

# “Missed Gall Bladder Cancer During Cholecystectomy - What Price Do We Pay?”

## An Experience of a Tertiary Care Center from India

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### ABSTRACT

**Background:** The incidence of missed gall bladder cancer (GBC) is increasing with rising numbers of cholecystectomies in North India. Most of these are misrepresented as Incidental gall bladder (IGBC) cancer at referral. Our aim was to analyze the differences in presentation patterns and outcomes of missed GBC and IGBC.

**Material and methods:** A Retrospective analysis of patients referred to as IGBC. Missed GBC were identified as IGBC presenting with any one criteria (Suspicious findings on preoperative ultrasound and/or intraoperative during the Cholecystectomy; Presentation with symptoms or metastasis within one month; pT4 lesion). The outcome of missed GBC was compared to remaining IGBC patients.

**Results:** Sixty-seven patients were included in the study. The median age of presentation was 50 years and the majority were females (83.6%). Index-cholecystectomy was Laparoscopic, open, and lap converted to open in 44.7%, 50.7 and 4.4% respectively. The median time to presentation was 30 days (15-720 days). Forty-eight (71.6%) had features of malignancy before index cholecystectomy (ultrasound-21; intraoperative findings-27). Thirty-four (50.7%) had metastatic disease at presentation (Liver-28; peritoneal-23; omental-six). Twenty-one (31.3%) underwent completed extended cholecystectomy (HDR-8; multi-visceral resections-3). Missed GBC had a poorer overall survival over IGBC (16.5Vs 35.3 months P=0.05).

**Conclusion:** Significant proportion of IGBC were missed GBC. This emphasizes the need for careful interpretation of imaging before cholecystectomy in areas endemic to GBC.

**Key words:** Incidental gallbladder cancer, missed gallbladder cancer, management

### INTRODUCTION

Laparoscopic cholecystectomy is one of the most frequently performed surgical procedures. Although commonly performed for benign indications like cholecystitis or biliary colic, the chance for the gall bladder to harbor malignancy ranges between 0.25-0.89% and this emphasizes the need for routine

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histopathological examination of the resected gall bladder specimens (1,2). The incidence of incidentally detected gall bladder (IGBC) is much higher in the endemic regions like Chile, Northern India (3). The increasing rate of cholecystectomy explains the rising incidence of IGBC in the past two decades.

The most accepted definition of incidental gall bladder cancer is when the diagnosis is made only on the histopathological examination of the resected gall bladder specimen with no preoperative suspicion on clinical examination and imaging (4). The standard of care for resectable IGBC is the completion of extended cholecystectomy at an appropriate time (5). These tumors are usually early gall bladder cancer and their prognosis has been found to be the best of all gall bladder cancer (6).

When we analyzed the preoperative and intraoperative records of patients presented to us with referral diagnoses of IGBC, we realized that many patients had suspicious features of GBC beforehand and hence these were actually missed GBC and not true IGBC. We considered them as two separate groups. One group of patients who presented after being diagnosed as GBC on histopathology had a better outcome. We label this group of patients as truly incidental. Another group of patients who were referred to us (after cholecystectomy) had either metastatic disease or advanced gall bladder cancer at presentation and were also labeled as IGBC by the referring surgeon. We labeled these patients as missed GBC. On the critical evaluation of the pre-cholecystectomy imaging and clinical profile, it was found that this group of patients had enough pointers toward GBC, however, due to unknown reasons they were subjected to cholecystectomy. The outcome of this group of patients with missed diagnosis of GBC was dismal in comparison to the second group, the true IGBC.

With this observation, we tried to analyze the various other prognostic factors among the two groups to evaluate the difference in overall outcome between the two groups.

## MATERIAL AND METHOD

A retrospective analysis of patients admitted between January 2013 and December 2017 with a diagnosis of incidental carcinoma gallbladder at referral was performed after taking clearance from the Institutional ethics committee. Patients with histological evidence of malignancy in the cholecystectomy specimen and patients presenting with port site/scar site adenocarcinoma following cholecystectomy with

no other remote or recent history of malignancy were considered as incidental carcinoma gall bladder cancer and included in the study.

Details regarding the index cholecystectomy were noted as documented in the referral letter or by a telephonic conversation with the operating surgeon. These included preoperative imaging findings, the technique of index cholecystectomy, and intraoperative findings. The clinical presentation and time interval from cholecystectomy to the time of presentation were also noted.

