Original Article

Post-Cholecystectomy Syndrome in Laparoscopic Cholecystectomy: Single Center Experience of Related Factors

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Abstract

Background: Post-cholecystectomy syndrome is one of the most common complications of laparoscopic cholecystectomy. The present study aimed to investigate factors affecting post-cholecystectomy syndrome in laparoscopic cholecystectomy surgery in patients with gallstones.

Materials and Methods: In this prospective cohort study, 100 patients with gallstones who underwent laparoscopic cholecystectomy were included. Patients were evaluated and followed up for 6 months using a checklist of possible factors affecting post-cholecystectomy syndrome, including demographic, non-biliary, biliary, and extrabiliary factors.

Results: Among the 100 patients participating in this study, 21 (21%) experienced post-cholecystectomy syndrome within 6 months. Higher age (P-value<0.001), male gender (P-value: 0.048), involvement with diabetes (P-value: 0.038), involvement with gastritis (P-value: 0.005), and increased CBD diameter (P-value<0.001) were significantly associated with the occurrence of PCS. Logistic regression analysis revealed that only *Helicobacter pylori* infection had a significant impact on the incidence of PCS (SE: 1.053, CI95%: 2.592- 160.858, P-value: 0.004), whereas linear regression did not.

Conclusion: The results obtained from this study showed that old age, diabetes, *Helicobacter pylori* infection, male gender, and gastritis are related to the occurrence of post-cholecystectomy syndrome.

Keywords: Gallbladder, Gallstones, Cholelithiasis, Post-cholecystectomy syndrome, Laparoscopy

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Introduction

Gallstone disease is one of the most common gastrointestinal disorders and is considered a significant global health concern[1]. The National Institutes of Health estimates that approximately 3,000 deaths per year are attributable to complications of gallstone disease[2]. Risk factors for gallstone disease include gender, race, age, obesity, dyslipidemia, the use of contraceptives, Hyperinsulinemia, diabetes mellitus, and alcohol consumption. In managing many of the gallbladder-related disorders, cholecystectomy is indicated[3].

Laparoscopic cholecystectomy has shown better outcomes in treating patients with gallstones compared to open surgery [4]. It offers benefits such as less postoperative pain, smaller incisions, shorter postoperative ileus, reduced blood loss, shorter hospital stays, improved aesthetics, quicker recovery, and earlier return to normal activities and work[4-6]. Despite laparoscopic cholecystectomy being the "gold standard" treatment for symptomatic gallstones, this therapeutic method is associated with some complications. A common and significant complication in patients undergoing cholecystectomy is post-cholecystectomy syndrome[7].

The term post-cholecystectomy syndrome (PCS) was first described by Womack and Crider in 1947 as "the presence of symptoms after cholecystectomy"[8]. PCS describes persistence of biliary colic or upper quadrant abdominal pain, accompanied by various gastrointestinal symptoms similar to those experienced before cholecystectomy[9], such as intolerance to fatty foods, nausea, vomiting, heartburn, bloating, indigestion, diarrhea, jaundice, and intermittent episodes of abdominal pain[10]. Studies show 10-15% of patients undergoing laparoscopic cholecystectomy develop PCS[11].

PCS usually manifests in the recovery phase following surgery, but it can last for several months or even years. The origins of PCS can be classified into two primary groups: non-Biliary causes, which include reflux esophagitis, peptic ulcers, irritable bowel syndrome, and pancreatitis; and Biliary causes, which encompass bile duct injuries and strictures, bile leaks, retained stones, dropped stones, bilomas or chronic abscesses, long cystic duct remnants, Oddi sphincter dysfunction or dyskinesia, and diarrhea induced by bile salts. Among these, bile duct injuries represent the most critical factor contributing to PCS and are regarded as the most severe complications linked to laparoscopic cholecystectomy, occurring at an average rate of 0.2%[11-13]. Considering the significant occurrence of PCS and the necessity of recognizing related risk factors to mitigate or lessen its frequency, along with the insufficient research on these risk factors within the Iranian population, this study seeks to explore the elements that affect post-cholecystectomy syndrome in patients who are undergoing laparoscopic cholecystectomy for gallstones.

