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A Multi Centric Prospective Study Of Clinico-radiological Characteristics Among Gall Stone Disease Patients

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Abstract

Objective: The prevalence of gall stone disease is rapidly increasing. Hence in this study the clinical profile and radiological characteristics of patients with gall stone disease has been discussed.

Materials and Methods: We have conducted a study on patients with gall stone, choledocholithiasis & obstructive jaundice at three tertiary care hospitals in India. Age, gender and BMI(Body mass index) of patients were recorded. Lab investigations and USG(Ultrasonography) abdomen were performed for all patients, whereas CECT(Contrast enhanced computed tomography) abdomen & MRI(Magnetic resonance imaging) were performed as per requirement.

Results: Overall mean age of patients was 52.60±17.54 years. Out of which, majority were females 58.9% (112), and 41.1% (78) were males. Mean BMI was 23.36±4kg/m^2. Gallstones were seen in 126 patients (66.3%), among which 6 cases had single stones and 120 cases had multiple stones. Prevalence of subclinical hypothyroidism was observed in 21.57% cases. Further, 8.4% & 22.6% cases underwent CT(Computed tomography) scan and MRI, respectively. CBD stones were diagnosed on USG in 73.1% cases & cholecystitis in 29.4% cases. MRI revealed CBD stones in 93% cases, of which 55% had single stone & 45% had multiple stones. Mean stone size in single & multiple categories were 7.79±2.02 mm and 6.69±3.26 mm, respectively. The mean CBD diameters were 10.47±3.04 mm and 11.11±3.18 mm in two categories. Neglected CBD (Common bile duct) stent was observed in 9 cases.

Conclusion: We have drawn a conclusion that gallstone is commonly encountered in daily practice. A strong differential of gallstone disease should be kept in mind for every patient who present with abdominal pain, fever or jaundice. USG is 73% sensitive in diagnosing gall stone and choledocholithiasis.

Keywords: Cholecystitis, Cholangitis, Gall stone disease, Jaundice.

INTRODUCTION

Gall stone disease is known to mankind since ancient times and is known to be reported more than 3500 years ago in autopsies done on Egyptian mummies. It is an important cause of hospital admissions due to gastrointestinal disorders 1,2. Several studies reported that approximately 10-15% American population have gall

stones 3. Even though, its prevalence varies across the globe, it is clearly evident from the published data that a significant population is affected by the gall stone disease; at times even reaching an epidemic proportion 4-10. A population based ultrasonographic surveys reported a prevalence between 6.1 – 15.6% in India 11,12. The prevalence also tends to vary with the geographic distribution (prevalence is more in North and Central India as compared to South and western India) 13. Occurrence of gall stones is influenced by multiple factors such as age, gender, ethnicity, dietary habits, obesity, rapid weight loss, diabetes mellitus, dyslipidemia, and hypothyroidism, etc.

Majority of gall stone disease patients remain asymptomatic. However, presence of gall stones predisposes to its complications such as biliary colic, cholecystitis, choledocholithiasis, cholangitis, and biliary pancreatitis, etc. Besides these, presence of long-standing gall stones is the most important risk factor for development of gall bladder cancer. Although, it is true that the increased prevalence of the disease can be attributed to increased diagnostic expertise, however, it also implies that this leads to increased tendency to undergo cholecystectomy and increased cost of treatment. Moreover, particularly after the emergence of laparoscopic surgery, the rate of cholecystectomy was also reported to be gone up 14.

Gall stone disease contributes to more than 98% of all gall bladder and biliary tract diseases either directly or indirectly 15. Given the variations in its prevalence, geographic distribution, complications, treatment cost and epidemiology in general, it is important to explore and report data from more number of centres. In this study, we decided to report data on gall stone disease from three tertiary care centres with an aim to study the clinico-radiological profile of patients suffering with the gall stone disease.

Materials and Methods:

Ethics Statement: This study was performed according to the principles of the Declaration of Helsinki. The study protocol was approved by the respective Institutional Ethical Committees, DCGI registered, NABH accredited. All participants have given a formal written informed consent for being included in the study.

Research Design: A multi-centric hospital based prospective study of patients visiting to Gastroenterology, General surgery and Radiology departments with diagnosis of gall stone disease was conducted. Patients with age >18 years of either sex were included in study. Patients those were symptomatic for cholelithiasis, choledocholithiasis, biliary pancreatitis and hospitalized in the gastroenterology and surgery departments for the same during January 2018 to June 2021 were considered for analysis. Patients with incidental diagnosis of gall stone disease were excluded from analysis. Informed consent from included participants was obtained.