Preoperative evaluation with complete blood counts, renal function, and liver function tests was performed. Staging workup included ultrasound abdomen, contrast-enhanced computed tomography of the abdomen and pelvis, and/or positron emission tomography (PET/CT) as indicated.

Histological reports of the cholecystectomy specimens were reviewed and confirmed. Patients with resectable disease underwent surgery after initial optimization. All patients with obstructive jaundice at presentation underwent preoperative biliary drainage (ERC/PTBD). Palliative chemotherapy was started after histological confirmation in patients with metastatic disease at presentation and good performance status. Patients who had serum bilirubin of more than 3 mg/dL underwent biliary drainage before initiation of palliative chemotherapy.

Staging laparoscopy was performed in all patients undergoing surgery for potentially resectable lesions. In the absence of distant metastasis (liver surface, omental, peritoneal), sampling and frozen sections of the aortocaval lymph node were done in all patients. Resection was performed only if frozen was found to be negative. Completion of extended cholecystectomy (CEC) included anatomical resection of segments IVB and V with standard lymphadenectomy. Hepatic duct resection (HDR) was performed in the presence of a positive cystic duct margin or when a residual tumor was involving the bile duct. Colonic and gastric resections were performed in the presence of gross tumours involving the colon and stomach respectively. Pancreaticoduodenectomy was added in patients with gross duodenal or pancreatic head involvement.

### *Postoperative management*

All patients in the postoperative period were encouraged to have early ambulation, early feeding, and aggressive chest physiotherapy. Adjuvant chemotherapy was given to all patients undergoing curative resection. Follow-up included clinical examination and

blood investigations every three months. Ultrasound abdomen was performed every 3 months. CECT abdomen and pelvis were performed annually.

### *Chemotherapy regimen*

The chemotherapy regimen included Inj. Gemcitabine (800 mg/m<sup>2</sup>) and Inj. Oxaliplatin (100 mg/m<sup>2</sup>). In both palliative and adjuvant settings, 6 cycles of the above regimen were given every 2 weeks (Day 1 and Day 8).

The outcomes were assessed in form of overall survival, which is calculated as the duration from the index cholecystectomy to the death due to any cause. We divided patients of incidental carcinoma gall bladder into two groups based on the clinical profile at presentation, pre-cholecystectomy imaging, and Intra-operative findings at index cholecystectomy into missed gallbladder cancer and Truly Incidental gall-bladder cancer) and their outcomes were compared.

### *Missed carcinoma gall bladder*

Patients with any of the following criteria were considered as a missed group of GBC:

1. Presence of suspicious findings on pre-operative ultrasound or any cross-sectional imaging (Focal thickening > 5 mm; soft tissue lesion in gall bladder; hepatoduodenal lymphadenopathy; loss of interface with the liver; signs of dissemination).
2. Intra-operative findings suggestive of gall bladder cancer like wall thickening; mass lesion, significant lymphadenopathy, or adjacent organ infiltration.
3. Presentation with locally advanced disease or metastasis within one month from index cholecystectomy.

### *Truly incidental gall bladder cancer*

Patients who had no pre-operative suspicion of malignancy on imaging or during the intraoperative period (including cut section) but were diagnosed as gallbladder cancer on histological examination.

### *Statistics analysis*

Data was entered and analysis was performed using the Statistical Package for the Social Sciences (SPSS for Windows, Version 22.0; SPSS Inc, Chicago, Ill).  $\chi^2$  or Fisher's exact test was used for univariate comparison; continuous variables were analyzed by using the unpaired Student's t-test. All p-values less

than 0.05 were considered statistically significant. Survival analysis was performed using Kaplan-Meier curves.

## **RESULTS**

A total of 67 patients who were referred to as IGBC were included in the study. The median age of the study population was 50 years with a strong female preponderance (83.6%). All the patients underwent index cholecystectomy elsewhere and were referred. Laparoscopic cholecystectomy was performed in 30 (44.7%), open cholecystectomy in 34 (50.7%), and lap converted to open surgery in three patients (4.4%). Subtotal Cholecystectomy was performed in 3 out of 34 patients who underwent open cholecystectomy (8.8%).

