

# Epidemiological and Outcome Study of Gallbladder Cancer Patients from North Indian Centre's Experience

Kuldeep Singh\*

Consultant, Department of Gastroenterology, Apex Hospital, Jaipur, Rajasthan, India

**\*Address for Correspondence:** Dr. Kuldeep Singh, DM (Gastroenterology), Consultant, Department of Gastroenterology, Apex Hospital, Jaipur, Rajasthan, India

**E-mail:** [kuldeepsngh122@gmail.com](mailto:kuldeepsngh122@gmail.com)

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## ABSTRACT

**Background:** Gallbladder cancer (GBC) is a highly aggressive tumor of the biliary tract and shows a particularly high burden in the Gangetic belt of North India. Because the disease is often clinically silent in early phases, many patients are diagnosed late, contributing to poor survival outcomes. This study aimed to describe the epidemiology, associated risk factors, clinical features, and management outcomes of GBC patients treated at a tertiary care center in Rajasthan.

**Methods:** A total of 60 newly diagnosed GBC patients from December 2023 to July 2024 were included in this prospective study. Information regarding demographic characteristics, risk factors, clinical signs and symptoms, laboratory and imaging findings, staging, treatment provided, and follow-up was documented. Diagnosis was confirmed by ultrasonography and/or contrast-enhanced CT. Treatment decisions were individualized according to current standard protocols and disease stage.

**Results:** The average age of the patients was 51.8 years, with a marked female predominance (73.3%). Most belonged to rural regions. Gallstones were noted in 80% of cases, obesity in 40%, multiparity in 57.5%, and diabetes in 21.6%. The majority presented with abdominal pain (94%), followed by jaundice (65%), abdominal distention (60%), and pruritus (53.3%). Advanced-stage disease (Stage III/IV) was observed in 73.4%, and metastatic spread in 80%, primarily to the liver (60%) and omentum (33%). Curative surgery could be performed in 26.6% of patients, while biliary drainage (SEMS/PTBD) was required in 40%. The overall prognosis remained poor, in line with existing literature from high-incidence Indian regions.

**Conclusion:** GBC remains a significant health problem in North India, with a strong association to gallstone disease and higher prevalence among postmenopausal women. The tendency for late presentation limits curative treatment opportunities. Strengthening early detection strategies, especially among high-risk women with persistent right upper abdominal pain, may help improve clinical outcomes.

**Key-words:** Gallbladder carcinoma, Demographic profile, Risk factors, Outcome, Indian population

## INTRODUCTION

In India, gallbladder cancer (GBC) occurs most frequently in northern and northeastern states of Uttar Pradesh, Bihar, Odisha, West Bengal and Assam <sup>[1]</sup>. GBC is about twice as common in women compared to men and is the most common digestive system malignancy in women in north Indian cities <sup>[2]</sup>. The disease is most common among females (2–6 times more common) aged 65 years or older <sup>[3–6]</sup>.

There is significant geographical and ethnic variation in the incidence of gallbladder cancer. The disease is commonly reported from regions such as Chile (16–27 per 100,000), Japan (7 per 100,000), parts of northern India, Central Europe, including Poland (14 per 100,000), Israel (5 per 100,000), and southern Pakistan (11 per 100,000). In contrast, the incidence is relatively low in Western countries, including the United States (about 1.5 per 100,000) and most of Europe <sup>[6]</sup>.

Most cases are diagnosed at an advanced stage of the disease. The 5-year survival rate of patients with GBC remains low <sup>[7]</sup>. Common risk factors include gallstones, porcelain gallbladder (present in fewer than 1% of gallbladder specimens), female gender, ethnicity, genetic susceptibility, and lifestyle factors. Among risk factors, gallstones is considered the strongest risk factor of GBC

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(3.01 to 23.8) <sup>[8–10]</sup>. Chronic bacterial infections such as *S. typhi* carriers (RR of 12.7 to 167) <sup>[11–13]</sup>, *H. pylori* with an odds ratio of 6.5 in Japanese patients and 5.86 in Thai patients, and has an RR of 2.6 to 6.53. PSC also increases the risk of developing GBC. Congenital anomalous pancreatic biliary duct junction (APBDJ) carries a RR of 3% to 18% of GBC. A family history of GBC, though rare, is clearly a risk factor <sup>[14–16]</sup>.

