Prevalence and determinants of gastroparesis symptoms among T2DM patients in Tabuk City

ABSTRACT

Background: Development and progression of gastrointestinal complications in T2DM patients are one of the main contributors in the clinical course of the disease. Therefore, early recognition of gastroparesis is an important issue, despite this is not an easy task.

Objectives: to estimate the prevalence and identify determinants of gastroparesis symptoms among T2DM patients.

Patients and methods: A cross-sectional study was conducted in Tabuk city, Saudi Arabia among all patients diagnosed with T2DM patients and attended the chronic illness clinics of King Khalid Armed Forces hospital throughout the period April-May, 2022. An interview questionnaire was utilized including 5 main parts: Demographic data of patients, medical history, weight and height measurements, the most recent hemoglobin A1c , and the Gastroparesis Cardinal Symptoms Index (GCSI) to estimate the prevalence of gastroparesis.

Results: The study included 348 T2DM patients. More than half of them (57.8%) were females. Their age ranged between 23 and 75 years with an arithmetic mean±standard deviation of 54±11.3 years. The commonest reported gastroparesis symptoms were stomach fullness (45.1%), nausea (42%), loss of appetite (42%)and feeling excessively full after meals (41.1%). Overall, the prevalence of gastroparesis symptoms among T2DM patients was 11.8%. Multivariate logistic regression analysis revealed that females were at high significant risk for developing gastroparesis symptoms compared to males (Adjusted odds ratio “AOR”==2.49, 95% confidence interval “CI”: 1.18-5.27), p=0.016. Participants`

glycated hemoglobin level was not significantly associated with gastroparesis symptoms after controlling for confounder effect.

Conclusion: The prevalence of gastroparesis symptoms among T2DM patients was not high. Symptoms were more likely to affect female than male patients. However, they were not independently associated with glycemic control or treatment with metformin.

Keywords: T2DM, Gastroparesis, Prevalence, Determinants, Saudi Arabia

1. INTRODUCTION

The International Diabetes Federation (IDF) has described diabetes mellitus (DM) as one of the highest global health emergencies of the 21st century [1]. Currently, it has affected approximately 415 million adults aged between 20 and 79 worldwide [2].

The Kingdom of Saudi Arabia (KSA) has one of the highest prevalence rates of type 2 diabetes mellitus all over the world.[1]The Arabian Gulf wealth, including KSA has led to better living conditions resulting in an increase in urbanization, major changes in nutrition, decreased physical activity, and further dependency on migrant workers [3]**.** In KSA, the prevalence of DM in adults was 25% [4]. Recent research in Saudi Arabia suggested that more than 44% of individuals aged 55 or older had severe to uncontrolled diabetes with long-term complications [5].

Development and progression of gastrointestinal complications in T2DM patients are one of the main contributors in the clinical course of the disease. Therefore, early recognition of gastroparesis is an important issue, despite this is not an easy task. Moreover, the impairment of gastric motor-evacuation function in T2DM patients is associated with inability to work as well as it impacts the quality of life in patients, increasing the risk of the progression of other microvascular and macrovascular diabetic complications [6-8].

It has been documented that the prevalence of gastroparesis symptoms was higher in Type 1 diabetes (T1DM) rather than type 2 diabetes (T2DM) [9], however, literature suggested that upper gastrointestinal symptoms are common in T2DM but with inconsistent

evidence [10].

Most internists and gastroenterologists still think that early diabetic gastroparesis manifestations are the symptoms of different gastrointestinal diseases and often diagnose the problem too late [11].

Up to our knowledge, there is no accurate estimation of the prevalence of gastroparesis symptoms in T2DM patients in KSA, therefore, this study aimed to explore the magnitude and determinants of gastroparesis symptoms among T2DM patients.