A validated proforma was filled by the principal investigator which included demographic and anthropometric data such as dietary habits, BMI and medical history, drug history and hypothyroid symptoms for each participant in the study. Diagnosis of the gall stone disease was made either on Ultrasonography, contrast enhanced CT scan of the abdomen or MRI of the abdomen with cholangiopancreatography. For borderline cases without clear evidence of gall stone disease, a combination of these modalities was used. Early morning fasting blood samples were collected from both cases and controls groups patients and sent for thyroid profile and lipid profile during their hospital stay. Complete blood counts, liver function tests, serum amylase, and serum lipase were done using standard laboratory methods. Diagnosis of pancreatitis was made based on revised Atlanta classification.

Sample size: As per the study by Rai and Kumar (2017), the incidence of CBD stones in Indian population ranges between 10-15%. Referring to in the incidence of 15%, a sample of 196 individuals was estimated that can provide this incidence with 95% confidence for the proposed study. In six cases, the data could not be obtained and hence the analysis was performed on 190 patients.

Statistical methods: The demographic and behavioral characteristics of patients included in the study were recorded and summarized in terms of mean and standard deviation for continuous variables and frequencies and percentage for categorical variables. The descriptive statistics for various biochemical parameters were expressed in terms of mean and standard deviation. The prevalence of CBD and the descriptive statistics for various dimensions as observed under USG, CT and MRI were obtained for patients. The analyses were performed using SPSS version 20.0 (IBM Corp) software.

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Results:

The mean age of patients in our study was 52.60 ± 17.54 years and there was female preponderance with 112 (58.9%) cases as compared to male with 78 (41.1%). The mean BMI of patients was 23.36 ± 4.00 kg/m2, while the mean waist circumference was 90.05 ± 14.33 cm. As regards to dietary and behavioral habits, majority of patients-153 (80.5%) had a mixed diet, while 50 (26.3%) were alcoholic and 29 (15.3%) were smokers. The descriptive statistics for demographic and behavioral characteristics of patients were obtained as shown in Table 1. Among 190 cases, 177 (93.2%) had Cholelithiasis and 160 (84.2%) had Choledocholithiasis. There were 34 (17.9%) patients diagnosed with Pancreatitis, while 22 (11.6%) had Cholangitis and 8 (4.2%) had calculous cholecystitis. 9 patients in our study had already undergone either laparoscopic or open cholecystectomy (4.7%) and 9 patients (4.7%) had neglected CBD stent.

The descriptive statistics like mean, standard deviation and median for various biochemical parameters are represented in Table 2. In our study the prevalence of sub-clinical hypothyroidism was 21.57 % (41 cases). Out of 190 cases, 163 (85.8%) were evaluated exclusively by USG, 6 (3.1%) under CT and 22 (11.6%) under MRI. There were 18 (9.5%) patients with both USG and MRI evaluations, while 7 (3.7%) had USG and CT evaluations and only 1 (0.5%) case had CT and MRI investigations. There were 2 (1.05%) patients with all the three investigations. The number of patients undergoing different types of evaluations has been depicted through Venn diagram in Figure 1.

CBD stone was observed in 139 (73.1%) cases, out of which 93 (66.9%) had single stone, while 46 (33.1%) had multiple stones. In the single category, the mean stone size was 11.68 ± 5.71 mm, while the mean CBD diameter was 10.49 ± 3.59 mm. In the multiple stone category, the mean stone size was 9.12 ± 4.35 mm, while the mean CBD diameter was 11.11 ± 3.25 mm. Cholecystitis was observed in 56 (29.5%) cases, whereas acute cholecystitis was observed in 27 (48.2%) cases, while chronic Cholecystitis was observed in 29 (51.8%) patients. Cholelithiasis was observed in 126 (66.3%) cases with USG. Further, GB stones were observed in 126 (66.3%) cases; amongst these, 6 (4.7%) had a single stone with a mean stone size of 9.17 ± 3.13 mm, while 120 (95.3%) had multiple stones with a mean stone size of 10.21 ± 4.31 mm. Acute pancreatitis was seen in 41 (21.6%) cases. The details of the findings on patients under USG shown in Table 3.

Furthermore, out of 190 patients, 16 (8.42%) were evaluated with CT scan (Table 4). Amongst these, 14 (87.5%) showed CBD stones, out of which 10 (71.4%) had a single stone, while 4 patients (28.6%) had multiple stones. The mean stone size in single stone category was 10.38 ± 6.93 mm, while CBD diameter was 7.43 ± 0.53 mm. For those with multiple stones, the average stone size was 13.67 ± 1.15 mm and average CBD diameter was 22.33 ± 3.79 mm. There was only one patient of Cholecystitis, while 8 (50%) cases of Cholelithiasis. All these Cholelithiasis patients had multiple GB stones with mean size of 7.43 ± 2.51 mm. There were 5 (31.25%) cases of acute pancreatitis.

