

Original Article

Correlation of Gastric Scintigraphy and Clinical Symptoms in the Diagnosis of Gastroparesis and its Impact on Quality of Life: A Pan India Real World Study

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ABSTRACT

Background: Gastroparesis with its varied etiology is one of the major health issues in India. Poor correlation between delayed gastric emptying and its symptoms is well-known. This study was planned to evaluate the proportion of confirmed gastroparesis by scintigraphy among patients with suggestive clinical features, their underlying aetiologies and clinical profiling in a real-world setting in India.

Settings and Design: Patients clinically diagnosed with gastroparesis, presenting varying degrees of symptoms for at least 12-weeks, were enrolled in this multicentric, cross-sectional, clinico-epidemiological study.

Results: Overall, 196/201 enrolled patients underwent gastric scintigraphy; 88 (45%) were found to be scintigraphically positive and 108 (55%) patients were only clinically positive. Underlying etiologies of gastroparesis were idiopathic (51.2%), type-2 diabetes (44.8%), type-1 diabetes (2.5%) and psychological conditions (1.5%). Most patients presented symptoms like postprandial fullness (75.6%), bloating (50.7%), abdominal pain (45.3%), nausea (41.3%), abdominal discomfort (40.3%), early satiety (37.8%) and vomiting (17.9%) of moderate severity. Common dietary risk factors were fatty diet (66.7%), fiber-rich food (57.7%) and carbonated drinks (18.9%). Weight loss (6.5%), esophagitis (5.5%) and electrolyte disturbances (0.5%) were the associated complications. About 89.8% were on proton-pump inhibitors, followed by prokinetics (51.8%) and antiemetics (8.4%). The mean PAGI-QoL score was 3.6 ± 0.94 , suggesting a moderate effect of gastroparesis on QoL.

Conclusion: Poor correlation exists between gastric scintigraphy and gastrointestinal symptoms, thus reiterating the significance of the clinical diagnosis of gastroparesis, especially in diabetes. Only about half of the patients were prescribed prokinetics, emphasizing the need for appropriate pharmacotherapy using prokinetics for holistic management of gastroparesis.

KEYWORDS: Delayed gastric emptying, gastroparesis, prokinetics, gastric scintigraphy.

Introduction

Gastroparesis is a condition characterized by a delay in gastric emptying associated with upper gastrointestinal symptoms, without mechanical obstruction.¹ Multiple etiologies govern gastroparesis, however, diabetes, post-surgical complications, and idiopathic causes account for the majority of gastroparesis cases.² Symptoms of gastroparesis (of varying severity) include early satiety, nausea, vomiting, postprandial fullness, abdominal pain/discomfort, and bloating. Patients with other upper gastrointestinal disorders like functional dyspepsia often experience similar symptoms, posing a challenge in diagnosing gastroparesis. The recommended diagnostic gold standard test for assessing gastric emptying is gastric scintigraphy carried out using a solid meal tagged with a radio-labelled compound like Technetium-99m sulphur colloid.³ Treatment approaches of gastroparesis are multimodal, based on etiology, co-morbid conditions, risk factors and/or associated complications. Prokinetics are commonly used for the management of gastroparesis, which offers prompt symptomatic relief.³

Although there is worldwide literature on gastroparesis, there is a paucity of evidence from the Indian milieu. A few Indian studies on type-2 diabetes (T2DM) patients have demonstrated hyperglycemia-mediated delayed gastric emptying⁴ and poor correlation of delayed gastric emptying with symptoms of gastroparesis.⁵ However, scarcity of data about contributing risk factors, etiologies, etc that are directive of the demographic and clinical profile among Indian population would offer impelling indication to undertake the present investigation.

Thus, this pan-India study was planned to understand the demographics and clinical profile of patients with gastroparesis. This study was also intended to assess the clinical history, risk factors, complications, impact on the quality of life (QoL), and diagnostic and management practices in Indian patients with gastroparesis.