2. MATERIAL AND METHODS

A cross-sectional study design was conducted in Tabuk city, which is located 2200 feet above sea level and with moderate climate in comparison with other Saudi cities. It has a population of nearly 700,000 (2019 estimated census) [12]. All patients diagnosed with T2DM and attended the chronic illness clinics of King Khalid Armed Forces hospital in Tabuk throughout the period April-May, 2022 were eligible for inclusion in the study, provided that their age is 18 years or more and less than or equal 75 years. Patients with gestational diabetes, T1DM, acute diabetic complications, **s**evere cardiac, lung and mental problems, gastrointestinal diseases and those with previous gastric surgery were excluded from the study.

An interview questionnaire was utilized in the present study. It includes 5 main parts: Demographic data of the patients (age, gender, marital status, and body mass index), medical history (duration of diabetes, presence of other comorbid chronic diseases, treatment of diabetes, and fasting blood glucose), which were collected from the patient`s medical record, weight and height measurements (weight and height were measured by the researcher and filled in the questionnaire). Weight was measured by digital valid machine in kg. It was measured as the subject wore the ordinary clothes. Extra clothes were removed before measurements. Height was measured by a valid machine in meters. Footwear was removed before measurement. Body mass index (BMI) assessed the body weight relative to

height. It was calculated as weight in kilograms divided by height in meters squared, rounded to one decimal place. Obesity in adults was defined according to the National Institute of Health categorization as BMI greater than or equal to 30 kg/m², while BMI from 25-29.9 kg/m² was considered overweight, BMI from 18.5- 24.9 was considered normal while BMI < 18.5 was considered underweight [13]. In addition, the most recent hemoglobin A1c, taken within the last three months, was recorded from the patients` charts. The Gastroparesis Cardinal Symptoms Index (GCSI) to estimate the prevalence of gastroparesis among T2DM patients. GCSI composed of three subscales of symptoms, chosen to measure important symptoms related to gastroparesis, that is nausea/vomiting (nausea, retching, and vomiting), postprandial symptoms/early satiety (stomach fullness, inability to finish a normal-sized meal, feeling excessively full after meals, and loss of appetite, and bloating (bloating, and visibly larger stomach or belly after meals [14]. GCSI includes 9 questions and each question is scored according to symptoms` severity from 0 (no symptoms to 5 (Severe symptoms). Total scores ≥ 1.90 was selected as a cutoff to diagnose gastroparesis [15,16]. Data were collected by the investigator and trained medical students.

The data were collected and verified by hand then coded before computerized data entry. The statistical Package for Social Sciences (SPSS) software version 26.0 was used for data entry and analysis. Descriptive statistics (e.g. number, percentage, mean, range, standard deviation) and analytic statistics using chi-square, Fischer exact and independent samples t-tests were applied. Multivariate logistic regression analysis was performed to control for the confounding effect and p-values ≤0.05 were considered statistically significant.

3. RESULTS

The study included 348 T2DM patients. More than half of them (57.8%) were females. Their age ranged between 23 and 75 years with an arithmetic mean±standard deviation of 54±11.3 years. The majority (80.2%) were married. Table 1

More than half (52%) of them were obese as illustrated in Figure 1. History of other chronic diseases was observed among 70.4% T2DM patients; particularly hypertension (50.6%) and dyslipidemia (47.1%). Figure 2

Duration of diabetes ranged between 6 and 10 years among 31.7% of patients whereas it exceeded 15 years among 22.1% of them. Fasting blood glucose was 126 mg/dL or more among 66.4% of patients while HbA1c% exceeded 7% in 57.4% of patients. Metformin was the commonest reported medication (90.4%). Table 2

Table 3 and Figure 3 show that the commonest reported gastroparesis symptoms were stomach fullness (45.1%), nausea (42%), loss of appetite (42%) and feeling excessively full after meals (41.1%).

