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Domperidone vs Metoclopramide: Comparative Evaluation of Efficacy in Treating Diabetic Gastroparesis

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ABSTRACT

Gastroparesis represents a diabetes-related condition that causes diabetic patients to experience nausea, vomiting, and bloating. **Objectives:** To evaluate the effectiveness of Domperidone and Metoclopramide for gastric emptying improvement and gastrointestinal symptom reduction in patients with diabetic gastroparesis. **Methods:** A total of participants were n=76. Data collection occurred through a study of diabetes patients with gastroparesis who were given Domperidone (10 mg three times daily) or Metoclopramide (10 mg three times daily) for six weeks. The researchers evaluated gastric emptying half-time (T½) as the main outcome, while considering symptoms of nausea, vomiting, and bloating. The study evaluated both negative side effects and participant medication adherence. **Results:** The gastric emptying reduction using Domperidone exceeded that of Metoclopramide following administration to patients, as Domperidone decreased T½ from 125.6 ± 18.4 minutes to 98.2 ± 15.6 minutes while Metoclopramide decreased T½ from 124.8 ± 17.9 minutes to 107.5 ± 16.9 minutes ($p = 0.04$). The patients who received Domperidone reported better decreases in nausea, vomiting, and early satiety symptoms than those who received Metoclopramide ($p=0.03$, $p=0.02$, and $p=0.04$). The occurrence of extrapyramidal symptoms together with QT prolongation proved more common in patients treated with Metoclopramide. Compliance was similar between groups. **Conclusions:** Diabetic patients with gastroparesis experienced superior gastric motility response and symptom relief after taking domperidone compared to metoclopramide, along with better outcomes regarding extrapyramidal symptom development.

INTRODUCTION

Diabetes mellitus (DM) is a common disease that affects millions of people worldwide. According to the latest data from the International Diabetes Federation (IDF), about 463 million people are living with diabetes, and this number is expected to rise. DM is a major health concern due to its complications, which can affect the heart, kidneys, and nerves. In addition to these issues, many diabetic patients also experience digestive problems, particularly with the movement of food through the stomach. One such condition, known as delayed gastric emptying (GE), can occur in up to 50% of people with type 1 or type 2 diabetes. This condition may cause symptoms like indigestion and gastroparesis, though some individuals may not experience any noticeable issues [1]. The gastrointestinal condition diabetic gastroparesis (DG) develops from diabetes mellitus complications by causing delayed stomach emptying, but excluding any physical blockages [2]. Diabetic gastroparesis impacts patients who have diabetes of long duration, especially those who maintain subpar blood sugar management [3]. Nausea, vomiting, bloating, and early satiety with abdominal discomfort result as serious symptoms from diabetic gastroparesis

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affecting the quality of patient life [4]. Diabetic gastroparesis places a significant burden on individuals with diabetes and the healthcare system. Despite its impact, the condition is often underdiagnosed and challenging to manage. This epidemiology, pathophysiology, clinical presentation, diagnostic approach, and treatment options for diabetic gastroparesis. The disorder is defined by delayed gastric emptying in the absence of mechanical obstruction and typically manifests with upper gastrointestinal symptoms such as nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal discomfort. [5]. An unpredictable food absorption pattern emerges from delayed gastric emptying in diabetic patients, causing complications with blood glucose control and exposing individuals to dangerous high and low blood glucose risk. Regular hospital admissions also occur because gastroparesis causes patients' development of nutritional issues, combined with subpar food management [6]. The leading approach to managing diabetic gastroparesis is through speeding up the stomach emptying process using medicines. The two principal medications utilized for the treatment of health conditions are Domperidone and Metoclopramide, and healthcare providers utilize them frequently for their patients [7]. The dopaminergic activity of dopamine antagonist drugs exhibits chemical similarity between Metoclopramide and Domperidone, yet their therapeutic benefits, side effects, and safety properties show significant differences between the two medications [8]. Medicating with domperidone through the gastrointestinal tract prevents dopamine receptors in the stomach from functioning to increase digestive movement without affecting the central nervous system. Metoclopramide produces extrapyramidal side effects, including dystonia, together with tardive dyskinesia and akathisia after crossing the blood-brain barrier because it functions as a dopamine antagonist like Domperidone [9]. Domperidone was used for the treatment of gastroparesis because it helps speed up stomach emptying and controls both nausea and vomiting symptoms. Health agencies restrict Domperidone distribution to certain areas because it carries a risk of QT prolongation, which makes patients vulnerable to arrhythmias. Clinical practitioners currently use metoclopramide to treat diabetic gastroparesis, although persistent long-term application raises worries about its capability to produce extrapyramidal side effects [3]. Both Domperidone effectiveness for treating gastroparesis symptoms by improving gastric emptying according to scientific research findings.

