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Original Research

To investigate the function of real-time ultrasonography in assessing gallbladder volume in type 2 diabetes mellitus patients

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ABSTRACT:

Aim: To investigate the function of real-time ultrasonography in assessing gallbladder volume in type 2 diabetes mellitus patients. **Methods:** The Department of Radiology performed a cross-sectional prospective research. The study comprised 50 type 2 diabetes mellitus patients with a duration of 5 years or more and diabetic complications as cases, as well as 55 age and gender matched healthy controls. The presence of symptoms such as dysphagia, abdominal fullness, nausea, vomiting, diarrhoea, faecal incontinence, urine incontinence, gustatory perspiration, impotence, and so on was used to diagnose autonomic neuropathy. 3ml fasting blood samples were taken from all patients under aseptic conditions and utilised to estimate fasting blood sugar and postprandial blood sugar. **Results:** Mean age of the T2DM patients was 43.58±6.98 and in the healthy controls 49.88±7.69 (p=0.41). In the cases, 35 were males and 15 were females and in the control group 35 were males and 15 were females. In the present study, BMI (27.08±3.21kg/m^2), FBS (160.88±24.09mg/dl), PPBS (248.01±38.01mg/dl), Fasting gall bladder volume (36.15±8.02cm^3), post fatty meal gall bladder volume (16.91±7.87cm^3), ejection fraction (52.04±18.02cm^3) were significantly increased in type 2 diabetes mellitus patients compared with healthy controls. In the study group, T2DM patients were also subdivided broadly into without complications and those with diabetic complications. T2DM patients without diabetic complications were reported in 30(60%) patients. Peripheral neuropathy was observed in 8(16%), peripheral neuropathy & Autonomic neuropathy was reported in 6(12%) cases. In the present study, fasting GB Volume (cm^3), post fatty meal GB Volume (cm^3) and ejection fraction (%) were compared between the T2DM patients without complications and with complications. The fasting GB Volume (cm^3) was not statistically significant between two groups (p=0.32). The post fatty meal gallbladder volume (cm^3) was statistically significant between the two groups (p<0.001). **Conclusion:** Ultrasound examination of gall bladder volume (fasting and post-prandial) and Ejection Fraction are useful criteria to determine gallbladder function. Gallbladder function should be assessed frequently in T2DM patients since inadequate gallbladder emptying may lead to gallstone development and related problems. Further investigations with high sample size are recommended.

Keywords: Chronic diabetics, Fasting gall bladder volume, Ultrasonography,

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INTRODUCTION

Diabetes mellitus is the most common endocrine disorder in humans, characterised by metabolic abnormalities that result in long-term complications involving the kidneys, gastrointestinal tract, nerves, and blood vessels, resulting in significant morbidity and mortality. Several studies indicate that diabetics have an increased risk of gallbladder disease. [1-3] This has been attributed to cholecystomegaly and impaired gall bladder contraction, primarily due to diabetic autonomic neuropathy. Though gallstone formation is most often caused by gallbladder stasis, other risk factors include sex, genetic factors, obesity, parity, diet, drugs, hyperlipidaemia, and ileal resection. [4]

The purpose of this study was to compare gall bladder volumes in chronic diabetics and controls. Ultrasonography is the preferred modality of choice for assessing gall bladder volume because it is safe, non-invasive, less expensive, takes less time, and is more accurate. This study also aimed to correlate gall bladder volume in patients with chronic diabetes with other patient parameters such as age, gender, body mass index (BMI), parity, and hyperlipidaemia. Autonomic neuropathy is responsible for a variety of manifestations in the gastrointestinal tract, including

nocturnal diarrhoea, oesophageal dysmotility, gastropathies, constipation, and gallbladder dysfunction, which is a result of vagal neuropathy and leads to decreased gastrointestinal motility. Diabetes mellitus duration has a significant positive correlation with gallbladder disease prevalence. The type of treatment has no significant association, and fasting plasma glucose levels are inversely related to gall bladder disease. [5] Gallbladder involvement in diabetic autonomic neuropathy is typically manifested by an increased incidence of gall stones and a significant increase in gall bladder volume[6], as well as poor concentration and visualisation, with no symptoms of gallbladder disease. [7] The current study aims to determine the prevalence of gallbladder diseases in patients with type 2 chronic diabetes, the relationship between diabetes duration and gallbladder disease, and the comparison of gallbladder dysfunction in patients with and without autonomic neuropathy, as well as in healthy individuals. Gall bladder motility is reduced in chronic diabetics due to autonomic neuropathy, which, along with hypertriglyceridemia and obesity, is a major risk factor for cholelithiasis. [8-10] Gall bladder emptying is regulated by both the sympathetic and parasympathetic nervous systems, with the parasympathetic controlling contractility and the sympathetic controlling relaxation. Gallbladder motility is reduced due to autonomic nervous system dysfunction and a poor response to gastrointestinal hormones such as cholecystokinin, motilin and secretin. [11]