Overall, the prevalence of gastroparesis symptoms among T2DM patients was 11.8% as seen in Figure 4. Female T2DM patients were more likely than males to develop gastroparesis symptoms (15.4% vs. 6.8%), 0.014. there is a significant association between the level of hemoglobin A1c and the development of gastroparesis symptoms as 23.5% of patients whose HbA1c% ranged 10% or more compared to none of those whose HbA1c% was less than 5% had gastroparesis symptoms, p=0.049. However, 26.7% of patients whose HbA1c% ranged between 5 and 6% had gastroparesis symptoms. Other studied factors (age, marital status, body mass index, history of other chronic diseases, duration of diabetes, level of fasting blood glucose, metformin treatment) were not significantly associated with gastroparesis symptoms. Table 4

Multivariate logistic regression analysis revealed that females were at high significant risk for developing gastroparesis symptoms compared to males (Adjusted odds ratio “AOR”==2.49, 95% confidence interval “CI”: 1.18-5.27), p=0.016. Participants` hemoglobin A1c level was not significantly associated with gastroparesis symptoms after controlling for confounding effect. Table 5

4. DISCUSSION

As the research in the area of the magnitude and determinants of gastroparesis among T2DM patients is still relatively deficient, the present study was conducted in trying to fill this gap of knowledge. In the present study, the prevalence of gastroparesis symptoms among T2DM patients was 11.8%. This rate coincides with the lower limit of the figures reported from specialized centers as the rate ranged between 10% and 30% [17-19] . Also, it is very close to the rate reported by Almogbel RA, et al in their study carried out in Qassim (10.8%) [20]. However, it is higher than the rates reported recently in Jeddah (7.9%) [21] and Riyadh (6.3%) [22]. In Ukraine, the prevalence of diabetic gastroparesis symptoms was very high compared to our figure (45.5%) [11]. In India (2016), the prevalence of delayed gastric emptying was 28.6% [23]. The difference in the rates of gastroparesis symptoms among T2DM patients between studies could be explained by variations in the demographic characteristics of patients, level of glycemic control as well as the study settings.

In the present study, the commonest reported symptoms of gastroparesis were stomach fullness (45.1%), nausea (42%), loss of appetite (42%), feeling excessively full after meals (41.1%). In a recent Saudi study carried out in Jeddah, the commonest reported symptoms were bloating (34.8%), and stomach fullness (26.6%) and the lowest common was vomiting (4.1%) [21]. In Qassim, bloating (63.9%), stomach fullness (55.1%) and early satiety (48.3%) were the commonest reported symptoms [20]. In Israel, The commonest reported symptoms were stomach or belly visibly larger after a meal (53%), bloating (48.8%), post-prandial fullness (44.6%) and nausea (24.8%) [24].

In the current study and in agreement with others [20,22,24,25], female patients were more likely than males to develop gastroparesis symptoms, even after controlling for the confounding effect in multivariate logistic regression analysis. This finding could be attributed to the influence of female sex hormones on the gastrointestinal motility [26-28], as females have a longer delay in gastric emptying time than males [29].

Metformin use has been observed as a risk factor for gastroparesis symptoms among T2DM patients in some studies, [22,24,30,31] who attributed this association to the synergistic effect of metformin with gastroparesis to induce gastrointestinal symptoms, or the likelihood of the association of post-prandial distress syndrome with the presence of gastrointestinal symptoms, rather than delay in gastric emptying. Alam et al (2010) attributed the association between metformin use and gastroparesis symptoms to delayed gastric emptying induced by Dipeptidyl peptidase (DPP)-IV inhibition [32] . However, in these studies, symptoms of diarrhea, nausea, abdominal pain and heartburn, which are commonly reported with metformin use are not frequently observed, this could eliminate the possibility of association of metformin use with gastroparesis symptoms. The current study revealed no association between metformin use and gastroparesis symptoms among T2DM patients.

The present study showed that in univariate analysis, there was an association between glycemic control and gastroparesis symptoms. However, after controlling for the confounding effect in multivariate analysis, this effect disappeared. On the other hand, literature showed conflicting results regarding the association between glycemic control and gastroparesis symptoms [12,22,24,25,33,34].