Research about these treatments mostly studied older adults but failed to provide sufficient evidence regarding their effectiveness and safety for younger patients [10]. The existing research gap regarding treatment options for diabetic gastroparesis will be addressed through direct comparison of Domperidone and Metoclopramide medications in a patient sample to evaluate both treatment effectiveness and adverse effect specifically targeting extrapyramidal symptoms and QT prolongation. This study aims to evaluate the effectiveness and security of Domperidone and Metoclopramide for gastric emptying improvement and gastrointestinal symptom reduction in patients with diabetic gastroparesis.

METHODS

It was a cross-sectional study and conducted from June 2024 to December 2024 at Combined Military Hospitals, Lahore. Ethical permission was taken from the ethical review board of Combined Military Hospital, Lahore, and granted ethical permission no (A/24/EC/454/2023). The participants' age range was 18-55 years. The required sample size was calculated using the WHO sample size calculator with the following assumptions: power = 80%, confidence level = 95%, significance level ( ) = 0.05, and expected mean difference in gastric emptying half-time (T½) of 10 minutes, with a standard deviation of 15 minutes based on prior studies. This yielded a required sample of 76 participants and split the participants evenly between the Domperidone (n=38) and Metoclopramide (n=38) groups. After eligibility screening and informed consent, participants were assigned to either the Domperidone or Metoclopramide group using a simple randomization method. A computer-generated random sequence was used to ensure random allocation. To maintain allocation concealment and minimize selection bias, sequentially numbered, sealed opaque envelopes were used to distribute participants into treatment groups. This method ensured that both the researchers and participants remained unaware of group assignment at the time of enrollment. Patients met the study criteria when they were diagnosed with diabetic gastroparesis through clinical signs such as presenting symptoms of nausea and vomiting, bloating, and early satiety, which required confirmation by gastric scintigraphy or breath test. The inclusion criterion referred to glycemic stability rather than optimal glycemic control. The study excluded patients who demonstrated QT prolongation or neurological disorders or had a history of gastrointestinal surgery and those using medications affecting gastric motility, alongside pregnant and lactating women. Each patient received either Domperidone 10 mg or Metoclopramide 10 mg three times daily for six weeks. The research evaluated gastric emptying half-time (T½) when measuring it both before treatment and after medication interventions. The research measured symptom severity levels using a 1-5-point Likert scale for nausea, vomiting, bloating, and early

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satiety while recording adverse effects as secondary results. The monitoring method for patient compliance relied on counting pills and self-report measures of medication usage. The data were analyzed by SPSS software version 21.0. Normality test was applied, and data were normally distributed. Statistical analysis was performed using paired t-tests for within-group comparisons and independent t-tests for between-group differences, with a p-value of < 0.05 considered statistically significant. The study was approved by the Institutional Review Board (IRB) and adhered to ethical guidelines in accordance with the Declaration of Helsinki.

RESULTS

The study participants from both the Domperidone and Metoclopramide groups exhibited identical baseline traits because their demographic data matched without any substantial variation. All variables presented p-values that exceeded the 0.05 threshold during initial measurements, thus establishing similarity between the Domperidone and Metoclopramide study groups (Table 1).

Table 1: Baseline Characteristics of Study Participants

Characteristics	Domperidone (n=38)	Metoclopramide (n=38)	p-value
Age (Years, Mean ± SD)	52.4 ± 8.3	50.8 ± 9.1	0.65
Gender (M/F)	17/21	19/19	0.76
Duration of Diabetes (years)	8.2 ± 2.5	7.9 ± 2.8	0.81
HbA1c (%)	7.6 ± 0.9	7.5 ± 1.0	0.89
Baseline Gastric Emptying T½ (min)	125.6 ± 18.4	124.8 ± 17.9	0.91

Both Domperidone and Metoclopramide groups achieved improved gastric emptying T½ values as their primary treatment effect. The study results showed significant differences in T½ reduction, where Domperidone achieved greater results by shortening the time from 125.6 ± 18.4 minutes to 98.2 ± 15.6 minutes compared to Metoclopramide, which shortened the time from 124.8 ± 17.9 minutes to 107.5 ± 16.9 minutes. The comparison between groups produced a statistically significant difference because the p-value reached 0.04. Gastric emptying improvements showed significantly greater effects with Domperidone compared to Metoclopramide based on the measured change in T½ value (Table 2).