Methods

Objective: To determine the factors influencing post-cholecystectomy syndrome in patients undergoing laparoscopic cholecystectomy for gallstones within 6 months of follow-up.

Research Methodology: This prospective cohort study was meticulously designed and conducted at a tertiary medical center from January 2022 to July 2023. The study focused on patients diagnosed with gallstones who underwent laparoscopic cholecystectomy, a minimally invasive surgical procedure aimed at removing the gallbladder.

To be included in the research, participants had to meet specific inclusion criteria: a confirmed diagnosis of gallstones and informed written consent to participate. The exclusion criteria were as follows: 1) patients whose surgical procedure had to be converted to a laparotomy during the operation, 2) patients who became uncontactable for any reason before completing a 6-month follow-up, and 3) individuals with incomplete demographic and clinical records that could hinder the study's integrity.

Based on the research conducted by Shirah et al.[۸] and Filip et al.[۱۴]A sample size of 100 individuals was determined with 70% power. This calculation was performed with a confidence level of 95% and a permissible maximum error of 0.09.

Data collection involved a comprehensive assessment of various factors: demographic information such as gender and age, alongside medical history indicators, including body mass index (BMI), diabetes mellitus, addiction, and alcohol consumption. Other relevant medical conditions, such as reflux esophagitis, peptic ulcer disease, H. pylori infection, irritable bowel syndrome, or chronic pancreatitis, were meticulously recorded. Additionally, important anatomical and procedural details were noted, such as the biliary duct diameter, occurrences of bile leakage, and any retained or spilled stones within the abdominal cavity.

All patients underwent an endoscopic evaluation to assess for peptic ulcer disease and esophagitis. Additionally, Helicobacter pylori infection was evaluated by acquiring endoscopic specimens and performing subsequent analysis.

Complications like biloma or chronic abscess, long residual cystic duct, stricture or dyskinesia of the Oddi