Some important limitations of the present study should be addressed. Being a single-center study could impact the ability to generalize the findings over other centers, despite the fact that this center is the main one caring for T2DM patients in Tabuk city. Using a cross-sectional design could affect the establishment of the causal relationship between dependent and independent variables. The absence of normal non-diabetic control to compare with diabetic subjects could be a limitation of the study. Finally, the possibility of presence of false positive cases was not ruled out by performing gastroduodenoscopy in patients with positive gastroparesis symptoms, to exclude mechanical causes of symptoms.

5. CONCLUSION

The Prevalence of gastroparesis symptoms among T2DM patients was not high and coincides with most of the rates reported from Saudi Arabia. Symptoms were more likely to affect female than male patients. However, they were not independently associated with glycemic control or use of metformin. Based on study results, we recommend screening for T2DM patients regarding gastroparesis symptoms and performing gastroduodenoscopy for positive cases to exclude mechanical reasons. Conduction further multicenter longitudinal prospective study including patients from different disciplines to achieve a clearer image of the situation.

CONSENT

Informed consent was taken from all participants in this study. Also, the purpose of the study was well explained and confidentiality and privacy will be guaranteed.

ETHICAL APPROVAL

The approval of the regional Research and Ethics committee (Institutional Review Board) and those of the hospital medical director has been collected and preserved by the author.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Table 1: Demographics of T2DM patients, King Khalid Armed Forces hospital, Tabuk, Saudi Arabia

	Number	**Percentage**
Gender		
Male	147	42.2
Female	201	57.8
Age in years		
Range	23-75	
Mean±SD	54.0±11.3	
Marital status		

Single	19	5.5
Married	279	80.2
Divorced	13	3.7
Widowed	37	10.6

SD: Standard deviation

Table 2: T2DM related history among patients, King Khalid Armed Forces hospital, Tabuk, Saudi Arabia

	Number	Percentage
Duration of diabetes in years		
≤5	100	28.7
6-10	110	31.7
11-15	61	17.5
>15	77	22.1
Fasting blood glucose (n=342)		
≤99 mg/dL	34	9.9
100-125 mg/dL	81	23.7
≥126 mg/dL	227	66.4
Glycated hemoglobin %		
<5	11	3.8
5-6	30	10.5
>6-7	81	28.3
>7-8	77	26.8
>8-9	39	13.6
>9-10	17	5.9
>10	32	11.1
Treatment (n=332)*		
Metformin	300	90.4
Other oral hypoglycemic	208	62.7
Insulin	132	39.8

*Not mutually exclusive

Table 3: Prevalence and severity of gastroparesis symptoms among T2DM patients, King Khalid Armed Forces hospital, Tabuk, Saudi Arabia

Symptoms	None N (%)	Very mild N (%)	Mild N (%)	Moderate N (%)	Severe N %)	Very severe N (%)
Nausea	202 (58.0)	48 (13.8)	56 (16.1)	24 (6.9)	15 (4.3)	3 (0.9)
Retching	256 (73.6)	28 (8.0)	32 (9.2)	15 (4.3)	15 (4.3)	2 (0.6)
Vomiting	297 (85.3)	13 (3.7)	19 (5.5)	15 (4.3)	2 (0.6)	2 (0.6)
Stomach fullness	191 (54.9)	38 (10.9)	59 (17.0)	44 (12.6)	13 (3.7)	3 (0.9)
Not able to finish a meal	215 (61.8)	41 (11.8)	48 (13.8)	29 (8.3)	13 (3.7)	2 (0.6)
Feeling excessively full after meals	205 (58.9)	41 (11.8)	58 (16.7)	30 (8.6)	12 (3.4)	2 (0.6)
Loss of appetite	202 (58.0)	61 (17.6)	46 (13.2)	25 (7.2)	14 (4.0)	0 (0.0)
Bloating	212 (61.0)	30 (8.6)	51 (14.7)	37 (10.6)	12 (3.4)	6 (1.7)
Stomach or belly visibly larger	215 (61.8)	38 (10.9)	43 (12.4)	39 (11.2)	9 (2.6)	4 (1.1)

