ORIGINAL RESEARCH

Estimation Of Gallbladder Volume in the Type 2 Diabetes Mellitus: A Randomized Trial

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Abstract
Introduction: Diabetes mellitus is a type of metabolic disorder characterized by increase in blood glucose level due to defect in the secretion of insulin, action of insulin or combination of both.Early diagnosis of diabetes and prediabetes is essential using recommended HbA1C criteria for different types except for gestational diabetes.
Materials and method: Simple random sampling method was used to select the sample and allocate into diabetic and control group. A detailed history, complete physical examination and routine & appropriate investigations were done for all patients.
Result: Approximately 40% of the T2DM group reported a family history of gallstones, compared to just 15% in the control group, suggesting a potential genetic predisposition among diabetic patients.
Conclusion: The mean gallbladder volume in the T2DM group was about 30% larger than in the control group in both fasting and postprandial states, a notable difference.Peripheral neuropathy was the most common complication, present in about 60% of the T2DM group, highlighting the importance of monitoring and managing this complication in diabetic care.
Keyword: Type2 DM, gall bladder, HbA1c,

Introduction

The prevalence of diabetes is increasing year by year both in developed and developing countries.[1]It is one of the chronic noncommunicable diseases (CNCDs) which have emerged as a leading global health problem. It is also a known risk factor for blindness, vascular brain diseases, renal failure, and limb amputations. It has been projected that a total of 424.9 million adult patients have experienced diabetes, and it is anticipated that this number will climb to 628.6 million individuals. The incidence of diabetes mellitus is greatest in the WHO area that encompasses eastern Mediterranean countries. The vast majority of people who are diagnosed with diabetes have type 2 diabetes mellitus, often known as T2DM. This accounts for around 90 percent of all cases.[2] In diabetic individuals, the prevalence of gallstone disease was found to be much greater than in the general population, coming in at 24.8% against 13.8%, according to research that was conducted in Italy.[3] A further research carried out in New Zealand found that diabetic patients had a prevalence ofGuillain barre syndrome that was 32.7 percent, while controls only had a frequency of 20.8 percent.[4] Ultrasonography has been selected as the modality to measure gallbladder volume because it accurately evaluates both the gallbladder and the billiary tree 95.0 percent of the time, it does not cause any discomfort, it is safe, economical, less time consuming and   accurate.[5] Even though it is theoretically simpler in individuals who have fasted for at least six hours beforehand, the best non-invasive test for identifying gallstones in the gallbladder does not involve any particular preparation from the patient. It has a high level of specificity (90–95% accuracy) and a high level of sensitivity (90–95% accuracy), and it does not use ionising radiation. The presence of a dilated intrahepatic or extrahepatic bile duct may also be indicative of a distant blockage in the biliary system.[6] *Dodds et al.*[7] used a simple ellipsoid method to calculate the volume of the GB in 1985. The formula they used was as follows: $V = \pi/6 (L \times B \times H)$, where L is the length, W is the width, and H is the height or anteroposterior (AP) dimensions of the GB; the constant $\pi/6$ has a value of 0.523, where is a constant

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(22/7).*Chapman et al*.[8] used ultrasonography to examine the GB volume of diabetics and control groups and their findings further validated the findings of *Dodds* et al research.[9] An inquiry that is not intrusive, such as ultrasonography, may be used to identify the pre and post prandial gall bladder volume in diabetes patients, which can disclose the functioning state of the gall bladder and help diabetic patients make decisions for early management. Evaluation of the functioning of the gall bladder should be standard practice for diabetic patients. The present study was done to evaluate GB volume in T2DM patients having peripheral neuropathy by USG and compare them with control group.

Methodology
Thiscase control studywas conducted on total sample of 194 patients who were equally distributed under Diabetic group and Control group (97 patients each). The study subjects were chosen as per the inclusion and exclusion criteria:

Inclusion criteria
T2DM patients with peripheral neuropathy

Exclusion criteria
1. Diabetics on drugs capable of interfering with autonomic function or inhibit cholecystokinin release (alpha methyldopa , atropine , NSAIDS)
2. Patients who had known endocrine related diseases such as rheumatoid arthritis, systemic sclerosis, SLE.

3. Pregnant diabetic patients

A detailed history, complete physical examination and routine & appropriate investigations were done for all patients.The chi-square test was utilized to analyze the frequency differences between the two groups. If the p-value was less than 0.05, then it was regarded to be statistically significant.