Methodology

Study design and patient population

This multi-center, cross-sectional, clinico-epidemiological study was conducted between February 2017 and January

2018 across six centres in India (Jaipur, Bhopal [2 centers each], Guwahati, Hyderabad and Ahmedabad). Patients (≥ 18 years) diagnosed clinically based on symptoms of gastroparesis, viz. postprandial fullness, bloating, abdominal pain, nausea, abdominal discomfort, early satiety and vomiting and willing to participate were included in the study. Patients with obstruction of gastric outlet, small bowel or colon, gastro-intestinal haemorrhage or perforation, chronic cardiac, hepatic, neurological and/or renal diseases (as per physician discretion), and pregnant or lactating women were excluded from the study. In addition, patients who could not provide responses to QoL questionnaire and subsequent written authorization were also excluded from the study.

Severity of symptoms was assessed as mild, moderate and severe. Risk factors such as fatty diet, carbonated drinks and fibre diet were noted. Complications such as malnutrition, weight loss, esophagitis and electrolyte disturbances were noted.

Patients underwent assessment of gastric emptying by gastric scintigraphy, using a standard solid meal tagged with radiolabelled Technetium-99m. Four hours imaging technique with scans taken at 0, 1, 2 and 4 hours after ingestion of food was used.

Delayed gastric emptying was defined as $>60\%$ retention at 2 hours postprandially and/or $>10\%$ retention at 4 hours. Correlation of clinical symptoms and percentage positive gastric scintigraphy was obtained. Etiologies of gastroparesis were also noted.

The study protocol was approved by institutional ethics committees. The study was conducted in accordance with the principles of Declaration of Helsinki, International Council on Harmonization Good Clinical Practice (ICH GCP) guidelines, and Indian regulatory guidelines (Indian Council of Medical Research and Indian GCP guidelines). All patients provided written consent in the patient authorization form to participate in the study.

Study endpoints

The primary study endpoints included percentage of patients with confirmed gastroparesis by scintigraphy, and demographic characteristics (average age, gender, BMI, socio-economic status) of patients with gastroparesis.

The secondary endpoints included average duration for the development of gastroparesis from the diagnosis of underlying etiology, proportion of gastroparesis patients with various risk factors, co-morbidities and complications. Additionally, current treatment modalities for gastroparesis and QoL (by Patient Assessment of Upper Gastrointestinal Disorders -Quality of life [PAGI-QoL] score) were also assessed.

Study assessment tool (PAGI-QoL)

Disease (gastroparesis)-specific QoL was assessed by PAGI-QoL survey with scoring on a 6-point Likert scale. The questionnaire was administered by physician or designee. It was used to assess the patients' health related QoL within the last 2 weeks.⁶ It consisted of 30 items assessing five domains: Daily Activities, Clothing, Diet and Food Habits, Relationship, and Psychological Well-Being and Distress.^{7,8} The PAGI-QoL provides numerical values for QoL in patients with disordered gut motility.⁷

Overall PAGI-QoL scores are means of all factors after reversing individual scores; a mean PAGI-QoL score of 0 represents poor QoL while 5 reflects the best QoL.

Statistical methods

No formal sample size calculation was required for this study. Continuous variables were summarized using descriptive statistics: n (number of patients), mean and standard deviation. Summary of categorical data were evaluated using numbers and percentages. PAGI-QoL questionnaire was assessed by 2 sample t-test. All statistical analyses were done using Statistical Analysis System® version 9.4 software.

Results

Overall, 201 patients met the inclusion criteria of this study, which included 115 males (57.2%) and 86 females (42.8%) (mean [SD] age: 46.8 [14.17] years; **Table 1**).

Table 1: Demographics and Baseline Characteristics.

