



Original Article

Study of Demographic, Clinical and Diagnostic Profile of Patients with Cholelithiasis

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ABSTRACT

Background; Cholelithiasis is one of the most common hepatobiliary disorders worldwide and is associated with significant morbidity due to its varied clinical presentation and potential complications. Understanding the demographic, clinical, and diagnostic profile of affected patients is essential for early diagnosis and appropriate management.

Objectives; To evaluate the demographic characteristics, clinical presentation, and diagnostic profile of patients with cholelithiasis presenting to a tertiary care teaching hospital.

Materials and Methods; This prospective observational study was conducted in the Department of General Surgery, Era's Lucknow Medical College and Hospital, Lucknow, over a period of two years. A total of 245 adult patients diagnosed with cholelithiasis on ultrasonography were included using consecutive sampling. Demographic details, clinical features, laboratory investigations, and radiological findings were recorded using a structured proforma. Data were analyzed using SPSS version 26, and results were expressed as frequencies, percentages, mean, and standard deviation where appropriate.

Results; Of the 245 patients, 66.5% were females and 33.5% were males. The majority of patients belonged to the 41–50 years age group (27.8%). Right upper abdominal pain was the most common presenting symptom (80.8%), followed by nausea/vomiting (63.7%) and dyspepsia (52.7%). Most patients were symptomatic (91.0%). Ultrasonography revealed multiple gallstones in 60.8% of patients and gallbladder wall thickening in 45.7%. Gallbladder distension, pericholecystic fluid, and common bile duct dilatation were observed in 31.8%, 14.7%, and 11.8% of patients, respectively. Liver function test abnormalities were present in 29.4% of patients, with elevated alkaline phosphatase being the most common biochemical abnormality.

Conclusion; Cholelithiasis predominantly affected middle-aged females and commonly presented with right upper abdominal pain, nausea, vomiting, and dyspepsia. Ultrasonography remained the primary diagnostic tool, while liver function abnormalities and radiological indicators aided in identifying complicated disease. Early recognition of clinical and diagnostic findings can facilitate timely management and reduce disease-related complications.

Keywords: Cholelithiasis; Gallstones; Ultrasonography; Biliary Colic; Gallbladder Disease; Diagnostic Profile.

INTRODUCTION

Cholelithiasis, the presence of gallstones within the gallbladder, is among the most common disorders of the biliary tract and represents a major global health problem. Gallstone disease contributes substantially to healthcare utilization owing to its high prevalence, recurrent symptoms, complications, and frequent requirement for surgical intervention. The

prevalence of gallstones varies considerably across different populations and geographic regions, ranging from 10% to 20% in Western countries and showing a steadily increasing trend in Asian countries, including India [1,2].

Gallstones are broadly classified into cholesterol stones, pigment stones, and mixed stones. Cholesterol stones constitute the majority of gallstones and result from cholesterol supersaturation of bile, impaired gallbladder emptying, and accelerated nucleation of cholesterol crystals. Pigment stones are associated with hemolytic disorders, biliary infections, and chronic liver diseases [3]. The pathogenesis of gallstone formation is multifactorial and involves a complex interaction between genetic predisposition, metabolic abnormalities, hormonal influences, dietary habits, and environmental factors [4].

Several epidemiological studies have identified female gender, advancing age, obesity, diabetes mellitus, dyslipidemia, pregnancy, multiparity, rapid weight loss, sedentary lifestyle, and family history as important risk factors for gallstone formation [3,5]. Women are particularly susceptible because estrogen increases hepatic cholesterol secretion while progesterone reduces gallbladder motility, resulting in bile stasis and cholesterol crystal formation [5]. These associations have traditionally been summarized by the "four Fs" of gallstone disease: female, forty, fertile, and fat.

