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# The impact of gastroparesis on diabetes control: Patient perceptions

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# ABSTRACT

The impact of gastroparesis on diabetes management and control from the patient perspective has not been well characterized. The **aim** of this study was to identify patient perceptions regarding the impact of gastroparesis on managing their diabetes.

*Methods:* Patients with diabetes being referred for gastroparesis were enrolled in this prospective study. Gastroparetic symptom severity was assessed with the Patient Assessment of Upper GI Symptoms (PAGI-SYM). A questionnaire examined the impact of gastroparesis on diabetes related symptoms and control.

*Results:* 54 diabetic gastroparesis patients (36 T1DM, 18 T2DM) participated. Duration of diabetes averaged 17.4  $\pm$  1.4 years and gastroparetic symptoms 5.1  $\pm$  1.1 years. Patients rated their most severe symptoms as postprandial fullness, early satiety, and nausea. Two thirds of diabetic subjects identified that since their diagnosis of gastroparesis, their diabetes was more difficult to control (44 of 54 patients) and that extra time and effort were required for care of their diabetes (45 of 54). Patients with T1DM, compared to those with T2DM, more often expressed that since developing gastroparesis, their blood sugars have been higher, they have had more frequent episodes of hypoglycemia, and they found that their gastroparetic symptoms worsened if blood sugars were too high.

*Conclusions:* Gastroparesis has a significant impact on patients' perceived ability to self-manage and control their diabetes. T1DM patients, in particular, associate their gastroparesis with episodes of hyper- and hypo-glycemia, and find their gastroparetic symptoms worsen with poor control. Future research should focus on strategies to support self-management of patients with diabetic gastroparesis.

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### Introduction

Delayed gastric emptying is a common complication in many patients with long standing diabetes mellitus. Gastroparesis affects approximately 30% to 40% of individuals with type 1 (T1DM) and about 20% of individuals with type 2 diabetes (T2DM) (Horowitz, O'Donovan, Jones, et al., 2002; Intagliata & Koch, 2007; Samson, Vermeijden, Smout, et al., 2003). However, the effects of the delayed emptying are variable with some individuals exhibiting only mild

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symptoms while others experience severe nausea, vomiting and fullness. The cause of diabetic gastroparesis is still not well understood but is likely to be multifactorial in nature including factors such as vagal neuropathy, enteric nerve dysfunction, and hyperglycemia (Horowitz et al., 2002).

Diabetic gastroparesis has been associated with poor glycemic control and increased frequency of hypoglycemia as well as a reduced quality of life (De Kort et al., 2012; Talley, Bytzer, et al., 2001; Talley, Young, et al., 2001). From a health provider perspective, the difficulties of achieving good glycemic control in diabetic patients with gastroparesis are known (Rayner & Horowitz, 2006). In diabetic gastroparesis, nausea, vomiting, and early satiety and the delayed gastric emptying can make glucose control difficult. In patients with gastroparesis treated with insulin, the delays in gastric emptying can result in severe hypoglycemia immediately following meals due to the delayed emptying of the meal from the stomach which is then followed by a period of hyperglycemia as the insulin effects wane and the meal is finally absorbed (Cherian & Parkman, 2012). This is all exacerbated by the fact that the rate of gastric emptying is often unpredictable and mediated by a number of different factors (Chang, Rayner, Jones, & Horowitz, 2010).

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While the effect of gastroparesis on diabetes management and control has been described from the provider perspective, the impact of gastroparesis on diabetes management and control from the patient perspective has not been well characterized. The aim of this study was to identify the perceptions of diabetic patients regarding the impact of gastroparesis on managing their diabetes. Through this study, we wished to gain insight to help improve patients understanding of diabetic gastroparesis.

# 2. Methods

The study population consisted of patients with diabetes, either T1DM or T2DM, who have gastroparesis. Subjects were recruited from gastroparesis patients referred to the senior author (HPP) at the GI practices of Temple University Hospital. Subjects were of either sex and between the ages of 18 and 70 years. Subjects, with an established diagnosis of diabetes, were required to have delayed gastric emptying on gastric scintigraphy defined as greater than 60% retention at 2 h and/or greater than 10% retention at 4 h (Abell, Camilleri, Donohoe, et al., 2008). Exclusion criteria were prior gastric surgery, acute or chronic renal insufficiency or known psychiatric disease or eating disorders.

For this study, subjects filled out questionnaires during their initial appointment in the GI clinic. In addition, data regarding level of diabetes control (most recent Hgb-A1c levels) and diagnostic testing (upper endoscopy and gastric emptying results) were abstracted from the Medical Record.

This study was approved by the Institutional Review Board of Temple University.

# 2.1. Questionnaires

#### 2.1.1. Patient Assessment of Upper GI Symptoms (PAGI-SYM)

This validated questionnaire assesses symptoms of gastroparesis over the prior two weeks with severity of symptoms scored by the patient as none = 0 to very severe = 5 (Rentz, Kahrilas, Stanghellini, et al., 2004; Revicki, Rentz, Dubois, et al., 2004). The higher the score, the more severe the symptom. The PAGI-SYM includes a total of 20 items and includes the following subscales: nausea and vomiting, early satiety, bloating, upper abdominal pain, lower abdominal pain and heartburn and regurgitation. The total score is calculated by taking the mean of the subscores.