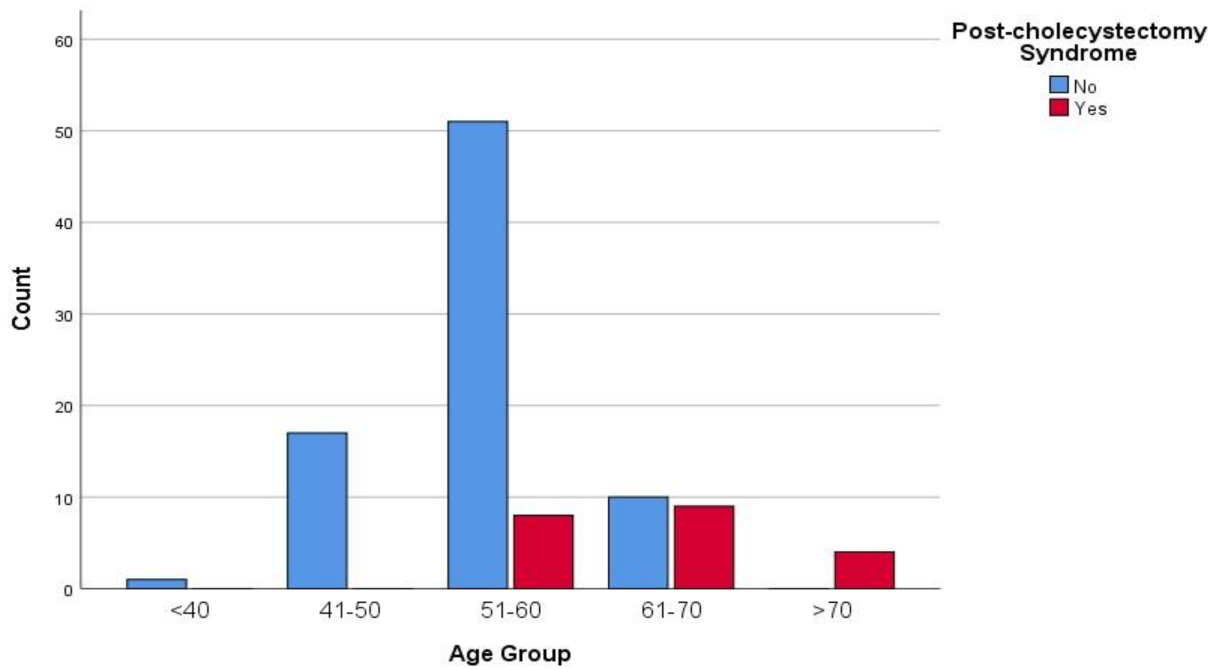

Figure 1. PCR visualization of HVS I [143 bp] and HVS II [126 bp]. Notes: M = Marker; 7D = Day 7.

sphincter, as well as bile salt-induced diarrhea or gastritis, were also documented.

Following the surgical intervention, patients were monitored for 6 months to assess the presence or absence of PCS. In this study, PCS was specifically defined as the resurgence of symptoms reminiscent of those experienced prior to the gallbladder removal[15]. This thorough follow-up aimed to provide valuable insights into the long-term outcomes and complications associated with laparoscopic cholecystectomy.

Data analysis: All statistical analyses were conducted using SPSS version 27. Quantitative data are presented as either mean ± standard deviation or median with interquartile range, depending on their distribution. Qualitative data are presented as frequency and percentage. Comparisons of quantitative data utilized the Independent Samples t-test and the Wilcoxon Rank-Sum test. For qualitative data comparisons, Pearson's Chi-Square test and Fisher's Exact Test were applied. Adjustments for comparisons between two groups were performed using univariate regression. To analyze factors influencing the occurrence and timing of post-concussion syndrome (PCS), logistic and linear regression were used. A significance level of 0.05 or lower was considered statistically significant for all tests.

Ethical consideration: This study was approved by the ethical committee of Shahid Beheshti Medical University (IR.SBMU.MSP.REC.1402.121).

Results

Among the 100 participants, 21 (21%) developed PCS symptoms within six months post-surgery. The onset of PCS occurred, on average, 1.85 ± 1.01 months postoperatively, with a median time of 1.50 (1.00, 2.75) months. Notably, no cases of bile leakage, retained stones, long cystic duct remnant, biloma, chronic abscess, or stump syndrome were observed in this cohort.

Demographics: Age: The mean age of the participants was 56.11 ± 7.24 years. The mean age for those with PCS was 63.67 ± 6.84 years, while the mean age for those without PCS was 54.10 ± 5.93 years. The Kolmogorov-Smirnov test confirmed a normal distribution of ages (p=0.149). An Independent Sample T-test revealed a significant difference in mean age between the two groups, with the PCS group being significantly older than the non-PCS group ($p < 0.001$) (Figure 1).

Gender: There were 54 (54%) female and 46 (46%)

male patients. Among the PCS group, 14 (66.7%) were male, and 7 (33.3%) were female. In the non-PCS group, 47 (59.5%) were female, and 32 (40.5%) were male. Using Pearson's Chi-square test to assess for significant differences between the two groups, the proportion of male patients in the PCS group was significantly higher ($p = 0.048$).

Body Mass Index (BMI): The average BMI of the participants was 30.87 ± 1.82 kg/m². The mean BMI for the PCS group was 31.00 ± 1.28 kg/m², while for the non-PCS group, it was 30.84 ± 1.94 kg/m². The Kolmogorov-Smirnov test confirmed the normal distribution of BMI ($p = 0.200$). Using the Independent Sample's T-test to examine significant differences between the two groups and given the violation of the equal variance assumption (Levene's test, $p = 0.022$), there was no significant difference in mean BMI between the groups ($p = 0.645$) (Table 1).

Risk factors:

Smoking: Smoking was observed in 33 (33%) of the patients. In the PCS group, 9 (42.9%) patients smoked, while in the non-PCS group, 24 (30.4%) patients smoked. Pearson's Chi-square test indicated no significant difference in smoking status between the two groups ($p = 0.305$).