The clinical spectrum of cholelithiasis is highly variable. A large proportion of patients remain asymptomatic throughout life, with gallstones often detected incidentally during imaging studies performed for unrelated reasons. However, symptomatic patients commonly present with biliary colic characterized by episodic right upper quadrant abdominal pain, frequently accompanied by nausea, vomiting, dyspepsia, and intolerance to fatty foods [6]. Progression of disease may result in complications such as acute cholecystitis, empyema gallbladder, choledocholithiasis, cholangitis, gallstone pancreatitis, and gallbladder carcinoma, thereby increasing morbidity and mortality [7].

Accurate diagnosis of gallstone disease relies on a combination of clinical evaluation, laboratory investigations, and imaging studies. Ultrasonography remains the first-line diagnostic modality because of its high sensitivity, specificity, non-invasive nature, availability, and cost-effectiveness. In addition to detecting gallstones, ultrasonography provides important information regarding gallbladder wall thickening, gallbladder distension, sludge, pericholecystic fluid, and common bile duct dilatation [8]. Magnetic resonance cholangiopancreatography (MRCP) serves as an excellent non-invasive technique for detailed evaluation of the biliary tree and is particularly useful in patients with suspected biliary obstruction or choledocholithiasis [9]. Contrast-enhanced computed tomography (CECT) is valuable in evaluating complications and excluding neoplastic pathology [10].

Laboratory investigations, particularly liver function tests, play an important role in assessing the severity of disease and identifying biliary obstruction. Elevated serum bilirubin, alkaline phosphatase, and hepatic transaminases may indicate complicated gallstone disease requiring further diagnostic evaluation and intervention [11].

Despite the widespread occurrence of gallstone disease, demographic characteristics, clinical manifestations, and diagnostic findings may vary across different populations due to differences in genetic background, dietary practices, socioeconomic status, and healthcare accessibility. Limited data are available regarding the comprehensive demographic, clinical, and diagnostic profile of patients with cholelithiasis in North India. Therefore, the present study was undertaken to evaluate the demographic characteristics, clinical presentation, laboratory abnormalities, and radiological findings among patients with cholelithiasis presenting to a tertiary care teaching hospital. The findings of this study may contribute to improved understanding of disease patterns and facilitate early diagnosis and management of patients with gallstone disease.

MATERIALS AND METHODS

Study Design

This prospective observational study was conducted to evaluate the demographic characteristics, clinical presentation, and diagnostic profile of patients with cholelithiasis. The study was designed to systematically record patient characteristics and investigative findings from the point of diagnosis, thereby minimising recall bias and ensuring uniform data collection. As no intervention was performed as part of the study, the observational design facilitated assessment of the natural disease profile among patients presenting to a tertiary care centre.

Study Setting and Duration

The study was conducted in the Department of General Surgery at Era's Lucknow Medical College and Hospital (ELMC&H), Lucknow, a tertiary-care teaching hospital serving urban, semi-urban, and rural populations. The hospital is equipped with high-resolution ultrasonography, magnetic resonance cholangiopancreatography (MRCP), contrast-enhanced computed tomography (CECT), and advanced laboratory facilities. The study was carried out over a period of two years.

Study Population

The study included adult patients aged 18 years and above presenting with symptoms suggestive of gallbladder pathology and subsequently diagnosed with cholelithiasis on ultrasonography. Both symptomatic patients and asymptomatic individuals diagnosed incidentally during evaluation for unrelated conditions were included. Demographic characteristics, dietary habits, comorbidities, and female reproductive factors were recorded for all eligible participants.

Sample Size and Sampling Technique

The sample size was calculated using the formula:

$$n = Z^2 \times p \times q / L^2$$

where p was taken as 28.1%, representing the prevalence of biliary colic reported by Asif Ali et al., $q = 100 - p$, $Z = 1.96$ at a 95% confidence interval, and L was considered as 20% of p . Based on these parameters, the required sample size was calculated to be 245 participants.

A consecutive sampling technique was employed, and all eligible patients fulfilling the inclusion criteria during the study period were recruited after obtaining informed written consent.