| Parameters | 18 -30 years N=33 (16.4%) | 31 -50 years N=86(42.8%) | >50 years N=82(40.8%) | Overall N=201(100%) |
|---------------------------------|------------------------------|-----------------------------|--------------------------|------------------------|
| Gender | | | | |
| Male | 22 (66.7%) | 49 (57.0%) | 44 (53.7%) | 115 (57.2%) |
| Female | 11 (33.3%) | 37 (43.0%) | 38 (46.3%) | 86 (42.8%) |
| Age (years) | | | | |
| Mean ± SD | 25.3 ± 3.40 | 41.7 ± 5.29 | 60.8 ± 6.97 | 46.8 ± 14.17 |
| Weight (kg) | | | | |
| Mean ± SD | 64.5 ± 9.57 | 68.3 ± 9.05 | 69.6 ± 9.50 | 68.2 ± 9.44 |
| Height (m) | | | | |
| Mean ± SD | 1.6 ± 0.07 | 1.6 ± 0.07 | 1.6 ± 0.07 | 1.6 ± 0.07 |
| BMI (kg/m²) | | | | |
| Mean ± SD | 23.7 ± 2.86 | 25.4 ± 2.78 | 25.8 ± 3.28 | 25.3 ± 3.08 |
| Waist circumference (cm) | | | | |
| Mean ± SD | 91.2 ± 7.61 | 93.3 ± 9.09 | 94.4 ± 9.09 | 93.4 ± 8.89 |
| Socio-economic class | | | | |
| Lower | 0 | 0 | 0 | 0 |
| Upper Lower | 0 | 5 (5.8%) | 6 (7.3%) | 11 (5.5%) |
| Lower Middle | 5 (15.2%) | 15 (17.4%) | 24 (29.3%) | 44 (21.9%) |
| Upper Middle | 27 (81.8%) | 58 (67.4%) | 42 (51.2%) | 127 (63.2%) |
| Upper | 1 (3.0%) | 8 (9.3%) | 10 (12.2%) | 19 (9.5%) |

Socio-economic status was assessed by Kuppuswamy classification

Most of the patients (63.2%) belonged to upper middle class based on Kuppuswamy scale of socio-economic status.

A total of 196 patients underwent the diagnostic procedure of gastric scintigraphy, of which 88 (45.0%) were scintigraphically positive while 108 (55.0%) were only clinically positive. Remaining 5 patients failed to undergo the procedure due to technical/personal reasons (**Figure 1**).

Dietary pattern and its correlation with gastroparesis symptoms

Dietary pattern analysis revealed that most patients consumed fatty diet (185, 92.0%), fibre rich food (167, 83.1%), excessively brewed tea (139, 69.2%), carbonated drinks (66, 32.8%) and coffee (56, 27.9%) (**Table 2**). Daily consumption of these foods with more than one serving was noticed maximally for excessively brewed tea, followed by fiber-rich food and fatty diet. Remarkably, a higher number of patients consumed more than one serving of fatty diet compared to fiber rich food and about one-fourth of the total patients consumed at least one serving of carbonated drink per day.

The symptoms of gastroparesis consisted of, but not limited to, postprandial fullness, bloating, early satiety, nausea, vomiting, abdominal pain and discomfort. These symptoms exacerbated in approximately 70% patients after consuming fatty diet (134, 72.4%) and fiber-rich food (116, 69.5%). Excessively brewed tea (40, 23.88%), carbonated drinks (38, 18.9%), and coffee (8, 4%) also exacerbated the symptoms. Presentation of the given symptoms in a specific time-period of a day was largely based upon the type of food consumed. Therefore, these dietary substances constitute one of the major risk factors leading to exacerbation of gastroparesis symptoms (**Table 3**).

Lifestyle habits

Overall, 38 (~20%) patients reported eating in position other than upright state (**Table 4**). Relatively higher number of patients reported consuming very spicy food (127, 63.2%) and going to bed immediately after completing the meal (129, 64.2%). In addition, a higher

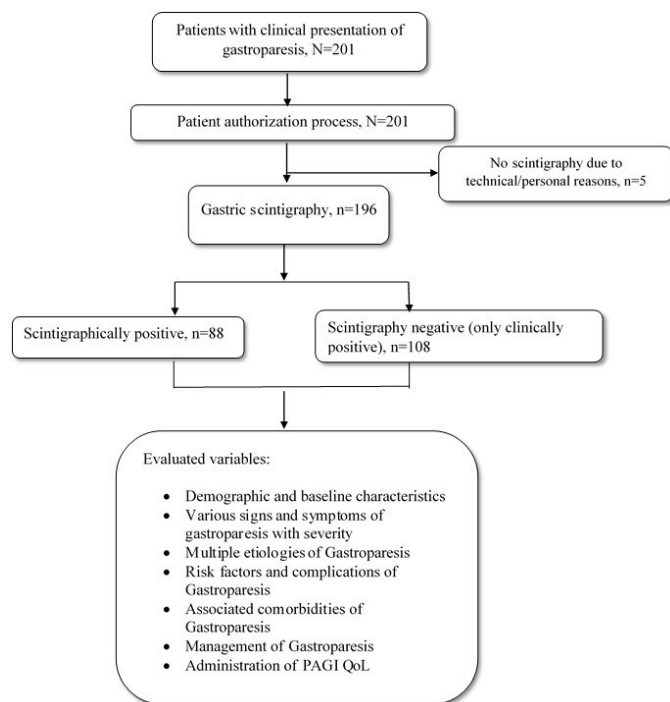


Figure 1: Study Design.

number of patients reported inactive (65, 32.3%) or sedentary (45, 22.4%) lifestyles.