Table 4: Factors associated with gastroparesis symptoms among T2DM patients

	Gastroparesis		p-value
	No N=307 N (%)	Yes N=41 N (%)	
Gender			
Male (n=147)	137 (93.2)	10 (6.8)	
Female (n=201)	170 (84.6)	31 (15.4)	0.014*
Age in years			
Mean±SD	54.0±11.3	54.1±11.1	0.986˚
Marital status			
Single (n=19)	18 (94.7)	1 (5.3)	
Married (n=279)	248 (88.9)	31 (11.1)	
Divorced (n=13)	10 (76.9)	3 (23.1)	
Widowed (n=37)	31 (83.8)	6 (16.2)	0363
Body mass index			
Underweight (n=2)	2 (100)	0 (0.0)	
Normal (n=42)	34 (81.0)	8 (19.0)	
Overweight (n=123)	112 (91.1)	11 (8.9)	
Obesity (n=181)	159 (87.8)	22 (12.2)	0.337*
History of other chronic diseases			
No (n=103)			
Yes (n=245)	93 (90.3)	10 (9.7)	
	214 (87.3)	31 (12.7)	0.437*
Duration of diabetes in years			
≤5 (n=100)	90 (90.0)	10 (10.0)	
6-10 (n=110)	98 (89.1)	12 (10.9)	
11-15 (n=61)	53 (86.9)	8(13.1)	
>15 (n=77)	66 (85.7)	11 (14.3)	0.812*
Fasting blood glucose (n=342)			
≤99 mg/dL (n=34)	26 (76.5)	8 (23.5)	
100-125 mg/dL (n=81)	74 (91.4)	7 (8.6)	
≥126 mg/dL (n=227)	202 (89.0)	25 (11.0)	0.066*
Glycated hemoglobin %			
<5 (n=11)	11 (100)	0 (0.0)	
5-6 (n=30)	22 (73.3)	8 (26.7)	
>6-7 (n=81)	75 (92.6)	6 (7.4)	
>7-8 (n=77)	68 (88.3)	9 (11.7)	
>8-9 (n=39)	36 (92.3)	3 (7.7)	
>9-10 (n=17)	13 (76.5)	4 (23.5)	
>10 (n=32)	29 (90.6)	3 (9.4)	0.049*
Metformin treatmen (n=332)			
No (n=32)	28 (87.5)	4 (12.5)	
Yes (n=300)	265 (88.3)	35 (11.7)	0.535**

*Chi-square test **Fischer Exact test

˚ Independent samples t-test

Table 5: Predictors of gastroparesis among T2DM patients: Multivariate logistic regression analysis

	B	SE	AOR	95% CI	p-value
Gender					
Male[a]			1.0	---	
Female	0.916	0.381	2.49	1.18-5.27	0.016

[a]: Reference category B: Slope SE: standard error

AOR: Adjusted odds ratio CI: Confidence interval

Term of hemoglobin a1c was not significant and removed from the final regression model