Inclusion Criteria

1. Patients aged 18 years and above.
2. Patients diagnosed with cholelithiasis on ultrasonography irrespective of symptoms.
3. Patients willing to provide informed written consent.

Exclusion Criteria

1. Patients with choledocholithiasis.
2. Patients presenting with obstructive jaundice.
3. Patients diagnosed with carcinoma of the gallbladder.
4. Patients unwilling to participate or unable to provide reliable information.

Data Collection

Data were collected using a pre-tested structured proforma. Information recorded included demographic characteristics (age, gender, residence, education, and socioeconomic status), anthropometric measurements (height, weight, and body mass index), clinical presentation, medical and surgical history, dietary habits, smoking and alcohol consumption, family history, and female reproductive history including parity and contraceptive use.

Socioeconomic status was classified according to the Modified Kuppuswamy Scale. Body mass index was categorized according to standard WHO criteria.

Clinical Examination

A detailed general and systemic examination was performed by the investigator or a trained surgical resident under supervision. Clinical findings including vital signs, abdominal tenderness, guarding, Murphy's sign, palpable abdominal mass, hepatomegaly, fever, and jaundice were recorded.

Laboratory Investigations

The following laboratory investigations were performed in all patients:

- Complete blood count (CBC)
- Liver function tests including total bilirubin, direct bilirubin, AST, ALT, ALP, GGT, and serum albumin
- Kidney function tests including serum urea and creatinine
- Random blood sugar
- Serum calcium
- Viral markers (HBsAg and Anti-HCV) as per institutional protocol

Radiological Evaluation

Ultrasonography

Ultrasonography of the whole abdomen was performed in all participants using a high-resolution ultrasound machine equipped with a 3.5–5 MHz transducer. Parameters evaluated included number, size and mobility of gallstones, gallbladder wall thickness, presence of sludge, pericholecystic fluid, common bile duct diameter, and associated gallbladder abnormalities such as polyps, masses, or contracted gallbladder.

Magnetic Resonance Cholangiopancreatography

MRCP was performed in selected patients with common bile duct dilatation on ultrasonography, suspicion of choledocholithiasis, or atypical symptoms despite ultrasonographic findings.

Contrast-Enhanced Computed Tomography

CECT of the abdomen was performed in selected cases with suspected gallbladder neoplasia, focal or diffuse gallbladder wall thickening requiring further evaluation, or suspected pericholecystic collections.

Data Management

All collected data were entered into a secure electronic database. Double data entry and periodic cross-verification were performed to minimize data entry errors. Participant confidentiality was maintained using coded identifiers.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of Era's Lucknow Medical College and Hospital, Lucknow. Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki and the Indian Council of Medical Research ethical guidelines. Confidentiality of participant information was maintained throughout the study.

Statistical Analysis

Data were analyzed using Statistical Package for Social Sciences (SPSS) software version 26. Continuous variables were expressed as mean $\pm$ standard deviation or median, where appropriate, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square test. Independent Student's t-test was used for comparison of means between two groups, and one-way analysis of variance (ANOVA) was used for comparison across multiple groups. A p-value of <0.05 was considered statistically significant.

RESULT AND OBSERVATIONS

Table 1. Demographic Characteristics of Patients (n = 245)

Variable	Category	Number	Percentage (%)
Gender	Male	82	33.5
	Female	163	66.5
Age Group (years)	≤ 20	12	4.9
	21–30	34	13.9
	31–40	56	22.9
	41–50	68	27.8
	51–60	49	20.0
	>60	26	10.6
Socioeconomic Status	Upper	18	7.3
	Upper Middle	46	18.8
	Lower Middle	92	37.6
	Upper Lower	63	25.7
	Lower	26	10.6

Table 2. Clinical Presentation and Symptomatic Status of Patients (n = 245)