Out of 190 patients, 43 (22.6%) cases were evaluated with MRI with MRCP as shown in Table 5. CBD stone was observed in 40 (93.02%) cases out of which 22 (55%) had single stone, while 18 (45%) had multiple stones. The mean stone size in the single and multiple categories were 7.79 ± 2.02 mm and 6.69 ± 3.26 mm respectively, while the mean CBD diameters were 10.47 ± 3.04 mm and 11.11 ± 3.18 mm in the two categories respectively. Cholecystitis was observed in 13 (30.2%) cases, while Cholelithiasis was observed in 32 (74.4%) cases. Amongst these 32 cases, single GB stone was observed in 5 (15.6%) cases with a mean size of 5.60 ± 3.58 mm, while 25 had multiple stones with a mean size of 8.69 ± 4.76 mm. There were 10 (23.3%) cases of acute pancreatitis observed under MRI.

The consensus on diagnosis between two or more scanning modalities was determined by referring to patients with different scanning evaluations. There were 7 patients evaluated with both USG and CT scan exclusively (Figure 1). On USG, all patients showed a single stone, while on CT, 2 (28.6%) patients showed a single stone, 3 (42.85%) had multiple stones and 2 (28.6%) did not show any stones. Out of these 7 cases, there were 2 (28.6%) cases of Cholecystitis on USG, but no such occurrence on CT was found. There were 3 (42.85%) cases of Cholelithiasis on USG, while 2 (28.6%) of these cases had also the same diagnosis on CT. There

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were no cases of pancreatitis on USG, however, 1 (14.28%) case of acute pancreatitis was observed on CT among these patients.

In our study, 18 (9.47%) patients were evaluated with both USG and MRI. The CBD stone was observed in all the 18 (100%) patients on both USG and MRI. There were 14 (82.35%) patients in our study, on whom there was an agreement on the number of stones (single/multiple), resulting into a kappa coefficient of 0.653 (95% CI: 0.319-0.987), thereby indicating a good agreement. Further, there was perfect agreement in the diagnosis of Cholecystitis, Cholelithiasis and Pancreatitis (kappa coefficient:1.0).

There was only 1 (0.52%) case with both CT and MRI evaluations. CT indicated multiple stones, while MRI indicated single stone. Both showed absence of Cholecystitis, while Cholelithiasis presence was indicated by both the methods. Multiple GB stones and acute pancreatitis were observed under both the evaluations on this patient. There were 2 (1.05%) cases who had all the three evaluations. All the three scan types showed single stone in both the cases. Cholecystitis and Cholelithiasis were absent according to all the three methods, while there was absolute consensus on acute pancreatitis in both the patients.

DISCUSSION

Cholelithiasis is a common clinical situation encountered by Gastroenterologists and Surgeons. It usually affects the adult population and involves both the genders, predominantly obese and multiparous women in middle age. Obese women secrete more cholesterol into their bile than a non-obese female, hence predisposing to gall stone disease 16. It is commonly believed that bile stasis is the prime factor for formation of gall stone 17. Gallstone disease represent a major health problem and are a major cause of morbidity and mortality throughout the world 18. In 2nd century B.C., Charaka and in 6th century B.C., Sushruta from India were also familiar with this disease entity 19, 20.The prevalence rate or incidence rate of gallstone disease is significantly increased in past couple of decades in India and western world due to increased intake of fatty and high calorie diet along with excessive intake of alcohol 21. In symptomatic cholelithiasis, the common clinical symptoms are pain in the right upper quadrant of abdomen or epigastric pain, which may radiate to the back. Biliary colic is generally present in 10–25% of patients 22. Moreover, this may be associated with fever, bilious vomiting, obstructive jaundice, loss of weight or appetite 23.

