

This is a **Sample** version of the  
**Gastroparesis Cardinal  
Symptom Index (GCSI)**

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- GCSI Overview information
- GCSI Scoring/ Administration instructions
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# Development and validation of a patient-assessed gastroparesis symptom severity measure: the Gastroparesis Cardinal Symptom Index

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## SUMMARY

*Background:* Patient-based symptom assessments are necessary to evaluate the effectiveness of medical treatments for gastroparesis.

*Aim:* To summarize the development and measurement qualities of the Gastroparesis Cardinal Symptom Index (GCSI), a new measure of gastroparesis-related symptoms.

*Methods:* The GCSI was based on reviews of the medical literature, clinician interviews and patient focus groups. The measurement qualities (i.e. reliability, validity) of the GCSI were examined in 169 gastroparesis patients. Patients were recruited from seven clinical centres in the USA to participate in this observational study. Patients completed the GCSI, SF-36 Health Survey and disability day questions at a baseline visit and again after 8 weeks. Clinicians independently rated the severity of the patients' symptoms, and both clinicians and patients rated

the change in gastroparesis-related symptoms over the 8-week study.

*Results:* The GCSI consists of three sub-scales: post-prandial fullness/early satiety, nausea/vomiting and bloating. The internal consistency reliability was 0.84 and the test-re-test reliability was 0.76 for the GCSI total score. Significant relationships were observed between the clinician-assessed symptom severity and the GCSI total score, and significant associations were found between the GCSI scores and SF-36 physical and mental component summary scores and restricted activity and bed disability days. Patients with greater symptom severity, as rated by clinicians, reported greater symptom severity on the GCSI. The GCSI total scores were responsive to changes in overall gastroparesis symptoms as assessed by clinicians ( $P = 0.0002$ ) and patients ( $P = 0.002$ ).

*Conclusion:* The findings of this study indicate that the GCSI is a reliable and valid instrument for measuring the symptom severity in patients with gastroparesis.

## INTRODUCTION

Gastroparesis is a chronic gastrointestinal disorder defined by delayed gastric emptying of food solids with or without liquids. Gastroparesis is suspected on the basis of clinical symptoms, such as post-prandial

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# Gastroparesis Cardinal Symptom Index (GCSI)

## Scoring & administration instructions

### Overview:

Most gastroparesis clinical studies rely on patient reports of symptoms, either based on physician interviews or patient-completed questionnaires. We developed a patient-based symptom instrument, the GCSI, to assess the severity of gastroparesis-related symptoms for clinical trials. The GCSI total score was based on a combination of nausea/vomiting, postprandial fullness/early satiety and bloating sub-scales.

Based on the results of this study, the GCSI is a reliable measure of symptom severity, and we have documented evidence supporting the construct validity and responsiveness of the GCSI in gastroparesis patients. The reliability of the GCSI is acceptable for group level comparisons.<sup>29, 30</sup> The findings suggest that the GCSI total scores are internally consistent and have excellent reproducibility.

Patients reporting greater gastroparesis-related symptom severity also report greater numbers of bed disability and restricted activity days. The findings demonstrate that, as the mean GCSI score increases, a greater number of disability days are reported. A similar relationship is observed between the GCSI score and the number of restricted activity days: as the mean GCSI score increases, indicating greater symptom severity, an increasing frequency of restricted activity days is reported.

In conclusion, the GCSI is a relatively brief symptom severity instrument for gastroparesis with demonstrated reliability and evidence supporting construct validity and responsiveness to change in clinical status.

### Scoring:

The GCSI consists of three subscales selected to measure important symptoms related to gastroparesis: nausea/vomiting (three items), post-prandial fullness/early satiety (four items) and bloating (two items).

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## Gastroparesis Cardinal Symptom Index (GCSI)

This questionnaire asks you about the severity of symptoms you may have related to your gastrointestinal problem. There are no right or wrong answers. Please answer each question as accurately as possible.

For each symptom, please circle the number that best describes how severe the symptom has been during the past 2 weeks. If you have not experienced this symptom, circle 0. If the symptom has been very mild, circle 1. If the symptom has been mild, circle 2. If it has been moderate, circle 3. If it has been severe, circle 4. If it has been very severe, circle 5. Please be sure to answer every question.

Please rate the severity of the following symptoms during the past 2 weeks.

	None	Very Mild	Mild	Moderate	Severe	Very Severe
1. nausea (feeling sick to your stomach as if you were going to vomit or throw up)	0	1	2	3	4	5
2. retching (heaving as if to vomit, but nothing comes up)	0	1	2	3	4	5
3. vomiting	0	1	2	3	4	5

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