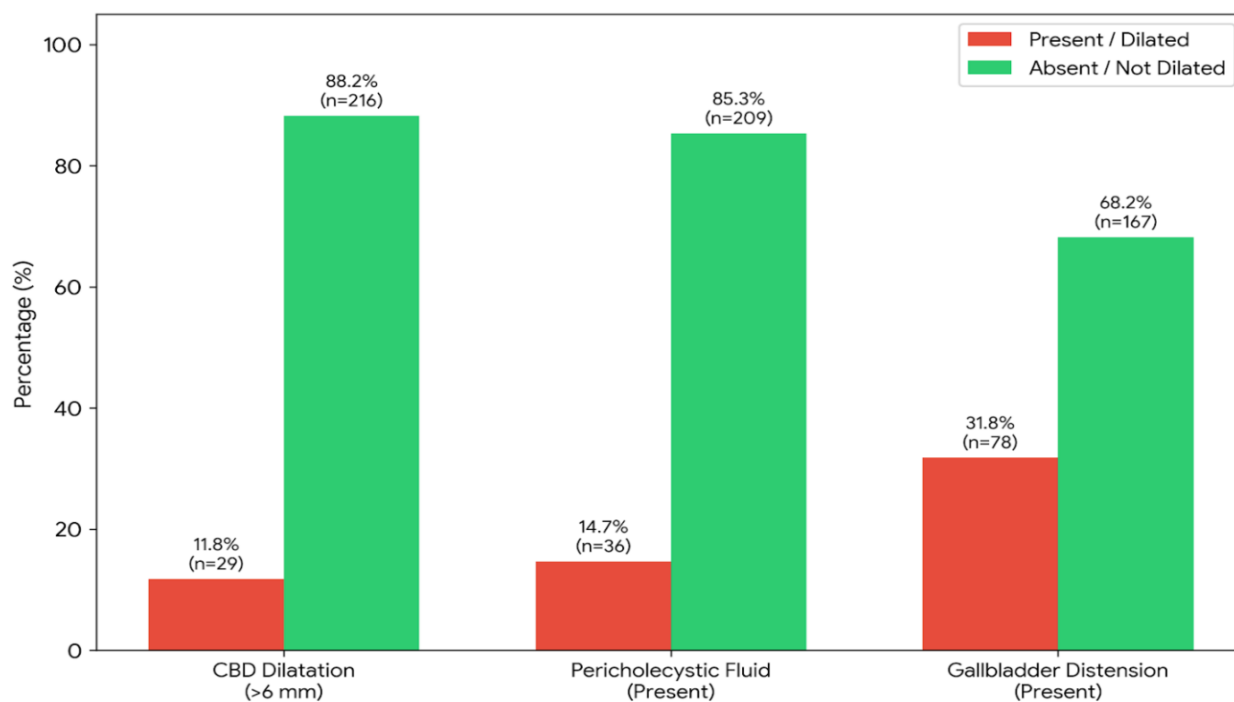
Clinical Feature	Number	Percentage (%)
Right upper abdominal pain	198	80.8
Nausea and/or vomiting	156	63.7
Dyspepsia	129	52.7
Fatty food intolerance	94	38.4
Fever	41	16.7
Jaundice	29	11.8
Symptomatic	223	91.0
Asymptomatic	22	9.0

Table 3. Ultrasonographic Findings-I (Gallstone Characteristics and Gallbladder Wall Thickness) (n = 245)

Parameter	Category	Number	Percentage (%)
Number of Gallstones	Single gallstone	96	39.2
	Multiple gallstones	149	60.8
Gallbladder Wall Thickness	Thickened (>3 mm)	112	45.7
	Not thickened	133	54.3

Table 4. Ultrasonographic Findings-II (n = 245)

Parameter	Category	Number	Percentage (%)
Gallbladder Distension	Present	78	31.8
	Absent	167	68.2
Pericholecystic Fluid	Present	36	14.7
	Absent	209	85.3
CBD Dilatation	Dilated (>6 mm)	29	11.8
	Not dilated	216	88.2

Ultrasonographic Findings (n = 245)**Figure; 1 Ultrasonographic Findings-II (n = 245)****Table 5. MRCP Utilization and Findings (n = 245)**