Most patients with gallbladder cancer present at a relatively advanced stage, which contributes to its poor overall prognosis. In advanced disease, the median survival is typically about 6 months, and the 5-year survival rate remains close to 5%. Delayed diagnosis commonly occurs because early symptoms resemble those of more common conditions, such as gallstone disease or acid peptic disorders and are therefore often overlooked. Additionally, routine imaging investigations like abdominal ultrasonography have limited sensitivity in detecting early-stage GBC, further contributing to late detection <sup>[17]</sup>.

## MATERIALS AND METHODS

**Study Design, Study Period and Population-** We studied the demographic characteristics, risk factors, clinical profile, investigations and management protocol of 60 patients diagnosed as GBC from December 2023 to July 2024. The demographic characteristics include age, sex, and socioeconomic status.

**Assessment of Risk Factors and Clinical Profile-** Nonclinical risk factors include parity, obesity, menstrual status, and use of contraceptive pills among premenopausal females. Diagnosis of gallstones and diabetes was taken as a clinical risk factor. Vegetarian and non-vegetarian diets were included in dietary habits. Clinical profile included presenting symptoms, duration of symptoms, presence of jaundice, stage and extent of disease, number and sites of metastasis.

**Data Collection and Diagnostic Evaluation-** A structured questionnaire prepared specifically for this study was used to conduct patient interviews. Clinical features were recorded based on history and physical examination, along with relevant imaging findings. The diagnosis of gallbladder cancer and the presence of gallstones were confirmed through ultrasonography and contrast-enhanced computed tomography (CT) scans.

**Treatment Protocol and Follow-up-** Treatment was explained and was decided based on recent guidelines in the form of curative or palliative treatment. Patients were followed up post-treatment.

**Statistical Analysis-** Data were compiled and analyzed using descriptive statistics. Continuous variables were presented as mean±standard deviation (SD), and categorical variables were expressed as frequencies and percentages. No comparative or inferential statistical tests were applied due to the observational study design.

## RESULTS

A total of 60 patients were included in the study. The median age was 51.8 years, with the highest proportion (43.33%) belonging to the 51–60 years age group. Patients aged 41–50 years accounted for 23.3%, and those above 60 years and below 40 years comprised 16.66% each. Most patients were from Jaipur (23.33%), followed by Sikar (15%) and Jhunjhunu (11.66%), while 50% belonged to other surrounding districts of Rajasthan.

There was a clear female predominance, with 73.33% females and 26.66% males. Regarding dietary habits, 70% were vegetarians, whereas 30% consumed a non-vegetarian diet. Among metabolic and reproductive factors, diabetes mellitus was present in 21.6% of patients, and obesity in 40%. Multiparity (>3 children) was observed in 57.5% of females, while oral contraceptive pill use was reported in 7 patients. Smoking was noted in 8.4%, and alcohol consumption in 5.4% of the study population.

**Table 1:** Demographic profile of patients

| Demographic characteristics | n (%)       |
|-----------------------------|-------------|
| Study population            | 60          |
| Median age                  | 51.8 years  |
| Age distribution (years)    |             |
| <40                         | 10 (16.66%) |
| 41-50                       | 14 (23.3%)  |
| 51-60                       | 26 (43.33%) |
| >60                         | 10 (16.66%) |
| Districts                   |             |
| Jaipur                      | 14 (23.33%) |

|                        |             |
|------------------------|-------------|
| Sikar                  | 7 (15%)     |
| Jhunjhunu              | 9 (11.66%)  |
| Others                 | 30 (50%)    |
| Male                   | 16 (26.66%) |
| Female                 | 44 (73.33%) |
| Vegetarian             | 42 (70%)    |
| Non vegetarian         | 18 (30%)    |
| Diabetes mellitus      | 13 (21.6%)  |
| Obesity                | 24 (40%)    |
| Oral contraceptive use | 7 (2.8%)    |
| Multiparty (>3)        | 23 (57.5%)  |
| Smokers                | 14 (8.4%)   |
| Alcoholics             | 9 (5.4%)    |