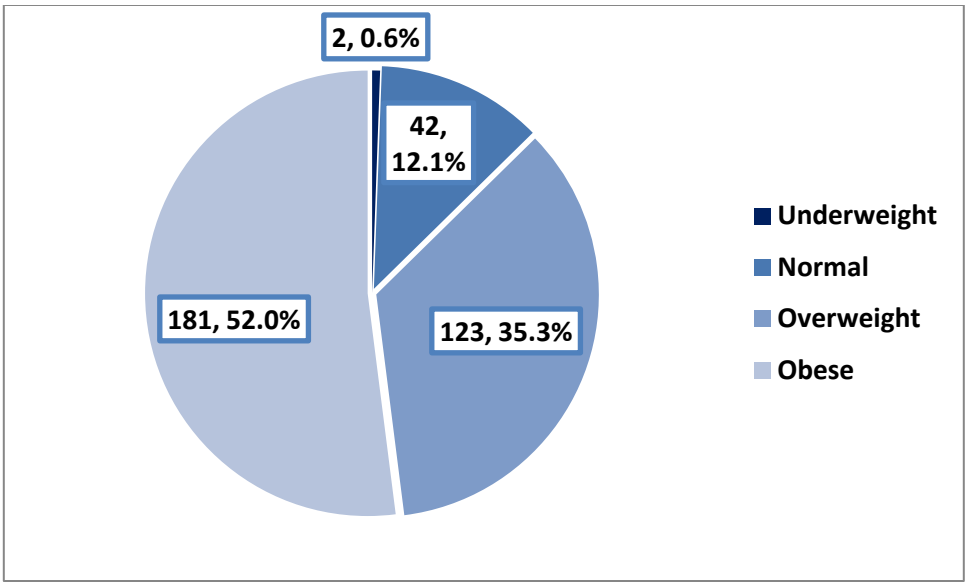

Figure 1: Body mass index of the T2DM patients, King Khalid Armed Forces hospital, Tabuk city

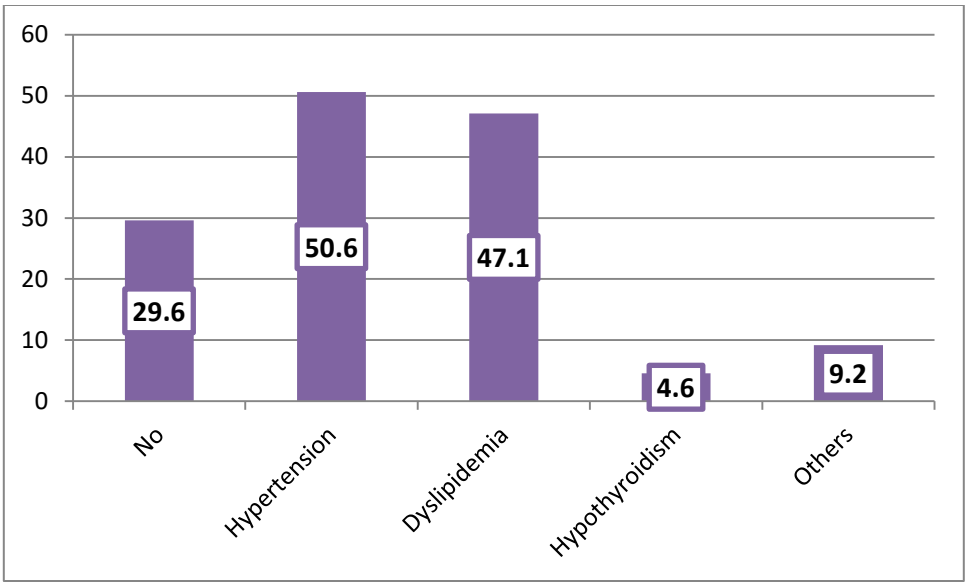

Figure 2: History of other chronic diseases among T2DM patients, King Khalid Armed Forces hospital, Tabuk city