A total of 58.2% of patients presented with the histopathology reports at presentation, while the rest of the patients presented only after the onset of symptoms like abdominal pain, and jaundice port site metastasis following the index cholecystectomy. The median time for a presentation from the index cholecystectomy was 30 days (15-720 days). 32 (47.7%) patients presented with obstructive jaundice. 34 (50.7%) patients were found to have metastatic disease on evaluation. Out of these 34, liver, omental, and omental deposits were found in 28 (82.3%), 23 (67.6%), and six (17.6%) patients respectively. Other sites of metastasis like supra-clavicular nodes in eight (23.5%), port site or scar site metastasis in 10 (29.4%), and skeletal metastasis in one patient (2.9%) were noted.

The remaining 33 (49.2%) patients who were found resectable on initial evaluation underwent staging laparoscopy. Among these, 12 patients (36.3%) were found to have metastatic disease. Curative surgery was only performed in 21 (31.3%) patients. Completion of extended cholecystectomy with standard lymphadenectomy alone was performed in nine patients (42.8% of the resected patients) and the rest of the patients needed additional procedures. Hepatic duct resections (HDR) were performed in eight (30%) and the remaining three (14.2%) needed multi-visceral resections; Hepato-pancreatic-duodenectomy (HPD) in two and distal gastrectomy with right hemicolectomy in one.

### *Analysis of missed carcinoma gall bladder patients*

The diagnosis of GBC was probably missed at the time of index cholecystectomy in 71.6% of patients.

Suspicious findings in the ultrasonography reported prior to the cholecystectomy were present in 21 out of which, 18 has suspicious gall bladder wall thickening and three had soft tissue lesions in the gall bladder. Intraoperative findings suggesting the possibility of gall bladder cancer were noted in 27 patients (*table 1*). In comparison to the other group of patients who were noted in 27 patients. In comparison to the other group of patients who were truly incidental, the patients with missed carcinoma gall bladder had shown higher tumor stage, higher incidence of metastatic disease on evaluation, and hence a low rate of curative resections (*table 2*).

**Table 1 - Distribution of patients missed carcinoma gall bladder group**

Character	n (%)
Preoperative imaging	21 (43.8%)
Intraoperative findings at index cholecystectomy	27 (56.3%)
Presentation within one month of index cholecystectomy with metastasis/persistent symptoms	22 (45.8%)

*Survival analysis*

The mean overall survival in the study group was 23.4 months. Patients who could undergo a curative resection had longer overall survival (50.6 months Vs

**Table 2 - Characteristics of true and missed gallbladder cancer groups compared**

Variable	Truly Incidental (n=19)	Missed Gall Bladder cancer (n=48)	P Value
Age	52.2±9.8	51.2±9.3	0.69
Gender			0.49
Male	4	7	
Female	15	41	
Type of cholecystectomy			0.67
Open	8	26	
Laparoscopic	10	20	
Lap converted to open	1	2	
Modality of presentation			0.25
With HPR	9	30	
With symptoms	10	18	
Intraoperative bile spillage			
Present	3	27	
Absent	16	21	
Duration of Presentation for curative resection from IC			0.03
< 30 days	14	22	
> 30 days	5	26	
T Stage			0.01
T1	9	8	
T2	10	25	
T3	0	14	
T4	0	1	
Obstructive jaundice			0.26
Present	7	25	
Not present	12	23	
Liver metastasis			0.10
Present	5	23	
Not present	14	25	
Peritoneal metastasis			0.01
Present	2	21	
Not present	17	27	
Omental mets			0.10
Present	0	6	
Not present	19	42	
Overall metastasis			<0.01
Present	8	38	
Not present	11	10	
Curative surgery			0.03
Done	11	10	
Not done	8	38	

7.7 months,  $p < 0.01$ ). Among the metastatic patients who received palliative chemotherapy, the survival was found to be 12.2 months in comparison to 3.7 months in patients who could not receive palliative chemotherapy. As expected, patients with truly incidental carcinoma had better mean overall survival in comparison to the patients with missed GBC (35.3 months Vs 16.5 months,  $p$  Value = 0.05). The Kaplan Meier plots that show the survival analysis were depicted in *fig. 1*.

## DISCUSSION

The incidence of gallbladder cancer (IGBC) after cholecystectomy is on a rising trend (7). Completion extended cholecystectomy is the standard treatment of incidentally detected gall bladder cancer. Conventionally Incidental gall bladder cancer is believed to be associated with better survival than clinically detected gall bladder cancer (8). This difference has been attributed to the fact that a significant proportion of IGBC patients harbor early disease. In a study published by Choi et al, the incidences of T1, T2, and T3 tumors in IGBC patients were 25.3%, 47%, and 25% respectively and this finding is in concordance with the distribution in our study ( T1 25.3%, T2 52.2% and T3 20.8%) (9).