The most common presenting symptom among the patients was abdominal pain, which was reported in 54 (94%) cases. Jaundice was present in 39 patients (65%), while abdominal fullness and pruritus (itching) were noted in 36 (60%) and 32 (53.3%) patients, respectively. Cholelithiasis was associated with 48 patients (80%). About the anatomical site of tumor involvement, diffuse involvement of the gallbladder was seen in 21 patients (35%), followed by disease localized to the fundus in 16 (26.6%), body in 14 (23.4%), and neck in 9 (15%) cases. Based on disease stage at diagnosis, 16 patients (26.6%) had early-stage disease (Stages 1 and 2), whereas the majority, 44 patients (73.44%), presented with advanced-stage disease (Stages 3 and 4). Metastatic disease was identified in 48 patients (80%). Among metastatic sites, the liver was the most involved organ (36 patients; 60%), followed by omental deposits (20 patients; 33.33%), lung metastasis (12 patients; 20%), and bone involvement (6 patients; 10%) (Table 2).

**Table 2:** Clinical characteristics

|                    |             |
|--------------------|-------------|
| Pain               | 54 (94%)    |
| Jaundice           | 39 (65%)    |
| Abdominal Fullness | 36 (60%)    |
| Itching            | 32 (53.3 %) |
| Cholelithiasis     | 48 (80%)    |
| Epicerter of GBC   |             |
| Fundus             | 16 (26.6%)  |

|                  |             |
|------------------|-------------|
| Body             | 14 (23.4%)  |
| Neck             | 9 (15%)     |
| Diffuse          | 21 (35%)    |
| Stages 1 and 2   | 16 (26.6%)  |
| Stage 3 & 4      | 44 (73.44%) |
| Metastasis       | 48 (80%)    |
| Liver            | 36 (60%)    |
| Omental deposits | 20 (33.33%) |
| Lung             | 12 (20%)    |
| Bones            | 6 (10%)     |

Laboratory evaluation of the patients showed that the mean hemoglobin level was  $8.1 \pm 3.2$  g/dL, with values ranging between 4.2 to 12.8 g/dL, indicating that anemia was common in the study population. The mean serum bilirubin was  $12.8 \pm 4.8$  mg/dL (range: 0.4–25.3 mg/dL), and the mean serum alkaline phosphatase (ALP) level was  $938.6 \pm 456.7$  IU/L (range: 79–2255 IU/L), suggesting cholestatic liver enzyme elevation in many patients. Serum albumin levels ranged from 1.9 to 5.2 g/dL, while the total protein levels ranged from 3.5 to 8.3 g/dL, with a mean value of  $6.9 \pm 1.0$  g/dL (Table 3).

**Table 3:** Lab Parameters of Patients in the Study (N=60)

| Lab parameter         | Mean $\pm$ SD     | Ranges        |
|-----------------------|-------------------|---------------|
| Hb (g/dl)             | 8.1 $\pm$ 3.2     | 4.2-12.8      |
| Sr. Bilirubin (mg/dl) | 12.8 $\pm$ 4.8    | 0.4-25.3      |
| Sr. ALP (IU/L)        | 938.6 $\pm$ 456.7 | 79-2255       |
| Serum albumin (g/dl)  | 4.8-8.3           | 1.9-5.2       |
| Total protein (g/dl)  | 6.9 $\pm$ 1.0     | 3.5 $\pm$ 0.9 |

Of the 60 patients included in the study, biliary drainage interventions were required in 24 (40%), whereas 36 (60%) did not require any biliary procedure at the time of presentation.