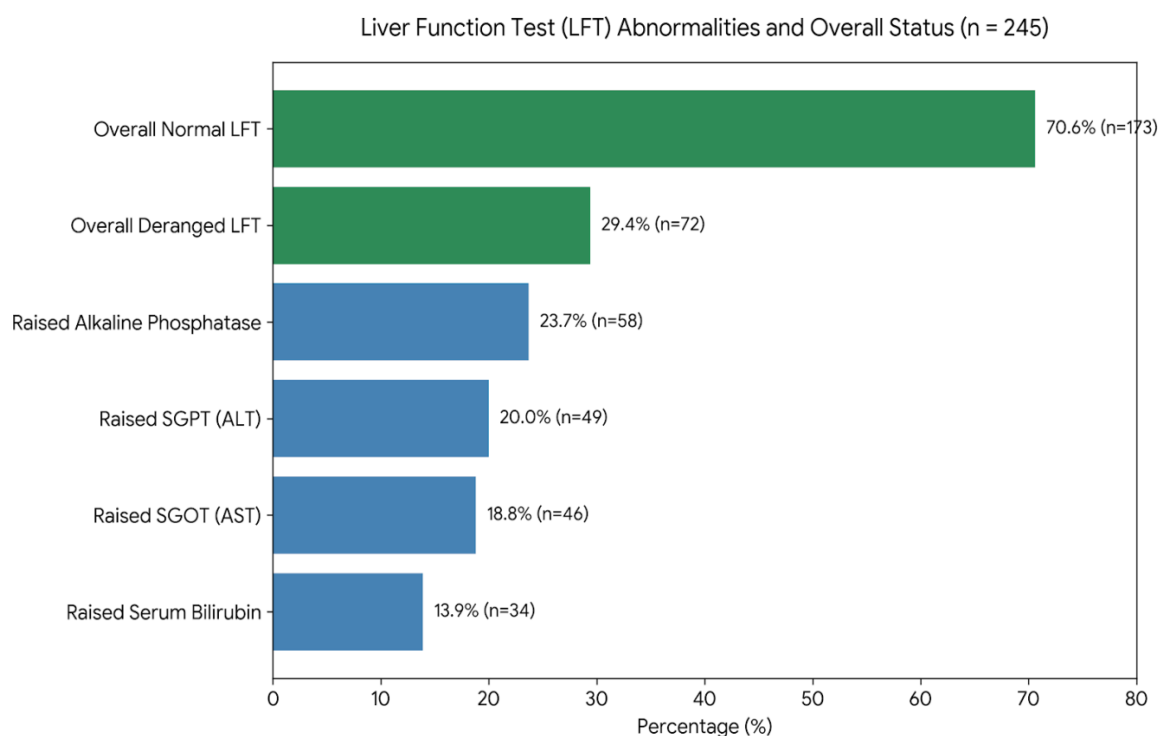
Parameter	Category	Number	Percentage (%)
MRCP Utilization	Performed	8	3.3
	Not performed	237	96.7
CBD Status (n=8)	Dilated (>6 mm)	5	62.5
	Normal	3	37.5
Cystic Duct Status (n=8)	Dilated (>3 mm)	3	37.5
	Normal	5	62.5

Table 6. CECT Utilization and Findings (n = 245)

Parameter	Category	Number	Percentage (%)
CECT Utilization	Performed	6	2.4
	Not performed	239	97.6
Gallbladder Wall Thickening Pattern (n=6)	Focal	2	33.3
	Diffuse	4	66.7

Table 7. Liver Function Test Abnormalities and Overall LFT Status (n = 245)

Parameter	Number	Percentage (%)
Raised Serum Bilirubin	34	13.9
Raised Alkaline Phosphatase	58	23.7
Raised SGOT (AST)	46	18.8
Raised SGPT (ALT)	49	20.0
Overall Deranged LFT	72	29.4
Overall Normal LFT	173	70.6