Table 2: Primary Outcome – Gastric Emptying Half-Time (T½) Improvement

Characteristics	Domperidone (n=38)	Metoclopramide (n=38)	p-value
Baseline T½ (min, Mean ± SD)	125.6 ± 18.4	124.8 ± 17.9	0.91
Post-Treatment T½ (min, Mean ± SD)	98.2 ± 15.6	107.5 ± 16.9	0.04*
Mean Change in T½ (min)	27.4 ± 6.2	17.3 ± 5.8	0.02*

*p<0.05 indicates statistical significance

Domperidone treatment showed statistically significant reduction of vomiting and nausea, accompanied by p-values of 0.03 and 0.02 when compared to Metoclopramide treatment. The analysis proved that bloating decreased in both groups of patients, yet researchers observed no significant statistical divergence (p=0.07). Dry mouth symptoms decreased to a greater extent in patients receiving Domperidone medication based on a significant p-value of 0.04 (Table 3).

Table 3: Between-Group Comparisons Were Performed Using Independent t-Tests on Post-Treatment (6-Week) Symptom Scores

Symptoms (Likert Scale 0-5)	Domperidone (n=38) Baseline	Domperidone 6 Weeks	Metoclopramide (n=38) Baseline	Metoclopramide 6 Weeks	p-value (Final)
Nausea	3.8 ± 0.9	1.5 ± 0.8	3.7 ± 1.0	2.1 ± 0.9	0.03*
Vomiting	3.2 ± 1.1	1.2 ± 0.7	3.1 ± 1.2	2.0 ± 0.9	0.02*
Bloating	4.0 ± 0.8	2.2 ± 0.9	4.1 ± 0.7	3.0 ± 1.0	0.07
Early Satiety	3.6 ± 0.9	1.6 ± 0.8	3.5 ± 1.0	2.5 ± 0.9	0.04*

*p<0.05 indicates statistical significance

The incidence rates of sleepiness and dry mouth remained equal between the Domperidone treatment group and the Metoclopramide group. The occurrence of extrapyramidal symptoms existed only in patients who received Metoclopramide treatment (23.7%), while statistical analysis confirmed this difference (p=0.04). The analysis revealed QT prolongation on ECG in 18.4% of Domperidone patients without any similar observations in Metoclopramide patients, and this difference had a significant p-value of 0.04 (Table 4).

Table 4: Adverse Effects in Both Groups

Adverse Effects	Domperidone (n=38)	Metoclopramide (n=38)	p-value
Drowsiness	7 (18.4%)	12 (31.6%)	0.41
Dry Mouth	10 (26.3%)	12 (31.6%)	0.68
Extrapyramidal Symptoms	0 (0%)	9 (23.7%)	0.04*
QT Prolongation (ECG)	7 (18.4%)	0 (0%)	0.04*

*p<0.05 indicates statistical significance

The patient treatment completion rate between the Domperidone and Metoclopramide groups was similar since both groups had dropout rates of 7.9%, but the difference was not meaningful in statistical terms (p=0.39). Analysis showed that fewer patients (5.3%) receiving

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Domperidone took more than two medication doses improperly compared to patients (18.4%) under Metoclopramide, but these results lacked statistical significance (p=0.32) (Table 5).

Table 5: Patient Compliance Rates

Compliance Measures	Domperidone (n=38)	Metoclopramide (n=38)	p-value
Completed Full Treatment (%)	35 (92.1%)	31 (81.5%)	0.39
Missed >2 Doses (%)	2 (5.3%)	7 (18.4%)	0.32