Result
The objective of the research was to assess the volume of the gallbladder (GB) in Type 2 Diabetes Mellitus (T2DM) patients who were experiencing peripheral neuropathy and to compare these findings to those obtained from a control group consisting of non-diabetic, healthy individuals. The study involved various analyses based on age, gender, Body Mass Index (BMI), family history of gallstones, HbA1c levels, duration of diabetes, blood pressure, blood sugar levels, and gallbladder volume. The T2DM group had a slightly older mean age compared to the control group, with the highest prevalence of diabetes in the 51-60 age group.Notably, the prevalence of type 2 diabetes reaches its highest point between the ages of 51 and 60, after which it begins to decline, with only 3 percent of type 2 diabetes patients being in the age bracket of 71 to 80, in comparison to 12 percent in the control group. When compared to the age distribution of the control group, the T2DM group has a slightly older mean age (52.6 years with a standard deviation of 9.5) than the control group (51.62 years with a standard deviation of 12.9).

Table 1: Describing the study groups as per GENDER

Gender	T2DM		Control	
	N	**%**	**N**	**%**
Male	42	43.00	45	46.00
Female	55	57.00	52	54.00
Total	**97**	**100.0**	**97**	**100.0**

Table-1 illustrates the gender breakdown of individuals belonging to two distinct groups: those diagnosed with Type 2 Diabetes Mellitus (T2DM) and a control group that does not have T2DM. There were a total of 97 people distributed across the two groups. In the type 2 diabetes (T2DM) group, there are 42 males (43 percent), and 55 females (57 percent). In the control group, there are 52 females and 45 males (representing a 46 percent gender split) (54 percent). Comparatively, out of 97 people in each group, 26 people with type 2 diabetes and 15 people in the control group have a positive family history of gallstones. The percentage of people in the T2DM group with a positive family history is higher. On the other hand, 72 people in the type 2 diabetes group (74 percent) do not have a family history of gallstones, while 82 people in the control group (85 percent) do not have such a history in their families. These findings point to a possible genetic or familial link between type 2 diabetes and the predisposition to gallstones, as they indicate a higher incidence of a family history of gallstones in the T2DM group compared to the control group.

Table 2: Describing the study groups as per Gall bladder Volume

	T2DM		Control		p-value
	Mean	**SD**	**Mean**	**SD**	
Gall bladder Volume	27.4	17.4	18.57	3.07	0.00*

*p<0.05 significant

Table-2 presents a comparison between individuals who have Type 2 Diabetes Mellitus (T2DM) and a control group who do not have T2DM in terms of the mean gallbladder volume. In the type 2 diabetes group, the mean gallbladder volume is significantly higher at 27.4 cm, with a standard deviation (SD) of 17.4 cm. In contrast, the mean gallbladder volume in the control group is significantly lower at 18.57 cm, with a much narrower SD of 3.07 cm. A p-value of 0.00 demonstrates that there is a statistically significant difference between the two groups in terms of the marked difference in mean volumes.

Table 3: Describing the study groups as per GB measurement

Blood Sugar	T2DM	Control	p-value
	Mean±SD	Mean±SD	
Fasting Gall bladder volume (FGBV)	33.33±6.42	30.03±6.30	**0.05**
Post prandial Gall bladder volume PPGBV	20.62 ±12.86	12.23± 3.92	

Table-3 presents a comparison between people who have Type 2 Diabetes Mellitus (T2DM) and a control group regarding the volume of their gallbladders while they are fasting and after they have eaten. The mean fasting gallbladder volume (FGBV) in the group of people with type 2 diabetes is 33.33 cm (with a standard deviation of 6.42) This is a little bit higher than the mean of 30.03 cm (with a standard deviation of 6.30) in the group of people who did not have type 2 diabetes. A p-value of 0.05 indicates that the difference in FGBV that exists between the two groups is only slightly significant from a statistical point of view. Although the postprandial gallbladder volume (PPGBV) drops in both groups during the postprandial state, as was to be expected, the drop is more pronounced in the group that has type 2 diabetes. The mean PPGBV for the T2DM group is 20.62 cm, with a standard deviation of -12.86 cm3. This is a sizeable increase compared to the mean PPGBV for the control group, which is 12.23 cm with a standard deviation of 3.92 cm. The mean gallbladder volume in the T2DM group was about 30% larger than in the control group in both fasting and postprandial states, a notable difference.

Peripheral neuropathy was the most common complication, present in about 60% of the T2DM group, highlighting the importance of monitoring and managing this complication in diabetic care.