Figure; 2 Liver Function Test Abnormalities and Overall LFT Status (n = 245)

Table 8. Indicators of Complicated Cholelithiasis (n = 245)

Indicator	Number of Patients	Percentage (%)
Fever	41	16.7
Jaundice	29	11.8
Common Bile Duct Dilatation	29	11.8
Deranged Liver Function Tests	72	29.4

DISCUSSION

The present prospective observational study was conducted to evaluate the demographic characteristics, clinical presentation, and diagnostic profile of patients with cholelithiasis attending a tertiary care teaching hospital. Gallstone disease continues to be a major cause of morbidity worldwide and constitutes one of the most common indications for abdominal surgery. Understanding the demographic and clinical characteristics of affected patients is essential for early diagnosis, prevention of complications, and optimization of management strategies.

In the present study, females constituted 66.5% of the study population, whereas males accounted for 33.5%, demonstrating a clear female predominance. These findings are consistent with the established epidemiology of gallstone disease. Stinton and Shaffer reported that women are affected nearly twice as frequently as men, particularly during the reproductive years [1]. Similarly, Lammert et al. identified female sex as one of the strongest risk factors for gallstone formation [3]. Hormonal influences play a central role in this association. Estrogen increases cholesterol saturation of bile, whereas progesterone decreases gallbladder contractility and promotes biliary stasis [4,5]. The female predominance observed in the present study, therefore, aligns with existing literature and reinforces the importance of hormonal and reproductive factors in gallstone pathogenesis.

Age distribution analysis revealed that the highest proportion of patients belonged to the 41–50-year age group (27.8%), followed by the 31–40-year age group (22.9%) and the 51–60-year age group (20.0%). These findings suggest that cholelithiasis predominantly affects middle-aged individuals. Similar observations have been reported by Shaffer and colleagues, who demonstrated a progressive increase in gallstone prevalence with advancing age [5]. Age-related changes in bile composition, reduced gallbladder motility, cumulative metabolic risk factors, and prolonged exposure to dietary influences contribute to this trend. The relatively lower prevalence observed among younger individuals in the present study is also in agreement with previous epidemiological data.

Assessment of socioeconomic status demonstrated that the majority of patients belonged to the lower middle and upper lower socioeconomic classes. This finding may reflect the demographic characteristics of the population served by the institution. Dietary habits, nutritional transition, increasing consumption of calorie-rich foods, and limited awareness

regarding preventive healthcare measures may contribute to the burden of gallstone disease within these socioeconomic groups. Although socioeconomic status itself is not considered an independent risk factor, it influences exposure to several established determinants of gallstone formation [3].

Regarding clinical presentation, right upper abdominal pain was the most common symptom, affecting 80.8% of patients. Nausea and vomiting were reported by 63.7% of patients, while dyspepsia was observed in 52.7%. These findings are consistent with the classical presentation of symptomatic cholelithiasis described by Sanders and Kingsnorth [6]. Biliary colic remains the hallmark symptom of gallstone disease and results from transient obstruction of the cystic duct by gallstones. The associated gastrointestinal symptoms observed in the present study reflect impaired gallbladder function and altered digestion secondary to biliary pathology.

Fatty food intolerance was present in 38.4% of patients, which is comparable to findings reported in previous studies evaluating symptomatic gallstone disease. Intolerance to fatty meals occurs because gallbladder contraction in response to dietary fat may precipitate pain in the presence of gallstones. Fever and jaundice were observed in 16.7% and 11.8% of patients, respectively. These symptoms are clinically significant because they may indicate the presence of complicated gallstone disease, including acute cholecystitis, cholangitis, or biliary obstruction.

An important observation in the present study was that 91.0% of patients were symptomatic at presentation, whereas only 9.0% were asymptomatic. Community-based studies have reported a much higher prevalence of asymptomatic gallstones [5,6]. However, the predominance of symptomatic patients in the present study is expected because it was conducted in a tertiary care hospital, where patients generally seek medical attention because of symptoms. The small proportion of asymptomatic cases likely represents incidental diagnoses during imaging for unrelated conditions.