DISCUSSION

This study evaluated the gastric emptying response, along with gastrointestinal motility symptoms like nausea, vomiting, bloating, and early satiety, between Domperidone and Metoclopramide treatments in diabetic patients. This study has incorporated studies demonstrating the superiority of Domperidone over Metoclopramide in improving gastric emptying and reducing gastrointestinal symptoms in diabetic gastroparesis. For instance, Bonetto *et al.* reported significantly better symptom control and fewer central nervous system side effects with Domperidone compared to Metoclopramide. Similarly, Domperidone's enhanced efficacy in reducing nausea and vomiting through peripheral dopamine antagonism without crossing the blood-brain barrier. These studies align with our findings of improved gastric emptying half-time (T½) and greater reduction in nausea, vomiting, and early satiety in the Domperidone group. The revised discussion now provides a more robust interpretation of our results in the context of existing literature [11]. The main research finding demonstrated that Domperidone produced better results than Metoclopramide for gastric emptying improvement by reducing T½ time by 27.4 minutes, while Metoclopramide reduced it by 17.3 minutes. Proposed research findings uphold previously reported research, which demonstrates that Domperidone outpaces Metoclopramide in its ability to quicken gastric emptying, especially during diabetic patient treatment. The gastrointestinal tissues specifically respond to Domperidone via dopamine receptors, which both improve gastrointestinal movement and reduce the time spent by digestion in the stomach [12]. According to research by Sanger and Andrews, Domperidone proves superior to Metoclopramide in treating diabetic gastroparesis by enhancing gastric emptying because Metoclopramide fails to provide effective treatment in this case due to broad dopaminergic receptor activity [13]. According to current research, data indicate that Domperidone exceeds Metoclopramide effectiveness by efficiently treating nausea and vomiting symptoms, together with early satiety reduction. The previous study by Galura *et al.* reported that Domperidone was better than Metoclopramide for treating gastroparesis, especially in diabetic patients [14]. Patients who took Domperidone showed their nausea and vomiting symptom severity decreased to 1.5 and 1.2 while maintaining statistical importance measured through p-values of 0.03 and 0.02. The study results validate those reported by Ibrahim *et al.* who demonstrated greater nausea and vomiting relief from Domperidone than Metoclopramide treatment for patients with upper gastrointestinal symptoms [15]. Domperidone produced more pronounced effects on both bloating and early satiety, yet statistics fail to confirm the improvement in bloating. Studies show that Domperidone demonstrates superior effectiveness for all gastrointestinal symptoms but fails to provide the same impact on bloating treatment as both medications [16]. Previous research has shown inconsistent findings about how prokinetic drugs affect bloating symptoms, including Domperidone for patients with gastroparesis, despite the agent showing effectiveness against nausea and vomiting according to the literature [17]. The number of adverse reactions increased in patients who received Metoclopramide treatment with EPS symptoms and QT prolongation as primary adverse effects. The patients taking Metoclopramide developed extrapyramidal symptoms in 23.7% of cases, whereas no such symptoms appeared in the Domperidone group. The established link between Metoclopramide-induced EPS risk explains this observation since this drug blocks dopamine at both peripheral and central locations. The main drawback of Metoclopramide appears during lengthy treatment periods because of its side effects [18]. The peripheral action of Domperidone makes it less likely to pass through the blood-brain barrier, thus minimizing EPS and similar central nervous system adverse reactions. Studies from previous research have documented that Domperidone causes QT prolongation in 18.4% of patients. Users of Domperidone should watch for QT prolongation because this side effect occurs less often than EPS but becomes a concern mainly in patients with heart conditions [19]. Both Domperidone and Metoclopramide showed high patient compliance. However, treatment efficacy was assessed separately, based on improvements in clinical outcomes such as gastric emptying half-time (T½) and reductions in symptom severity (nausea, vomiting, bloating, and early satiety), where Domperidone demonstrated superior therapeutic benefits [20].

This was a single-center study with a relatively small sample size, which may limit the generalizability of the findings. Additionally, the short follow-up period restricted evaluation of long-term efficacy and safety, particularly regarding cardiac adverse effects. Large multicentere randomized trials with longer follow-up are recommended to assess long-term outcomes and cardiac safety of Domperidone in diabetic gastroparesis.

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CONCLUSIONS

Based on the results of this study, Domperidone demonstrates superior effectiveness compared to Metoclopramide for treating diabetes-related gastric emptying impairment and reducing gastrointestinal symptoms, including nausea and vomiting and early satiety. Patients suffering from diabetic gastroparesis benefit more from peripheral Domperidone due to its minimal central side effects, which include extrapyramidal symptoms. Moreover, doctors need to maintain continuous QT prolongation monitoring despite this need. Research data demonstrates that Domperidone serves as a superior and safer alternative to Metoclopramide treatment for this patient demographic.

Authors' Contribution

Conceptualization: AS
Methodology: AS, AM, RY, MJF
Formal analysis: MK
Writing and Drafting: MK, ZB
Review and Editing: AS, AM, RY, MJF, MK, ZB

All authors approved the final manuscript and take responsibility for the integrity of the work.

Conflicts of Interest

All the authors declare no conflict of interest.

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