MATERIALS AND METHODS

After receiving clearance from the protocol review committee and the institutional ethics committee, a cross-sectional prospective research was undertaken at the Department of Radiology. Following informed permission, a comprehensive history was obtained from the patient or family. All patients were informed about the procedure's approach, risks, advantages, outcomes, and related complications. There were 100 patients in all. 50 were type 2 diabetes mellitus patients with a duration of 5 years or more with diabetic complications as cases, and 55 were age and gender matched healthy controls. A complete medical history, presenting symptoms, diabetes mellitus duration, diabetes mellitus family history, method of therapy, exercise, diet, oral hypoglycemics, insulin, whether treatment was regular, and history of diabetic complications were all noted. All of the research individuals were subjected to thorough general and systemic exams. The presence of tingling and numbness in the palms and soles was used to diagnose peripheral neuropathy. The presence of symptoms such as dysphagia, abdominal fullness, nausea, vomiting, diarrhoea, faecal incontinence, urine incontinence, gustatory perspiration, impotence, and so on was used to diagnose autonomic neuropathy. 3ml fasting blood samples were taken from all patients under aseptic conditions and utilised to estimate fasting blood sugar and postprandial blood sugar.

Real-time ultrasonography was used to assess gall bladder capacity in type 2 diabetes mellitus patients and controls while fasting and 45 minutes after a standardised fatty meal. Patients with cholecystectomy, acute or chronic hepatocellular illness, and liver cirrhosis, as well as those with jaundice, gall bladder abnormalities, or disorders, were eliminated. Patients' and controls' informed permission was acquired and kept secret. The gall bladder was examined with the GE voluson P8. Fasting T2DM patients and controls were assessed for gall bladder volume. Gallbladder volume was evaluated again in T2DM patients and controls after a standardised fatty meal.

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STATISTICAL ANALYSIS

Independent student‘t’ test was used to test the significance in both type 2 diabetes mellitus patients and control subjects. $p < 0.05$ was considered as statistically significant. Data analysis was carried out using Statistical Package for Social Science (SPSS), Version 24.0

RESULTS

In the present study, 50 type 2 diabetes mellitus patients as cases and 50 healthy subjects underwent sonographic evaluation of the gallbladder volume in both fasting state and post prandial (after standardized fatty meal) state. Laboratory parameters like fasting blood sugar and post prandial blood sugar were measured in all the subjects. In this study, mean age of the T2DM patients was 43.58±6.98 and in the healthy controls 49.88±7.69 (p=0.41). In the cases, 35 were males and 15 were females and in the control group 35 were males and 15 were females. In the present study, BMI (27.08±3.21kg/m^2), FBS (160.88±24.09mg/dl), PPBS (248.01±38.01mg/dl), Fasting gall bladder volume (36.15±8.02cm^3), post fatty meal gall bladder volume (16.91±7.87cm^3), ejection fraction (52.04±18.02cm^3) were significantly increased in type 2 diabetes mellitus patients compared with healthy controls as shown in [Table 1]. In the study group, T2DM patients were also subdivided broadly into without complications and those with diabetic complications. T2DM patients without diabetic complications were reported in 30(60%) patients. Peripheral neuropathy was observed in 8(16%), peripheral neuropathy & Autonomic neuropathy was reported in 6(12%) cases as shown in [Table 2]. In the present study, fasting GB Volume (cm^3), post fatty meal GB Volume (cm^3) and ejection fraction (%) were compared between the T2DM patients without complications and with complications. The fasting GB Volume (cm^3) was not statistically significant between two groups (p=0.32). The post fatty meal gallbladder volume (cm^3) was statistically significant between the two groups

(p<0.001). The ejection fraction (%) difference observed in the mean value between the two groups was statistically significant with a p<0.03 [Table 3 & 4].

Table 1: Comparison of BMI, FBS, PPBS, FGBV, PPGBV between T2DM & Controls

Parameters	T2DM Cases Mean±SD	Controls Mean±SD	P Value
Body Mass Index (Kg/m^2)	27.08±3.21	23.98±4.75	0.001
Fasting Blood Sugar (mg/dl)	160.88±24.09	93.72±7.35	0.0001
Post Prandial Blood Sugar (mg/dl)	248.01±38.01	118.31±5.87	0.001
Fasting Gall bladder volume (cm^3)	36.15±8.02	32.11±7.75	0.0001
Post Fatty Meal GB Volume (cm^3)	16.91±7.87	10.12±9.58	0.0001
Ejection Fraction (cm^3)	52.04±18.02	76.29±6.75	0.015

Table 2: T2DM patients without and with diabetic complications

	Number	Percentage
Without Complications	30	60
Peripheral Neuropathy	8	16
Peripheral Neuropathy + Autonomic Neuropathy	6	12
Peripheral Neuropathy + Retinopathy	2	4
Peripheral Neuropathy + Diabetic Nephropathy	2	4
Peripheral Neuropathy + Autonomic Neuropathy + IHD	1	2
Peripheral Neuropathy + Diabetic Nephropathy +post renal transplant	1	2