Alcohol: Alcohol consumption was noted in 10 (10%) of the patients. In the PCS group, 2 (9.5%) patients consumed alcohol, compared to 8 (10.1%) in the non-PCS group. The Fisher's Exact test showed no significant difference in alcohol consumption between the two groups ($p > 0.99$).

Diabetes (DM): Diabetes was observed in 16 (16%) of the patients. In the PCS group, 7 (33.3%) patients had diabetes, while in the non-PCS group, 9 (11.4%) patients had diabetes. The Fisher's Exact test revealed that diabetes was significantly more prevalent in the PCS group ($p = 0.038$) (Table 1).

Underlying diseases:

Helicobacter pylori: *H. pylori* infection was observed in 11 (11%) of the patients. In the PCS group, 5 (23.8%) patients had H. pylori infection, while in the non-PCS group, 6 (7.6%) patients were infected. The Fisher's Exact Test revealed a higher, though not statistically significant, prevalence of *H. pylori* infection in the PCS group ($p = 0.050$).

Gastritis: Gastritis was observed in 10 (10%) of the patients. In the PCS group, 6 (28.6%) patients had gastritis, compared to 4 (5.1%) in the non-PCS group. The Fisher's Exact test showed a significantly higher prevalence of gastritis in the PCS group ($p = 0.005$).

Reflux esophagitis: Reflux esophagitis was observed in 7 (7%) of the patients. In the PCS group, 3 (14.3%)

Table 1. Pearson Correlations among Key Study Variables (N=249).

Variables	Groups		p-value
	PCS +	PCS -	
Demographics			
Age	63.67 ± 6.84	54.10 ± 5.93	<0.001
Sex	14 (7.66%)	32 (40.5%)	0.048
BMI (kg/m^2)	31.00 ± 1.28	30.84 ± 1.94	0.645
Risk factors			
Smoking	9 (42.9%)	24 (30.4%)	0.305
Alcohol	2 (9.5%)	8 (10.1%)	0.99
Diabetes Miletus	7 (33.3%)	9 (11.4%)	0.038
Underlying diseases			
H. Pylori	5 (23.8%)	6 (7.6%)	0.05
Gastritis	6 (28.6%)	4 (5.1%)	0.005
Gastroesophagial reflux	3 (14.3%)	4 (5.1%)	0.159
Other Findings			
CBD diameter (mm)	5 (4-6)	3 (3-4)	0.267
Surgery duration (min)	41 (38-42)	39 (37-42)	0.493
Pancreatitis	1 (4.8%)	3 (3.8%)	0.99
Oddi sphincter dysfunction	2 (9.5%)	2 (2.5%)	0.193
Intra-abdominal Gallstones	1 (4.8%)	2 (2.5%)	0.511

* Quantitative data are reported as median with interquartile range, and qualitative data are reported as number and percentage.

Table 2. Logistic regression model for examining factors influencing the incidence of PCS.

Variable	B	S.E	Wald	F.D	P	Exp (B)
Age	0.384	0.217	3.139	1	0.076	1.469
BMI	0.290	0.239	1.469	1	0.226	1.336
CBD diameter	-0.366	1.214	0.091	1	0.763	0.694
Surgery duration	0.009	0.142	0.004	1	0.952	1.009
Sex (male)	0.870	0.758	1.318	1	0.251	2.386
DM	1.678	0.993	2.857	1	0.091	5.357
H. pylori	3.016	1.053	8.204	1	0.004	20.418
Smoking	0.400	0.782	0.261	1	0.609	1.492
Alcohol	-1.448	1.324	1.196	1	0.274	0.235

patients had reflux esophagitis, while 4 (5.1%) patients in the non-PCS group had the condition. The Fisher's Exact test revealed no significant difference in the prevalence of reflux esophagitis between the two groups (p = 0.159) (Table 1).