The mean age of patients in our study was 52.6 years. In other studies, by Channa et al 24 and Khan et al 25 mean age was slightly lower than our study i.e. 45.9 and 42.8 years respectively. There was female preponderance in the current study with 112 female patients(58.9%) as compared to 78 male patients (41.1%). This was in conjunction with majority of the previous reported studies26-29. The mean BMI of patients was 23.36 ± 4.00 kg/m2, while the mean waist circumference was 90.05 ± 14.33 cm, both of these markers are on higher side of normal values as per Indian standards. As regards with dietary habits and addictions, majority i.e. 153 (80.5%) patients had mixed diet, while 50 (26.3%) patients were alcoholic and 29 (15.3%) were smokers. This was in contradiction to the study by Harshi TW Weerakoon et al and Sherlock 31, where the incidence of diabetes, alcoholism, smoking, tobacco chewing and dietary habits does not correlate with gallstone formation. Out of 190 patients, 16 (8.42%) were evaluated with CT scan. Among these, 14 (87.5%) showed CBD stones, 10 (71.4%) had single stone, while 4 (28.6%) had multiple stones. In another study done by Jenkins et al, 32 64.9% patients had multiple stones and 35.1% had solitary stones. Sebahattin and Colleagues 30 study also had similar findings, showing multiple stones in 66.1% and single stone in 33.9% patients. Jalali et al 33 also reported a similar incidence of multiple stones compared to single stones (69% vs.31%). While a study done by Aslam et al 28 reported higher incidence of multiple stones (84.5%) compared to single stones (15.4%). Mofti AB et al 34 also reported a higher incidence of multiple stones compared to solitary stones (89.44% vs. 11.56%). In a case control study done on 668 female patients those who underwent cholecystectomy for gallstone disease, the proportion of hypothyroidism was 2.4% 35 while in another study, it was reported to be 8% and 6% in patients with choledocholithiasis and cholelithiasis, respectively 36. In the present study, we report a much higher prevalence of subclinical hypothyroidism (21.5%).

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Given the differences in geographical distribution of the disease and a wide spectrum of associated manifestations, it is important that more data from different centers need to be reported.

CONCLUSION

We have drawn a conclusion that gallstone is commonly encountered in daily practice. A strong differential of gallstone disease should be kept in mind for every patient who present with abdominal pain, fever or jaundice. Prevalence of subclinical hypothyroidism was 21.57%. USG is 73% sensitive in diagnosing gall stone and choledocholithiasis

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LIST OF TABLES AND FIGURES

Figure 1: Venn diagram showing number of patients with different evaluations

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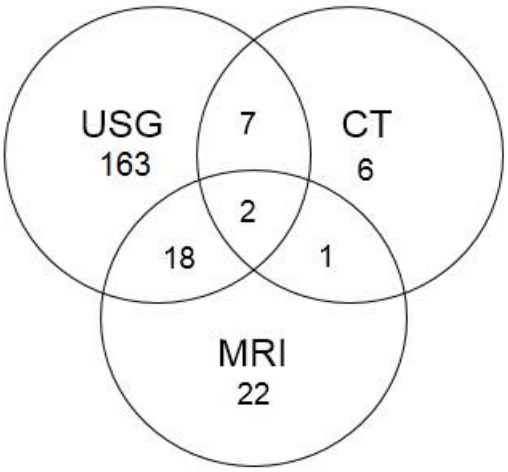

USG= Ultrasonography, CT=Computed tomography, MRI=Magnetic resonance imaging.

Table 1: Descriptive statistics for various demographic and behavioral characteristics of patients (n=190)

Variable		**Descriptive statistics**
Age in years [Mean ± SD]		52.60 ± 17.54
Gender	Female	112 (58.9%)
	Male	78 (41.1%)
BMI (kg/m^2)		23.36 ± 4.00
WC (cm)		90.05 ± 14.33
Diet	Mixed	153 (80.5%)
	Veg	37 (19.5%)
Alcohol	Yes	50 (26.3%)
Smoking	Yes	29 (15.3%)
Diagnosis	Cholelithiasis	177 (93.2%)
	Choledocholithiasis	160 (84.2%)
	Pancreatitis	34 (17.9%)
	Cholangitis	22 (11.6%)
	Calculous cholecystitis	8 (4.2%)

BMI= Body mass index, SD=Standard deviation, WC=Waist circumference.

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Table 2: Descriptive statistics for various biochemical parameters

Parameter	Mean ± SD
TSH	3.47 ± 6.31
T4	6.72 ± 3.81
LDL (mg/dl)	98.43 ± 51.61
TG (mg/dl)	136.48 ± 111.87
TC (mg/dl)	145.9 ± 95.84
Total bilirubin	4.73 ± 4.8
AST	115.09 ± 149.12
ALT	125.6 ± 147.18
ALP	567.57 ± 374.45
Hb (%)	11.99 ± 1.91
TLC	10230.88 ± 4864.66
Platelet count	2.55 ± 1.03

TSH=Thyroid stimulating hormone, T4=Thyroxine, LDL=Low density lipoprotein, TG=Triglycerides, TC=Total cholesterol, AST=Aspartate transaminase, ALT= Alanine transaminase, ALP=Alkaline phosphatase, Hb=Hemoglobin, TLC=Total leucocyte count.