Table 3: T2DM Patients without and with diabetic complications

Parameter		Mean±Sd
Fasting *GBV	Without Complication	32.12 ±8.65
	With Complication	34.19 ±8.21
Post Fatty Meal *GBV	Without Complication	15.38 ±7.74
	With Complication	21.38 ±7.69
Ejection Fraction	Without Complication	59.81 ±18.12
	With Complication	44.53±18.13

Table 4: Independent Samples Test of T2DM patients without and with diabetic complications

Independent Samples Test	Student 't' test	Df Degree of freedom	p' value
Fasting *GBV	-1.14	42.87	.26
Post Fatty Meal *GBV	-3.65	42.88	.002
Ejection Fraction	3.44	42.97	.003

DISCUSSION

Diabetics in particular those with T2DM have an increased prevalence of gallstones.[12] Diabetic subjects are reported to have a two to three fold increase in the prevalence of cholesterol gall stones.[13] Chapmann et al. conducted a large study involving 271 diabetic subjects, reported that there is increased incidence of cholesterol gallstones in T2DM patients. A highly significant increase in gall bladder volume was also observed in T2DM group. Conventional real time ultrasonography is a simple noninvasive investigation for evaluation of gall bladder volume. In a similar study C.GAUR et al who examined 40 patients of NIDDM, 10 patients of IDDM and 50 healthy controls, found that patients with NIDDM had statistically significant larger fasting gall bladder volume and these values were highly significant amongst patients with autonomic neuropathy. They also had significant larger post fatty meal gallbladder volume and these values were high in patients with autonomic neuropathy.[14] In a study by PG Raman et al,[13] who studied 50 NIDDM patients and 30 controls, found that 32% of diabetic patients had ultrasonographic evidence of gallstones as compared to 6.7% in healthy controls. They also found that mean fasting gall bladder volume was significantly increased in diabetic patients (26 cm3) as compared to control population (15.8cm3). Furthermore, mean fasting gallbladder volume of diabetic patients with gallbladder disorders (28.1 cm3) was found to be significantly larger than that of those patients without gallbladder disorder (24.6 cm3) Mean percentage of contractions (Ejection fraction) of gallbladder 60 minutes after fatty meal was reduced in diabetic patients (53%) and it was further reduced in the patients with gall bladder disorder (41.8 %). Mean duration of diabetes was significantly longer in diabetic patients with gallbladder disorder. In a study by Agarwal AK et al., reported that mean fasting gallbladder volume in T2DM was 25.87 ±13.90 ml, with a minimum value of 9.30 ml and maximum value of 88 ml and higher gallbladder volumes were seen in

patients with autonomic neuropathy.[15] In a study by C A Ugbaja et al., reported that diabetic patients with neuropathy have significant abnormalities of gall bladder function, presumably due to autonomic nerve dysfunction. These patients also have a higher prevalence of gallstones, suggesting that ultrasound screening may be useful.[16] In a study conducted by Garjesh S. Rai et al., observed that higher fasting gall bladder volume and reduced percentage of contraction in T2DM patients attributed to autonomic neuropathy. Suggested that, hepatobiliary ultrasonography in chronic diabetics can be used as screening tool for early diagnosis of complication and to avoid its serious consequences when presents in emergency and undergone for surgery.[17] In our study the fasting GB Volume difference was not statistically significant between T2DM patients without complications and T2DM patients with complications, but there was significant difference between the two in the post fatty gallbladder volume with a mean value of 15.38 cm3 in patients without complications and a mean value of 21.38 cm3 in patients with complications. Furthermore, percentage of ejection fraction showed significant difference with a mean value of 60% in patients without complications and a mean value of 40 % in patients with complications. There was significant difference in fasting gallbladder volume between the T2DM patients and the control group with a $p< 0.001$. Our study results matched the previous studies demonstrating the increased fasting GB Volume, post fatty meal GB Volume and decreased ejection fraction in the T2DM patients.[13,14] Longer the mean duration of T2DM, there was an increase in the mean fasting GB Volume and decrease in ejection fraction (%). In our study we also found there was a significant difference in Body Mass Index (BMI) between the T2DM patients and control group with a $p<0.001$.

It is known that patients with diabetes often develop cholelithiasis and gall bladder stasis is considered to be one of the causes.[14]Stasis leads to lithogenicity of bile and incomplete gall bladder emptying leading to sequestration of cholesterol and nidus formation, thereby predisposing to gallstone formation. The mechanism responsible for cholecystoparesis is attributed to vagal neuropathy.

CONCLUSION

Ultrasound examination of gall bladder volume (fasting and post-prandial) and Ejection Fraction are useful criteria to determine gallbladder function. Gallbladder function should be assessed frequently in T2DM patients since inadequate gallbladder emptying may lead to gallstone development and related problems. Further investigations with high sample size are recommended.

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