Discussion

The rationale behind focusing on gallbladder volume in T2DM patients is rooted in the understanding that diabetes mellitus, as a metabolic disorder, can have widespread effects on various organ systems. There were 97 people in each of the two groups, and they are distributed proportionally the same way. In the type 2 diabetes (T2DM) group the prevalence of type 2 diabetes reaches its highest point between the ages of 51-60 (34%), whereas the age group 31-40 is the age group that is most common in the control group (23%) and a significant portion of the T2DM group were obese (BMI ≥30), contrasting sharply with the control group where the majority had a normal BMI (18.5-24.9). Comparatively, out of 97 people in each group,

26 people with type 2 diabetes and 15 people in the control group have a positive family history of gallstones. The percentage of people in the T2DM group with a positive family history is higher. Khare and Gupta (2015)[10] investigated the frequency of asymptomatic gallstones in patients with type 2 diabetes mellitus and found Patients who have type 2 diabetes mellitus and are middle-aged or older have a significant frequency of asymptomatic gallstones in their bodies and have higher BMI. Sodhi et al (2014)[11] found the independent risk variables for gallstone development were old age (relative risk [RR] 1.54, confidence interval [CI] 1.1-2.1), female sex (RR 1.6, CI 1.0-1.9), and body mass index (RR 1.5, CI 1.3-2.5). Growing older, being female, and having a higher body mass index were each shown to be individually related with gallstone disease. Agunloye et al (2013)[12] identified the prevalence of GS in both type 1 and type 2 DM patients and found The ratio of males to females in the positive cases was 3:4, and 51.92 percent of those who had type 2 diabetes were above the age of 40. It was shown that 56 patients, or 48.3 percent, had a body mass index (BMI) that was more than 25 kg/m ^{2} and conclude that, the GSD in diabetes is considerably affected by age, BMI, and the length of time the patient has had the condition. Also, Agarwal et al (2004)[13] found a correlation between the volume of the gall bladder in diabetes patients and characteristics such as age, gender, body mass index, number of children, hyperlipidemia, and autonomic neuropathy. However, AL-yasiri et al (2012)[14] found no statistically significant difference between diabetic and non-diabetic patients with regard to the effects of age, parity, or a family history of GBD. Similarly, Ranganath and Basawaraj (2021)[15] reported no significant for age and BMI, however It was recommended that all patients with type 2 diabetes undergo evaluation to determine whether or not they have enlarged gallbladder volumes when fasting in order to evaluate the risk of developing gall stone disease. In our study, The mean gallbladder volume in the T2DM group was about 30% larger than in the control group in both fasting and postprandial states, a notable difference. Similarly, Various authors

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Ikhuoriah TA,Olatunji O, Adeyinka B, and Oboh D(2022)[16], Ranganath andBasawaraj (2021)[15]Tahnia et al (2021)[17]Olokoba et al (2008)[18]Osaweet al (2016)[19]concluded that fasting gallbladder volume and GB wall thickness were significantly increased in type 2 diabetics when compared to controls.Thakral et al (2022)[20] showed that chronic diabetics had a gall bladder capacity that was much greater (43.47), compared to that of controls (28.45). Moreover, Reddy et al (2020)[21] investigated the effects of diabetes on gall bladder volume using ultrasonography among patients suffering from diabetic neuropathy have been reported to have greater FGBV and PPGBV but a lower GBCI when compared with controls. Understanding the changes in gallbladder volume that occur in diabetic patients is important from a medical standpoint because it may have implications for the treatment of diabetes as well as the complications that are associated with it. The findings of this study could be used to inform more targeted approaches in the treatment of patients with type 2 diabetes, particularly those patients who have complications such as peripheral neuropathy. This is due to the fact that changes in gallbladder function can cause a wide variety of symptoms and disorders in the gastrointestinal tract. In addition, it has the potential to shed light on potential preventative measures against gallbladder-related disorders, which are prevalent in populations of diabetics.

Conclusion

The study highlights several critical aspects of the health profile of individuals with Type 2 Diabetes Mellitus, especially in relation to gallbladder volume, which is significantly higher in diabetic patients than in healthy individuals. The findings demonstrated that patients with Type 2 Diabetes Mellitus (T2DM) exhibit significantly higher gallbladder volume compared to non-diabetics. Key findings include a higher prevalence of obesity, poor glycemic control, and a genetic predisposition to gallstones in T2DM patients. The study also highlighted that long-standing diabetes exacerbates these issues. These insights emphasize the necessity for comprehensive diabetes management strategies that not only focus on glycemic control but also address related risk factors like obesity and hypertension. This integrated approach is crucial for reducing complications and improving overall patient outcomes in T2DM.

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