Symptoms of gastroparesis

All enrolled patients presented with one or more of the classical symptoms of gastroparesis. Majority of the patients reported postprandial fullness (152, 75.6%); while approximately half of the patients had bloating (102, 50.7%) and abdominal pain (91, 45.3%). Other symptoms included nausea (83, 41.3%), abdominal discomfort (81, 40.3%), early satiety (76, 37.8%) and vomiting (36, 17.9%). These symptoms were of ‘moderate severity’ in most of the patients (**Figure 2**).

Complications of gastroparesis

Out of 201 patients, only 24 (~12%) presented with gastroparesis associated complications (**Table 3**). Weight loss was reported in 13 (6.5%) patients, which developed in a mean duration of 1.3±2.5 years. This was followed by esophagitis (11, 5.5%), with a mean duration of 0.3±0.3 years. Only 1 (0.5%) patient presented with electrolyte disturbances.

Table 2: Summary of Personal History.

| Parameters | Different Food Items | | | | | |
|---|------------------------|-------------------|--------------------------|---------------|-------------------------------|--------------|
| | Fiber Rich Food, n (%) | Fatty Diet, n (%) | Carbonated drinks, n (%) | Coffee, n (%) | Tea Excessively brewed, n (%) | Other, n (%) |
| Whether consumed frequently | | | | | | |
| Yes | 167 (83.1) | 185 (92.0) | 66 (32.8) | 56 (27.9) | 139 (69.2) | 4 (2.0) |
| Frequency | | | | | | |
| Daily | 125 (74.9) | 132 (71.4) | 10 (15.2) | 38 (67.9) | 128 (92.1) | - |
| Weekly | 42 (25.1) | 53 (28.6) | 25 (37.9) | 16 (28.6) | 11 (7.9) | 4 (100.0) |
| Monthly | - | - | 31 (47.0) | 2 (3.6) | - | - |
| Number of servings per day | | | | | | |
| 1 | 92 (55.1) | 78 (42.2) | 50 (75.7) | 41 (73.2) | 33 (23.7) | 1 (25.0) |
| 2-3 | 54 (32.3) | 79 (42.7) | 15 (22.7) | 15 (26.8) | 97 (69.8) | 2 (50.0) |
| 4-5 | 3 (1.8) | 14 (7.6) | 1 (1.5) | - | 6 (4.3) | 1 (25.0) |
| >5 | 18 (10.8) | 14 (7.6) | - | - | 3 (2.1) | - |
| Exacerbation of gastroparesis symptoms after consumption of food | | | | | | |
| Yes | 116 (69.5) | 134 (72.4) | 38 (57.6) | 8 (14.3) | 40 (28.8) | - |
| If Yes, please specify symptom | | | | | | |
| Nausea | 33 (28.4) | 34 (25.4) | 13 (34.2) | 2 (25.0) | 6 (15.0) | - |
| Abdominal pain | 14 (12.1) | 44 (32.8) | 2 (5.3) | 2 (25.0) | 9 (22.5) | - |
| Postprandial fullness | 74 (63.8) | 80 (59.7) | 10 (26.3) | 2 (25.0) | 15 (37.5) | - |
| Early satiety | 38 (32.8) | 34 (25.4) | 4 (10.5) | 1 (12.5) | 8 (20.0) | - |
| Bloating | 40 (34.5) | 40 (29.9) | 11 (28.9) | 3 (37.5) | 20 (50.0) | - |
| Vomiting | 6 (5.2) | 2 (1.5) | 2 (5.3) | - | - | - |
| Please specify time of the day when symptoms exacerbated | | | | | | |
| Morning | 53 (45.7) | 62 (46.3) | 2 (5.3) | 4 (50.0) | 20 (50.0) | - |
| Afternoon | 26 (22.4) | 59 (44.0) | 8 (21.1) | 4 (50.0) | 26 (65.0) | - |
| Night | 65 (56.0) | 92 (68.7) | 17 (44.7) | 2 (25.0) | 14 (35.0) | - |