However, we observed that not all patients with incidentally detected gall bladder cancer managed in our institute had the same outcome. On the detailed evaluation of the preoperative investigations clinical presentation and Intra-operative findings during index surgery, we could identify that a significant number of patients (71.6%) had one or other features suggestive of gall bladder cancer at the time of index cholecystectomy which was ignored. We strongly feel that this group of patients was missed cases of gallbladder cancer rather than incidentally detected. These groups of patients had a higher stage at presentation, higher incidence of intra-operative bile spillage (43.75% Vs 15.7%), and higher incidence of metastasis after index cholecystectomy (79.1% vs 42.1%). The presentation of these patients for curative resection was also delayed after the index cholecystectomy (more than 30 days from IC - 54.1%vs 26.3%) in comparison to the truly incidental group. These factors had a negative impact on the survival of patients with IGBC. Vega et al From MD Anderson had shown that when the duration for the curative resections from index cholecystectomy was greater than 60 days, it had a negative impact on five-year disease-free survival. They also showed that in a stage-matched disease, upfront curative resections

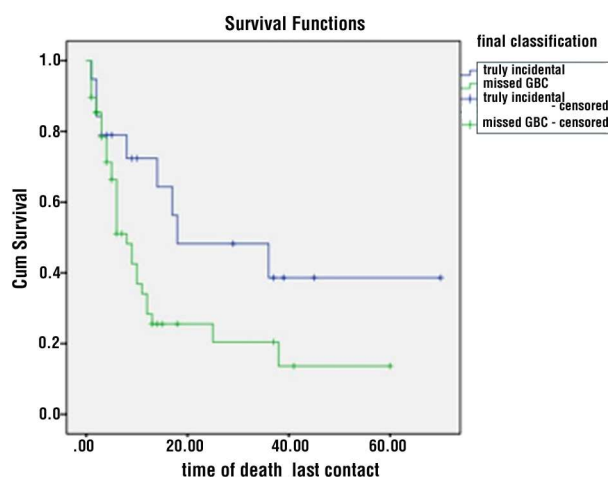


Figure 1 - KM curve comparing the survival between missed (false) Incidental and truly incidental group

are associated with better survival than the patients who underwent curative resections after cholecystectomy (10). Similarly in our study, the overall survival was found to be significantly low in patients with missed gall bladder cancer (16.5 months) compared to those with truly incidental cancer (35.3 months). This finding reiterates the prognostic impact of diagnosing gallbladder cancer in the preoperative period and all the more reason to have a careful and detailed evaluation of all patients with gallstone disease, especially in areas with a high incidence of gallbladder cancer.

Although the exact mechanism behind this impact of cholecystectomy on the prognosis of gall bladder cancer is still unknown, the incomplete *en bloc* resections and violation of the oncological plane between the gall bladder and liver during cholecystectomy causing the exfoliation of tumor cells might be a plausible explanation (11).

In most of the patients of our study, cholecystectomy was performed based on clinical presentation and trans-abdominal ultrasonography findings. Even though at times it is difficult to differentiate the malignant conditions from chronic cholecystitis by ultrasonography alone, many subtle markers that point towards the diagnosis of malignancy of gall bladder like irregular wall thickening, presence of mass lesion, infiltration into adjacent liver, associated hepatoduodenal lymph nodes have been described in the literature (12). In our study, these suspicious findings were present at the time of index cholecystectomy in 43.8% (85% wall thickening, 15% focal mass lesions) on preoperative ultrasound in patients with missed diagnosis of gall bladder cancer. A low threshold to further evaluate these patients with cross-sectional imaging like

Contrast-enhanced computed tomography of the abdomen or MRI would help us delineate the extent and confirm the diagnosis of malignancy (13,14).