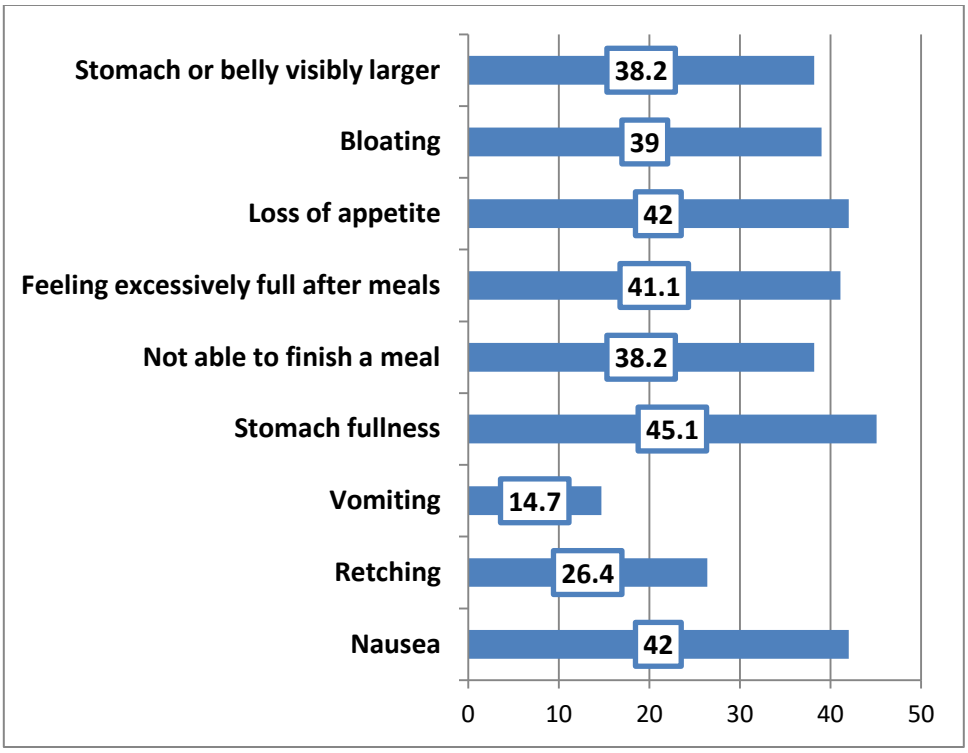

Figure 3: Frequency distribution of gastroparesis symptoms among T2DM patients, King Khalid Armed Forces hospital, Tabuk

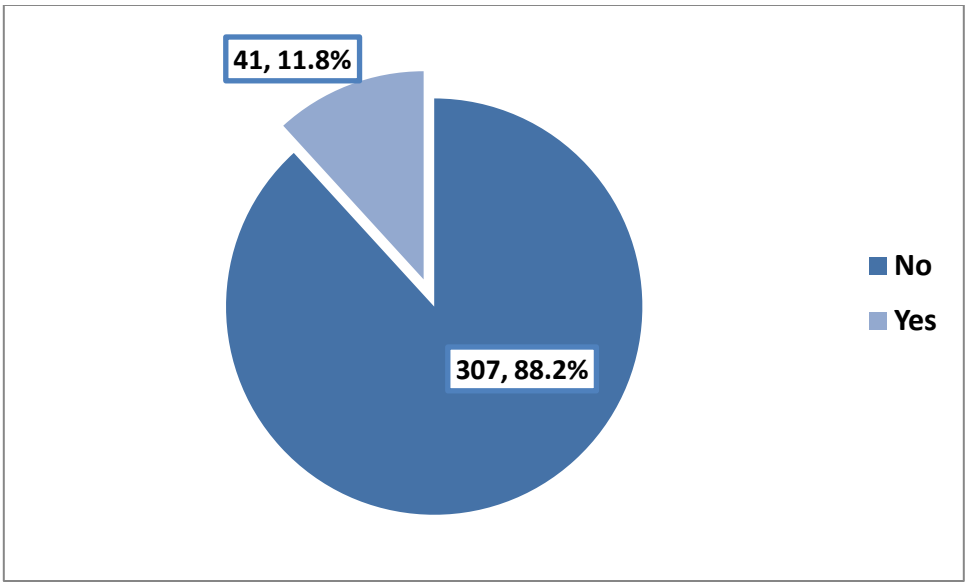

Figure 4: Prevalence of gastroparesis symptoms among T2DM patients, King Khalid Military hospital, Tabuk, Saudi Arabia