Surgical Findings:

Common bile duct diameter: The mean diameter of the common bile duct (CBD) among the participants in this study was 3.69 ± 1.10 mm. In the PCS group, the mean CBD diameter was 4.86±1.15 mm, whereas in the non-PCS group, it was 3.38 ± 0.86 mm. The Kolmogorov-Smirnov test indicated that the distribution was not normal (p<0.001). The Wilcoxon Rank-Sum Test revealed a significantly higher mean CBD diameter in the PCS group (p<0.001). However, when comparing CBD diameters between the two groups, adjusting for age and gender as covariates, no significant difference was found (p=0.267).

Surgery duration: The mean surgery duration for participants in this study was 39.70 ± 2.51 minutes. The mean surgery duration for the PCS group was 40.05 ± 2.80 minutes, while for the non-PCS group, it was 39.61 ± 2.44 minutes. The Kolmogorov-Smirnov test indicated that the distribution was not normal (p = 0.019). Using the Wilcoxon Rank-Sum test, no significant difference in mean surgery duration was observed between the two groups (p = 0.493).

Pancreatitis: Pancreatitis was observed in 4 (4%) patients. Among the PCS group, 1 (4.8%) patient had pancreatitis, whereas 3 (3.8%) patients in the non-PCS group had this condition. Using Fisher's Exact test, no significant difference was found between the two groups (p > 0.99).

Oddi sphincter dysfunction: Sphincter of Oddi dysfunction (stenosis or dyskinesia) was noted in 4 (4%) patients. In the PCS group, 2 (9.5%) patients had this condition, compared to 2 (2.5%) patients in the non-PCS group. Fisher's Exact test revealed no significant difference between the groups (p=0.193).

Gallstone spillage: Release of gallstones in the peritoneal cavity occurred in 3 (3%) patients. In the PCS group, 1 (4.8%) patient had this issue, while 2 (2.5%) patients in the non-PCS group were affected. Fisher's Exact test indicated no significant difference between the groups (p = 0.511) (Table 1).

Regression model: In the regression analysis examining the factors influencing the occurrence of post-cholecystectomy syndrome using Binary Logistic Regression, considering variables such as age, gender, BMI, surgery duration, CBD diameter, smoking and alcohol consumption, diabetes, and *H. pylori* infection, as presented in Table 2, only *H. pylori* infection was found to significantly influence the occurrence of the syndrome.

In the Linear Regression analysis examining factors influencing the time to onset of post-cholecystectomy syndrome, with consideration of variables such as age, gender, BMI, surgery duration, smoking and alcohol consumption, diabetes, and *H. pylori* infection, as shown in Table 3, no significant variables were found. The CBD diameter was excluded from the model due to high collinearity.

Table 3. Linear regression model for examining factors influencing the time of PCS onset.

Variable	Unstandardized coefficient		Standardized coefficient	P	t	Convergence	
	S. E	B	Beta			VIF	Tolerance
Age	0.015	0.001	0.010	0.925	0.095	1.124	0.890
Sex	0.215	-0.027	-0.013	0.899	-0.128	1.120	0.893
DM	0.295	0.511	0.185	0.087	1.732	1.147	0.872
H. pylori	0.341	-0.127	-0.039	0.710	-0.372	1.114	0.897
BMI	0.060	0.042	0.075	0.488	0.696	1.167	0.857
Smoking	0.219	0.009	0.004	0.967	0.042	1.037	0.965
Alcohol consumption	0.343	-0.577	-0.171	0.096	-1.683	1.034	0.967
Duration of alcohol consumption	0.041	0.062	0.152	0.137	1.500	1.033	0.968

Discussion

In this study, it was determined that patients with PCS exhibited significantly higher age and a predominance of male gender.

The presence of diabetes, gastritis, and an increased diameter of the CBD demonstrated a significant relationship with the occurrence of PCS. Logistic regression analysis revealed that only Helicobacter pylori infection was significantly associated with the incidence of PCS, whereas linear regression was not.