Percentages were calculated based on total number of patients consuming a specific food item

Underlying etiology and average duration of gastroparesis development from diagnosis of etiology

The underlying etiology of gastroparesis for most patients was either idiopathic (103, 51.2%) or type 2 diabetes (90, 44.8%), while in few patients it was type 1 diabetes mellitus (5, 2.5%) or psychological disorders (3, 1.5%) (Table 5). Like the dietary pattern, the presentation of typical symptoms varied with the type of aetiology (Figure 3). The average duration of gastroparesis (mean±SD) development from diagnosis of T2DM, T1DM and

psychological disorders was found to be 58.2±55.82, 133.6±91.53 and 27.3±42.16 months respectively (Table 5).

Co-morbid conditions

About one-fourth (55, 27.4%) of the study patients reported co-morbidity/significant medical history. Most commonly reported co-morbidities were acid-peptic disease (32, 15.9%), hypertension (19, 9.4%), dyslipidaemia (18, 8.9%), and hypothyroidism (10, 4.9%).

Table 3: Summary of Risk Factors and Associated Complications of Gastroparesis.

| Risk Factors | Overall (N=201), n (%) |
|---|------------------------|
| Dietary factors and habits | |
| Fatty diet | 134 (66.7) |
| Fiber rich food | 116 (57.7) |
| Excessively brewed tea | 40 (19.9) |
| Carbonated drinks | 38 (18.9) |
| Coffee | 8 (4.0) |
| Lifestyle factors | |
| Less physical activity (sedentary and extremely inactive) | 110 (55.7) |
| Smoking | 5 (2.5) |
| Alcohol intake | 4 (2.0) |
| Associated complications | |
| Weight loss | 13 (6.5) |
| Esophagitis | 11 (5.5) |
| Electrolyte disturbances | 1 (0.5) |

Percentages were calculated based on overall number in the column header

Management of gastroparesis

Out of 201 patients, 166 (82.6%) were on pharmacotherapy (proton-pump inhibitors (147, 89.6%), prokinetics (84, 51.2%) and antiemetics (13, 7.9%) (Table 6). A higher proportion of patients (192, 95.5%) were asked to follow specific dietary measures like low-fat, low-fiber diet (163, 84.9%), small frequent meals (160, 83.3%), not to lie down immediately after eating (147, 76.6%), chew well/eat slowly (130, 67.7%) and avoid coffee, tobacco, carbonated drinks, and stress (61, 31.8%).

Quality of life (QoL)

Assessment of QoL score was performed for all 201 patients using PAGA-QoL questionnaire (Figure 4). The mean±SD total score was found to be 3.6±0.94, suggesting a moderately disturbed QoL in patients with gastroparesis.

Discussion

This study enrolled 201 patients from 6 different centres across the country. The majority of the patients enrolled in our study were aged 31-50 years, with a mean±SD age

GASTROPARESIS SYMPTOMS BY FREQUENCY AND SEVERITY

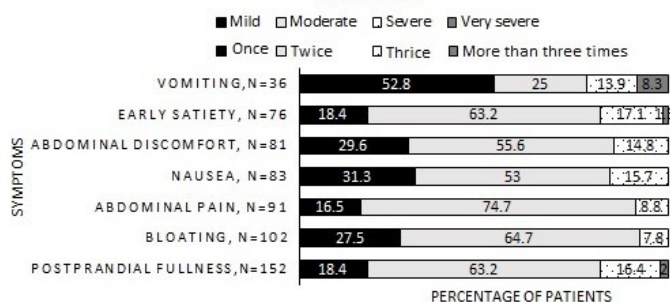


Figure 2: Gastroparesis Symptoms by Frequency and Severity. Percentage was calculated based on total number of patients presenting each symptom, only vomiting is studied by frequency, all other symptoms by severity.

of 46.8±14.17 years, which is in accordance with several reported studies.^{1,10} Based on the literature, the onset age of disease was found to be 13 years, but prevalence is reported to be higher in adults above 30 years compared to the younger population. This is likely due to multiple risk factors such as altered dietary and lifestyle habits, reduction in physical activity and development of comorbidities such as diabetes mellitus with age progression.^{1,10}

