 1 year of follow up.

Atypical gall stone symptoms	Baseline (n=13)	At 1 year of follow up (n=13)	P value
Pain abdomen other than RUQ	8	6	0.15
GERD symptoms	8	7	0.16
Anorexia	4	4	0.9
Abdominal fullness	8	7	0.16
Dyspepsia	7	7	0.9
Bloating	6	5	0.32

At the 1-year follow-up, no significant change in atypical symptoms was observed in either group. Biochemical analyses remained within normal ranges and showed no significant differences between groups (Table 4).

Table 4: Comparison of biochemical parameters at 1 year of follow up.

Parameters	Observational group (n=13)	Interventional group (n=13)	P value
Haemoglobin	12.64±0.97	13.1±1.12	0.88
TLC	8038.4±142.1	7069±2163.1	0.09
Total bilirubir	0.83±0.26	0.79±0.23	0.34
SGOT	22.7±4.36	27.92±15.21	0.88
SGPT	21.45±10.33	28.37±22.97	0.83

DISCUSSION

GSD is prevalent in North India, where asymptomatic cases are commonly diagnosed incidentally.[8] Two major concerns must be addressed when considering watchful waiting in asymptomatic GSD: atypical symptoms and the high prevalence of CaGB. This study suggests that, similar to Western populations, the course of asymptomatic GSD in North India is benign, with no serious biliary complications. Laparoscopic cholecystectomy did not significantly improve atypical symptoms.

Three patients in the observation group (23%) developed biliary colic during follow-up, a higher proportion than reported in previous studies. For example, Gracie and Ransohoff's 15-year study noted symptoms in 10%, 15%, and 18% of their cohort at 5, 10, and 15 years, respectively, with only 0.3% experiencing biliary complications.[9] Our findings suggest a higher likelihood of developing biliary colic in North India's asymptomatic GSD patients, particularly those with larger stone sizes, indicating a potential need for prophylactic cholecystectomy in this population.

Patients with asymptomatic GSD often report atypical abdominal symptoms, which did not improve significantly after laparoscopic cholecystectomy or worsen with watchful waiting. These findings could be attributed to other common abdominal pathologies in the Indian population, unaffected by cholecystectomy. Contrary to our findings, Mentes et al. reported improved gastrointestinal quality of life post-cholecystectomy in asymptomatic GSD patients, suggesting that longer follow-up durations may reveal benefits not captured in this study.[2]

The potential development of CaGB is another critical concern in managing asymptomatic GSD. Although no histologic evidence of neoplasia was found in our study, CaGB's poor prognosis and its occurrence in GSD patients without prior biliary colic highlight the need for cautious monitoring. High-risk populations, such as those in Chile, recommend cholecystectomy for gallstones irrespective of symptomatic status, suggesting a possible parallel for North India.[10]

Economic considerations and surgical risks also influence management decisions. Prophylactic cholecystectomy, despite advancements in laparoscopic techniques, still carries risks and higher costs compared to watchful waiting.[11] Current guidelines recommend cholecystectomy for specific high-risk groups, which may need reevaluation based on stone size and symptom development.

Due to the COVID-19 pandemic, this pilot study was limited to 26 subjects. Future large-scale, multi-center trials with longer follow-up are needed to further explore the impact of cholecystectomy on atypical symptoms and the risk of severe complications in North India's asymptomatic GSD patients.

CONCLUSION

This study suggests that laparoscopic cholecystectomy does not significantly improve atypical abdominal symptoms or reduce the risk of gallbladder carcinoma in North India's asymptomatic GSD patients. However, patients with large stone sizes are more likely to become symptomatic within a year, potentially benefiting from prophylactic surgery. Further large-scale studies with longer follow-up durations are necessary to validate these findings and guide management decisions for asymptomatic GSD patients in high-risk regions.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Sakorafas GH, Milingos D, Peros G. Asymptomatic cholelithiasis: is cholecystectomy really needed? a critical reappraisal 15 years after the introduction of laparoscopic cholecystectomy. Dig Dis Sci. 2007;52(5):1313-25.
2. Bülent Mentes B, Akin M, Irkörücü O, Tatliciolu E, Ferahköe Z, Yildinm A, et al. Gastrointestinal quality of life in patients with symptomatic or asymptomatic cholelithiasis before and after laparoscopic cholecystectomy. Surg Endosc. 2001;15(11):1267-72.
3. Patiño JF, Quintero GA. Asymptomatic cholelithiasis revisited. World J Surg. 1998;22(11):111924.
4. McSherry CK, Ferstenberg H, Calhoun WF, Lahman E, Virshup M. The natural history of diagnosed gallstone disease in symptomatic and asymptomatic patients. Ann Surg. 1985;202(1):59-63.
5. Dutta U, Bush N, Kalsi D, Popli P, Kapoor VK. Epidemiology of gallbladder cancer in India. Chin Clin Oncol. 2019;8(4):33.
6. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394-424.
7. Batra Y, Pal S, Dutta U, Desai P, Garg PK, Makharia G, et al. Gallbladder cancer in India: A dismal picture. J Gastroenterol Hepatol. 2005;20(2):309-14.
8. Mallath M, Patil P. Cholecystectomy for asymptomatic gallstones can reduce gall bladder cancer mortality in Northern Indian women. Indian J Gastroenterol Off J Indian Soc Gastroenterol. 2005;25:147-51.
9. Gracie WA, Ransohoff DF. The Natural History of Silent Gallstones. N Engl J Med. 1982;307(13):798–800.
10. Roa I, Aretxabala X de, Roa J, Araya JC, Villaseca M, Guzmán P, et al. Is gallbladder cancer a disease with bad prognosis? Rev Med Chil. 2002;130(11):1295-302.
11. Gollan JL, Bulkley GB, Diehl AM, Elashoff JD, Federle MP, Hogan WJ, et al. Gallstones and Laparoscopic Cholecystectomy. JAMA. 1993;269(8):1018-24.

Cite this article as: Mohan A, Kushwaha A, Srikanth MVVS, Gupta M, Rathore YS, Chumber S. Role of laparoscopic cholecystectomy in atypical/asymptomatic gall stone disease patients: a randomized controlled trial from a tertiary care centre in North India. Int Surg J 2024;11:1506-9.