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Original Research Article

To Correlate the Level of Carbohydrate Antigen 19-9 (CA19-9) to Benign and Malignant Gall Bladder Disease

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Conflict of interest: Nil

Abstract:

Background: CA 19-9 is widely used for diagnosis of pancreatic carcinoma and cholangiocarcinoma but there is no proper study to associate it with histological grade and TNM staging of pancreatic and cholangiocarcinoma.

Methods: Hospital based, observational type of study was conducted in the Department of surgical gastroenterology S P Medical college Bikaner between April 2024 to July 2025.

Results: Mean CA19-9 level in malignant group was 542 ±723 U/ml and in benign group was 34 ± 63 U/ml. There was significant difference in mean level of CA19-9 in benign and malignant groups (p value =0.01).

Conclusion: CA19-9 levels are valuable tool to add in the preoperative diagnosis of the gall bladder carcinoma.

Keywords: CA19-9, Gallbladder cancer (GBC), Malignant.

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Introduction

Gallbladder cancer (GBC) is one of the most common and aggressive malignant neoplasms of the biliary system, accounting for 3% of all tumors. [1]

Carbohydrate antigen 19-9 (CA19-9) is a glycoprotein antigen which is expressed on cells of hepatobiliary epithelium. CA19-9 has been considered a tumor marker for biliary, pancreatic and gastric malignancies. The upper normal limit of CA19-9 is 37 U/ml. Elevated levels of CA 19-9 are also associated with certain benign conditions but with levels more than 1000 U/ml, the specificity for malignancy is approximately 100 percent. Because of this CA19-9 is currently considered the standard tumor marker assessment in diagnosis and prognosis of pancreatic and biliary cancers. However, multiple case reports and studies have shown that elevated CA19-9 levels beyond 1000 U/L occur in non-neoplastic/benign conditions as well [2] this led to doubt its specificity. CA19-9 levels that are three times higher than the upper normal limit, raises concerns for malignant disease. CA 19-9 serum levels have a sensitivity and specificity of 79-81% and 82-90% respectively for the diagnosis of pancreatic cancer in symptomatic patients; but are not useful as a screening marker because of low positive predictive value. [3]

Due to limited study in India, we conducted a study to estimate serum levels of Carbohydrate antigen 19-9 (CA19-9) in 40 patients with malignant gallbladder diseases and 40 patients with benign gallbladder diseases.

Material and Methods

- **Study Design**: Hospital based observational type of study.
- **Study Period**: Study was conducted from approval of ethics committee till sample size achieved.

Inclusion Criteria

- Cases: - Histologically diagnosed patient with Gall bladder carcinoma who had given written informed consent for study
- Controls: - Patients with benign Gall bladder disease who diagnosed by radiological and biochemical investigation.

Exclusion Criteria

- Who have history of any other cancer
- Patients with Tuberculosis, retroviral diseases and hepatitis.
- Subjects who are not willing for study
- Age below 14 years

Statistical analysis: Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL,

USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared by student's t-test. Probability was considered to be significant if less than 0.05.

For significance cut off values are as follows →

P > 0.05 = not significant

P < 0.05 = significant

Observations and Results

Table 1: Socio-demographic profile

Variable	Benign gall bladder disease	Malignant gall bladder disease	p-value
Age in years	56.23 ± 11.32	57.02 ± 11.05	>0.05
Male: Female	6:24	5:25	>0.05

Incidence of gall bladder cancer is highest in > 50 years of age so gall bladder cancer is mainly a disease of older age group. Most of cases in both groups were female. Carcinoma gall bladder is mainly a disease of female in our study.

Both of groups in our study were comparable

Table 2: Comparison of mean levels of tumor markers in case and control group

CA19-9 (U/ml)	Benign gall bladder disease	Malignant gall bladder disease	p-value
Mean	34	542	0.001
SD	63	723	

Mean CA19-9 level in malignant group was 542 ± 723 U/ml and in benign group was 34 ± 63 U/ml. There was significant difference in mean level of CA19-9 in benign and malignant groups (p value =0.01).

Discussion

The incidence of GBC had increased in recent years worldwide. In this study we analyzed the correlation between tumor markers and different clinicopathological features of GBC and compare of mean level of these markers in GBC cases and benign gall bladder disease.

In our study there were significant difference in mean level of CA19-9 in case and control groups (P Value < 0.05). These results are comparable to study, Chaube A, et al. [4] and Yun-Feng Wang, et al. [5]which showed there were significant association between CA125, CA19-9 and Carcinoma gallbladder. And conclude that they have a diagnostic potential for GBC.

GBC is one of the aggressive malignant neoplasms of the biliary system. Early-stage GBC lacks typical clinical manifestation, so most patients are at the advanced stage at the time of diagnosis. It is therefore important to diagnose GBC earlier.

Currently, the diagnosis of GBC mainly depends on non-invasive auxiliary imaging and invasive examination such as laparoscopy and biopsy. However, there is no ideal single tumor marker for the diagnosis and prognosis of GBC. [9-11] when these markers are used individually for the diagnosis of GBC, inconsistent results have been obtained. [6-9].

Conclusion

CA19-9 is a valuable tool to add in the preoperative diagnosis of the gall bladder carcinoma. Till now there is no definitive tool to confirm gall bladder carcinoma preoperatively. So, in that scenario raised marker level along with CECT abdomen finding gives high index of suspicion of gall bladder carcinoma and it helps surgeon to preplan the type of surgery (open/ laparoscopic) and radical/non radical surgery and frozen section of specimen can be planned accordingly. This helps in referring the patient to higher centers if such technical facilities are not available. This prevents the patient to unnecessary undergo two surgeries and there by decrease morbidity of the patient and cost of treatment.

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