Table 4: Summary of Dietary/Lifestyle History

| Parameters | Overall (N=201) |
|---|-----------------|
| Do you have the habit of eating in the upright position | |
| Yes | 163 (81.1%) |
| No | 38 (18.9%) |
| Number of meals taken during a day | |
| < 3 | 107 (53.2%) |
| 3 | 78 (38.8%) |
| >3 | 16 (8.0%) |
| Do you eat a very spicy food | |
| Yes | 127 (63.2%) |
| No | 74 (36.8%) |
| Do you go to bed immediately after finishing the meal | |
| Yes | 129 (64.2%) |
| No | 72 (35.8%) |
| Average time required to finish daily meals (in minutes) | |
| Mean ± SD | 17.3 ± 8.21 |
| Physical activity level of patient, (n=201) | |
| Extremely active | 10 (5.0%) |
| Vigorously active | 13 (6.4%) |
| Moderately active | 68 (33.8%) |
| Sedentary | 45 (22.4%) |
| Extremely inactive | 65 (32.3%) |
| Type of exercise, (n=136) | |
| Brisk walking | 32 (23.5%) |
| Cardio | 6 (4.4%) |
| Jogging/running | 30 (22.0%) |
| Yoga | 22 (16.2%) |
| Multiple types of exercise [4] | 46 (33.9%) |
| No. exercise (in hours per day), (n=136) | |
| Mean ± SD | 0.4 ± 0.33 |

Percentages were calculated based on overall number in the column header

Table 5: Summary of Average Duration for Development of Gastroparesis from the Diagnosis of Underlying Etiology

| Average duration (in months), n (%) | Mean ± SD (months) |
|-------------------------------------|--------------------|
| T1DM, (n=5) | 133.6 ± 91.53 |
| T2DM, (n=90) | 58.2 ± 55.82 |
| Idiopathic, (n=103) | NA |
| Psychological disorder, (n=3) | 27.3 ± 42.16 |

Table 6: Summary of Patients Treated with Various Modalities for Gastroparesis

| Category, n (%) [1], | Overall (N=201), n (%) |
|---|------------------------|
| Pharmacotherapy given | |
| Yes | 166 (82.6) |
| No | 35 (17.4) |
| If Yes | |
| Proton pump inhibitors | 149 (89.8) |
| Prokinetics | 86 (51.8) |
| Antiemetics | 14 (8.4) |
| Other specify | 6 (3.6) |
| Neuropathic pain modulators | 5 (3.0) |
| Antidepressants | 1 (0.6) |
| Patient asked to follow any dietary measures | |
| Yes | 192 (95.5) |
| No | 9 (4.5) |
| If yes, it included | |
| Low- fat, low-fiber diet | 163 (84.9) |
| Small frequent meals i.e. - meals per day | 160 (83.3) |
| Do not lie down immediately after eating | 147 (76.6) |
| Chew well and eat slowly (mince meals) | 130 (67.7) |
| Avoid coffee, tobacco, carbonated drinks, stress | 61 (31.8) |
| Other | 1 (0.5) |

Percentages were calculated based on overall number in the column header

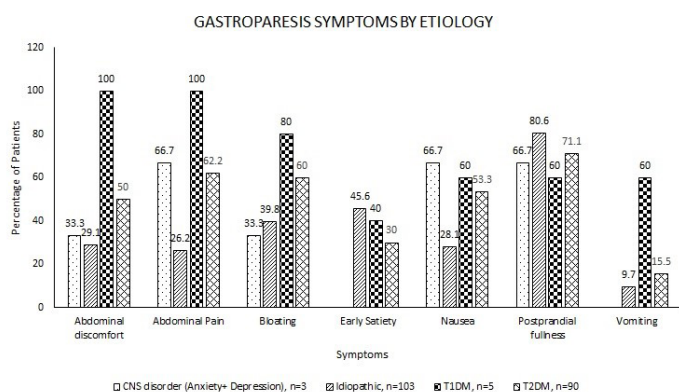


Figure 3: Gastroparesis Symptoms by Etiology. Patient percentages are calculated based on total number of patients under each etiology.