Table 3: Prevalence of CBD stone and descriptive statistics for various dimensions as observed under USG (n=190)

USG evaluation (n=190)				**Descriptive statistics**
CBD Stone	No (n=51)		Stone size (mm) [Mean ± SD]	-
			CBD Diameter (mm) [Mean ± SD]	9.17 ± 2.23
	Yes (n=139)	Single (n=93)	Stone size (mm) [Mean ± SD]	11.68 ± 5.71
			CBD Diameter (mm) [Mean ±	10.49 ± 3.59

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			SD]	
		Multiple (n=46)	Stone size (mm) [Mean ± SD]	9.12 ± 4.35
			CBD Diameter (mm) [Mean ± SD]	11.11 ± 3.25
Cholecystitis	No (n=134)			134 (100%)
	Yes (n=56)	Acute [No. (%)]		27 (48.2%)
		Chronic [No. (%)]		29 (51.8%)
Cholelithiasis	No [No. (%)]			64 (33.7%)
	Yes [No. (%)]			126 (66.3%)
GB Stones	No (n=64)			-
	Yes (n=126)	Single (n=6)	Stone size (mm) [Mean ± SD]	9.17 ± 3.13
		Multiple (n=120)	Stone size (mm) [Mean ± SD]	10.21 ± 4.31
Pancreatitis	No [No. (%)]			149 (78.4%)
	Acute [No. (%)]			41 (21.6%)

CBD= Common bile duct, GB=Gallbladder, SD=Standard deviation, USG=Ultrasonography

Table 4: Descriptive statistics for various dimensions of CBD as observed under CT (n=16).

CT evaluation (n=16)				**Descriptive statistics**
CBD Stone	No (n=2)	No (n=2)	Stone size (mm) [Mean ± SD]	-
			CBD Diameter (mm) [Mean ±	-

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			SD]	
	Yes (n=14)	Single (n=10)	Stone size (mm) [Mean ± SD]	10.38 ± 6.93
			CBD Diameter (mm) [Mean ± SD]	7.43 ± 0.53
		Multiple (n=4)	Stone size (mm) [Mean ± SD]	13.67 ± 1.15
			CBD Diameter (mm) [Mean ± SD]	22.33 ± 3.79
Cholecystitis	No [No. (%)]			15 (93.75%)
	Yes [No. (%)]			1 (6.25%)
Cholelithiasis	No [No. (%)]			8 (50%)
	Yes [No. (%)]			8 (50%)
GB Stones	No (n=8)			-
	Yes (n=8)	Single (n=0)	Stone size (mm) [Mean ± SD]	-
		Multiple (n=8)	Stone size (mm) [Mean ± SD]	7.43 ± 2.51
Pancreatitis	No [No. (%)]			11 (68.75%)
	Acute [No. (%)]			5 (31.25%)

CBD= Common bile duct, CT=computed tomography, GB=Gallbladder, SD= standard deviation, USG=Ultrasonography,

Table 5: Descriptive statistics for various dimensions of CBD as observed under MRI (n=43).

MRI evaluation (n=43)	**Descriptive statistics**

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CBD Stone	No (n=3)		Stone size (mm) [Mean ± SD]	-
			CBD Diameter (mm) [Mean ± SD]	-
	Yes (n=40)	Single (n=22)	Stone size (mm) [Mean ± SD]	7.79 ± 2.02
			CBD Diameter (mm) [Mean ± SD]	10.47 ± 3.04
		Multiple (n=18)	Stone size (mm) [Mean ± SD]	6.69 ± 3.26
			CBD Diameter (mm) [Mean ± SD]	11.11 ± 3.18
Cholecystitis	No [No. (%)]			30 (69.7%)
	Yes [No. (%)]			13 (30.2%)
Cholelithiasis	No [No. (%)]			11 (25.6%)
	Yes [No. (%)]			32 (74.4%)
GB Stones	No (n=11)			-
	Yes (n=32)	Single (n=5)	Stone size (mm) [Mean ± SD]	5.60 ± 3.58
		Multiple (n=25)	Stone size (mm) [Mean ± SD]	8.69 ± 4.76
Pancreatitis	No [No. (%)]			33 (76.7%)
	Acute [No. (%)]			10 (23.3%)

CBD= Common bile duct, GB=Gallbladder, MRI=Magnetic resonance imaging,

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