PCS affects at least 15% of individuals, with symptoms that may last from days to years. Modern medicine recognizes two primary categories of risk factors: biliary tract factors and non-biliary tract factors, such as acute or chronic gastritis, peptic ulcers, and malignant gastrointestinal tumors. Additionally, 20% to 40% of patients may experience persistent or recurrent symptoms. However, studies suggested that further investigation is needed in this regard[16-19].

In this regard, Mahfouz et al. reported no significant associations between age, nationality, or place of residence and PCS. However, a significant correlation was found between gender and PCS, with females achieving higher scores than males. Additionally, females reported a higher quality of life than males[20]. In the current study, patients' quality of life was not assessed; however, males had a higher prevalence of PCS, which was one of the differences between the studies. This difference between the two studies may stem from differences in the study populations. Our study had a smaller statistical population, which was one of its limitations. It should be noted that gender did not affect PCS in the regression model. Male gender is a risk factor of challenging or complicated cholecystitis based on previous studies, such as Ambe et al[21]. If we consider PCS as a complication of cholecystectomy, it seems that the relationship between male gender and PCS is rational. However, more studies in this regard should be conducted in the future.

Zhou et al. conducted a systematic review on risk factors of PCS. They illustrated that reoperative complications have been recognized as a significant risk factor for PCS[22]. We did not assess reoperative complications in the current study, but it was found that complications did not differ between patients with and without PCS. This difference between the studies may be due to differences in study design: we conducted ours as a cross-sectional study, whereas the study mentioned was a systematic review. Regarding study discrepancies, differences in study design and follow-up duration have led to inconsistent findings across studies. Shorter follow-up periods may capture only transient postoperative discomfort, whereas extended follow-up is essential for identifying the true nature of chronic syndromes. Additionally, demographic and regional variability may also influence the outcomes observed[23].

Studies suggested that higher age and involvement with underlying disease, especially irritable bowel syndrome and dyspepsia, are risk factors for PCS. Our study showed that age and underlying diseases, including diabetes and gastritis, were significantly higher in patients with PCS, but they did not correlate with PCS. Therefore, further large-scale studies are needed to examine predictors of PCS, as results from previous studies are controversial.

Manifestations of PCS vary considerably among patients and are attributable to diverse etiologies. These symptoms necessitate tailored diagnostic and therapeutic approaches. Predominantly, the manifestations observed after cholecystectomy appear to result from concomitant medical conditions and physiological alterations stemming from the surgical removal of the gallbladder[13]. Based on our searches, limited studies have investigated the role of *H. pylori* in PCS. Shirah et al. evaluated 273 patients with PCS and found that 15.8% were infected with *H. pylori*. They did not assess the role of *H. pylori* as a risk factor for PCS[8]. In the current study, we evaluated 100 patients with *H. pylori* infection and found that 23.8% of patients with PCS were infected. We observed a significant association between *H. pylori* infection and PCS using logistic regression, although this association was not observed in linear regression. Therefore, it seems that eradicating *H. pylori* infection in patients undergoing cholecystectomy is beneficial, but further investigation is still needed.

This study had a limited number of patients, and issues such as selection bias, measurement error, and residual confounding limit its generalizability. Additional research is needed to confirm the findings, as factors such as gastrointestinal diseases and specific medications were not examined. Recommended objectives include: exploring genetic and epidemiological factors associated with PCS; investigating *H. pylori*'s molecular mechanisms and its impact on the immune system and inflammation related to PCS; studying the relationship between the gut microbiota and PCS; and evaluating the effectiveness of various *H. pylori* treatments and dietary/lifestyle interventions for PCS prevention.

Conclusion

The symptoms of PCS can significantly impair patients' quality of life. Our research highlights that age, gender, diabetes, and *H. pylori* infection are important factors to consider when discussing cholecystectomy with patients. Therefore, individuals at high risk for PCS should receive comprehensive counseling about the risks and benefits of the procedure. Identifying these risk factors can facilitate targeted monitoring and interventions for affected patients.

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Conflict of Interest

The authors declare no conflicts of interest related to this study.

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