Among those who underwent biliary drainage, self-expanding metallic stents (SEMS) were placed in 16 patients (26%). Four patients (14%) were referred for percutaneous transhepatic biliary drainage (PTBD), while four patients (14%) could not undergo any biliary intervention due to financial constraints (Table 4).

**Table 4:** Biliary drainage interventions

|                                |          |
|--------------------------------|----------|
| Not Required                   | 36 (60)  |
| Required                       | 24 (40%) |
| Self-expanding metallic stents | 16 (26%) |
| Referred for PTBD              | 4 (14%)  |
| Non-Affording                  | 4 (14%)  |

## DISCUSSION

Gallbladder cancer represents the leading cause of mortality among biliary tract cancers. In high-incidence regions such as West Bihar and Eastern Uttar Pradesh, it ranks as the third most common malignancy of the gastrointestinal tract <sup>[18]</sup>.

The present study, conducted in Apex Hospital Malvia Nagar, Department of Gastroenterology and Hepatology, showed the mean age of the patients to be 51.8 years, with a range of 24-69 years and the fifth decade as the peak age of presentation. Similar results were observed in other studies from India <sup>[18-20]</sup>. Our study demonstrated a clear female predominance, with gallbladder cancer occurring more frequently in older women. The overall male-to-female ratio in the present study was 1:2.7. These results aligned with the results of other studies <sup>[18,19,21]</sup> where it was reported to be 1:3, 1:3 and 1:2.5, respectively.

Most of the patients in our study had a poor socioeconomic background, similar to that reported in another study <sup>[19]</sup>. Was this relation associated with disease causation or only because patients from low socioeconomic strata harbor gallstones for a longer duration of time and neglect their disease? needs further evaluation.

There are multiple risk factors in gallbladder carcinogenesis; among them, the most common is gallstones. In our study, gallstones were present in 48 (80%) of cases with gallbladder cancer, which is comparable to a study from India where they are seen in 86% of cases <sup>[22]</sup>. Similar observations have been reported in previous Indian studies. Pandey *et al.* noted gallstones in 70% of patients with gallbladder cancer <sup>[22]</sup>. Likewise, another study <sup>[23]</sup> documented gallstones in 41 out of 56 Southwestern American Indian patients (73.2%). A study from Chile, a region with a high incidence of GBC, reported gallstones in 53 out of 54

patients with resectable disease <sup>[24]</sup>. Collectively, these findings support a strong association between gallstones and the development of GBC. Long-standing gallstones can induce persistent mucosal irritation and chronic inflammation, which may promote the formation of carcinogenic substances such as secondary bile acids and, over time, contribute to malignant transformation <sup>[25]</sup>.

Although the exact mechanism linking gallstones and gallbladder cancer is not fully understood, both conditions are more frequently observed in females and are associated with obesity, multiparity, and the use of oral contraceptive pills. These factors suggest a possible role of altered endogenous estrogen metabolism in the development of gallstones and subsequent carcinogenesis <sup>[26-28]</sup>. In our study, 40% (24/60) of the patients were obese, all of whom were females, and a higher parity was noted in 52.22% (7/60) of them. Additionally, 15.90% (7/44) of female patients reported past or current OCP usage. Diabetes mellitus is another recognized risk factor, as it can promote gallstone formation and may independently increase the likelihood of GBC, even in the absence of gallstones <sup>[29]</sup>. In the present analysis, diabetes was observed in 21.6% (13/60) of patients.

Previous reports have suggested that individuals consuming non-vegetarian diets, particularly red meat or mustard oil containing carcinogenic contaminants, may have a higher predisposition to GBC compared with vegetarians <sup>[30,31]</sup>. However, in our study population, 70% (42/60) of patients were vegetarians and only 30% (18/60) consumed non-vegetarian foods, indicating that factors other than dietary habits may play a more substantial role in disease development. Additionally, existing literature shows that 0.19% to 3.3% of patients undergoing cholecystectomy for presumed benign conditions are incidentally diagnosed with gallbladder carcinoma on histopathological examination <sup>[32-34]</sup>.