#### 2.1.2. Hospital Anxiety and Depression Survey (HADS)

The HADS questionnaire is a self-report scale for anxiety and depression. The 14 item survey is scored on a 4 point scale ranging from 0 to 3. A score of 8 or above is considered abnormal. The tool is reported to have good reliability and validity (Andrew, Barczak, & Allan, 1987; Zigmond & Snaith, 1983).

## 2.1.3. Gastroparesis and diabetes survey

A questionnaire developed for this study examined the impact of gastroparesis on diabetes related symptoms and control, with responses ranging from strongly agree (+2) to strongly disagree (-2) on a 5-point Likert scale. Six questions were asked: 1) Since developing gastroparesis, it has been more difficult to control my diabetes (blood sugar levels); 2) Since developing gastroparesis, it has required extra time and effort on my part to care for my diabetes; 3) Since developing gastroparesis, my blood sugars have been higher; 4) Since developing gastroparesis, I have had more frequent episodes of hypoglycemia (low blood sugar); 5) Since developing gastroparesis, I find that my gastroparesis symptoms improve if my blood sugar levels are controlled; and 6) Since developing gastroparesis, I find that my gastroparesis symptoms worsen if my blood sugar levels are high. In addition, patients were asked for if they were aware of their recent Hgb-A1c value. The patients were asked if they knew if they had

T1DM or T2DM, as well as questions to help differentiate T1DM from T2DM (age of onset of diabetes, weight at time of diagnosis of diabetes, initial treatment for diabetes, current treatment for diabetes, and if they ever had an episode of diabetic ketoacidosis). Face validity of the questionnaire was established using the expert opinions of gastroenterologists and endocrinologists and the questionnaire was piloted to access readability and comprehension.

# 2.2. Statistical methods

Descriptive variables are listed as percentages or means and SEMs, where appropriate. Student's t tests were used to determine significant differences (Portney Gross & Watkins, n.d.). In this exploratory study, no corrections were made for multiple comparisons. Pearson Product Moment Correlation was used to assess the association between variables. Pearson correlation, *r* was used to evaluate the strength and direction of relationship. Criteria used for defining a strong versus moderate versus weak association between variables consisted of the following: correlations ranging from 0.00 to 0.25 indicate little or no relationship; those from 0.25 to 0.50 suggest a fair degree of relationship; values of 0.50 to 0.75 are moderate to good; and values above 0.75 are considered good to excellent (Portney Gross & Watkins).

#### 3. Results

## 3.1. Patients

Table 1 shows the demographic and clinical information in the patients with diabetic gastroparesis subdivided into T1DM and T2DM. As expected, individuals with type 2 diabetes were older and heavier than the individuals with type 1 diabetes. Fifty four individuals with diabetic gastroparesis (36 T1DM and 18 T2DM) participated. Fifty percent of individuals were being treated with medications for their gastroparesis. Of the individuals receiving medications, 19 were taking metoclopramide, 4 were receiving domperidone and 6 were taking erythromycin. Two of the individuals were receiving two medications. All but 6 patients were taking insulin. The duration of diabetes averaged 17.4 years and the duration of gastroparesis averaged 5.1 years. As can be seen on Table 1, compared to T2DM, the T1DM subjects with gastroparesis had a higher HgbA1c and longer duration of diabetes. The duration of gastroparesis symptoms was not different in the 2 groups. Two thirds of the patient cohort for this study knew their recent Hgb-A1c levels.

Table 1	
Demographic and clinical information by grou	ps.

	All DGp	T1 DGp	T2 DGp	p value
	(n = 54)	(n = 36)	(n = 18)	T1 vs T2
Age (years) Gender	$\begin{array}{c} 44.2  \pm  2.0 \\ 37  {\rm f} / 17  {\rm m} \end{array}$	$\begin{array}{l} 40.1\pm2.4\\ 24~{\rm f}/12~{\rm m} \end{array}$	52.3 ± 2.9 13 f/5 m	0.004
Ethnicity Caucasian African American	35 12	24 7	11 5	
Latino Mixed	6 1	5	5 1 1	
BMI Age onset DM (yrs)	$37.1 \pm 1.1$ 26.4 + 2.2	$25.4 \pm 1.0$ 20.9 + 2.2	$30.5 \pm 2.3$ $38.7 \pm 3.4$	0.024 <0.001
Duration of Diabetes (yrs) Age onset Gp Sx (yrs)	$17.4 \pm 1.4$	$19.1 \pm 1.8$ $30.7 \pm 1.9$	$13.4 \pm 1.6$ $45.1 \pm 4.0$	0.058 <0.001
Duration of Gp (yrs) Hgb-A1c (%)	$5.0 \pm 2.1$ $5.1 \pm 1.1$ $8.17 \pm 0.21$	$6.0 \pm 1.5$ $8.50 \pm 0.21$	$3.0 \pm 0.8$ $7.39 \pm 0.40$	0.179
Patient aware of Hgb-A1c Gastric Retention, 2 h (%)	64.8% (35  of  54) 64.7 + 2.3	66.6% (24  of  36) 67.0 + 2.8	61.1% (11  of  18) 59.9 + 3.6	0.143
Gastric Retention, 2 h (%)	$37.3 \pm 2.8$	$42.1 \pm 3.7$	$39.9 \pm 3.0$ 28.0 ± 3.0	0.015

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