Real-World Healthcare Resource Utilization of Patients Treated with Metoclopramide Nasal Spray for Diabetic Gastroparesis (DGP)

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Background and Objectives

- **Diabetic gastroparesis (DGP) is a chronic disorder of the stomach characterized by delayed gastric emptying and debilitating symptoms,** including nausea, vomiting, early satiety, bloating, and abdominal pain.[1]
- The mainstay of treatment for DGP over 40 years has been oral metoclopramide however nausea and vomiting interfere with oral intake of medications leaving patients poorly controlled and requiring further intervention.[2,3]
- Unpredictable gastric emptying causing altered absorption of oral drugs, including oral hypoglycemic drugs, may results in poor glucose control.[4]
- Patients with DGP experience:
  - **3x greater emergency room costs,**
  - **3x greater inpatient admission costs, and**
  - **2x greater outpatient costs,**

  compared to non-gastroparesis, diabetic patients.[5]
- In June 2020, **metoclopramide (MCP) nasal spray, (GIMOTI®) became the first non-oral outpatient treatment** FDA approved for patients with acute and recurrent DGP based on comparative bioavailability and a single-dose, crossover pharmacokinetic study.[6,7]
- In a Phase 3 double-blind, placebo-controlled trial, subjects in the moderate-to-severe nasal MCP cohort experienced **a significant reduction in nausea and upper abdominal pain (*P*<0.05)** compared to the placebo group although the study did not meet its primary endpoint of a reduction in total symptom score at week four (*P*=0.881) for all patients.[8]
- With >2 years post-approval, real-world experience, the aims of this study were to examine healthcare resource utilization (HCRU) among nasal MCP-treated patients.

Methods

- Retrospective cohort study of patients receiving nasal MCP.
- Specialty pharmacy data from EVERSANA™ were linked to the Symphony Integrated DataVerse® (SID) via Datavant Tokenization and matching, a process that allows for the de-identification of patient health information and subsequent relinkage with other datasets.
- Patients ≥18 years of age with a dispense of nasal MCP after approval (06/22/2020) were selected.
- Patients were required to have ≥6 months pre-index (nasal MCP dispense date) and ≥6 months post-index (**Figure 1**).
- HCRU was described as physician office (PO), hospital outpatient (HO), inpatient hospitalization, and emergency department (ED) visits.
- Visits were categorized using a combination of place of service and common procedural terminology codes for evaluation and management.
- Mean, all-cause and separately DGP-related (nausea/vomiting and gastroparesis) visits were calculated in the six-month interval prior to MCP Nasal initiation (pre-period) vs. the six-month interval post-initiation of MCP Nasal (post-period).
  - Nausea, vomiting, and gastroparesis-related HCRU were assessed by examining only insurance claims with ICD-10 diagnosis codes specific to each condition.
- A comparison of the pre-period and post-period HCRU was assessed using the Wilcoxen signed-rank test.

Figure 1: Study Cohort Selection Criteria

Steps

1. **1,569** Number of patients with a record of prescription for GIMOTI® from EVERSANA™ Specialty Pharmacy.*
2. **879** Any patients with matching Datavant Tokenization between specialty pharmacy and SID Database.
3. **602** Number of patients who initiated treatment with GIMOTI®.†
4. **315** Number of patients with at least one medical and pharmacy claim in SID Database.
5. **294** At least one medical or pharmacy claims more than six months prior to date of treatment initiation with GIMOTI® and six months or more following initiation of GIMOTI®.

* A written prescription does not indicate the patient received GIMOTI®. Patients who may not receive GIMOTI®, do plan denials or other factors.

† Record of ≥1 dispense of GIMOTI® from EVERSANA™ Specialty Pharmacy.

Results

Demographics and Clinical Characteristics

- Of the 294 patients meeting the study criteria, 77% were female **(Figure 1a)**.
- Mean age at initiation of MCP was 52.1 years (SD=14.0).
- 69% of patients were commercially insured.
- Mean Charlson Comorbidity Index score was 1.7 (SD=1.8).

Figure 1a

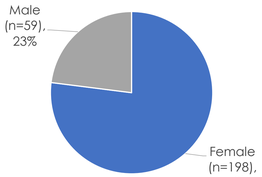
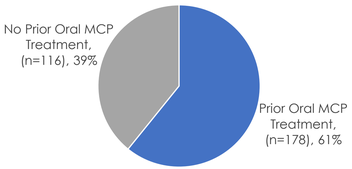


Figure 1b



Treatment Characteristics

- Of the 294 patients, 60.5% (n=178/294) had a history of oral MCP utilization prior to initiation of GIMOTI® **(Figure 1b)** and 43.8% (n=129/294) utilized oral MCP in the immediate six months prior to initiation of GIMOTI®.
- Mean duration of oral MCP prior to GIMOTI® was **8.1 months** (SD=12.5).
- During GIMOTI® treatment, patients received an **average of 2.6 prescriptions** (SD=2.4) for GIMOTI® during the six-month follow-up period.