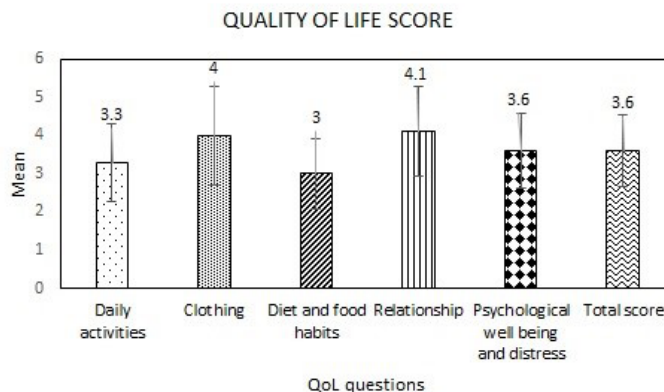


Figure 4: PAGA-QoL Score. PAGA-QoL instrument consisted of 30 items, each with response options based on a 6-point Likert scale, PAGA-QoL scores range from 0 (lowest QoL) to 5 (highest QoL).

Unlike the earlier data reporting female preponderance,¹¹ our population was male predominant. This may be due to the unwillingness of female patients to participate in a clinical study due to a lack of awareness and social barriers. The mean \pm SD weight (kg), height (m), BMI (kg/m²) and waist circumference (cm) of overall patients were 68.2 ± 9.44 , 1.6 ± 0.07 , 25.3 ± 3.08 and 93.4 ± 8.89 , respectively, which was in line with the earlier reports.^{1,11,12}

Socio-economic status revealed that most patients belonged to the upper-middle class. Moreover, most of the patients in our study had sedentary or extremely inactive lifestyle and altered dietary habits such as fatty diet, fibre-rich food, and carbonated drinks, which are known risk factors for gastroparesis and associated symptoms.

Gastric emptying scintigraphy of a solid-phase meal is considered as the standard for diagnosis of gastroparesis, as it quantifies the emptying of a physiologic caloric meal.^{13,14} Many studies have demonstrated poor correlation between the classical symptoms and delayed gastric emptying.^{1,15,17} In this study, gastric scintigraphy was performed on 196 patients, of which only 88 (45.0%) were scintigraphically positive while 108 (55.0%) were only clinically positive. This finding highlights the importance of clinical diagnosis of gastroparesis for early patient identification and appropriate management. This discordance between symptoms and scintigraphy test is probably because factors in addition to slow gastric emptying contribute to symptoms. Furthermore, higher inter-individual and intra-individual variability in gastric emptying rates is considered a limitation of gastric emptying (motor) testing.¹⁴ Another cause of discordance could be because gastric emptying even as measured by standardized testing can vary with time in the same patient. So, labelling a patient as having gastroparesis (or not) based on a single point in time may not be accurate.¹⁶ It is also not known whether measuring gastric emptying of a standardized meal diet reflects what happens chronically in patients' real life, which depends on the nature and the quantity of food consumed. More importantly, there is also a discrepancy between liquid and solid-phase gastric emptying, and if only the later were measured, a significant number of patients would have been missed. So, gastric emptying is only one (and

perhaps the most extreme) manifestation of disordered gastric motility. Subtle forms of dysmotility within different regions of the stomach may be more responsible for the pathogenesis of symptoms rather than the overall delayed gastric emptying. This fact may account for the lack of correlation between symptoms and results of gastric scintigraphy testing.¹⁶

Impairment of gastric function is associated with symptoms that are typically exacerbated due to specific food intake. Therefore, dietary risk factors leading to gastroparesis were also studied in the enrolled population. Maximum patients consumed a fatty diet, followed by fibre-rich food, excessively brewed tea, carbonated drinks, and minimally coffee. These observations corroborate an earlier study that recommended low-calorie food for gastroparesis patients in addition to dietary modifications.¹⁸

It is also known that the cardinal symptoms of gastroparesis largely remain the same, irrespective of the etiology, but with varying intensity.³ In our study, the symptoms of gastroparesis were recorded to be of moderate severity in the order of postprandial fullness > bloating > abdominal pain > early satiety > nausea and vomiting, which is consistent with the reported literature.¹⁹ However, some studies have reported vomiting in diabetes and abdominal pain in idiopathic gastroparesis as the most common symptoms.^{3,20,21}

Complications associated with gastroparesis based on scintigraphy were monitored in all enrolled patients, of which only ~12% presented with complications that included weight loss, followed by esophagitis and electrolyte disturbances. This observation corresponds with the reported literature.^{10,22} Timely diagnosis and suitable treatment will aid in preventing complications which in turn would help in improving the QoL of patients.