GBC either remains asymptomatic for a long time or presents with highly nonspecific clinical features. Commonly, symptoms are related to associated gallstones <sup>[35]</sup>. In our study, abdominal pain (94%), followed by jaundice (65%), abdominal fullness (60%) and itching (53.3%) were the most common presenting symptoms. Consistent results were reported in other studies <sup>[18,36]</sup>.

In our study, laboratory evaluation revealed that anemia (hemoglobin <10 g/dL) was present in 172 patients (80.9%). Hyperbilirubinemia (serum bilirubin >2 mg/dL) was noted in 70.4% of cases, while elevated alkaline phosphatase levels (>100 IU/mL) were observed in 78.5% of the patients. Similar laboratory abnormalities have also been described in previous studies <sup>[19,21]</sup>.

The overall prognosis of gallbladder cancer remains poor, largely because the majority of patients are diagnosed at an advanced stage. Several factors contribute to this delayed presentation, including limited disease awareness, particularly among individuals from lower socioeconomic backgrounds, and the difficulty in distinguishing early symptoms of GBC from those of common gallstone-related disorders. Additionally, the therapeutic response to currently available chemotherapy regimens is often suboptimal, further contributing to unfavorable outcomes <sup>[37]</sup>.

Preoperative abdominal imaging, including both ultrasonography and contrast-enhanced CT, demonstrated the presence of gallstones in 48 patients (80%). A gallbladder mass lesion was identified in 54 out of 60 patients (90%) on imaging studies.

In the present study, early-stage disease (Stage I and II) was identified in 16 out of 60 patients (26.6%), while the majority, 44 patients (73.44%), presented with advanced or metastatic disease. Similar stage distribution has been reported in previous Indian studies. One study noted early-stage disease in 16.18% of cases, with 83.82% presenting at an advanced stage <sup>[38]</sup>. Another study from India by Batra et al. documented an even lower proportion of early-stage tumors (approximately 5%), with the overwhelming majority (95%) being diagnosed at either locally advanced or metastatic stages <sup>[39]</sup>.

Metastatic lesions were seen in 48(80%) of cases. Common sites of involvement were liver 36 (60%), omentum (60%), lung (20%) and bones (10%). Similar results were observed in other studies <sup>[21,40]</sup>.

Management is curative in the early stages of the form of surgery. Unresectable, metastatic, and recurrent GBC patients are managed with palliation therapy in the form of drainage procedures, including ERCP with stent placement and PTBD. In our center 24 (40%) patients needed a biliary procedure. ERCP with metallic SEMS was placed in 24 (26%) patients, while 4 were referred for PTBD. All patients who underwent ERCP palliated with

stent placement were later discharged after obtaining the surgeon's and an oncologist's opinion.

For unresectable, recurrent, or metastatic GBC after relief of biliary obstruction, palliative radiochemotherapy may be beneficial. Systemic chemotherapy is recommended only for patients who have a satisfactory performance status and preserved organ function. A phase III randomized clinical trial comparing gemcitabine alone with a combination of gemcitabine and cisplatin in 410 patients with unresectable, recurrent, or metastatic gallbladder cancer showed a significant survival benefit with the combination regimen. The median overall survival was 11.7 months with gemcitabine plus cisplatin compared to 8.1 months with gemcitabine alone (hazard ratio 0.64; 95% confidence interval 0.52–0.80;  $p < 0.001$ ) <sup>[41]</sup>.

## CONCLUSIONS

GBC is a common entity in India, especially in the Gangetic belt. It predominantly affects post-menopausal females. Most patients have associated gallstones; therefore, females in their forties and fifties with persistent pain in the right hypochondrium or any change in the character of pain should be evaluated thoroughly. Despite advances in gallbladder imaging, the disease is still detected at a late stage in the majority of cases, leaving very limited possibilities for curative treatment. Due to this delay in diagnosis, palliative care, such as biliary drainage procedures, often becomes the most appropriate management approach.

## CONTRIBUTION OF AUTHORS

One author has only contributed to this article.

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