HCRU

- For DGP-related HCRU (**Figure 2a**), both PO and HO visits declined in the post-period vs. pre-period, respectively (PO=0.18 vs. 0.29, *p*<0.01; HO=1.6 vs. 1.0, *p*<0.01).
- The **mean number of all-cause PO visits was significantly less** in the post-period at 2.0 compared to the pre-period at 2.2 (*p*=0.03, **Figure 2a**).
- There were fewer inpatient hospitalizations and ED visits both all-cause and DGP related although statistical significance was not achieved (**Figure 2b**).

Figure 2a: Nausea, vomiting, and DGP-associated HCRU in the pre-nasal MCP period vs. post-nasal MCP period

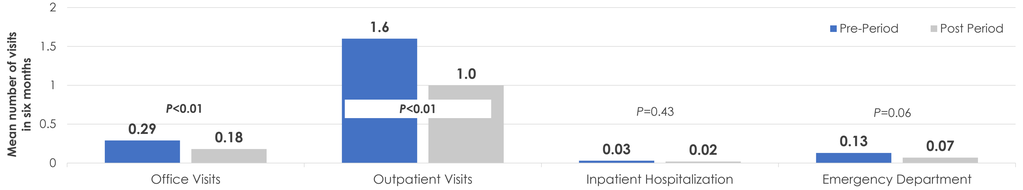
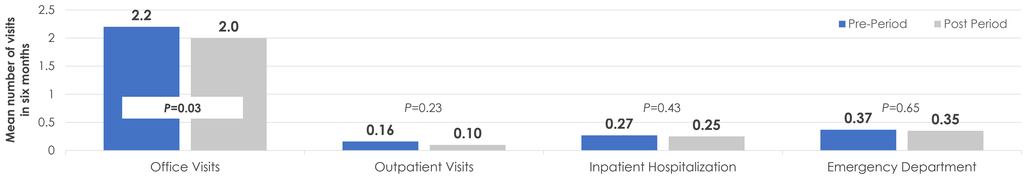


Figure 2b: All-cause HCRU in the pre-nasal MCP period vs. post-nasal MCP period



Discussion

- **DGP is a debilitating outcome of diabetes which leads to significant HCRU due to delayed gastric emptying resulting in poor absorption of oral therapies, including oral MCP.**
- **Patients using nasal MCP for the treatment of DGP experienced significantly fewer all-cause PO visits in the six-month period following treatment compared to the six-month period prior treatment and significantly reduced DGP-related utilization of outpatient (office or hospital) resources.**
- **Fewer PO visits overall and DGP-related hospital outpatient visits may be related to better control of symptoms, considering ~44% of patients were treated with oral MCP in the six months prior to receiving nasal MCP.**
- **A matched comparison of HCRU outcomes between patients treated with nasal MCP compared to oral MCP is ongoing to test this hypothesis.**

Abbreviations DGP = diabetic gastroparesis; ED = emergency department; HCRU = healthcare resource utilization; HO = hospital outpatient; ICD-10 = International Classification of Diseases-10th Revision; MCP = metoclopramide; PO = physician office; SD = standard deviation; SID = Symphony Integrated DataVerse®.

References **1.** Horowitz M et al., *Diabetologia.* 1989; 32:151-9. **2.** Shakhatreh M et al., Metoclopramide for the treatment of diabetic gastroparesis. *Exper Rev Gastronenterol Hepatol.* 2019; 13(8):711-721. **3.** Lata PF, Pigarelli DL. *Ann Pharmacother.* 2003;37(1):122-126. **4.** U.S. FDA Gastroparesis Clinical Evaluation of Drugs for Treatment Guidance for Industry. August 2019. **5.** Chen YJ et al., *Am J Gastroenterol.* 2020;115 (Supplement):686-687. **6.** GIMOTI® (metoclopramide) nasal spray [prescribing information]: Solana Beach, CA: EVOKE PHARMA®; 2021. **7.** Gajendran M et al., Metoclopramide nasal spray for management of symptoms of acute and recurrent diabetic gastroparesis in adults. *Expert Rev Endocrinol Metab.* 2021; 16(2):25-35. **8.** McCallum RW et al., Poster presented at: Digestive Disease Week 2017; Washington, DC.

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