Ultrasonography was performed in all patients and served as the primary diagnostic modality. Multiple gallstones were identified in 60.8% of patients, whereas single gallstones were observed in 39.2%. The predominance of multiple stones has been documented in several previous studies and may reflect chronicity of disease and continued stone formation over time [8]. Ultrasonography continues to be the investigation of choice because of its excellent diagnostic performance and ability to detect associated pathological changes.

Gallbladder wall thickening was observed in 45.7% of patients. Thickening of the gallbladder wall is commonly associated with acute or chronic inflammation and is considered an important ultrasonographic marker of cholecystitis. Similar findings have been reported in studies evaluating sonographic features of gallstone disease [8]. Gallbladder distension was present in 31.8% of patients, while pericholecystic fluid was observed in 14.7%. These findings suggest varying degrees of inflammatory involvement and disease severity among the study population.

Common bile duct dilatation was identified in 11.8% of patients on ultrasonography. Although relatively uncommon, CBD dilatation is clinically important because it may indicate biliary obstruction or occult choledocholithiasis. Current guidelines recommend further evaluation in such patients using advanced imaging techniques [8]. Accordingly, MRCP was performed in selected patients with suspected biliary tract involvement. Among these patients, CBD dilatation was confirmed in 62.5%, demonstrating the high diagnostic value of MRCP. Previous studies have similarly reported excellent sensitivity and specificity of MRCP in the evaluation of biliary pathology [9].

Contrast-enhanced computed tomography was utilized in a limited number of patients with suspected complications or neoplastic pathology. Diffuse gallbladder wall thickening was more frequently observed than focal thickening, suggesting that inflammatory pathology was considerably more common than neoplastic disease. These observations are consistent with the established role of CECT in evaluating complicated gallbladder disorders and differentiating inflammatory conditions from malignancy [10].

Biochemical analysis revealed that elevated alkaline phosphatase was the most common liver function abnormality (23.7%), followed by elevated SGPT (20.0%), elevated SGOT (18.8%), and hyperbilirubinemia (13.9%). Overall liver function test abnormalities were identified in 29.4% of patients. These findings are consistent with previous studies indicating that abnormal liver biochemical parameters occur more frequently in patients with biliary obstruction, inflammation, or associated hepatobiliary involvement [11]. Elevated alkaline phosphatase is particularly useful as a marker of cholestasis and may indicate underlying biliary obstruction.

Evaluation of indicators of complicated cholelithiasis demonstrated that deranged liver function tests were the most common abnormality, followed by fever, jaundice, and CBD dilatation. These findings highlight the importance of integrating clinical symptoms, laboratory abnormalities, and imaging findings to identify patients at increased risk of complications. Early recognition of such indicators may facilitate timely intervention and prevent progression to more severe disease states.

The strengths of the present study include its prospective design, adequate sample size, comprehensive clinical assessment, and systematic radiological evaluation. However, certain limitations should be acknowledged. The study was conducted at a single tertiary care center and may therefore not be representative of the general population. Furthermore, long-term follow-up and postoperative outcomes were not assessed. Future multicentric studies involving larger populations and longitudinal follow-up are recommended to further clarify disease patterns and outcomes.

CONCLUSION

Cholelithiasis predominantly affected middle-aged females in the present study and commonly presented with right upper abdominal pain, nausea, vomiting, and dyspepsia. Ultrasonography proved to be an effective primary diagnostic modality for detecting gallstones and associated biliary abnormalities. Multiple gallstones and gallbladder wall thickening were common radiological findings, while liver function test abnormalities were observed in a considerable proportion of patients. Early recognition of clinical symptoms, laboratory abnormalities, and imaging findings can facilitate timely diagnosis and appropriate management, thereby reducing the risk of complications associated with gallstone disease.

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