Major causes of gastroparesis are reported to be diabetes, idiopathic, and post-surgical.²³ In this study, we observed the underlying etiologies to be idiopathic and T2DM in the majority of patients, while few patients had T1DM and psychological conditions (anxiety and depression) as a cause for gastroparesis, which is in agreement with the reported literature.²³ Furthermore, this is the first of its kind study to investigate the average duration of gastroparesis development from the

diagnosis of underlying etiology. The mean \pm SD time of gastroparesis development from T1DM incidence was 133.6 ± 91.53 months, whereas after T2DM incidence was 58.2 ± 55.82 months and from psychological disorder was 27.3 ± 42.16 months. This observation might aid in considering prophylactic measures of gastroparesis once a patient is diagnosed with a primary disease.

Among 201 patients, 27.4% presented significant medical history. Of these, most patients reported a history of acid-related disorders. Reported literature has shown a strong co-relation between gastroesophageal reflux disease (GERD) with gastroparesis.²⁰ Additionally, patients also reported comorbid conditions like dyslipidemia, hypertension, and hypothyroidism.²⁴ Thus, the clinician should give due consideration to such comorbid conditions while evaluating patients with gastroparesis.

Management of gastroparesis for its symptoms is crucial to maintain patients QoL. Among 201 patients, 82.6% were given pharmacotherapy. Of the treated cohort, the majority of patients were on proton pump inhibitors (rabeprazole, pantoprazole, omeprazole, esomeprazole, and lansoprazole), followed by prokinetics (domperidone, levosulpiride, itopride, and acotiamide) and antiemetics (ondansetron and metoclopramide). Proton pump inhibitors may help in reducing the symptoms of hyperacidity but may not be adequate in controlling dysmotility symptoms. Prokinetic agents help augment gastric motility, thus are recommended for prompt symptomatic relief in gastroparesis patients.¹ According to the American Gastroenterological Association (AGA) guidelines for gastroparesis, the primary therapy indicated for gastroparesis is dietary manipulation, combined with the administration of prokinetic and antiemetic agents.²⁵ Our study recorded only 51% patients on prokinetics, which could be the reason for persisting gastrointestinal symptoms, affecting overall QoL. Therefore, there is a need for knowledge dissemination on the role of prokinetics in addressing the symptoms of gastroparesis for holistic management in such patients.

Gastroparesis has a significant impact on the patients' QoL, either due to the primary disease or due to associated symptoms and complications. The mean \pm SD (Min: Max) total score on the PAGI-QoL was found to be 3.6 ± 0.94 (0.7: 4.8), suggesting a moderate effect of

gastroparesis on patients' QoL. This is in concordance with literature reporting the negative impact of gastroparesis on patients QoL.^{10,20}

Our study has several strengths. This is the first of its kind, pan India study which elucidated demographic and clinical profiling of gastroparesis. Patients of varying ages, socioeconomic status were evaluated. Our study has used standard and validated methods for diagnosis of gastroparesis giving credibility to the results reported. All the questionnaires used in the study were administered to the patients by a physician or a designee, which enabled them to capture information with greater accuracy and confidentiality. This study generated vital information that augmented the understanding and awareness of clinical profiling, diagnosis, and management of Indian patients with gastroparesis. However, this study also has some limitations. This was a single visit study and lacked long-term outcome data. Further, being a non-interventional study, no data were collected on the altered treatment modalities.

Conclusion

This study reiterates the significance of the clinical diagnosis of gastroparesis, especially in patients with diabetes. Gastric scintigraphy studies, the gold standard for diagnosis of gastric emptying, has poor correlation with clinical symptoms of gastroparesis. Gastroparesis moderately affected the QoL of these patients. About half of the patients were prescribed prokinetics, emphasizing the need for appropriate pharmacotherapy using prokinetics for the holistic management of gastroparesis.

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