Completion extended cholecystectomy (CEC) is the standard surgical procedure for IGBC with tumours higher than T1b (15,16). In the current study CEC was only possible in 21(31.63%) patients which is significantly low when compared to other published literature. We assume that the low CEC rate is due to the presence of a significant number of patients with higher tumor burden who were missed in the evaluation done prior to the index cholecystectomy. This observation is supported by the fact that the CEC rate was low in patients with missed gall bladder cancer compared to true IGBC (20.8% vs 57.8%). The need for hepatic duct resections was described in up to 52% of incidentally detected gall bladder cancer who undergo complete oncological resections (17). In our study, hepatic duct resections were performed in 30% of the patients due to a positive cystic duct margin on the frozen section during the radical resection. Neoadjuvant chemotherapy was not given to any of our patients. All the patients who underwent the curative resections in our study had a good overall survival in comparison to the unresectable patients (50.6 months vs 7.7 months). This outcome was probably due to various factors like more patients with curative resections had early gall bladder cancer, good tumor biology, and an R0 resection achieved in every patient.

The study reiterates the need for better awareness among the surgeons who regularly perform cholecystectomy regarding the need for a careful preoperative evaluation, the importance of documentation of intraoperative details, and timely referral in suspected or diagnosed cases of gall bladder cancer to a higher center. In areas like northern India with a higher incidence of gallbladder cancer, a need for a lower threshold to evaluate any suspicious findings on the preoperative radiology with cross-sectional imaging is advisable for the identification of patients harboring gallbladder malignancy. Surgeons should defer cholecystectomy in case of any suspicion and refer the patient to a higher center for further evaluation and curative resection. In patients with suspicious findings on the cut section performed on the table after the cholecystectomy, a frozen section of the suspected lesion should be done. In case of malignancy on histopathology the patient should be informed about the situation and should be referred as soon as possible. All the necessary details like intraoperative bile spillage, the extent of cholecystectomy

performed, port through which the gallbladder specimen was retrieved, should be clearly mentioned on the referral card.

All the patients of incidental gall bladder cancer should be aggressively evaluated like any other gall bladder cancer to look for any evidence of disseminated disease. Positron Emission Tomography (PET CT) is sensitive in picking up the residual tumour in the liver bed in 78% and extrahepatic metastasis in 50% of patients. However, its sensitivity in picking up peritoneal deposits is still questionable (18). In the patients who are fit for curative resections and deemed resectable on radiological investigations, staging laparoscopy helps in identifying small peritoneal deposits and liver surface deposits in 33% of patients (19,20). In our study Staging laparoscopy had prevented unnecessary laparotomies in 36.3% patients with the resectable disease on preoperative radiology.

We strongly believe that such a proactive approach will help in reducing the serious problem of misrepresentation of gall bladder cancer cases as the incidental carcinoma gall bladder and helps in timely appropriate management.

The study was retrospective in nature and conducted in a tertiary care center, there were recall and referral biases which were unavoidable. Even though findings like irregular gall bladder wall thickening alone does not serve as a definitive marker for malignancy on preoperative findings, considering our prior experience and the high incidence of gall bladder cancer in North India this factor was considered an indication of malignancy in our study. Thirdly we have considered all the patients with pT3 disease as missed carcinoma gall bladder even though the possibility to differentiate chronic cholecystitis or xanthogranulomatous cholecystitis from GBC using preoperative ultrasound and intraoperative findings would be an oversimplification (21). However, it was an attempt to re-emphasize the need for a lower threshold to suspect malignancy in high-incidence areas and to be managed only in centers regularly dealing with gall bladder cancers in higher volumes.

## CONCLUSIONS

Our study showed that a significant number of patients with incidentally detected gallbladder cancer are actually missed cases of gallbladder cancer at the time of index cholecystectomy. This group of patients had a poor outcome when compared to the remaining IGBC patients. The study also strongly militates the need for careful preoperative evaluation in all patients

of gallstone disease in endemic areas. Watchful evaluation and timely management of IGBC might translate into improved outcomes.

### *Conflict of interest*

There are no conflicts of interest to disclose with respect to all the authors and co-authors who were involved in the study.

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### *Author's contributions*

Santhosh Irrinki: drafted the work, revised it critically for important intellectual content and made substantial contributions to the conception or design of the work; or the acquisition, and analysis. Pradeep Kumar: made substantial contributions to the conception or design of the work; or the acquisition. Kailash Kurdia: revised manuscript critically for important intellectual content. Vikas Gupta: made substantial contributions to the conception or design of the work and revised it critically for important intellectual content. BR Mittal: made substantial contributions to the conception or design of the work. Rajendra Kumar: made substantial contributions to the conception or design of the work and revised it critically for important intellectual content. Ashim Das: made substantial contributions to the conception or design of the work. Thakur Deen Yadav: made substantial contributions to the conception or design of the work, revised it critically for important intellectual content approved the version to be published, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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